



Comité de Déontovigilance des Entreprises du Médicament (Codeem)

**Self-Regulation: Ethics Surveillance and Monitoring Systems in the
Pharmaceutical Industry in Europe**

February 26, 2013

Based on a consultancy work done by Ashley Santner

Table of Contents

I. <u>OVERVIEW OF OBJECTIVES</u>	3
A. A case for self-regulation systems in the pharmaceutical industry	4
B. Description of self-regulation systems in selected European countries	5
1. Sweden	5
2. Denmark	7
3. United Kingdom	10
4. Spain	12
5. Finland	14
II. <u>TOOLS AND METHODOLOGIES FOR IMPLEMENTATION OF A SELF-REGULATION SYSTEM</u>	16
A. Tools	16
1. Pre-approval	16
2. Dual structure complaint review	17
3. Training	17
4. External observer networks	18
B. Methodologies	20
1. Operational issues for violations	20
<i>a. Verification and control</i>	20
<i>b. Measurement</i>	21
<i>c. Coverage</i>	22
2. Comprehensive review, sampling and audits	23
<i>a. Comprehensive review</i>	23
<i>b. Review by sampling</i>	23
<i>c. Audits</i>	23
III. <u>SPECIFIC AREAS OF INTEREST BY COUNTRY</u>	25
A. Pharmaceutical advertizing and marketing	25
B. Medical product promotion	27
C. Relations with healthcare professionals: Visits to hospitals and doctors' offices	29
D. Conflict of interest	32
E. Non-intervention studies	33
F. Gifts	37
G. Booths or stands at events including conferences and galas	39
IV. <u>ANNEX: CODES OF NATIONAL ASSOCIATIONS</u>	44

I. OVERVIEW OF OBJECTIVES

The “Ethical Business Provisions Applicable to Pharmaceutical Professionals and Members of the Leem” (DDP) are recommendations on responsible business practices concerning health and the environment, created by the Leem in September 2011 and updated on 31 March 2012 and on 29 January 2013.

The Ethics Committee for the pharmaceutical industry in France (Codeem) seeks to create a self-regulated monitoring and surveillance system for breaches of professional ethics in the pharmaceutical industry in France to comply with Article 11-1 of DDP, that “Codeem alert the Leem Board of Directors of any collective practices deemed non-compliant with the DDP and shall take or propose measures to remedy such non-compliance.” Additionally, through a self-regulated system, Codeem could develop an effective means to identify and rectify ethical trends before they become violations.

Specifically, the creation and implementation of such a self-regulated ethics monitoring system is to identify unacceptable practices and potential ethical breaches of French pharmaceutical industry professionals in their relations with doctors, pharmacists and institutions such as the National Safety Agency of Medical and Health Products (ANSM). The European benchmark created by this report allows the Codeem to decide which previously tested mechanisms they could consider.

Leem/Codeem documents, including their Ethical Business Provisions (DPP) and research on the European Federation of Pharmaceutical Industries and Associations (EFPIA), International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and national associations’ websites may provide further reading and useful information.

This report also benefitted from extensive interviews with European pharmaceutical compliance professionals and national associations. The author would like to thank Malene Abildstrøm Head of Secretariat, Ethical Committee for the Pharmaceutical Industry, Denmark, Nathalie Billon, Director of Scientific Relations, Sanofi; Carsten Blæsberg, Chief Consultant, M.Sc. in Economics, Association of the Pharmaceutical Industry (LIF), Denmark; Ingrid Callies, Permanent Secretary of the Codeem, France; Dominique Laymand, Vice President, Compliance and Ethics EMEA, Bristol-Myers Squibb; Santiago Páramo, Farmaindustria Deontological Supervision Unit, Spain; Rikard Pellas, Compliance Officer, Leg Apotekare, LIF, Sweden; Marie-Claire Pickaert, Deputy Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA); Tiina Satti, Legal Counsel, Senior Advisor, Association of the Pharmaceutical Industry (PIF), Finland and Heather Simmonds, Director, Prescription Medicines Code of Practice Authority, United Kingdom for their cooperation.

A. A case for self-regulation systems in the pharmaceutical industry

Self-regulation is generally understood as an alternative or supplement to government mandated command-and-control regulation. It begs the question of who undertakes the task of applying the regulatory process: a government, independent body, industry association, or a combination of interested parties. Even systems that rely solely on industry regulated procedures will usually have some form of government oversight or monitoring process remaining in place.

Self-regulation can be defined as some degree of regulatory authority over an industry or profession by an organization or association, which creates rules and monitors their implementation and does not necessarily derive its authority from the government. Ethical foundations on self-regulation in a business context include considerations of objectivity, autonomy, transparency and efficiency. The regulatory authority could be applied in addition to some form of government regulation or it could fill a vacuum in the absence of government oversight and regulation. In addition, self-regulated systems usually have sanctions that can be enforced against its members.

Whether regulation of pharmaceutical promotion is carried out directly by government or through industry self-regulation, there are five key components:

- National laws and regulations;
- The application of the law through codes and other standards;
- Monitoring of pharmaceutical promotion to ensure consistency with legal or other standards;
- Law enforcement with adequate sanctions to prevent violations; and
- Evaluation of regulatory effectiveness.

Experience in several European countries has demonstrated that self and co-regulatory mechanisms provide effective and efficient means to oversee activities and to contribute towards increased adherence to standards and good practice principles. Whereas government controlled systems can have drawbacks such as being time consuming and inefficient, many examples of self-regulatory mechanisms in the pharmaceutical industry present significant benefits in terms of effectiveness and efficiency. In order to promote self-regulation, targeted action should primarily concern how to involve national competent authorities in a dialogue with other stakeholders and to ensure that they are committed and willing to explore this system.¹

Industry self-regulation has been demonstrated to work well for a number of reasons, not simply because the penalties for transgression are substantial. Companies recognize that the alternative - direct government control - is less preferable, as it could be more costly and time consuming. Industry representatives make the case for self-regulation because they argue that companies in competition with each other are likely to be the most expert and sensitive critics of their competitor's behavior.

Research suggests that under this model, there are relatively few complaints and even fewer are upheld by the various bodies reviewing them, both governmental and non-governmental, which suggests companies are willing to change behavior. A strength of self-regulation is that it does not use government resources so that they can be better deployed elsewhere. It also reinforces ownership for responsible behavior amongst companies and accountability to the public without depleting resources.

¹ European Commission Code for Effective Open Voluntarism: Good design principles for self- and co-regulation and other multistakeholder actions.

B. Description of self-regulation systems in selected European countries

In this section, there will be a review of the self-regulation systems currently operating in selected countries: 1) Sweden; 2) Denmark; 3) United Kingdom; 4) Spain and 5) Finland.

1. Sweden

In Sweden, the research-based pharmaceutical industry is monitored by a trade association called LIF. LIF has approximately seventy-five members and associate companies who represent approximately eighty percent of the total sales of pharmaceuticals in Sweden. Generic companies are also bound by LIF's code, including companies that sell natural ingredients with pharmacists' approval. Non-LIF members are overseen by government authorities.

LIF has maintained a self-regulation system of the pharmaceutical sector since 1969 for the purpose of realizing the industry's aim of ensuring that the information supplied by pharmaceutical companies follows the ethical rules for the pharmaceutical industry.

All regulations are now gathered in a single code "The Ethical Rules for the Pharmaceutical Industry," which came into force on 1 October 2007 and was last revised in April 2012. The rules consist of:

1. Ethical rules for the pharmaceutical industry
2. Agreements on forms of collaboration with health care professionals etc.
3. Ethical rules as to co-operation between companies and user organizations and interest groups
4. Rules for non-interventional studies
5. Statutes concerning the Swedish Pharmaceutical Industry Information Examiner (IGM) and the Information Practices Committee (NBL)
6. Rules for procedure for the IGM and NBL
7. Rules regarding corruption and bribes
8. Ethical rules for interaction between pharmaceutical companies and veterinary care personnel
9. Ethical rules for interactions with politicians

As a part of the self-regulated system, the responsibility lies with Swedish marketing companies to ensure that the ethical rules for the pharmaceutical industry are also observed by parent companies and subsidiaries regarding activities available on the Swedish market or targeted at the Swedish public. It is also the duty of such companies, in license agreements or similar with business partners, to enjoin them to comply with the ethical rules for the pharmaceutical industry.

The Swedish Pharmaceutical Industry Information Examiner (IGM) and the Information Practices Committee (NBL) are an integral part of the self-regulation system. The IGM and NBL perform their duties independently and separately. Their overall activity consists primarily of monitoring the market, assessing cases as well as pre-examination of vaccine campaigns and information about prescription drugs on webpages to the general public.

LIF and IML members must comply with the rules and ethical agreements. As of 1 October 2009, FGL (the Association for Generic Pharmaceuticals) members must also comply with these rules.

The IGM is the self-regulated body that monitors and surveys the market for inappropriate publicity and responds to charges of compliance violations. The Swedish Medicinal Products Agency (MPA) monitors the pharmaceutical market, including the advertising and other marketing activities of pharmaceutical companies. The MPA may take action in cases of non-compliance and normally seeks a voluntary solution. A great majority of all cases regarding the advertising of medicinal products never go to court, but are

handled by the LIF through its two self-regulatory bodies: the Pharmaceutical Industry's Information Examiner (IGM), who is a physician; and the Information Practices Committee (NBL), which is a court-like body. A decision by the IGM can be appealed to the NBL. If an amicable solution is not found, the MPA can issue a prohibitive injunction subject to fines upon noncompliance, or refer the case to the NBL (Pharmaceutical Advertising 2012).

Here is a summary of the key actors and their roles:

- a. LIF's **Compliance Officer** decides, on his own initiative or upon notification or enquiry, if a location of a planned arrangement or event is acceptable. These decisions of inappropriate venues are publicly available on LIFs homepage in a database.
- b. The **Pharmaceutical Industry's Information Examiner (IGM)** is a medical doctor who spends about 60% of his time as a IGM. The IGM continuously examines information and other marketing activities for pharmaceuticals from the industry. The IGM handles approximately 100 cases per year. There is an average of 50 convictions per year. In the first half 2012, there were 24 investigations taken by the initiative of the IGM and 6 complaints, 71% led to conviction.
- c. The **Information Practices Committee (NBL)** committee consists of a chairperson and eleven members. The members represent legal, medical and pharmaceutical industry expertise. The interests of the general public, principally from the point of view as consumers, are also represented. The Board examines issues that IGM refers to it without having examined them and it also deals with appeals on decisions made by IGM, or LIF's Compliance Officer. The Board also examines issues in filed complaints from relevant authorities or anonymous sources. The NBL can also give general recommendations in matters that are considered to be of major principle importance.

One of the objectives of the NBL is transparency. All cases are available for the public on the website. Regarding sanctions, fees vary 40,000 sek, 90,000 sek, and 120,000 – 500,000 sek depending on the severity of the violation.

LIF has a Compliance Committee that shall be consulted before making changes in the ethical rules. LIF's board is made of pharmaceutical general directors. In LIF's view, the public has a relatively good relationship with pharmaceutical companies operating in Sweden.

2. Denmark

In Denmark, LIF is the trade association for the research based pharmaceutical industry, including both Danish and international companies. The Chief Consultant of the LIF is in charge of the policies regarding compliance and the image of the industry, as well as developing and implementing national codes. His background includes twelve years working on communication policy committee and marketing with prior experience working for the public authorities – the Danish Ministry of Health.

Pharmaceutical companies are now monitored through a self-regulation system administered by Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI). The Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI) was established in its current form by the Danish Association of the Pharmaceutical Industry (Lif), the Danish Generic Medicines Industry Association (IGL) and the Danish Association of Parallel Distributors of Pharmaceuticals (PFL) and aims, among other things, to ensure the control of the Danish Ethical Rules for Promotion of medicinal products towards Healthcare Professionals. While ENLI was established in April 2011, there has been self-regulation of the pharmaceutical industry since 1973. Prior to ENLI, the promotion activities of pharmaceutical companies concerning medicinal products were controlled by the industry committee NMI (the Danish Board of Drug Advertising) and later by the Danish Legal Board of Self-Regulation Concerning Pharmaceuticals (NSL).

ENLI ensures, via self-regulation and control, an ethical framework for the necessary and professional responsible collaboration between the pharmaceutical industry and healthcare professionals, hospitals, patient associations and public decision makers. ENLI serves as a voluntary supplement to the control carried out by the National Board of Health in Denmark (former Danish Medicines Agency).

A strong feature of the Danish self-regulation system is its independence through the arms-length principle, which means that the pharmaceutical industry in no way may affect the rulings made by ENLI. In addition, all persons of ENLI (employees and members – both in first and second instance) are independent of the Industry.

In Denmark, it is not permitted for pharmaceutical professionals to market a specific drug directly to the public.

ENLI is responsible for overseeing the following rules:

- Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals (The Promotion Code), which incorporates:
 - Rules agreed on by the Industry
 - Danish legislation
 - EFPIA code
 - IFPMA code
 - Directive 2001/83/EC
 - Ethical criteria from WHO
- Ethical Rules for Collaboration between Patient Groups, etc. and the Pharmaceutical Industry (The Patients Group Code)
- Ethical Rules for Pharmaceutical Companies' Relations with the Danish Hospital Sector (The Hospitals Code)
- Ethical Rules for the Pharmaceutical Industries' Donations and Grants to Hospitals (The Donations Code)
- Ethical Rules for Dialogue and Negotiations with Decision-makers (The Lobbying Code)

- Parts of the Executive Order on Promotion concerning promotion of medicinal products towards healthcare professionals (ultimately controlled by the Danish Medicines Agency) and relevant parts of Chapter 7 of the Danish Medicines Act.

ENLI is the independent ethical board of the pharmaceutical industry.

The ENLI consists of two instances: The first instance called the Legal and Medical Panel of Investigators and the second instance, the Board of Appeals. The first instance consists of up to five investigators including two Legal personnel and two/three Legal Investigators and two Medical Investigators, who are responsible for the surveillance and prevention of violations of the guides and codes including relations with HCPs, patient organizations and grant donations, lobbying, etc. The Legal Investigators are primarily charged with reviewing the notifications of events, expos and conferences, and the Medical Investigators primarily with any kind of promotional material. The investigators of the first instance can decide cases individually. But serious violations are decided by three investigators jointly, if the sanction is minimum DKK 75,000 in penalty.

The Head of the Secretariat of ENLI is Malene Abildstrøm, who is a legal attorney and also works as a member of the first instance (legal investigator). Furthermore, the Secretariat consists of one more lawyer (legal investigator) and an assistant and two students.

The Board of Appeal consists of four members: a Chairman, legally qualified; one medical professional (with clinical pharmacology knowledge); one person with experience from the industry (former employee); one legally qualified – who is also the secretary for the Board of Appeals. Rulings are made by simple majority voting with the chairman's vote decisive.

In the first instance, for a one year period there were reported 127 breaches but over half of them were small violations, considered as administrative or triviality violations such as late notification. 68 smaller violations were sanctioned only by reprimands, and 59 breaches were sanctioned by fines. The average fine is approx. 36,000 DKR or about 6,000 USD. There are few complaints reported by companies on one another or by healthcare professionals (only about 8-9 per year) due to the trust in the screening process (please see below).

Before the case moves to decision in first instance, companies are notified of the potential case raised against them as they have the right to be heard (in writing) before the decision is taken. Unless appealed, the decision of the first instance is made public and is available on the website of ENLI. Sanctions at this stage can range from reprimand and corrective action, monetary fines (less than 50% results to fines) to in the most severe violations, a public statement denouncing the companies' behavior.

If a company repeats the violation, the fines can be doubled. If a company wins on appeal, there is no cost of appealing; however, if it loses, it has to pay the final penalty, plus 50% of the penalty in appeal costs.

Complaints can be filed over pharmaceutical companies from the industry and outside the industry (e.g. by HCPs, authorities...). Importantly, ENLI can initiate an investigation on its own.

ENLI can impose the following sanctions:

- Reprimands to the company or in public for administrative or trivial violations
- Penalty of DKK 15.000 - 75.000 for promotion of marketing material
- Penalty of DKK 30.000 - 150.000 for all other violations
- Double penalty for repeated violations of similar offence
- Immediate cessation of the offending activity and signed undertaking to prevent recurrence

- Public critique by naming company
- Rectify incorrect information
- Withdraw illegal marketing materials
- Cancellation of planned event
- Correcting violating activity

Regarding transparency, all decisions made by ENLI are published on the website of ENLI when a company has breached a rule/Code and are published when the decision are final.

Regarding funding, the ENLI Budget in 2012 was 3,7 mio. DKR. Revenue is derived from:

- Fines (approx 40%)
- Report fees (due to report obligation. 350 DKR per report) (approx 40%)
- Fees for pre-approval (voluntary) (Approx 15%)
- Other fees (complaints; appeal etc): (approx 5%)

In case of deficit, 60% are covered by Lif, 20% are covered by Parallel importers and 20% are covered by IGL (Generics).

3. United Kingdom

In the United Kingdom, the control of medical advertising is based on the long established system of self-regulation supported by the statutory role of the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA administers the law on behalf of the Health Ministers. The law in the United Kingdom is based on a European Directive.

ABPI is a registered trade association who monitors the pharmaceutical industry in the United Kingdom. ABPI members supply 90% of all medicines used by the National Health System, and are researching and developing over two-thirds of the current medicines pipeline. There are over 180 members, who represent small, medium-sized, and large organisations, made up of pharmaceutical manufacturers, research bodies and those with an interest in the pharmaceutical industry operating in the United Kingdom. Pharmaceutical companies that are members of the ABPI all agree to comply with the requirements of the Code: it is a condition of membership. In addition there are around 50 non-member companies that have agreed to comply with the Code and accept the jurisdiction of the Prescription Medicines Code of Practice Authority (PMCPA).

The pharmaceutical industry in the United Kingdom is strongly in favor of the self-regulation system. About eighty percent of companies operating in the United Kingdom are adherents to the Code. There are many benefits to self-regulation. For one, companies are undertaking to make a public statement and demonstrating, at times, limits that are stricter than those required by law. i.e. on the number of times there can be cold calls. Companies also appreciate the flexibility of self-regulation, and it allows them to be more involved in the process, which in turn, protects them the possibility of more rigid regulation by the public authority.

The PMCPA was established by the Association of the British Pharmaceutical Industry (ABPI) in 1993 to operate the Code of Practice for the Pharmaceutical Industry independently of the Association itself. The ABPI Code of Practice for the Pharmaceutical Industry, administered by the PMCPA, is the self-regulatory system covering prescription medicines. The ABPI Code reflects and extends beyond UK law. Self-regulation should be the first means of dealing with complaints. The MHRA intervenes where there is a clear case for protection.

The Ethical Code was originally drafted in 1958 and put in place in 1968. The Code incorporates the principles set out in:

- The International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Practice
- The European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals
- The EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations
- The World Health Organisation's Ethical Criteria for Medicinal Drug Promotion
- Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC
- The Human Medicines Regulations 2012

The PMCPA is a separate division, both financially and through the day-to-day management. Their role is to provide informal advice and address queries. The staff is comprised of a Director with a background in pharmacology, an attorney, a pharmacist and medical professional with a legal background. Whenever a complaint arises, one member of the staff takes on the role of case preparation manager, and then there is a decision by a panel at the first instance. The complaint can then be brought to the Code of Practice

Appeal Board which is comprised of an independent, legal chairperson, a layman, a patients' representative, etc. with seventeen people in total.

The PMCPA is responsible for the provision of advice, guidance and training on the Code as well as for the complaints procedure. It is also responsible for arranging for conciliation between companies when requested to do so and for arranging for the scrutiny of advertising and meetings on a regular basis. The PMCPA is not an investigatory body as such. It asks the respondent company for a complete response and may ask the parties to a case for further information in order to clarify the issues. It is essentially an adversarial process in which the evidence to be taken into account comes from the complainant and the respondent company, though the Authority can seek evidence from third parties where necessary. A complainant has the burden of proving their complaint on the balance of probabilities. Anonymous complaints are accepted and like all complaints are judged on the evidence provided by the parties. The weight to be attached to any evidence may be adversely affected if the source is anonymous and thus in some instances it will not be possible for such a complaint to proceed.

The PMCPA has developed an extensive and robust system of receiving complaints. The majority of complaints are received from health professionals, while they may also come from pharmaceutical companies, voluntary disclosures and anonymous complaints of violations. There is a memorandum of understanding between the MHRA and the PMCPA to encourage self-regulation. There is also collaboration with the Serious Fraud Office due to implications with the UK Bribery Act. Complaints are all detailed in an annual report in an effort to increase awareness and promote transparency.

The industry recognizes that transparency is an important means of building and maintaining confidence. The operation of the Code, including the complaints procedure, is a demonstration of the industry's commitment to transparency as are the requirement to declare pharmaceutical company involvement in activities and materials and the publication of detailed reports of cases considered under the Code. The industry's global agreement to disclose certain clinical trial data is another example of the industry's commitment to transparency. Companies also have to publish the summary details and results of non-interventional studies as well as the monetary value of certain support to patient organizations. Other transparency changes will be effective in 2012 and 2013. These include disclosure of the total amount of fees paid to consultants for certain services and the total amounts paid to sponsor attendance at meetings organized by third parties.

The Code is an ever evolving document due to the concerns of the day. For example, there had been some questions as to interactions with patient organizations, so the PMCPA published good practices and public relations guidelines on this issue. The idea is to receive feedback because even criticism can be considered to be helpful in meeting the goals of the PMCPA.

4. Spain

The self-regulation and surveillance of pharmaceutical companies operating in Spain has seen dramatic development and improvement over the last decade. New legislation on transparency is expected to be implemented by 31 December 2013. The general sense is that there is a strong commitment from pharmaceutical companies operating in Spain to maintain compliance.

Ethical monitoring of the pharmaceutical industry has been in place since 1991. However, in 2004, the Code of Practice Surveillance Unit was created on the principle of a preventive philosophy and to actively monitor the application of the rules applicable to promotion of medicines. The Ethics and Surveillance team is composed of 5 staff members: a General Manager, three technicians and one secretary, none of whom have healthcare industry experience before assuming their position.

There are currently three areas of mandatory communications by pharmaceutical companies: hospitality and events (implemented in 2004), market research studies (implemented in 2008) and services (implemented in 2010). For hospitality and events, mandatory communication exists (ten days in advance) when the three following conditions concur: the event is organized – directly or indirectly – wholly or mainly -, by the notifying company; it includes at least an overnight stay; and it involves the participation of at least 20 HCP's having their activity in Spain. For market research studies, communication will not be mandatory if the sponsoring or the financing from the company shall not be in its majority; or the company does not have access before, during or after the study, to the identity of the participating HCP's and has not intervened in their selection beyond defining participating group described in the study protocol; or the study does not imply the direct or indirect remuneration of the participating HCP's; or the study involves paid participation of less than 20 HCPs. Similar conditions apply for services communication process. In the event of non-compliance, sanctions can be issued of up to 1,000 Euros for failure to communicate a required activity. *See RULES OF PROCEDURE FOR THE CONTROL BODIES articles 9.1, 10.1, and 11.1.*

Thanks to these communication processes, the Code of Practice Surveillance Unit (one of the self-regulation control bodies) is directly aware of the practices and activities carry out by the pharmaceutical companies and could, if necessary, adopt in advance precautionary measures against potential infringements of Code of Practice applicable provisions, or situations (practices/activities) that could damage pharmaceutical industry image or confidence.

Infringements will be classified as minor, serious and very serious based on the following criteria:

- Magnitude of the infringement, particularly its potential risk for the health of patients
- Impact on the scientific or medical community of the practice resulting in Code infringement
- Unfair competition
- Generalization of the infringement
- Repetition of the infringement
- Damage to the image of the pharmaceutical industry

There may be aggravating circumstances that shall be taken into account by the Jury for imposing the appropriate penalties:

- Degree of intentionality
- Failure to comply with previous warnings
- Concurrence of several infringements for the same action or promotional activity
- Financial benefit for the pharmaceutical company derived from the infringement

In Spain, control of compliance with the regulations on the promotion of medicines set out in the Code shall be the responsibility of the Code of Practice Surveillance Unit (USD), the Code of Practice Committee of the Pharmaceutical Industry (CD) and the Jury of the Association for Self-Regulation of Commercial Communications “Jury”, (herein after all of them referred as “the Control Bodies”).

The Control bodies main functions are: USD – active monitoring code compliance-, CD – search for mediation and conciliation-, Jury – issue resolutions.

The Director of the Code of Practice Surveillance Unit is appointed by the Board of Governors of FARMAINDUSTRIA at the proposal of the Steering Committee and with the approval of the Code of Practice Committee. These bodies are operated under the high standards of confidentiality, truthfulness, impartiality, independence and agility. The Director may attend the meeting of the Code of Practice Committee and shall be entitled to express his opinions but not to vote.

Members of the Code of Practice Committee are appointed by the Board of Governors of FARMAINDUSTRIA at the proposal of the Steering Committee, including at least three members who shall be technicians or professionals of recognized prestige and a Secretary from among the persons belonging to the Legal Department of FARMAINDUSTRIA, who shall assist the members and be entitled to express his/her opinions but not to vote.

The Jury is the independent out-of-court body in charge of adjudicating on complaints submitted on advertising issues. Its decisions are binding. Its activity is based on independence, transparency, accountability, etc., amongst other principles. The Jury is fully composed of independent lay experts: prestigious academics on Law, Economics, Sociology, Commercial Communications; retired advertising practitioners; ex-civil servants specialised on consumer affairs, etc. 25% of its members are nominated by the Spanish National Institute on Consumer Affairs (INC) amongst independent and prestigious academics, experts in consumer affairs, etc. All the Jury's decisions are clearly motivated and are published in Autocontrol's monthly newsletter and on its website. Actually composed by a President and 6 sections. *See Rules of Procedure for the Control Bodies article 8*

5. Finland

The Pharma Industry Finland (PIF) is the organization supervising pharmaceutical promotion of its member companies. There are 61 members to the PIF, and they all have agreed to abide by the rules made by the association itself.

In Finland, self-regulation has been used to control promotion of pharmaceutical products since 1959. The system is based on voluntary contracts and it has been totally independent from state authorities. Because of this, the system can be considered genuine self-regulation.

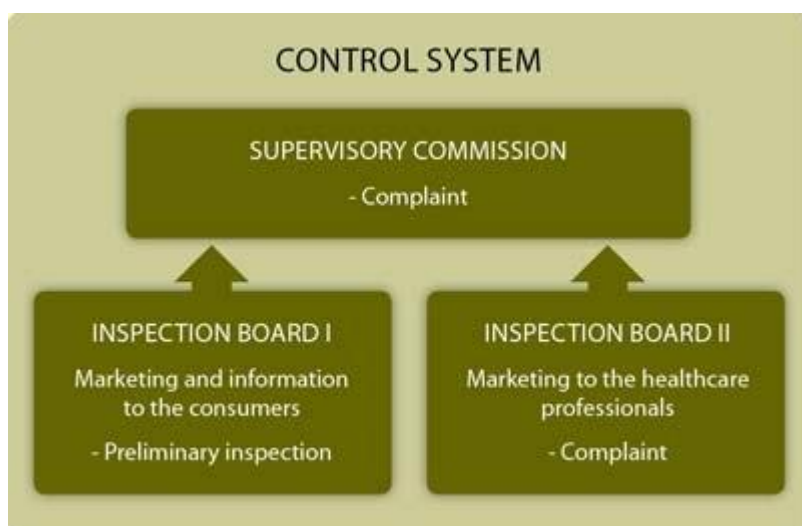
These rules are called the Code for the Marketing of Medicinal Products. It is defined in the Code that the member companies must resolve a violation of the Code following the system prescribed in the Code before submitting the case to authorities. Thus, in case of a dispute between the members, the self-regulatory system is the principal choice.

Promoting is controlled by two Inspection Boards (I and II) and the Supervisory Commission for the Marketing of Medicinal Products, the latest functioning as the appeal body. Members of these supervisory bodies come from outside the industry, except for one member of The Supervisory Commission.

The Inspection Board I supervises promotion targeted at consumers and it can take up marketing measures of a pharmaceutical company on its own initiative or on the basis of a complaint. This Inspection Board also conducts a preliminary inspection of marketing material targeted at consumers. All TV and radio commercials shall be checked by the Board I before they are presented to the public. The preliminary inspection creates a vast workload and due to that, the Board I meets weekly. In 2007, 73 commercials were accepted in this inspection and the Board received two complaints in total.

The Inspection Board II controls marketing targeted at healthcare professionals and, upon request, resolves marketing-related disputes between pharmaceutical companies that are members of the PIF. No preliminary inspection is made by the Board II; hence the supervision is only subsequent to promotion. In 2007, the Board met ten times and received eighteen complaints. The highest amount of complaints within the last five years is thirty-one, which were received by the Board II in 2004. The member companies have agreed to first try and resolve disputes between the companies involved. If an agreement is not achieved within a definite time frame, the dispute may be submitted to the right Inspection Board.

The Supervisory Commission is the highest supervisory body in the self-regulatory system. There are some situations where the Inspection Boards must submit cases directly to the Supervisory Commission. Generally the Commission serves as an appeal body to the decisions made by the Inspection Boards. The Supervisory Commission assembles for a meeting five to ten times a year, and the amount of complaints has varied between six and twenty-six per year during the last five years.



The industry has agreed on a voluntary Code for the Marketing of Medicinal Products. The purpose of the Code is to ensure that healthcare professionals and consumers receive correct information on medicines and their use.

The Code involves general provisions and provisions that are only apply to marketing to consumers or healthcare professionals. This division has been made mainly because in Finland it is illegal to promote prescription-only medicines to consumers. Of course, the target group also affects marketing and therefore the above mentioned division in the Code is reasonable.

The Code for Marketing Medicinal Products also includes provisions concerning sanctions, which are part of the self-regulatory system. The Inspection Boards or the Supervisory Commission can decide whether to admonish the pharmaceutical company for future reference, request the interested company to abstain from incorrect marketing, decide on the processing charge and sanctions, as well as order the company to correct its incorrect marketing. Moreover, the Supervisory Commission can impose a contractual penalty.

The member companies of the PIF have agreed to comply with the Code and to abide by the resolutions given by the supervisory bodies. In addition, they have agreed that, if the authority monitoring pharmaceutical promotion has a case on the table, the voluntary system will wait until the authority has given a decision. Only after that will it proceed with the case.

The following benefits can be derived from the self-regulatory system for pharmaceutical promotion:

- There are more experts to decide cases than the authority.
- The system can operate very fast and effectively.
- The substance, the industry, is well-known by the actors.

These were considered to be the weaknesses of the system:

- Lack of ability to renew itself.
- The monitoring of the promotion targeted to healthcare professionals could be more effective.

II. TOOLS AND METHODOLOGIES FOR IMPLEMENTATION OF A SELF-REGULATION SYSTEM

A. Tools

1. Pre-approval

National associations can employ different tools to ensure that pharmaceutical advertisements are truthful, not misleading to consumers and do not violate ethical rules. An example is whether a pre-approval or post-publication system is in place. In a pre-release system, advertisements are formally approved before they are released to the public. A post-publication system relies on a complaints procedure being applied after the advertisements are already on the market.

In some self-regulatory systems, such as in the **United Kingdom**, the manufacturer association PAGB (the Proprietary Association of Great Britain) pre-approves the advertisements. While member companies are always legally responsible for their advertising, the pre-publication approval system aims to help members ensure that their consumer advertising complies with the legal and voluntary requirements. The review process usually also involves representatives of the advertising industry and others.²

Whichever system is in place, there is always in addition a post-publication oversight of the advertising. Companies are in competition and are the first to point out and complain about a competitor should an unethical, misleading or unfair advertisement be broadcast to the public. Complaints by consumers and healthcare professionals also play a role in making these systems work.

In **Sweden**, there is a pre-approval process for vaccines campaigns to the general public, and companies are prohibited by ethical rules without pre-approval from advertising these campaigns, even though this is permitted by the medical law. The ethical rules state that they cannot mention the brand. There is also a pre-approval process for websites, which has demonstrated success.

In **Denmark**, member companies can voluntarily obtain pre-approvals of promotion activities. In case of a request for pre-approval, the first instance has to render a decision within 10 days.

In addition, member companies are required to pre-notify defined promotion activities, including all written product information and advertising (promotional material) as well as sponsorships to and organization of scientific events, both national and international. It is important to underline that the notification obligation is not to be seen as the same as pre-approval. ENLI requires companies to fulfill their notification obligations through an electronic case handling system on the ENLI website. Annually, the ENLI receives about 6,000 notifications, with approximately 60% on events and the rest on product information and advertising. Companies are required to provide the notification for an event within 10 days in advance of the event, and if the first instance through its sample control procedure review the case, the company shall receive a hearing letter within 10 days of receipt of the notification.

Pharmaceutical companies are obligated to report to ENLI activities:

- a. which are organized or co-organized by a pharmaceutical company, and the event is fully or partially targeted at Danish healthcare professionals;

² A summary of PAGB's advertising codes can be found here:
<http://www.pagb.co.uk/pagb/downloads/advertisingregulations/PAGB%20Summary%20Medicines%20Advertising%20Codes.pdf>.

- b. where a pharmaceutical company, not organizing or co-organizing the event, provides financial (sponsor) support to (i) a so-called third party event fully or partially targeted at Danish healthcare professionals or to (ii) the participation of Danish healthcare professionals;
- c. where a pharmaceutical company buys an exhibition stand at a congress in Denmark; and
- d. all kinds of printed promotion material targeted at healthcare professionals on the Danish market.

In **Finland**, there is a checklist of ten issues for self-care medicine marketers and advertising agencies to control before submitting their work to preliminary inspection.

2. Dual structure complaint review

Most national associations cited that an effective tool in setting up a self-regulation system included a dual structure for review of complaints because this framework strengthened credibility and impartiality of the system.

For example, in **Sweden**, LIF considers that it is helpful to have two levels of self-regulation including the “first-instance court” (IGM, only one person which makes it very efficient with rapid case management) and the “Supreme Court on appeal” (NBL, which includes 2 co-chairs, company representatives, representatives for medical expertise and representatives for the public interest, representing a 360 degree view).

In **Finland**, potential violations are controlled by two Inspection Boards (I and II) and the Supervisory Commission for the Marketing of Medicinal Products, the latest functioning as the appeal body.

Denmark’s LIF cites the separation of the two instances and appeal as a crucial factor to the success of the system.

3. Training

Many national associations rely on training as a tool to implement their ethical codes, prevent violations and reinforce positive behavior.

In **Sweden**, the LIF has created a mailing list group to raise awareness and engage the contact person for ethics within the member companies or other companies bound by the ethical rules. Bi-annually, the LIF offers compliance officer meetings in addition to *ad hoc* advice through case-by-case scenarios. As part of one of its most effective tools, the LIF offers a three day training courses (IMA training). According to LIF’s ethical rules (*see article 29*) the information officer of the pharmaceutical companies must have completed this training. These courses are fully booked generally. Open not only for pharmaceutical companies’ staff but also to consultants, PR agencies, etc., they can accommodate up to thirty people and are held four to five times per year.

In **Denmark**, tools that have been helpful in setting up this self-regulation system include guidelines, newsletters and training and seminars that can be tailored to the company and performed in house at the company’s expense.

In the **United Kingdom’s** experience, one of the most prominent tools for surveillance has been training. The PMCPA holds regular seminars on the requirements of the Code of Practice in London that are open to all, including pharmaceutical professionals, National Health Service officials and advertising representatives.

The seminars have been designed to explain the requirements of the Code:

- to those responsible for day-to-day commissioning and creation of promotional material and to those writing and approving copy and artwork;
- to those responsible for determining promotional methods including professional representation, hospitality to health professionals and the use of audio-visual and related communications technology;
- to those responsible for producing material aimed at patients or the general public and for those working with patient organizations.

The seminars also cover the procedures followed by the PMCPA, the Code of Practice Panel and the Code of Practice Appeal Board. The goals are to increase knowledge and provide informal advice. There are also specific trainings for in-house compliance officers through a compliance network meeting which occurs every quarter.

In **Spain**, annual training events were held with compliance officers from 2005-2008, and there is hope to continue this practice.

4. External observer networks

In some countries, external observer networks helped the national associations maximize their reach and gain buy in from stakeholders.

For instance, in the **United Kingdom**, the ABPI has a medical expert and a legal expert network that can provide their counsel and have done so in the past, in the instance of meetings and hospitality. There is no external board, but the PMCPA receives feedback from a number of sources. Each time that there is a proposed revision to the Code, there is an open opportunity for notice and comment, as well as consultations with MHRA, who advocate for increased self-regulation.

APBI also strives to maintain close contacts with Government, politicians, academia and the media. It has developed extensive links with health managers, patient advocacy groups, training and education bodies, research councils and other professional bodies in the healthcare field. To name a few examples, Social Audit in the United Kingdom, No Free Lunch and Healthy Skepticism, are part of a strong and developed network of observers.

With regard to **Spain**, please see above the developments regarding the Jury.

Conclusions

Of the tools that are most efficient, the LIF in **Sweden** recommends developing contacts in companies, creating and developing new education programs and being dedicated to ethical compliance.

According to the LIF in **Denmark**, the most important factors of a strong self-regulation system are:

1. The notification obligation in order to establish trust and control in the system and maintain a positive image with the industry, the authorities and the public
2. hearing rights for the companies
3. the use of guidelines by ENLI in order to prevent unacceptable behavior in an attempt to simplify the rules and training through examples
4. Establishing an “arms – length principle” underlying the full independency between LIF and ENLI meaning that LIF must not in any way or circumstances influence the concrete case handling and decisions taken by ENLI. Such decisions are 100% taken by ENLI. Neither employees at LIF or the committees or board of LIF are allowed to take initiatives that will

influence the control or decisions regarding cases or/and sanctions taken by ENLI in specific matters

5. The dual role of ENLI to show respect for the process which should not have too many inconsistencies and be firm, vigilant and professional while offering guidance

In the **United Kingdom**, a tool to reinforce the self-regulation system has been to work with national authorities. Take the UK Bribery Act as an example. The focus of an overarching approach to anti-bribery signifies to the pharmaceutical industry that no undue influence is acceptable other than what is right for the patient, the consequences for individual and society. Having support from the national authorities is essential to gain trust. Finally, the PMCPA launched an e-learning module for health professionals as part of the 2011 Code Awareness Campaign, which received positive feedback. The relationship to focus on is between the pharmaceutical professional and the healthcare provider.

Spain cites the strong commitment of pharmaceutical companies with the self-regulation system as the key element for success.

The pharmaceutical industry is working hard to make things better, and the national associations are there to help.

B. Methodologies

1. Operational issues for Violations

a. *Verification and Control*

In **Sweden**, there is no pre-approval for events, products promotion and advertisements (except vaccine campaigns and websites), but companies should send statutory copies to the IGM, in accordance with LIF's Ethical Code, Article 31. LIF cannot guarantee that companies send all material as statutory copies, but it has asked the IGM to produce a compilation, and then LIF sends reminders of the rules to companies that have sent only a few examples.

In **Denmark**, there is the option for pre-approval. In approximately 3-5 percentage of cases of activities covered by the notification obligation companies have requested a pre-approval. This option is normally used where the company is in doubt or there is a gray area on the issue. However, companies are required to pre-notify before any marketing activity (which includes all printed material and events). Once there has been pre-notification, the company essentially becomes liable for compliance to the ethical rules. 95% of breaches identified by ENLI are based on the screening of the pre-notified activities by companies.

Furthermore, ENLI has the obligation to control member companies' compliance, and ENLI has been charged with the flexibility to perform sample control (minimum requirement is 15% of all notified cases) and does so for approximately 40-50% of activities. This control is publicly available, and there is nearly 99% of compliance amongst companies activities (98% if you include administrative and triviality breaches).

It must also be noted that companies can complain. In Denmark, there are a very low number of complaints (7 complaints in Denmark vs. 80 in the United Kingdom, for example) because of pre-notification system, which gives ENLI the opportunity to intervene before, and be preventive to fix the practice at a very nearly stage. The control from early intervention and correction has led to successful ethical compliance in ENLI's view.

In the United Kingdom, the MHRA carries out pre-vetting of promotional material for all new chemical entities and certain other medicines such as those switching status from prescription only medicines to pharmacy medicines. Under the ABPI Code, material has to be certified. There is no requirement for the PMCPA to monitor materials, but there are certification requirements. However, the PMCPA provides informal guidance about the Code and its operation, which strengthens its presence for control.

According to **Spanish** legislation, companies are obliged, before using any printed promotional material, to submit those materials to the authorities in charge of supervising the promotion of medicines. In Spain, the self-regulation system includes three different communication processes for Events & Hospitality (Article 11), for Marketing Research Studies (Article 14.3) and for Contracted Services (Articles 16 & 17). The Rules of Procedure specify those cases upon which those communications are compulsory.

The Code of Practice Surveillance Unit is only aware of those activities and practices communicated by companies, so they can only respond to those practices and activities communicated. As stated in Article 21.2, companies could be sanctioned for not complying with the communication processes. Additionally, the Rules of Procedure, Article 13 includes an investigation process if there are suspicions of non-compliance.

Finland does not check all events or advertisements, but relies on complaints or its own initiative to seek out potential violations. PIF has to trust that other companies or individuals will take the initiative to file a complaint on the violating company.

b. Measurement

In **Sweden**, the LIF reports that the self-regulation system is well-known and respected throughout the industry due to LIF's pro-active approach to spreading information about their ethical rules. This is measured by the number of cases per year. Additionally, any legal entity or person (individual, healthcare professional, company or public official) can report a violation of the code. The IGM undertakes market surveillance (by scanning newspapers for example) and can start cases by his own initiative. Every case is open and published on the website, which increases compliance and credibility for the system.

The LIF in Sweden also works pro-actively through the role of the Compliance Officer, who visits companies and gives lectures about the ethical rules, but more importantly, companies (and HCP, general public, lawyers etc.) can always contact the Compliance Officer by telephone or e-mail for guidance. There is a compliance committee and also two general meetings each year for all the compliance officers at the company. Thus, the companies are well aware and have a comprehensive knowledge of the rules, which are the main reasons the system is effective.

In **Denmark**, success is measured by the annual report. At the time of the last report (2011) ENLI had only been in operation for nine months. The report also has an English summary, available on the website. Companies rely on everyone in the system for it to work. This has been evident through complaining companies who are agile and vigilant. The open complaint system gives access to everyone. With one exception: companies who do not agree to comply with the Codes are they only ones who cannot complain. In one case, a company became a member after filing a complaint, because it saw that ENLI handled its the complaint in a professional manner. Standing shoulder to shoulder benefits everyone and makes the system stronger with more members.

In the **United Kingdom**, cases can be measured and tracked through the public website. At the conclusion of any case, a case report is published summarizing the details. The success of the system is also measured in the annual reports available on the website (dating from 2006 to 2011). These show that complaints are dealt with seriously and that when there are breaches sanctions are used. The UK arrangements are looked to world-wide as an effective system. Much of this is due to the publication of detailed case reports and the fact that many of the complaints are from health professionals. The MHRA strongly supports self regulation and has made complaints under the Code.

An element of self regulation is that companies look out for competitor activities and will raise potential complaints on an inter-company dialogue basis (Paragraph 5.3 of the Constitution and Procedure). Inter-company complaints can only proceed if the Director of the PMCPA is satisfied that the complainant company informed the respondent company that it proposed to make a formal complaint and offered intercompany dialogue at a senior level in an attempt to resolve the matter, but that this was refused or dialogue proved unsuccessful. A formal statement detailing the actions taken must be provided. There is no way of knowing the number of potential breaches of the Code that are settled in this process. The complaints system is very open as matters the subject of media criticism can be taken up (Paragraph 6.1 Constitution and Procedure). Companies sometimes voluntarily admit a breach of the Code.

In accordance with Paragraph 5.1 of the Constitution and Procedure for the Code, when the Director receives information from which it appears that a company (being either a member of the ABPI or a

company which, although not a member, has agreed to comply with the Code and accept the jurisdiction of the Authority) may have contravened the Code, the Director must assign a member of the Authority (who may be the Director) to be the case preparation manager to process the matter and, if appropriate, prepare case papers for the Panel.

The most effective mechanism to ensure that companies adhere to the requirements of the Code is the scrutiny of their activities and material by their competitors and health professionals and appropriate administrative staff with whom they interact.

In **Spain's** view, it is very difficult to measure the success of the compliance mechanisms. However, they have an objective and measurable parameter that reflects the self-regulation system's success. Since the implementation of the communication processes (for events, studies, and services), every year the number of communications received have increased. More often companies, within their internal procedures (Standard Operating Procedures), contemplate the benefits and convenience of communicating on a voluntarily basis. This trend in itself represents a success, as it allows the Surveillance Unit to prevent in advance any possible misconduct against the Code. It is important to consider that in Spain, the work is contemplated under a preventive philosophy, so the goal is to improve the image and to strength the confidence in the pharmaceutical industry.

In **Finland**, PIF measures its success through reporting annually. The annual reports are printed and published and available on its website. Also, preliminary inspection is required for all radio and televisions advertisements, PIF can check the number of times that a company has sought this approval before it was accepted. PIF believes that its system is effective when it sees the results from the penalties and in communication with Finnish national authorities; PIF understands that their workload is dramatically decreased thanks to the PIF self-regulation system.

c. Coverage

In **Sweden**, it would be impossible to estimate the percentage of potential violations covered, but there are plenty of cases each year, which demonstrates, in LIF's view, that the system is effective. The IGM reviews approximately 100 cases per year (although not every one leads to a conviction). The NBL reviews approximately 30 cases per year.

In **Denmark's** view, they cover most violations, but there is no way of verifying unless someone else tells them. Companies are subject to internal audits for ethical rules; ENLI also plays a dual role for advice in this sense, which strengthens the relationship and garners trust.

In the **United Kingdom**, the number of complaints to the PMCPA in 2011 was 84, slightly fewer than in 2010 when 86 complaints were received. The number of cases (84) was more than those considered in 2010 (78). There was a little difference in the number of individual allegations (matters) considered in 2011 (259) compared with 2010 (241). Fewer matters were appealed in 2011 (36) than in 2010 (44). The number of matters successfully appealed in 2011 was 21 which was an increase on the 17 matters successfully appealed in 2010. Of the 36 matters appealed in 2011, 58% were successfully appealed and 42% were unsuccessfully appealed. The proportion of the Code of Practice Panel's rulings successfully appealed increased in 2011, 8% (21/259) compared with 7% (17/241) in 2010. 6% (15/259) were unsuccessfully appealed in 2011 compared with 11% (27/241) in 2010. The average time taken to complete consideration of a case which was the subject of appeal was less in 2011 (15 weeks) than in 2010 (16.9 weeks), so there is evidence of efficiency.

In **Spain's** view, it is very difficult to establish in advance a percentage. The self-regulation system applies to pharmaceutical companies that represent more or less the 90% of prescription-only medicines market in Spain. The Surveillance Unit is only aware of those activities and practices communicated. Apart from

our communication processes, we have several information sources: companies, healthcare professionals, general public, authorities, etc. Moreover, we have an open complaint procedure. This means that anyone can issue a complaint against any company subject to the Code.

In **Finland**, PIF does actually not receive a large number of complaints, so it is difficult to estimate to total number of potential violations. PIF cannot specify how it could improve its coverage of violations, but it has found that the number of complaints compared to the number of activities is small. The Finnish Generic Pharmaceutical Industry continued to opt out and did not subscribe to the Code of Ethics, so perhaps this could be an area of improvement.

2. Comprehensive Review, Sampling and Audits

a. Comprehensive review

In **Denmark**, there is mandatory reporting for medical product promotion. There is also mandatory reporting of marketing activities towards healthcare professionals to ENLI, which is operationally accomplished through a pre-vetting procedure.

In **Spain**, monitoring and surveillance is conducted solely by comprehensive review. For example, there is a daily review of hospitality and events that can be up to 35 – 40 communications per day.

b. Review by sampling

In **Sweden**, it is considered that companies have an incentive for compliance in order to avoid sanctions and bad reputation, so there is a trust that review by sampling is sufficient. According to the statutes of the IGM and NBI, the IGM is responsible for monitoring the market. In order for the IGM to be able to carry out this task, the pharmaceutical companies must send new, up-to-date drug information to the IGM, such as publications, advertisements, invitations, mailings, TV advertisements or information on websites. On request, the IGM may provide general advice on measures that have not yet been implemented. Such advice constitutes non-binding advance decisions.

Public webpages for POM products cannot be marketed for general public and must be non-promotional and pre-approved by IGM. There is currently twelve webpages of this type.

In **Denmark**, member companies are obligated to report promotion activities. Due to the high compliance rate of 98-99% of all notified activities, it was decided that full review of the intake would not be efficient use of resources. The notification obligation accounts for approximately 6,000 reports annually, including promotion materials, promotion events, sponsorships and exhibitions. Instead of full review, there is a review by sampling through a screening process where about 50 % of the notifications are randomly selected for further review. While there are clear criteria that cannot be violated, the screening process is not qualitative, but random.

In the **United Kingdom**, in terms of methodology for surveillance, paragraph 17 of the PMCPA's Constitution allows for legal and technical scrutiny of guidelines of a company's procedure. The PMCPA arranges for the scrutiny of samples of advertisements, detail aids, leave pieces, other promotional items and meetings on a continuing basis in relation to the requirements of the Code. However, there is no mandatory pre-approval for new products, so this scrutiny can be considered rather limited.

c. Audits

In **Sweden**, the LIF does not use audits. In fact, it does not deem them as necessary as the IGM may use the statutory articles which require mandatory reporting, publications, mailings, etc.

In **Denmark**, there are no audits carried out by LIF of ENLI because the screening process is deemed to be sufficient.

In the **United Kingdom**, in each case where a breach of the Code is ruled (there are approximately 4-5 convictions per year according to the Annual Report), the company concerned must give an undertaking that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the future. An undertaking must be accompanied by details of the action taken to implement the ruling. At the conclusion of a case a detailed case report is published. However, an undoubted effect of such a conviction is the unwanted negative publicity and damage to the reputation of the company.

Additional sanctions are imposed in serious cases. These can include:

- an audit of a company's procedures to comply with the Code, followed by the possibility of a requirement
- for the pre-vetting of future material
- recovery of material from those to whom it has been given
- the issue of a corrective statement
- a public reprimand
- advertising in the medical, pharmaceutical and nursing press of brief details of cases in which companies were ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand
- suspension or expulsion from the ABPI

In **Spain**, there is currently no auditing due to resource constraints, although if deemed necessary, the procedure could be implemented. The comprehensive review negates the need for an audit as the pharmaceutical companies are very aware that they are being monitored not only by the authority but also by their competitors. *Please see Article 13 of the Rules of Procedure*

III. SPECIFIC AREAS OF INTEREST BY COUNTRY

A. Pharmaceutical advertizing and marketing

Mintzes et al (2002) showed that exposure to advertising lead patients to request more drugs, and that these requests were usually complied with despite doctors reservations about the appropriateness of the treatment. Drug company promotion to the public includes disease awareness campaigns that can be run in countries that do not permit direct to consumer advertising as well as those that do. Patient groups are recruited to give the campaign a human face and supply stories for the media. In some cases high profile celebrities have been included to help the campaigns reach prime time television audiences (BMJ News, 1st June, 2002). (Moncrieff)

In Europe, article 97 of the Community Code states that “member states shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. Such methods shall in any event include legal provisions under which persons or organizations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Directive may take legal action against such advertisement, or bring such advertisement before an administrative authority competent either to decide on complaints or to initiate appropriate legal proceedings.”

1. Sweden

The Swedish Medicinal Products Act includes a basic provision that all advertising of medicinal products shall be kept up-to-date, factual, balanced, not be misleading and be compatible with good marketing practice. The advertising of medicinal products which are not authorized for sale in Sweden is not permitted. Advertising of medicinal products must also not be aimed at children and advertising of medicinal products available only on prescription must not be aimed towards the general public, with the exception of campaigns for vaccination against human infection diseases. Further, the Swedish Medical Products Agency has issued a regulation clarifying and specifying the rules governing the advertising of medicinal products for human use in Sweden.

Sweden adopted a new Market Practices Act, which entered into effect in July 2008. The Market Practices Act contains a general requirement that all marketing must be compatible with good marketing practice and fair towards consumers and the industry. The Market Practices Act also sets out specific rules on, among other things, misleading advertising, comparative advertising and special offers.

Detailed rules relating to pharmaceutical advertising can also be found in the Ethical Rules for the Pharmaceutical Industry issued by the Swedish Association of the Pharmaceutical Industry (LIF), last revised April 2012. Although not legally-binding, the LIF Rules are widely recognized by the pharmaceutical industry and applied by courts as an expression of fair and ethical marketing.

The LIF Rules include prohibitions on, among other things, advertisement of prescription drugs to the general public, off-label advertisement and pre-launch marketing. They also list rules with respect to e.g. comparative advertising, misleading, incomplete or unsubstantiated information and disguised advertisements.

Advertising and/or promotion is a very wide concept in Sweden and a great deal of the information that emanates from a pharmaceutical company on its own products is regarded as marketing material. Not only traditional adverts or promotion brochures fall within this definition, but also e.g. the unsolicited distribution by a pharmaceutical company of a scientific article covering the company’s own products will

be considered as a marketing activity if addressed to a physician or the general public (despite the fact that such article may, as such, be of a non-promotional nature).

2. Denmark

In Denmark, promotion of medicinal products towards the general public is not allowed. Pharmaceutical companies are thus obligated to report all kinds of printed promotion material targeted at healthcare professionals on the Danish market, whether in printed advertisements, leaflets, handouts or the like. Electronic texts are comparable with printed texts. Texts on websites are thus comparable with printed promotion and must be reported, if access to the promotion is restricted in a way that makes it inaccessible to the general public.

3. United Kingdom

Article 14.1 requires that:

‘Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by two persons on behalf of the company in the manner provided for by this clause. One of the two persons must be a registered medical practitioner or a UK registered pharmacist or, in the case of a product for dental use only, a registered medical practitioner or a UK registered pharmacist or a dentist.....The second person certifying on behalf of the company must be an appropriately qualified person or senior official of the company or an appropriately qualified person whose services are retained for that purpose.’

Article 14.3 states:

‘The following must be certified in advance in a manner similar to that provided for by Clause 14.1:

- educational material for the public or patients issued by companies which relates to diseases or medicines but is not intended as promotion for those medicines
- material relating to working with patient organisations as described in Clause 23 and its supplementary information
- material prepared in relation to joint working between the NHS and the pharmaceutical industry as described in Clause 18.5 and its supplementary information
- material relating to patient support programmes involving the provision to health professionals of items to be passed on to patients as described in Clause 18.2 and its supplementary information
- non promotional material for patients or health professionals relating to the provision of medical and educational goods and services, including relevant internal company instructions, as described in Clause 18.4 and paragraph 8 of its supplementary information.’

If there is a complaint about material, the company is asked to provide the certificate as required under Clause 14.

Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination campaigns carried out by companies and approved by the health ministers.

4. Spain

In Spain, the self-regulated and auto-controlled jury of Commercial Communications oversees the resolution process and is the independent out-of-court body in charge of adjudicating on complaints submitted on advertising issues. All the Jury's decisions are clearly explained and are published in Autocontrol's monthly newsletter and on its website.

5. Finland

In Finland, it is illegal to promote or advertize prescription-only medicines to consumers.

B. Medical product promotion

As a business, pharmaceutical companies' profits are heavily dependent on marketing. The greater the volume of medicines sold, the greater the return on investments. Promotion is a key factor driving sales volumes. However, when product sales are given priority over public health, promotion can lead to over-prescribing as well as poor quality prescribing and medicine use. This, in turn, leads to an increased risk of adverse effects and higher health-care costs. Prescribers often find themselves trapped between patients' needs and health-care priorities on the one hand and promotional influences on the other. Dual allegiances and conflicts of interest can cloud judgement and cause distortions in both the delivery of health care and the conduct of research in medicine. The pharmaceutical industry has recognized the need for guidance about how to implement its marketing practices so that health outcomes are enhanced (Lexchin and Ziganshina).

1. Sweden

According to the MPA Regulation LVFS 2009:6 on the marketing of medicinal products for human use and the LIF Rules (and MPA Regulation LVFS 1995:25 on the distribution of medicinal samples), free samples of medicinal products that have been authorized for sale in Sweden can be provided to persons qualified to prescribe the product, to those with a pharmacy authorization, to the responsible persons for medicinal products in pharmacies, to other retailers authorized to sell medicinal products, as well as pharmacists of hospital pharmacies (in the latter case, the sample may only be distributed by the healthcare professional). The sample may only be supplied in response to a written request, which has been signed and dated. The request must be kept and filed by the company. The company must also carefully check that the person sending the request is authorized to prescribe or dispense medicinal products.

Samples shall be distributed only with great restraint. Only one package of the smallest size shall normally be supplied on each occasion and the number of samples of each product each year to the same recipient must be limited. The sample must be marked with "medicinal sample, not for sale" and the expiry date, and it should be accompanied by a copy of the SmPC. The sample may not be used for the treatment of human beings or animals. Finally, it is not permitted to distribute free samples of medicinal products listed as narcotics by the MPA.

LIFs ethical rules article 26 (Drug samples):

Drug samples must be distributed in a very restricted manner, at most one per product per year to one and the same person. Drug samples of prescription drugs for human use may only regard new products. In this context a new product refers to a product that has been publicly available for less than two years. New strength or dosage form without new indication is not considered to be a new product. Further, samples shall be offered in conformity with that prescribed by the Medical Products Agency and specified

in regulations. Drug samples may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific drugs.

2. Denmark

According to Danish code Section 4.01, it is prohibited to promote medicinal products:

- a. which cannot be legally sold or distributed in Denmark
- b. magisterial medicinal products
- c. and the special medicinal products listed in Art. 3 of the Executive Order on Promotion.

Promotion of a medicinal product must be sufficiently complete and objective and it must not mislead or exaggerate the properties of the medicinal product. Information in promotion material must be consistent with the approved summary of product characteristics of the relevant medicinal product.

3. United Kingdom

The ABPI 2011 Code, which was fully effective from 1 May 2011, has introduced a rule about promotional aids which is new to the UK. Pharmaceutical companies are no longer permitted to provide promotional aids which previously habitually included stationery items, such as computer accessories for business use, pens, pads, diaries and calendars and clinical items, such as nail brushes, surgical gloves, tongue depressors, tissues and peak flow meters. The previous rule permitted these gifts if they were less than £6 in value, and names of medicines could be included on them if this would not be misleading. This change brings the UK into line with both PhARMA and Advamed on this particular point, according to UK Bribery Act.

4. Spain

Both the content and nature of promotional activities or materials as well as the interaction with the healthcare professionals must contribute to strengthening confidence in the pharmaceutical industry. In January 2004, additional measures were taken to reinforce this self-regulation system on promotion of medicinal products by (i) preparing and approving implementation guides, (ii) implementing the query system, published in a question and answer format, and (iii) making an in-depth reform of the Rules of Procedure, including the start-up of the Code of Practice Surveillance Unit as the body responsible for active monitoring of Code compliance.

The Code covers all promotional methods, including journal and direct mail advertising, the activities of medical representatives, the sponsorship of scientific congresses and scientific or professional meetings attended by health care professionals, the Internet, the use of audiovisual systems such as films, video recordings, data storage systems, and others that could arise in the future, and the provision of samples, gifts and hospitality.

The self-regulation system for the promotion of medicines of the pharmaceutical industry fully complies with the provisions of the Law of Unfair Competition. It collaborates with and belongs to Autocontrol, which is entrusted with the resolution of controversies, Autocontrol being the only Spanish private agency attached to the EJE-Net (European Extra-judicial Network) of the Commission.

5. Finland

The PIF code prohibits the distribution of free samples of medicinal products by pharmaceutical representatives directly to consumers. Free samples of medicines can be given only to persons who are authorized to prescribe or supply them, who factually prescribe or supply the medicinal product in

question, and therefore benefit from the opportunity to familiarize themselves with the product in question. A free sample of medicine refers to the smallest marketed package size of the medicinal product, given for free to the recipients to allow them to familiarize themselves with the product. Each recipient can be given only one free sample of each medicinal product, strength and pharmaceutical form in one calendar year.

C. Relations with healthcare professionals: Visits to hospitals and doctors' offices

1. Sweden

As a general rule, it is required that the co-operation between pharmaceutical companies and healthcare professionals is managed with good judgment and preserved credibility. In addition, such cooperation may not constitute any incentive for the healthcare professional to recommend, prescribe, purchase, supply, sell or administer specific drugs. In addition, the Swedish Medical Association has issued rules for their members regarding advertisement. These rules provide that physicians shall not present themselves as guarantors for any particular medicinal product. Thus, it is not permitted to have healthcare professionals endorse specific medicinal products in promotional materials.

During the period 2004-2007, strict regulations regarding healthcare management were developed. For example, today there must be a written invitation with product information in order to visit doctors; otherwise it is prohibited for a pharmaceutical professional to visit without prior approval.

In Article 33 of the LIF ethical rules, an invitation must be sent to the healthcare authority or delegated appointed contact person who decides if a meeting is permitted. Also, the general rule is that it should be in group. By way of exception, a single conference between employees and pharmaceutical companies may occur. Both group conferences and single conferences must be approved by the health authority. In practice, this is not a problem on the part of the pharmaceutical representative (in fact, in some cases, there is a problem where the health authority closes the door). There is a general good knowledge of this practice from doctors' point of view, thus it is based on an agreement between LIF and the Swedish Association of Local Authorities and Regions.

Regarding doctors' offices, the practice that has been established is that the written invitation to the healthcare authority contains a copy/tag that is sent back to the company with contact information. The LIF does not monitor what is said during these meetings, but if the pharmaceutical representative discusses or pushes prohibited issues, the HCP can report this to the IGM.

2. Denmark

In general, pharmaceutical sales representatives must conduct their relations with hospitals and doctors in a manner that is relevant to the HCP's work. There is no industry requirement that visits to GPs are arranged in advance (but the GP association has defined some informal guidelines). At hospital level there are such rules (both established by LIF and regional authorities). However, in practice, it may be more difficult to get a visit with a HCP without a prior appointment. During these visits, any mention of promotional materials must be in compliance with the rules.

HCP can report discussions that they feel cross the line and ENLI reports that in making complaints, HCP have felt compelled to do so in cases where their own professional integrity was violated. There is recognition by HCP that there is no common interest in violation. On the contrary, there is a high interest

in ethical behavior across the industry. Since April 2011, ENLI has only had two reported cases that led to sanctions deriving from inappropriate discussions that were notified to ENLI by HCP.

3. United Kingdom

Article 15.4 states:

‘Representatives must ensure that the frequency, timing and duration of calls on health professionals, administrative staff in hospitals and health authorities and the like, together with the manner in which they are made, do not cause inconvenience. The wishes of individuals on whom representatives wish to call and the arrangements in force at any particular establishment, must be observed.’

The Supplementary Information to Clause 15.4 states:

“The number of calls made on a doctor or other prescriber and the intervals between successive visits are relevant to the determination of frequency.

Companies should arrange that intervals between visits do not cause inconvenience. The number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. This does not include the following which may be additional to those three visits:

- attendance at group meetings, including audio-visual presentations and the like
- a visit which is requested by a doctor or other prescriber or a call which is made in order to respond to a specific enquiry
- a visit to follow up a report of an adverse reaction.

Representatives must always endeavour to treat prescribers’ time with respect and give them no cause to believe that their time might have been wasted. If for any unavoidable reasons, an appointment cannot be kept, the longest possible notice must be given.

When briefing representatives companies should distinguish clearly between expected call rates and expected contact rates. Contacts include those at group meetings, visits requested by doctors or other prescribers, visits in response to specific enquiries and visits to follow up adverse reaction reports. Targets must be realistic and not such that representatives breach the Code in order to meet them.”

Article 15.5 states

“In an interview, or when seeking an appointment for one, representatives must at the outset take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.”

Article 15.9 states

“Companies must prepare detailed briefing material for medical representatives on the technical aspects of each medicine which they will promote. A copy of such material must be made available to the Medicines and Healthcare products Regulatory Agency and the Prescription Medicines Code of Practice Authority on request. Briefing material must comply with the relevant

requirements of the Code and, in particular, is subject to the certification requirements of Clause 14.

Briefing material must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.”

In the event of a complaint regarding prior permission to call upon a hospital doctor a pharmaceutical company would need to demonstrate that it took steps to establish whether there was a policy before arranging any interview.

The Code applies to what representatives say as well as the materials they use. The briefing material is an important document.

Meetings with healthcare professionals, hospital administrators and other persons making decisions on the use and purchase of pharmaceutical products are not, of themselves, problematic under the UK Bribery Act. However, once “hospitality” is added to the agenda for such meetings or gifts beyond pens, pencils and paper necessary for the meeting (without the name of a particular medicine inscribed on them), that is where a concern is raised under the code, and as a result of this, under the Bribery Act.

Relationships with patient groups are another channel of influence for the industry. In some instances, patient groups appear to have been set up by drug companies. Two international groups are also linked to the industry and have been active in lobbying the European Commission to introduce direct to consumer advertising. IAPO (International Alliance of Patients Organizations) was founded and is funded by Pharmaceutical Partners for Better Healthcare, a consortium of about 30 companies, and GAMIAN (Global Alliance for Mental Illness Advocacy) was originally founded by Bristol Myers Squibb.

4. Spain

The Code is not intended to inhibit the exchange of medical and scientific information during the development phase of a product nor to limit the relationship between the pharmaceutical companies and the healthcare professionals, but to establish rules of conduct that the entire pharmaceutical industry agrees to adhere to.

Article 12 governs medical visits. Medical representatives should ensure that the frequency, timing and duration of visits to healthcare professionals, administrative staff in hospitals, and health authorities and the like, together with the manner in which they are made, do not cause inconvenience. Both when interviews are agreed and conducted, medical representatives should from the very outset take any reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent. Medical representatives must notify to the scientific service of the pharmaceutical company any information they receive from the professionals about the use of the medicines they promote, with particular reference to any untoward reactions reported to them by the persons they visit.

At each visit, medical representatives will provide to the person visited, or have available for him/her if requested, the current summary of product characteristics for each medicinal product they promote, accompanied by information on the different pharmaceutical forms and dosages, the prescription and dispensing conditions of the medicinal product, price information, the conditions of reimbursement by the National Health System, if applicable, and when feasible, the estimated cost of the treatment.

Companies shall adopt efficient measures and watch so the interactions between the medical representatives and other pharmaceutical company staff with the healthcare professionals (including any other person who, in the practice of his/her professional activity, can carry out or determine the activities

of prescribing, buying, distributing, dispensing or administering a medicine), complies with this Code and the applicable regulation provisions at any given time.

5. Finland

Regarding hospital visits, PIF has a special, separate code relating to pharmaceutical representatives, available on its website in its ethical code. It allows hospitals to decide whether or not to allow these visits. Some hospitals have their own codes of regulation, as well as instructions on the best way to handle representatives. PIF cannot confirm in practice how they manage it. If the hospitals have codes and have sent them, PIF has made them available to its members via their extranet.

PIF has found the issue of doctors' visits to be difficult to monitor and verify. Thus, it relies on the doctors to file a complaint if visits or the content of discussions violate its Code; however, it is challenging because the doctor or competitor would need to supply written proof i.e. pamphlets, documents given by the representative.

D. Conflict of interest

1. Sweden

A number of investigations have been initiated regarding financial support by the industry. There is also a review of the Swedish bribery legislation to address conflict of interest.

2. Denmark

In Denmark, it is permitted to use healthcare professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel. Regarding conflict of interest, ENLI follows the same rules as public administration in legal practice. There is an obligation to ensure no conflict. While no full disclosure is required, Danish legislation demands that all HCPs seek Danish Board of Health (DBH) for a pre-approval before they can act as a consultant or advisor for a company. A list of names of HCPs and companies collaborating in this way are published (the public list do not include disclosure of amounts for fees) on the DBHs homepage. Actual conflict towards any person is prohibited but this does not include a general conflict. There are rules against stocks and accepting paid job opportunities, for example a medical investigator cannot accept any paid consulting for a company. A ministerial working group will launch recommendations for adjustments of the authority based approval system and future disclosure in the first quarter of 2013.

3. United Kingdom

Complainants from outside the industry are asked if they have any direct or indirect commercial, financial or other interest in the matter of complaint or in pharmaceutical company complained about, such as being an employee or ex-employee. Such interests are disclosed to pharmaceutical company and would normally be included in the case report. (Paragraph 5.2 of the Constitution and Procedure).

If a member of the Code of Practice Appeal Board is concerned in a case either as complainant or respondent, that member does not receive copies of the papers circulated in connection with the case and is required to withdraw from the Appeal Board during its consideration. (Paragraph 4.4 of the Constitution and Procedure).

The complainant and the respondent are advised in advance of the membership of the Appeal Board, including potential co-optees, and asked if they have any objections to particular members and the grounds for such objections. Any member in respect of whom there are valid objections must withdraw from the Appeal Board during consideration of the case. The Chairman determines whether objections are valid.

Members of the Appeal Board must declare any other interest in a case prior to its consideration. Having consulted the representatives of the parties (if present), the Chairman determines whether it is appropriate for a particular member to remain for the consideration of the case.

The industry is also increasing its influence over central government policy in the United Kingdom through recently established government bodies such as the Pharmaceutical Industry Competitiveness Task Force, the Industry Strategy group and partnerships with health service bodies. The National Institute for Mental Health England (NIMHE) and the pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI), recently announced a formal partnership. The first production of this partnership is a compendium describing collaborative projects around the country entitled "Meeting of Minds." These projects are diverse and include the publication of guidelines, audit packs, toolkits, websites, directories and funding additional personnel including a pharmacist and a primary care liaison worker (NIMHE & ABPI, 2002).

4. Spain

In Spain, there is a high priority placed on monitoring for conflict of interest. In fact, in order to be employed by the Code of Practice Surveillance Unit, there is a requirement of having no prior professional experience in the pharmaceutical industry. Today, the Code of Practice Surveillance Unit is composed of 5 staff members, none of whom have healthcare industry experience before assuming their position.

Concerning services provided by HCPs, please see Rules of Procedure Article 17.3

5. Finland

PIF has specific rules on conflict of interest. Links to the pharmaceutical industry must be declared before becoming a member of the inspection board. The inspection board is neutral and independent so as not to have a real or perceived conflict of interest in making its decisions. For example, members must not be from the pharmaceutical industry, but usually have a medical or university background, or come from another stakeholder group. Any other conflict of interest must be reported.

E. Non-intervention studies

1. Sweden

Non-interventional studies are regulated by chapter IV in the LIF Ethics rules. Pharmaceutical companies must also appoint a body that shall approve and monitor non-interventional studies. The body that is appointed should include a physician, or where appropriate a pharmacist, to be responsible for monitoring the non-interventional studies (also including reviewing liability for such studies, in particular those for which pharmaceutical representatives are responsible). The responsible executive must certify that he or she has examined the report/publication and that it is compatible with the applicable laws and provisions.

The prescription of any drugs being studied must be clearly separated from the decision to include the patient in the study. The drug must be prescribed in the normal manner and in accordance with the terms of the marketing authorisation. The contribution of the medical representative may only be administrative in character and under the supervision of the medical department, which should also ensure that the representative has the relevant training. The representative's contribution may not be associated with the prescribing of drugs.

The study is to be conducted so that the parties maintain full confidence and an independent standing in relation to one another. The study should not result in undertakings or expectations concerning prescribing or use of the pharmaceutical company's products.

As with clinical trials, pharmaceutical companies must publish the information given in the summary of the report/publication for non-interventional studies. These studies are not approved by the Medical Products Agency but must be sent to the Ethics committee.

2. Denmark

Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study must comply with all of the following criteria:

- a) The study is conducted with a scientific purpose;
- b) There is a written study plan (protocol) and there are written contracts between healthcare professionals and/or the institutes at which the study will take place, on the one hand, and the pharmaceutical company sponsoring the study, on the other hand, which specify the nature of the services to be provided and, subject to clause c) immediately below, the basis for payment of those services;
- c) Any remuneration provided is reasonable and reflects the fair market value of the work performed; and the pharmaceutical company must, upon request, make information about how the remuneration was assessed available to ENLI;
- d) Study protocols concerning non-interventional studies (description of non-interventional studies) must be submitted to the Danish Medicines Agency for review and guidance;
- e) The Danish Act on Processing Personal Data (including the collection and use of personal data) must be complied with;
- f) The study must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product;
- g) The study protocol must be approved by the pharmaceutical company's scientific service as described in section 19.02, sub-section a);
- h) The study results must be analyzed by or on behalf of the contracting company and summaries thereof must be made available within a reasonable period of time to the company's scientific service (as described in section 19.02, sub-section a)). The scientific service must maintain records of such reports for a reasonable period of time. The pharmaceutical company must forward the summary report to all healthcare professionals that participated in the study and must make the summary report available to ENLI upon their request. If the study

shows results that are important for the assessment of benefit-risk, the summary report must be immediately forwarded to the relevant competent authority; and

i) Pharmaceutical sales representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product;

j) Pharmaceutical companies may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

A cooperation agreement exists between the authorities and companies for evaluation that there must be no marketing. ENLI does not handle this; the rules define criteria, but if there is a complaint, they can assist in the investigation.

3. United Kingdom

Non interventional studies are covered by Clause 13 of the Code. Non interventional studies are not monitored by the PMCPA.

Companies must have a scientific service to deal with the approval and supervision of non-interventional studies. Companies also have to publish the summary details and results of non-interventional studies of marketed medicines in a manner consistent with their parallel obligations with respect to clinical trials.

Non-interventional studies that are prospective in nature and involve the collection of patient data must be conducted for a scientific purpose. They must comply with the following criteria:

- there must be a written protocol and written contracts between the health professionals and/or the institutes at which the study will take place and the pharmaceutical company sponsoring the study, which specify the nature of the services to be provided and the payment for those services
- any remuneration must be reasonable and reflect the fair market value of the work
- in countries where ethics committees are prepared to review such studies, the study protocol must be submitted to the ethics committee for review
- data protection legislation must be complied with the study must not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine
- the company's scientific service must approve the protocol and must supervise the conduct of the study
- the study results must be analyzed and summaries must be made available within a reasonable period of time to the company's scientific service, which service shall maintain records of such reports; the summary report should be sent to health professionals who participated in the study. If the study results are important for the assessment of benefit-risk, the summary report should be immediately forwarded to the relevant competent authority

- sales representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service which will also ensure that the representatives are adequately trained for the role; such involvement must not be linked to the promotion of any medicine.

4. Spain

Communication process included in Article 14.3 exclusively applies to Market Research Studies. For studies and market research, there have been mandatory communications since 2008. Clinical trials and Non-interventional Studies are covered under articles 14.1 and 14.2. Those articles remind companies the obligation to comply with specific legislation applicable to those kinds of practices.

Please see above the conditions of communication.

Post-authorization observation studies shall be those epidemiological studies that meet the conditions of being post-authorization and observational. These must be conducted in accordance with the requirements of applicable legislation, among others, submission of the documentation to the AEMPS for registration and classification, submission to a Clinical Research Ethics Committee for evaluation, etc. These studies should in no case be undertaken as a procedure to promote a product or to induce prescription by healthcare professionals.

5. Finland

The pharmaceutical companies must have a scientific service unit responsible for the information distributed on the medicines of the company and for the correctness of such information as well as on the control of the non-interventional studies.

Prospective non-interventional studies, whereby individual healthcare professionals collect patient data, are permitted under the following conditions:

- a) The study is made for a scientific purpose;
- b) The study is accompanied with a written study protocol and with written contracts between the healthcare professionals or the units at which the study will take place and the company financing the study. The contracts must specify the nature of the services provided and the criteria of the compensation payable for the services;
- c) The compensation payable for the services is reasonable, reflecting the fair market price of such services;
- d) Whenever possible, the study protocol is approved by an ethics committee;
- e) The Personal Data Act is followed in connection with the study;
- f) The study does not constitute an incentive for the recommendation, prescription, purchase, supply, selling or administration of a particular medicinal product;
- g) The company's scientific service unit has approved the study protocol, monitoring the progress of the study;
- h) The company must analyze, or have another party analyze, the results of the study, and the scientific service unit must be provided with the respective summary within a reasonable time.

The scientific service unit maintains records of these summaries, stored for a reasonable period of time. The summary report must be sent to all healthcare professionals participating in the study, and, upon request, also to the use of the competent bodies of the Supervisory Commission for the Marketing of Medicinal Products. If the results of the study are important for the evaluation of the risk benefit relationship of the medicinal product, the summary report must also be sent immediately to the competent Authorities;

i) The medical sales representatives can participate in the implementation of the study in an administrative capacity only, under the control of the scientific service unit. The scientific service unit must ensure that the medical sales representatives have received proper training for the implementation of the study.

PIF has a paragraph in our Ethical Code on product safety during Phase 4 of non-intervention studies, but this paragraph has never (or not yet) been interpreted in practice nor does it have examples of this, so PIF is currently not monitoring the issue.

F. Gifts

1. Sweden

Great care must be taken when gifts or other benefits are offered to the public, as well as private medicinal practitioners, as the level of acceptance concerning gifts is extremely low in Sweden. Any person who gives, promises or offers any improper remuneration to an employee in respect of his service may be held guilty of bribery under the Swedish Criminal Code. Gifts which risk influencing professional decisions will also infringe the LIF Rules. The assessment whether a gift is improper or not shall be based on all available facts including: (i) to whom the gift is offered; (ii) in what context the gift is offered; (iii) the type and value of the gift; and (iv) the presentation of the offer. The gift should, as a general principle under the bribery rules, be related to and constitute a natural and useful part of the physician's medicinal practice (e.g. scientific literature). As a rule of thumb, the market value of a benefit according to said bribery rules should not exceed SEK 100, but a higher value may under certain circumstances be acceptable. Donations of money must never be granted to medicinal practitioners. It should be noted, however, that the LIF Rules contain a very strict limitation according to which no gifts which are not related to the physician's medicinal practice are allowed. Medicinal and educational goods and services intended to affect prescription patterns are likely to be considered unethical.

Gifts are not monitored by the LIF. The LIF ethical rules (article 40) is partly based on EFPIAs code and states that *"Gifts may only be distributed with considerable restraint, and may only refer to articles of little value and that are relevant (i.e. have a medical connection) to the professional. The term "little value" refers to no higher amount than at any time is determined by LIF's Board."* That value is 100 kr (approximately 10 Euros). The IGM have had some cases regarding gifts some years ago that did not have medical relevance (candy and cookbooks).

2. Denmark

In general, gifts must not be given or offered to healthcare professionals as part of marketing or otherwise with the intention of promoting the sales of a medicinal product unless such gifts are of insignificant value and relevant to the practice of the recipient. In practice, this is limited to a maximum value of 300 DKK from a pharmaceutical company to a healthcare professional per year. This implies that companies must track the number and value of gifts that are given per year to each HCP. The Danish Code (based on EFPIA code) also sets a ban on occasional gifts to HCPs. ENLI controls all gifts on an individual level, but does not currently verify the annual limit of each company.

3. United Kingdom

The medical profession is the industry's primary target. Routine marketing strategies include the provision of "hospitality," which can vary from the provision of lunchtime refreshments for local meetings to the financing of meals in expensive restaurants or the provision of expenses paid trips to attractive foreign locations for company presentations.

The General Pharmaceutical Council is the regulatory body for pharmacists and pharmacy technicians. The Council's Standards of conduct, ethics and performance state 'Do not ask for or accept gifts, rewards or hospitality that may affect, or be seen to affect, your professional judgment'.

Article 18.1 states:

No gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to administrative staff in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, except health professionals may be provided with items which are to be passed on to patients and which are part of a formal patient support program, the details of which have been appropriately documented and certified in advance as required by Article 14.3. The items provided must be inexpensive and directly benefit patient care. They may bear the name of the company providing them. They must not be given out from exhibition stands. They must not be given to administrative staff unless they are to be passed on to a health professional.

Article 18.3 states:

'Health professionals and appropriate administrative staff attending scientific meetings and conferences, promotional meetings and other such meetings may be provided with inexpensive notebooks, pens and pencils for use at such meetings. They must not bear the name of any medicine or any information about medicines but may bear the name of the company providing them.'

Clause 18.4 states:

Medical and educational goods and services which enhance patient care, or benefit the NHS and maintain patient care, can be provided subject to the provisions of Article 18.1. They must not be provided to individuals for their personal benefit. Medical and educational goods and services must not bear the name of any medicine but may bear the name of the company providing them.

4. Spain

To ensure the independence of the decisions related to the prescribing, dispensing, or administering of medicines with regard to business interests, no gifts, bonuses, pecuniary advantages or benefits in kind may be granted, offered, or promised by those who have direct or indirect interests in the manufacture, production or commercialization of medicines to healthcare professionals or to any person who, in the practice of his/her professional activity, can carry out or determine the activities related to the medicine prescription, dispensation or administration cycle, including their relatives, with the exception of inexpensive gifts related to the practice of medicine or pharmacy. Therefore, the provision of gifts such as items for professional use in the practice of medicine or pharmacy or office items of insignificant value is permissible.

It is envisaged that this article might change due to the last decision took at EFPIA level, prohibiting the provision of gifts.

5. Finland

Gifts are not prohibited unless they are under 25 euros and would be something that the doctor can use in practice. The distribution and offer of advertising gifts related to the marketing of medicinal products must be reasonable. The advertising gifts must have minor economic significance for the recipient, and they must have a bearing on their professional operation. Doctors and competitors are encouraged to make a complaint.

G. Booths or stands at events including conferences and galas

1. Sweden

Both the Swedish Criminal Code and the LIF Rules have placed great emphasis on all kinds of sponsoring, travel and events, but the LIF does not monitor events. Instead, the LIF counts on the fact that eventually, inappropriate information is reported to the IGM by competitive companies or a HCP. Article 37 states the following about social activities: "Independent social or leisure activities may not be offered by pharmaceutical companies or requested by healthcare/the pharmacies' staff, either in conjunction with conferences or other dealings. Simple social activities, such as background music or local performances, playing at the venue in connection with the meeting shall not be considered as offered by pharmaceutical companies provided that it has neither been organized, requested nor paid for by the pharmaceutical company."

Product information that is presented in exhibition stands or that is distributed at international scientific conferences or symposia may refer to drugs that are not registered in the country where the event is taking place, or that are registered in a different way, on the condition that:

- The event is an international scientific meeting with a majority of participants from countries other than the country where the event is taking place.
- Marketing material containing information about a drug that has not been granted marketing authorization in the country where the meeting is taking place must include details about the countries in which the drug has received marketing authorization, as well as the fact that it has not been granted such authorization in the country where the event is taking place.
- Marketing material that refers to prescribing information (indication, warning texts, etc.) that has been approved in a country or countries, although not in the country where the event is taking place, but where the drug is registered, must be followed by information that the registration terms may differ internationally.

The information must indicate the countries in which the drug has been approved, and specify that the drug has not been approved locally.

2. Denmark

The rules state that companies must provide the details of hospitality by value including the dinner and location. The criteria state that it must be 1. a reasonable level; 2. limited to travel costs meals registration and accommodation (for example, a short meeting cannot have dinner, but must be more than 2 hours long to offer dinner); 3. strictly limited to the main purpose of the event and only provided to healthcare professionals in their own right.

In connection with the holding of professional events, where pharmaceutical companies are given access to promotion and marketing of medicinal products, such promotion and marketing must be conducted separate from the rest of the event's professional content. When pharmaceutical companies are given the opportunity to advertise, exhibit, display movies, inform about products etc., it must be conducted on the basis of a preceding agreement on the conditions, including the financial terms and program of the event.

Promotion material, which appears on exhibition stands or is distributed to participants at international events outside of Denmark may, without regard to section 4.01, unless prohibited or otherwise regulated by local laws and regulations, refer to medicinal products (or uses), which are not registered in the country where the event takes place, or which are registered under different conditions, so long as:

- a. Any such promotion material (except for promotional aids) is accompanied by a suitable statement indicating countries in which the medicinal products is registered and makes clear that the medicinal product or use is not registered locally, and
- b. Any such promotion material, which refers to the prescribing information (indications, warnings, etc.) authorized in a country or countries where the medicinal product is registered should be accompanied by an explanatory statement indicating that registration conditions differ internationally.

In the past, there was a practice of inviting the spouse to events, but today trends have since long changed that type of behavior. Entertainment is prohibited as well as anything that signals luxury. Because there is such a focus on the level of detail, companies become more vigilant and it becomes more than a statement, but transfers into their way of thinking. Since competition is fierce, companies monitor each other and the relationship amongst them is a legitimate way to monitor and ensure compliance. In fact, there is evidence that even before a competitor complains about a company, it has generally tried to alert the company of its unacceptable behavior before reporting it.

3. United Kingdom

All international events that take place outside the responsible pharmaceutical company's home country, must be notified in advance to any relevant local subsidiary or local advice taken.

Health professionals and appropriate administrative staff attending scientific meetings and conferences, promotional meetings and other such meetings may be provided with inexpensive notebooks, pens and pencils for use at such meetings. They must not bear the name of any medicine or any information about medicines but may bear the name of the company providing them.

Article 19.1 states that

'Companies must not provide hospitality to members of the health professions and appropriate administrative staff except in association with scientific meetings, promotional meetings, scientific congresses and other such meetings, and training. Meetings must be held in appropriate venues conducive to the main purpose of the event. Hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting ie subsistence

only. The level of subsistence offered must be appropriate and not out of proportion to the occasion. The costs involved must not exceed that level which the recipients would normally adopt when paying for themselves. It must not extend beyond members of the health professions or appropriate administrative staff.'

Article 19.1 Supplementary Information

'The provision of hospitality is limited to refreshments/subsistence (meals and drinks), accommodation, genuine registration fees and the payment of reasonable travel costs which a company may provide to sponsor a delegate to attend a meeting. The payment of travel expenses and the like for persons accompanying the delegate is not permitted. Funding must not be offered or provided to compensate merely for the time spent by health professionals in attending meetings. The payment of reasonable honoraria and reimbursement of out of pocket expenses, including travel, for speakers, advisory board members and the providers of other professional services, is permissible. The arrangements for meetings must comply with Clause 19.1 with regard to hospitality and venues.

Companies should only offer or provide economy air travel to delegates sponsored to attend meetings. Delegates may of course organise and pay at their own expense the genuine difference between economy travel and business class or first class.

Pharmaceutical companies may appropriately hold or sponsor a wide range of meetings. These range from small lunchtime audio-visual presentations in a group practice, hospital meetings and meetings at postgraduate education centres, advisory board meetings, visits to research and manufacturing facilities, planning, training and investigator meetings for clinical trials and non-interventional studies, launch meetings for new products, management training courses, patient support group meetings and satellite symposia through to large international meetings organised by independent bodies with sponsorship from pharmaceutical companies.

With any meeting, certain basic principles apply:

- the meeting must have a clear educational content
- the venue must be appropriate and conducive to the main purpose of the meeting; lavish, extravagant or deluxe venues must not be used, companies must not sponsor or organise entertainment (such as sporting or leisure events) and companies should avoid using venues that are renowned for their entertainment facilities
- the subsistence associated with the meeting must be secondary to the nature of the meeting, must be appropriate and not out of proportion to the occasion
- any hospitality provided must not extend to a spouse or other such person unless that person is a member of the health professions or appropriate administrative staff and qualifies as a proper delegate or participant at the meeting in their own right
- spouses and other accompanying persons, unless qualified as above, may not attend the actual meeting and may not receive any associated hospitality at the company's expense; the entire costs which their presence involves are the responsibility of those they accompany.

Administrative staff may be invited to meetings where appropriate. For example, receptionists might be invited to a meeting in a general practice when the subject matter related to practice administration.

A useful criterion in determining whether the arrangements for any meeting are acceptable is to apply the question 'would you and your company be willing to have these arrangements generally known?' The impression that is created by the arrangements for any meeting must always be kept in mind.

Meetings organised for groups of doctors, other health professionals and/or for administrative staff which are wholly or mainly of a social or sporting nature are unacceptable.

Meetings organised by pharmaceutical companies which involve UK health professionals at venues outside the UK are not necessarily unacceptable. There have, however, to be valid and cogent reasons for holding meetings at such venues. These are that most of the invitees are from outside the UK and, given their countries of origin, it makes greater logistical sense to hold the meeting outside the UK or, given the location of the relevant resource or expertise that is the object or subject matter of the meeting, it makes greater logistical sense to hold the meeting outside the UK. As with meetings held in the UK, in determining whether such a meeting is acceptable or not, consideration must also be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, subsistence provided and the like. As with any meeting it should be the programme that attracts delegates and not the associated hospitality or venue.

Promotional material which is displayed or provided at international meetings held outside the UK may, unless prohibited or otherwise regulated by local laws and regulations, refer to medicines or their indications which are not registered in the country where the event takes place, or which are registered under different conditions, so long as any such material is accompanied by a suitable statement indicating countries where the product is registered and making clear that the product is not registered locally. Any such promotional material which refers to the prescribing information authorized in a country or countries where the medicine is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally.

The requirements relating to international meetings held in the UK are set out in the supplementary information to Article 3.

The requirements of the Code do not apply to the provision of hospitality other than to that referred to in Clauses 19.1 and 23.2 and the supplementary information to Clauses 20 and 22.2.

Article 19.1 Meetings Organised by Affiliates Outside the United Kingdom

Companies should remind their affiliates outside the United Kingdom that the ABPI Code of Practice must be complied with if UK health professionals attend meetings which they organise regardless of whether such meetings occur in the United Kingdom or abroad.

Given the requirements in the Code a pharmaceutical company would not be able to take health professionals to a show. The advice regarding dinners is given in the supplementary information to the Code. Pharmaceutical companies could provide dinner if this were justified by the educational content of the even and all other requirements of the Code were followed. Companies should not be providing gala dinners on describing dinners in that way.

The published case reports on the PMCPA website provide further guidance including examples of breaches of the Code.

Many companies have their own codes of conduct guidance etc which give very detailed information about conduct of meetings including limits for the cost of hospitality.

4. Spain

Since 2004, there are mandatory communications by pharmaceutical companies regarding hospitality and events. Failure to notify a scientific and promotional meeting or event, when such notification is obligatory, shall constitute an infringement of this Code.

Please review the conditions of communication

Pharmaceutical companies may organize or collaborate in events of a purely scientific-professional nature. It is not permitted to organize or collaborate in events containing elements or activities of an entertainment or recreational nature. This prohibition does not include welcome cocktails, work lunches and dress dinners that are usually included in the official programs of congresses and scientific meetings, provided they are reasonable and moderate and do not include additional elements (cultural, leisure or entertainment, etc.).

5. Finland

Marketing material made available at exhibition stands or distributed to the participants in international events may refer to medicinal products or indications of products with no marketing authorization in the country where the event is organized if:

- a. this material is accompanied with information on the countries where the product or indication has a marketing authorization, and the material clearly shows that the product or indication has no marketing authorization in the country where the event takes place;
- b. the information on the medicine is accompanied with a clarifying notice specifying that the information differs in accordance with the marketing authorizations in force in each separate country; and
- c. this is permitted by the national legislation of the place where the event takes place.

PIF does not monitor booths or stands at events itself, but relies on competitors of companies to report or file a complaint on what they see is unacceptable behavior. PIF does not really see this issue as a major problem in Finland.

IV. ANNEX: CODES OF NATIONAL ASSOCIATIONS

1. Sweden

Ethical rules for the pharmaceutical industry in Sweden (Revised 16 April, 2012.
Valid from 1 September, 2012)

2. Denmark

The Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals, 2011 (published in January 2012)

3. United Kingdom

Code of Practice for the Pharmaceutical Industry, 2nd edition 2012, together with the Prescription Medicines Code of Practice Authority: Constitution and Procedure

4. Spain

Spanish Code of Good Practices for the Promotion of Medicines and Interaction with Healthcare Professionals (2010)

5. Finland

Code of Ethics for the Pharma Industry Finland (PIF) (2008)

FOR FURTHER READING:

- Advertising of nonprescription medicines to the public: A significant contributor to healthcare: What is the best way to manage it? Regulation of nonprescription medicines advertising, http://www.wsmi.org/pdf/wsmi_brochureadvertising.pdf
- Association of the European Self-Medication Industry, Self-Regulation of Drug Promotion, www.pharmaceuticalpolicy.nl/Publications/Reports/putzeistreview.pdf
- European Advertising Standard Alliance's (EASA) Best Practice Self-Regulatory Model. (EASA has provided a ten-point checklist for a functional self-regulatory system.)
- European Commission's Corporate Responsibility Process in the field of pharmaceuticals, Platform on Ethics and Transparency
- European Commission Code for Effective Open Voluntarism: Good design principles for self- and co-regulation and other multi-stakeholder actions
- International Federation of Pharmaceutical Manufacturers and Associations, 2012 Comparison Chart including new IFPMA Code of Practice. (The Comparison Chart serves as a useful tool that provides a snapshot of the global research-based pharmaceutical industry's self-regulation mechanisms and the commitment of IFPMA members to ethical promotion of medicines, to healthcare professionals, for the safety and benefit of patients worldwide.)

BIBLIOGRAPHY:

1. (Moncrieff) Joanna Moncrieff, Is Psychiatry for Sale?: An Examination of the Influence of the Pharmaceutical Industry an Academic and Practical Psychiatry, Institute of Psychiatry (2003), <http://www.critpsynet.freeuk.com/pharmaceuticalindustry.htm>

2. (Pharmaceutical Advertising 2012) The International Comparative Legal Guide to Pharmaceutical Advertising 2012, A practical cross-border insight into pharmaceutical advertising (9th ed.)

Sweden:

<http://www.mannheimerswartling.se/Publikationer/ICLG%20Pharmaceutical%20Advertising%202012.pdf>

United Kingdom :

Pharmaceutical Promotion and the UK Bribery Act - Alison Dennis & Tony Lewis, Field Fisher Waterhouse LLP

http://www.ffw.com/pdf/PA12_Chapter-2_FieldFisherWaterhouse.pdf

3. Joel Lexchin and Lilia Ziganshina, Understanding and Responding to Pharmaceutical Promotion, World Health Organization/Health Action International

4. Denmark: Lif's ethical rules for dialogue and negotiations with decision-makers, <http://parno1.ipapercms.dk/LIF/Lifpublikationer/Etiskkodeks/Etisklobbykodeksuk/>

The pharmaceutical industry's code for advertising, etc., for medicinal products directed at healthcare professionals

http://www.lifdk.dk/graphics/Lif/dokumenter/etik%20og%20regler/ENLI_Ethical%20rules%20for%20promotion%20of%20medicinal%20products%20towards%20healthcare%20professionals.pdf

5. Spain:

Rules of Procedure for the Control Bodies of the Spanish Pharmaceutical Industry Self-Regulation System – Dec 2010

Implementation Guide of the Spanish Code of Practice for the Promotion of Medicines and Interaction with Healthcare Professionals – Dec 2010

Spanish Code of Practice for the Promotion of Medicines and Interaction with Healthcare Professionals – Dec 2010

6. Finland:

Kaisa Kyttä & Jyrki Tala, Review of the Self-Regulatory System for Pharmaceutical Promotion

http://www.optula.om.fi/Satellite?blobtable=MungoBlobs&blobcol=urldata&SSURIapptype=BlobServer&SSURIcontainer=Default&SSURIsession=false&blobkey=id&blobheadervalue1=inline;%20filename=09drs9bv_2.pdf&SSURIscontext=Satellite%20Server&blobwhere=1225117615186&blobheadername1=Content-Disposition&ssbinary=true&blobheader=application/pdf

Pif Code of Ethics: [http://www.pif.fi/Banners/PIF_Code_of_Ethics_08_final%20\(ID%203978\).pdf](http://www.pif.fi/Banners/PIF_Code_of_Ethics_08_final%20(ID%203978).pdf)

Ethical rules for the
pharmaceutical industry
in Sweden



Revised 16 April, 2012. Valid from 1 September, 2012.

CONTENTS

Ethical rules for the pharmaceutical industry	7
Background and purpose	7
Chapter I	
Rules governing drug information	8
Background and purpose	8
Area of application	9
Section I: Rules governing drug information to healthcare personnel	9
Section II: Rules governing drug information to the general public	9
General rules of conduct regarding the content and form of the information	10
Objectivity	10
Articles 1, 101, 2	10
Articles 3, 102	11
Articles 102 a, 103	12
Truthful presentation	13
Article 4	13
Article 104	13
Identification	14
Articles 5, 6	14
Articles 105, 106	15
Current knowledge	15
Articles 7, 107	15
Documentation and references	16
Articles 8, 9, 10	16
Articles 11, 108	17
Articles 109, 110	17
Article 111	18
Comparisons	18
Articles 12, 112	18

Discreditation	19
Articles 13, 113	19
General rules of conduct on disseminating information	19
Article 14	19
Articles 15, 114	19
Article 115	20
Specific rules of conduct for certain means of information etc.	20
Articles 16, 17	20
Articles 18, 19, 20, 21, 22	21
Articles 23, 24	22
Specific informational requirements concerning information to the general public	22
Articles 116, 117	23
Articles 117a 1-8	24
Articles 118, 119, 120, 121, 122, 123, 124, 25	25
Article 125	26
Drug samples	26
Articles 26, 126	26
Rules on responsibility	26
Articles 27, 127	26
Bearer of responsibility	26
Articles 28, 29	26
Articles 128, 129	27
Burden of proof	28
Articles 30, 130	28
Statutory copies	28
Articles 31, 131	28
Chapter II	
Agreements on forms of collaboration with healthcare etc.	29
Background and purpose	29

The rules governing the agreements	30
Consultation and assignment	30
Article 32	30
Product information	31
Article 33	31
Therapy-oriented training	33
Article 34	33
Scientific meeting and Congress	34
Article 35	34
Events	35
Article 36	35
Refreshments, expenses and remuneration	36
Article 37	36
Sponsorship	37
Article 38	37
Collaborative projects	39
Article 39	39
Gifts and aids	39
Article 40	39
Clinical trials	40
Article 41	40
Market research	41
Article 42	41

Chapter III

Ethical rules as to co-operation between LIF member companies and user organisations/interest groups	43
Background and purpose	43
Ethical rules	44
Transparency and contract	44
Article 43	44

Economic and other support	44
Article 44	44
Consultation	46
Article 45	46
Rules for co-operation	47
Article 46	47
Monitoring IGM and NBL	48

CHAPTER IV

Rules for non-interventional studies	49
Background and purpose	49
Difference between non-interventional studies and clinical trials	49
When are non-interventional studies performed?	50
Criteria for non-interventional studies	50
The study must be performed in the course of standard healthcare provision	50
Article 47	50
Responsible health authority	51
Article 48	51
Regional ethical vetting board	51
Article 49	51
Study plan/protocol	51
Article 50	51
The Swedish Data Protection Act (PUL)	52
Article 51	52
Ownership of data	52
Article 52	52
The company's internal process	52
Article 53	52
Quality assurance	52
Article 54	52
The Swedish Medical Products Agency	52

Article 55	52
Announcement	52
Article 56	52
Financial support for National Quality Registers within the health service	53
Background and purpose	53
Criteria for financial support to National Quality Registers	53
Article 57	53
Statutes of the Swedish Pharmaceutical Industry Information Examiner (IGM) and the Information Practices Committee (NBL)	54
Rules of procedure for the IGM and the NBL	66
Regarding corruption and bribes	72
Ethical rules for interaction between pharmaceutical companies and veterinary care personnel	73
Ethical rules for interaction between pharmaceutical companies and politicians	80

Ethical rules for the pharmaceutical industry

Background and purpose

Since they were originally adopted in 1969 by the Swedish Association of the Pharmaceutical Industry (LIF) and the Association of Representatives of Foreign Pharmaceutical Industries (RUF), the Rules governing drug information have been the primary document for specifying in greater detail the responsibility of pharmaceutical companies as regards information about drugs. In recent years, the LIF has, in part through its membership of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), been covered by these organisations' regulations. In addition, LIF has entered into a number of agreements regarding forms of co-operation between the pharmaceutical industry and healthcare etc. In addition, rules for non-interventional studies, rules for forms of co-operation with organisations/interest associations, rules for interaction between companies and personnel in veterinary care as well as rules for interaction between companies and politicians have been issued.

It is up to the Swedish marketing companies to ensure that the Ethical rules for the pharmaceutical industry are also observed by parent companies and sister companies in the event of activities on the Swedish market or targeted at the Swedish market. It is also the duty of such companies, in licence agreements or similar with business partners, to enjoin them to comply with the Ethical rules for the pharmaceutical industry.

LIF's Board of Directors has decided to gather the national and international regulations in a single code. On 13 June 2007, LIF's Board of Directors decided to adopt the new regulation specified in the Ethical rules for the pharmaceutical industry. The regulations entered into force on 1 October 2007 and were revised on 16 April 2012.

The member companies of LIF, Föreningen Innovativa Mindre Life Science Bolag (IML) and Föreningen för Generiska Läkemedel (FGL) follow the Ethical rules. The member companies of Föreningen Svensk Egenvård follow chapter I in the Ethical rules.

CHAPTER I

1.1 Rules governing drug information

1.2 Background and purpose

In order to ensure that the pharmaceutical industry performs its task of developing, manufacturing and marketing drugs correctly, the industry is obliged by law and by well-established legal principles to provide information, in connection with its marketing operations, about the properties, effects and appropriate applications of the drugs concerned. By supplying such information, the industry performs the important task of making the drugs known and permitting them to be used in a proper way. The information must conform to good business practice and must be presented in such a way that it gains credibility and a good reputation.

The rules are divided into two sections. The **first section** regulates drug information that is addressed to physicians and other healthcare personnel. As has been the case to date, the rules indirectly express the responsibility that the pharmaceutical industry has towards the general public as consumers of drugs.

The **second section** regulates drug information that is targeted to the general public. The underlying principle is that the function of such information – like that of information addressed to healthcare personnel, allows for the correct use of drugs. This information must also be compatible with good business practice and must be presented in such a way that it gains credibility and a good reputation.

In technical terms, the rules concerning drug information addressed to the general public have been formulated mainly by reference to the rules for drug information addressed to healthcare personnel. In order to permit a better overall view, the two sections are presented consecutively.

The rules are based both on applicable codified law – the Marketing Act and case law, as well as the provisions regarding drug information and drug advertising contained in domestic and EU pharmaceutical legislation and other enactments or in directives issued by government agencies – as well as on non-judicial standards such as the Code of Advertising Practice drawn up by the International Chamber of Commerce and the Code of Conduct adopted by EFTA's Pharmaceutical Industries Association. The regulations are concordant with WHO's ethical rules for marketing drugs and the IFPMA and the EFPIA Codes of Pharmaceutical Marketing Practices. An important part of the international regulations is that each national industry organisation must have a Compliance Officer who is responsible for the preventive work, e.g. providing advice and training. The Compliance Officer is also the contact person for IFPMA's Code Compliance Network.

The concept of good business practice in the area of drug information is also clarified by other non-statutory provisions, such as the International Code of Sales Promotion

and International Code of Marketing and Social Research Practice laid down by the International Chamber of Commerce.

Compliance with the rules is kept under constant scrutiny by the Pharmaceutical Industry's Information Examiner (IGM).

Questions as to whether the information supplied by the pharmaceutical industry and the marketing measures adopted by it are compatible with the rules and with good business practice are examined by the IGM and the Information Practices Committee (NBL). NBL also has the ongoing task of establishing further standards in this area.

1.3 Area of application

Section I

The rules in Section I apply to the information provided by the pharmaceutical industry that, in connection with the marketing the drugs, is targeted at or otherwise may reach physicians, dentists, veterinary surgeons, pharmacists or other personnel within Swedish healthcare or drug distribution.

The rules are applicable to any media used by the pharmaceutical industry in such marketing.

Section II

The rules in Section II apply to the information from the pharmaceutical industry that, in connection with the marketing of drugs on the Swedish market, is targeted at the general public.

The rules are applicable to any media used by the pharmaceutical industry in such marketing.

General rules of conduct regarding the content and form of the information

Objectivity

Section I Article 1

Drug information must include accurate, objective, meaningful and balanced particulars dealing adequately with the favourable and unfavourable properties of the drugs.

This fundamental principle is further defined in the following rules.

Section II Article 101

Article 1 is correspondingly applicable to information to the general public.

In applying the fundamental principle laid down in Article 1, special attention shall be paid to the general public's need for factual information for guidance in the area of self medication and to the importance of supplying the information in an easily accessible manner to the general public.

Instructions

Application of the overall principles in Article 1 to the provision of information to the general public shall be based on the general principle of market law that advertising measures shall be judged – and, consequently, also be devised – with reference to the effect they may be presumed to have on the target group. Thus, in devising and assessing the measures, it is important to take into account the fact that different target categories, as well as partly different market conditions, are involved here as compared with those governing the application of rules for drug information to healthcare personnel – for example, different media or different technical solutions may be involved. As provided in paragraph 2 of Article 101, special attention shall be paid to the general public need for factual information for guidance in self medication and to the importance of supplying the information in a form easily accessible to the general public.

Section I Article 2

The summary of product characteristics (SPC) that has been adopted for a drug constitutes the factual basis for information about the drug.

If an SPC has not yet been set, the applicable catalogue text according to Fass.se shall constitute the factual basis for information about the drug instead.

The information may only refer to drugs that have received marketing approval in Sweden. It may not contain indications or dosages other than those approved of for the drug, unless otherwise permitted by the Medical Products Agency.

If the Dental and Pharmaceutical Benefits Agency (TLV) has decided that a drug should be included in the pharmaceutical benefit, any restrictions applying to the decision must be clearly indicated in the drug information.

Article 3

Pharmaceutical companies must always maintain a high ethical standard.

Information about drugs must conform to good practice and good taste. Offensive presentations are not permitted.

Section II Article 102

Article 2 is applicable where appropriate to information to the general public. Any existing restrictions in TLV's decision regarding the benefits system does not need to be stated in information to the general public about drugs available without a prescription.

Information regarding pharmaceuticals may not be directed towards children under the age of 18.

Information to the general public regarding prescription drugs shall be supplied only to the extent permitted in the Medical Products Agency's provisions and that which applies according to laws and regulations. Information to the general public regarding prescription drugs may be done through Fass.se or such aids from the pharmaceutical industry that are intended to be handed to patients by physicians or other healthcare personnel in order to facilitate the correct use of their drugs.

In addition to what is stated in the previous paragraph, for the purpose of ensuring the public access to requested and easily comprehensible information on prescription drugs, information which fulfils the requirements below may also be provided on websites established and administered by pharmaceutical companies. The information may be provided solely on condition that pre-examination has taken place and resulted in an approval in accordance with the requirements below. Said pre-examined and approved information regarding certain drug(s) is, for the purpose of these ethical rules, defined as "*pre-approved website*", and shall, in all aspects, have as its factual basis what is stated on Fass.se and the summary of product characteristics as approved from time to time by the Medical Products Agency for the drug at issue. A *pre-approved website* may not in any part contradict the content of said information. There is however no requirement that this information be reproduced word by word or in its entirety on the *pre-approved website*. The content of the *pre-approved website* shall provide to the public, access to patient suited information regarding the drug in order to facilitate the correct use of the same. The name of the drug may be used in a domain name and may be mentioned on, but may not dominate or constitute a major part of, the *pre-approved website*. The regulations in this paragraph do not apply to drugs for vaccination of humans against infectious diseases. That pre-examination is also required for campaigns for such drugs follows from Article 102 a.

Article 102 a¹

Pre-examination and approval is, in addition to what is stated in article 102, also required in respect of campaigns in radio, TV and in other advertisements for vaccination of humans against one or more infectious diseases. The purpose of such campaigns shall be to provide the general public with necessary information regarding protection against infectious diseases through vaccination. Product name, product logotype, the generic name of the pharmaceutical or similar distinctive marks or features such as administration method or pharmaceutical form, may thus not appear. Such campaigns shall not be regarded as constituting marketing of a certain pharmaceutical, regardless of whether, at the time of the campaign, there is one or several, in Sweden, approved of pharmaceuticals for vaccination against the infectious disease or diseases that the campaign concerns. Such a pre-examined and approved campaign is, for the purpose of these ethical rules, defined as "*pre-approved vaccination campaign*". The pre-examination according to this article shall be performed for the purpose of ensuring that information in such campaigns is factual, reliable, up-to-date and balanced, as well as otherwise in full compliance with these ethical rules, insofar as they are applicable, and with applicable marketing legislation.

A vaccination campaign shall also contain information stating that the campaign is pre-examined and approved.

Instructions

The reference to paragraph 1 of article 2 implies that the information may not basically be at variance with the SPC that has been adopted for the drug or with the text in Fass.se that applies to the drug. In no case do the rules prescribe that the SPC or catalogue text in Fass.se must be reproduced in information to the general public (cf. articles 21 and 121).

Article 103

Article 3 is correspondingly applicable to information to the general public.

¹ The amendment to Article 102 and the consequential amendments and additions (new Article 102 a, amendments to Articles 114 and 117 and instructions for Article 105) was introduced by a decision by the Board of Directors of LIF on 12 May 2011 and will enter into force 1 July, 2011. Articles 102, 114 and 117 as well as the instructions for Article 105 in their previous wording will apply in relation to vaccination campaigns where the application for pre-examination has been submitted to IGM no later than on 30 June, 2011, provided that the campaign is later approved by IGM and initiated no later than on 31 December, 2011. Such campaigns may proceed up to and including 30 April 2012 at the latest.

Truthful presentation

Section I Article 4

Drug information must be truthful and may not contain any presentation in words or pictures that directly or indirectly – by implication, omission, distortion, exaggeration or ambiguity – is intended to mislead.

The requirement for truthful presentation entails e.g.

- 4.1 that information regarding the composition, active ingredients, properties and effects of a drug may not be incorrect, misleading or unverified,
- 4.2 that information regarding a drug may not be so brief or incomplete that it could be misunderstood,
- 4.3 that exaggerated claims about a drug's properties or effects may not be made. It may not be implied that a drug or an active substance has any special benefit, quality or property if this cannot be verified,
- 4.4 that the presentation may not be deceptive or suggestively misleading,
- 4.5 that expressions such as "better", "more effective", "cheaper", or similar may not be used unless it is made clear what is being compared, and if the claim has been substantiated in a qualified manner.
- 4.6 that expressions such as "safe" may not be used unless the claim has been substantiated in a qualified manner.
- 4.7 that the word "new" may not be used to describe a product or packaging that has been generally available for more than one year or that has a therapeutic indication that has been marketed generally for more than one year,
- 4.8 that the drug may be described as "drug of choice", "routine preparation" or the like only if the majority of specialists within the relevant therapeutic area consider the drug to be a first-line choice,
- 4.9 that it may not be claimed that a product does not have any side-effects, toxic risks or risk of misuse or dependence.
- 4.10 that images that are included in the information are neither misleading as regards the nature of a drug (e.g. whether it is appropriate to give the drug to a child) nor contain misleading assertions or comparisons (e.g. through the use of incomplete or statistically irrelevant information or uncommon scales).

Section II Article 104

Article 4 is applicable where appropriate regarding information to the general public.

The content of the drug information may not be formulated in such a way that it may have as an effect that the drug is used in a way which may result in damages or which is otherwise not appropriate, or formulated in such a way that it may lead to people not seeking the appropriate care.

Instructions

The truthfulness requirement is also of fundamental importance for information targeted to the general public. In principle, the examples given in article 4.1-4.10 illustrating this point shall also serve as guidelines for such information. In this respect, however, the specific medical and market conditions applying to information of this type must be taken into account.

Identification

Section I Article 5

Drug information must be easy to recognise as such; this applies irrespective of the form of the information and the medium used. Drug information must not be disguised.

Clinical evaluations, other investigations as well as studies following approval (also including retrospective investigations and studies) may not be used as disguised marketing measures. Such assessments, programmes and studies must be implemented with a primarily scientific purpose.

Information disseminated through media also containing scientific or other editorial material must be presented in such a way that it will be readily recognised as a marketing activity.

If the information material concerning drugs and their use, regardless of whether it is of a commercial nature or not, is financed by a company, this must be clearly evident in the material.

Written drug information must clearly show the name of the manufacturer concerned or of his representative who is responsible for the drug information in Sweden. The written drug information shall, in addition to the name of the manufacturer or representative, contain clearly visible information on the manufacturer's or the representative's address or web address or telephone number or a reference to fass.se, if the information regards drugs for which the relevant catalogue text is available at any time via Fass.se. Information about drugs on websites must also clearly show to whom the information is addressed as well as that the presentation (content, links, etc.) is adapted for the intended target group.

Article 6

Drug information must contain a clear statement about the year of publication or, in the case of Internet information, the date when the site was most recently updated, as well as a designation that makes it possible to identify the information without difficulty. However, this does not apply if the year of publication and the identity are apparent in some other way, e.g. as in an advertisement appearing in a journal.

Section II Article 105

Article 5 is applicable where appropriate to information to the general public.

Information regarding human drugs shall be presented in such a way that it is clear that the product is a drug.

Instructions

The identification criteria laid down in paragraphs 1 and 5 of article 5 are an expression of a general rule of market law and must be observed carefully. The term “written drug information” in the fifth paragraph of article 5 refers to all information conveyed in words or pictures, whether in print or in some other way, and also includes information conveyed via audio-visual media where appropriate. (Cf. articles 16 and 116.) Written information shall clearly contain information regarding name of the manufacturer concerned or of his representative who is responsible for the drug information in Sweden. The written drug information shall, in addition to the name of the manufacturer or representative, contain clearly visible information on the manufacturer's or the representative's address or web address or telephone number or a reference to fass.se, if the information regards drugs for which the relevant catalogue text is available at any time via Fass.se. However, for practical reasons the requirements cannot be applied to certain media used for advertising to the general public, for example certain types of advertising signs, however the responsible company must always be specified in the information.

Referral to Fass.se may not occur in a *pre-approved vaccination campaign*.²

Article 106

Article 6 is applicable where appropriate to information to the general public.

Current knowledge**Section I Article 7**

Drug information must be up-to-date. This implies for example that any information given about therapeutic results, side-effects and contra-indications must reflect up-to-date scientific views.

Section II Article 107

Article 7 is correspondingly applicable to information targeted to the general public.

² See note 1.

Documentation and references

Section I Article 8

Information as to the quality and efficacy of a drug shall be capable of substantiation by means of documentation. In this context, documentation is understood to mean any written or visual presentation containing reports on scientific facts and discoveries. Documentation to which reference is made in drug information shall be of a high scientific standard. It shall have been published or accepted for publication in a scientific journal or made public or accepted for public presentation at a scientific congress or symposium. Other documentation may be cited in exceptional cases, however only on the condition that it may be considered to be of great value to those to whom it is addressed. Unpublished documentation must meet the same quality requirements as published documentation in both contents and form and must be dated and signed by the investigator in charge.

Testimonials from individual patients may not be cited as documentation. Case studies shall be formulated as typical cases so that the identity of the individual patient is kept anonymous and the studies shall remain free from subjective evaluations from the patient.

Healthcare personnel may not, participate in drug information and offer their opinion as a guarantor for a particular drug or recommend a particular treatment.

Article 9

Documentation that has been compiled for a particular drug may be cited in support of information about another drug only on the condition that the documentation is obviously applicable to the latter drug as well. The citation shall then be expressed in such a way that it does not give the incorrect impression that the documentation was compiled for the drug being marketed. If necessary to avoid misunderstanding, the name of the drug to which the documentation refers shall be stated clearly in the information.

Article 10

Drug information that contains quotations, numerical data, diagrams, images, including graphics, illustrations, photographs or tables taken from a scientific study or deals with a comparison between drugs that is based on such a study, must clearly contain information about relevant sources and references to the documentation.

As to other cases, it is not normally necessary for reference to be made in the information to documentation that supports statements contained in the information. However, the pharmaceutical company shall always provide such reference(s) promptly on request.

Reference to documentation shall be made in the generally accepted form, thus ensuring that the source can be identified without difficulty.

Documentation not generally available shall, without delay and free of charge, be provided by the pharmaceutical company upon request.

Article 11

Documentation must be cited in a balanced and fair way.

The requirement for a fair and balanced presentation means e.g.:

- 11.1 that that the results of a study, which are contradicted by another study, may not be cited without reservation and that results that have been refuted must not be used,
- 11.2 that a study may not be cited in such a way that it could convey an incorrect or misleading impression of the nature, scope, implementation or importance of the study,
- 11.3 that a study performed in vitro or a study based on animal tests should not be cited in such a way that it could give an incorrect or misleading impression of the clinical value of the study,
- 11.4 that statements of comparisons between different drugs or alternative treatments should be expressed in such a way as to make clearly evident their statistical validity,
- 11.5 that the report of a study should not be cited or abstracted in such a way that the citation or abstract gives an inaccurate or misleading impression of the contents of the report and the conclusions stated therein.
- 11.6 that information containing such details referred to in article 10, first sentence in paragraph 1, be correctly reproduced (except when adaptation or alteration is required in order to satisfy applicable rules, in which case it must be clearly evident that adaptation or alteration has been made).

Section II Article 108

Article 8 is applicable where appropriate to information to the general public.

Instructions

In principle, the requirements stated in paragraph 2 of article 8 in respect of the nature of the documentation shall also be applied to information to the general public. However, the special scientific and market conditions applying to such information shall then be taken into account.

Article 109

Article 9 is applicable where appropriate to information to the general public.

Article 110

Paragraphs 3 and 4 of article 10, although not paragraphs 1 or 2, are applicable where appropriate to information to the general public.

Instructions

Since paragraphs 1 and 2 of article 10 do not apply to information provided to the general public, in no case is it necessary to make reference in the information to

documentation supporting data supplied therein. If reference to documentation is made, however, the third and fourth paragraphs apply where appropriate.

Article 111

Article 11 is applicable where appropriate to information to the general public.

Instructions

The requirement for documentation to be quoted in a fair and balanced way is also of great importance as regards information to the general public. In principle, the examples given in article 11.1-11.5 to illustrate what this requirement means shall also serve as guidelines in the matter of providing information to the general public. In this respect, however, the special scientific and market conditions applying to such information shall be taken into account.

Comparisons

Section I Article 12

Drug information that includes comparisons between effects, active ingredients, costs of treatment, etc., must be presented in such a way that the comparison as a whole is fair. The object(s) included in the comparison must be selected in a fair way, must be relevant and must be presented objectively and truthfully.

The requirement for a fair comparison means e.g.:

- 12.1 that the objects included in the comparison should always be clearly specified; thus, if required for sake of clarity, the complete name and generic designation of the compared drugs should be stated,
- 12.2 that the facts which the comparison is intended to clarify and the limitations inherent in the comparison must be stated in such a way that the comparison is not likely to mislead,
- 12.3 that comparison of properties of synonymous drugs, or of drugs with the same indications, shall give a comprehensive and fair picture of the properties compared,
- 12.4 that comparison of certain properties should not induce incorrect or misleading conclusions regarding properties not covered by the comparison.

Section II Article 112

Article 12 is applicable where appropriate to information to the general public. Comparisons between drugs or groups of drugs may not be included on *pre-approved websites*.

Instructions

In many cases, comparative advertising may be intended to facilitate the consumer's decision to buy. The examples in article 12.1-12.4 illustrate what is entailed by the requirement for an entirely fair comparison. In principle, these examples shall also

serve as a guideline in the provision of information to the general public. In this respect, however, the special scientific and market conditions applying to such information shall be taken into account.

Discreditation

Section I Article 13

Drug information

- 13.1 may not contain presentations in words or images that are likely to be perceived as denigratory to another pharmaceutical company or the pharmaceutical industry,
- 13.2 may not contain presentations likely to bring another drug into contempt or lay it open to ridicule, and
- 13.3 must be of such a nature that it respects the special nature of the the drug as well as the professional standing of the recipient.

Section II Article 113

Article 13 is correspondingly applicable to information to the general public.

General rules of conduct on disseminating information

Section I Article 14

- 14.1 Drug information shall be distributed selectively and should only be directed towards those who may be presumed to be in need of, or have an interest in, the information in question, unless otherwise indicated in the ethical agreements that the concerned associations for pharmaceutical companies have entered into.
- 14.2 Mailing lists must be kept up-to-date. Requests from healthcare personnel to be removed from promotional mailing lists must be complied with.

Article 15

Information on new findings regarding serious side-effects, contra-indications, limitations applying to indications or decisions concerning recall of manufacturing batches or drugs shall be sent out in the form of a separate communication. The term "Important Message" or similar expressions may only be used for such dispatches.

As regards regulations for the inclusion of warning statements in information, such regulations are contained in the Product Safety Act (SFS 1988:1 604).

Section II Article 114

Article 14 is correspondingly applicable to information to the general public.

In the event of enquiries which are made from individuals from the general public for advice regarding personal medical issues, the enquirer must be advised to consult a physician or other healthcare personnel.

Pharmaceutical companies may not actively disseminate information about prescription drugs on *pre-approved websites* to the general public. This includes, among other things, that pharmaceutical companies may not sponsor links to such website or in any other way actively promote such website. Supplying requested information, publishing a link to a *pre-approved website* on Fass.se, publishing a *pre-approved website's* address on such aids provided by the pharmaceutical industry as referred to in article 102 and other such corresponding measures, shall not constitute an active promotional activity. Publishing links on Fass.se shall be in compliance with the rules on additional information which LIF Service AB applies from time to time.

Dissemination through directly distributed informational material, addressed or non-addressed, is not allowed in a *pre-approved vaccination campaign*.³

Article 115

Article 15 is correspondingly applicable to information to the general public.

Specific rules of conduct for certain means of information etc.

Section I Article 16

Written drug information refers to information that is conveyed in words or pictures, whether in print or in some other way. The provisions related to written drug information are also applicable where appropriate to information conveyed via audio-visual media.

Article 17

Information concerning drugs for which the relevant catalogue text is available at any time via Fass.se must, in the event the catalogue text or SPC is not reproduced, contain at least the following particulars:

- 17.1 the name of the drug,
- 17.2 its dosage form and, if required, its strength,
- 17.3 its active ingredients, specified by generic name, as well as the quantities of these ingredients; the generic name must be positioned close to the name of the drug where this first appears as a headline or eyecatcher,
- 17.4 a balanced statement of product characteristics; this description shall contain required particulars about pharmacological group or other accepted group affiliation, together with indication or area of indications,
- 17.5 required warnings or restrictions as regards the use of the drug,

³ See note 1.

- 17.6 the name of the pharmaceutical company or its representative that is responsible for marketing the drug in Sweden. In addition to the name of the pharmaceutical company or its representative, information on the company's or representative's address or web address or telephone number or a reference to fass.se shall be provided,
- 17.7 such details referred to in article 6, and
- 17.8 (i) information about the date on which the summary of product characteristics was compiled or reviewed,
(ii) the status of the product (R_x or OTC),
(iii) if TLV has decided that the drug shall be part of the benefits system, the sales price for the packages that are marketed, which may be stated by a reference to fass.se, as well as the possible restrictions in the benefits system.

Article 18

In the event the current catalogue text for a drug is not available at any time via Fass.se, written information concerning the drug must contain the applicable catalogue text in full, or the adopted SPC.

Article 19

Catalogue text or SPCs that are reproduced in written drug information must, as the rest of the text, be easily legible. It must be positioned so that it is readily observed.

Article 20

Printed matter, advertisements or other informational material should not be larger in format or bulk than is required by the nature and content of the information. Directly distributed informational material shall be easy to handle and shall be dispatched in such a way as not to cause any unnecessary inconvenience to the addressees.

Article 21

Verbal drug information refers to information that is conveyed in person by representatives of pharmaceutical companies. Such information may be given in conjunction with personal visits, visits to clinics, training seminars, symposia, conferences and meetings of other kinds.

Meetings for conveying verbal information shall be aimed at presenting facts and objective data. Such meetings shall be arranged so as to fit in usefully and naturally with the execution of the recipients' duties.

Article 22

Verbal drug information is conveyed by pharmaceutical representatives and other authorised pharmaceutical advisers. In addition to such advisers, people with specialised knowledge may also be engaged in the provision of such information.

Representatives who convey verbal drug information must comply with and be well acquainted with all relevant requirements according to applicable rules, laws and provisions, and the companies are responsible for ensuring compliance with these.

The same applies to personnel who are involved in the preparation or approval of promotional material or activities.

The tasks must be carried out in a responsible and ethical manner.

Pharmaceutical representatives are trained and authorised in accordance with criteria that LIF has established or that apply according to regulations. Individuals undergoing training as pharmaceutical representative may, in accordance with these norms, convey verbal drug information under the supervision of an authorised pharmaceutical representative.

Article 23

When a verbal information activity is planned, the pharmaceutical company shall properly notify the person(s) concerned well in advance.

A notification of verbal information shall be formulated in such a way that it is instantly evident that it is a question of announcing such information as well as what the information is intended to comprise. The notification may not be made more comprehensive than is necessary to present the intended information. If the information applies to drugs that have not yet been granted marketing authorisation at the time when the notification is dispatched, but that are expected to have received such authorisation by the time the information is issued, this must be explicitly stated in the notification. The same applies to indications or dosages that have not yet been approved at the time of the notification, but that are expected to have been approved before the date when the information is issued.

Article 24

Entertainment and other benefits offered to those to whom verbal information is addressed may not be of such a kind or on such a scale that there is a risk that the recipients will let themselves be influenced thereby in the execution of their professional duties.

The pharmaceutical company must not offer or promise any compensation to recipients of information.

See also what is specified in chapter 2.

Specific informational requirements concerning information to the general public

Introduction

Regarding information supplied to healthcare personnel, a number of specific rules of conduct and informational requirements laid down in Section I, which are not applicable to information to the general public. This is the case for example with

articles 21-25, which are deemed to lack practical importance in this context. The specific informational requirements applying to information supplied to the general public are limited to a few main points listed in Article 117.

Section II Article 116

Article 16 is correspondingly applicable to information to the general public.

Article 117

Information to the general public shall normally, and when permitted by the chosen medium of information, include as a minimum the following particulars:

- 117.1 the name of the drug,
- 117.2 its dosage form,
- 117.3 its active ingredients specified by generic name or in some other suitable way,
- 117.4 the use of the drug to which the information relates, as well as statement of any necessary warning or limitations that are applicable to its use,
- 117.5 the name of the pharmaceutical company or its representative that is marketing the drug in Sweden. In addition to the name of the pharmaceutical company or its representative, information on the company's or representative's address or web address or telephone number or a reference to Fass.se, if the information regards drugs for which the relevant catalogue text is available at any time via Fass.se, shall be provided,
- 117.6 the details which are referred to in article 6, through reference in article 106,
- 117.7 if TLV has decided that the drug shall be part of the benefits system, the sales price for the packages that are marketed, which may be stated by a reference to fass.se if the information regards drugs for which the relevant catalogue text is available at any time via Fass.se, as well as the possible restrictions in the benefits system. This information is not needed regarding information about drugs available without a prescription.
- 117.8 if the information regards human drugs, an explicit and easily legible invitation to carefully study the information contained in the leaflet or, as applicable, on the outer packaging

If the information states that the drug is effective against a disease or symptom that requires consultation with a physician for diagnosis or treatment, the information shall clearly state that a physician should be consulted before the drug is used.

The regulations in this article shall not be applied to information provided on *pre-approved websites*.

Instructions

1. In general, it should be possible to fulfil the minimum requirements laid down in article 117.1-117.8. However, in exceptional cases the chosen medium of information may be such that, for practical or other reasons, it is not possible to fulfil a particular requirement, such as stating information about use of the drug. The lack of such information must then be accepted. As stated in the

instructions for article 105, it must correspondingly be accepted that certain kinds of written information cannot include the name of the manufacturer concerned, etc. However, the responsible company must always be specified in the information.

2. When judging which information should be considered necessary in a warning statement or a statement about limitations on use, the general principles stated in article 101 and the instructions provided for this article shall be taken into account.
3. As regards non-prescription drugs that are effective against a disease or symptoms of a disease that require contact with a physician for diagnosis or treatment, the drug information to the general public must include a clear recommendation to consult a physician before using the drug.

Article 117a

Information to the general public on *pre-approved websites* shall include the following particulars:

- 117a.1 information that the drug is a prescription drug;
- 117a.2 the drug's active ingredients specified by generic name or in some other suitable way;
- 117a.3 overview regarding the relevant area of therapy, that is, the use of the drug to which the information relates, as well as necessary warnings and limitations that are applicable to its use;
- 117a.4 the name of the pharmaceutical company or its representative that is marketing the drug as well as the address or web address or telephone number of the pharmaceutical company or its representative that is responsible for marketing the drug;
- 117a.5 information about the date on which the summary of product characteristics was compiled or reviewed;
- 117a.6 if TLV has decided that the drug shall be part of the reimbursement system, the restrictions, if any, mentioned in the TLV's decision;
- 117a.7 a clear reference to the summary of product characteristics as approved from time to time by the Medical Products Agency as well as a clear reference to complete information regarding the drug on Fass.se; and
- 117a.8 information that the website has been pre-examined and approved by the IGM.

Article 118

Article 18 is not applicable to information to the general public (see instructions for article 102).

Article 119

Article 19 is correspondingly applicable to information to the general public.

Article 120

Article 20 is applicable where appropriate to information to the general public.

Article 121

Article 21 is not applicable to information to the general public.

Instructions

The same rules apply to verbal information provided to the general public as to other forms of information to the general public, but not the special rules applying to verbal information to healthcare personnel.

Article 122

Article 22 is not applicable to information to the general public.

Instructions

See the instructions for article 121. The fact that high standards of training and good factual knowledge must be imposed on the representatives engaged for the provision of verbal information to the general public follows from the rules applying to the content of the information and from general principles of market law, in particular the requirement of good business practice.

Article 123

Article 23 is not applicable to information to the general public.

Article 124

Article 24 is not applicable to information to the general public.

Section I Article 25

- 25.1 In the course of verbal information, and according to applicable laws and directives, the pharmaceutical company's representatives must provide the addressees who are visited with a copy of the SPC for each drug that is presented, or have such information available.
- 25.2 In the course of verbal information, the addressees must be given an opportunity to report their experiences and views relative to the drug under discussion to the representatives of the pharmaceutical company. The representatives must forward these reports to the company.

Section II Article 125

Article 25 is not applicable to information to the general public.

Drug samples**Section I Article 26**

Drug samples must be distributed in a very restricted manner, at most one per product per year to one and the same person. Drug samples of prescription drugs for human use may only regard new products. In this context a new product refers to a product that has been publicly available for less than two years. New strength or dosage form without new indication is not considered to be a new product. Further, samples shall be offered in conformity with that prescribed by the Medical Products Agency and specified in regulations. Drug samples may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific drugs.

Section II Article 126

Article 26 is not applicable to the general public.

Rules on responsibility**Section I Article 27**

The responsibility for drug information extends to the information as a whole, its content as well as its form, including any statements of opinion therein, any clinical reports or any reprints of published articles. The fact that the content and form of the information originates from other sources is irrelevant from the point of view of responsibility.

Section II Article 127

Article 27 is correspondingly applicable to information to the general public.

Bearer of responsibility**Section I Article 28**

Responsibility for observance of the Rules Governing Drug Information rests with the pharmaceutical company concerned or its representative in Sweden. The representative is also responsible for information administered directly by the foreign principal.

Article 29

Within every pharmaceutical company, there shall be appointed a competent person from among the executive staff who shall be responsible in consultation with other persons concerned in the company, for ensuring that relevant regulatory requirements are satisfied and for supervising the company's external information

and its marketing practices. The person shall be the company's liaison officer in ethical matters related to informational and marketing activities (Information Officer in marketing ethics/Compliance Officer).

Pharmaceutical companies must also appoint a body that shall approve and monitor non-interventional studies. The body that is appointed should include a physician, or where appropriate a pharmacist, to be responsible for monitoring the non-interventional studies (also including reviewing liability for such studies, in particular those for which pharmaceutical representatives are responsible). The responsible executive must certify that he or she has examined the report/publication and that it is compatible with the applicable laws and provisions.

The information officer must approve all marketing material before it is taken into use. He must certify that he has studied the final marketing material and that it satisfies the requirements in the applicable rules on information and applicable laws and regulations, that it corresponds with the SPC as well as decisions and recommendations by the Dental and Pharmaceutical Benefits Agency (TLV), and that it is a true and impartial presentation of the facts.

The information officer must have completed training in marketing law (IMA training) arranged by LIF.

When appropriate in view of its size, organisation or product range, the pharmaceutical company may appoint more than one person, having the status and functions stated in the first paragraph, with responsibility for information. A clearly defined area of responsibility shall then be assigned to each of these persons.

In December of each year, every pharmaceutical company shall inform the LIF secretariat, in writing, of the name(s) of the person(s) who will be responsible for informational matters during the coming year. If more than one such person has been appointed, the area of responsibility of each person must be indicated. If a person is appointed with responsibility for informational matters in the course of a year, or if the area of responsibility of such a person is changed, the LIF secretariat shall be informed of this immediately in writing.

Section II Article 128

Article 28 is correspondingly applicable to information to the general public.

Article 129

Article 29 is correspondingly applicable to information to the general public.

Burden of proof

Section I Article 30

A pharmaceutical company should be able to substantiate any facts, statements, claims and other presentations in words or pictures contained in its drug information. The company shall be prepared, upon request of the Pharmaceutical Industry's Information Examiner or the NBL, to fulfil its obligation to produce supporting evidence without delay. Specific rules on documentation of statements of properties and effects of drugs are included in articles 8-11.

Section II Article 130

Article 30 is correspondingly applicable to information to the general public.

Statutory copies

Section I Article 31

According to the statutes for the IGM and NBL, the IGM is responsible for monitoring the market. In order for the IGM to be able to carry out this task, the pharmaceutical companies must send new, up-to-date drug information to the IGM, such as publications, advertisements, invitations, mailings, TV advertisements or information on websites. On request, the IGM may provide general advice on measures that have not yet been implemented. Such advice constitutes non-binding advance decisions.

Section II Article 131

Article 31 is correspondingly applicable to information to the general public. The regulation in this article does not apply to *pre-approved websites* or *pre-approved vaccination campaigns*.

CHAPTER II

2.1 Agreements on forms of collaboration with healthcare etc.

2.2 Background and purpose

The Swedish Association of the Pharmaceutical Industry (LIF) has entered into a number of agreements regarding forms of collaboration with the healthcare sector etc., to which other industry associations have adhered to.

The purpose of the agreements is to provide rules that promote that the collaboration is pursued with good judgment, with retained credibility, and in compliance with applicable laws, collective agreements and ethical rules.

According to statutes and good business practice, the industry is obliged to provide information about its products, such as their properties, effects, and suitable applications, as well as any possible side-effects and limitations. Correspondingly, in order to use the drugs properly, the healthcare sector etc. also has a need for such information. The collaboration comprises an important part of the employees' further training and increases their opportunities to participate in the research and development of pharmaceuticals.

Within the healthcare sector, the employees continually receive broad knowledge about the properties and clinical use of drugs. This knowledge has to be conveyed to the pharmaceutical companies so as to provide a basis for the development of both existing and new drugs.

The agreements apply to the information from the pharmaceutical companies that is targeted at or otherwise may reach physicians, dentists, veterinary surgeons⁴, pharmacists or other personnel within the Swedish healthcare sector or the distribution of pharmaceuticals.

The healthcare management is responsible for the employee's continued training and, in consultation with the employee, must reach agreement on which skills development he or she needs in order to perform his or her work duties and develop at work.

⁴ Ethical rules for interaction between pharmaceutical companies and personnel within veterinary care are presented in appendix 4.

2.3 The rules governing the agreements

Consultation and assignment

Article 32

Employees within the healthcare sector and at pharmacies are often form an important part of various activities, such as research, training, conferences, market studies, advisory boards and product development. Participation should normally entail an assignment that falls under normal work duties. If participation is that of a consultative nature, it thereby constitutes a secondary employment.

The following must be taken into consideration when pharmaceutical companies wish to engage healthcare personnel and pharmacies' employees for various assignments:

It is the duty of the employee, on request, to notify the healthcare management authority or, where appropriate, his or her immediate superior within a pharmacy company about the assignment/secondary employment and to provide those details that the health authority/ superior within the pharmacy company seems necessary in order to assess the assignment/secondary employment.

- The assignment should be agreed in writing between the staff member, the health authority/pharmacy company and the pharmaceutical company. At the health authority, the agreement constitutes a public document. There must be a legitimate need to implement the assignment before this is requested or introduced to the potential employee.
- The selection criteria for employees must be based on the identified need, and responsible individuals at the pharmaceutical companies must have the experience that is required in order to evaluate whether a particular person within the healthcare sector/pharmacy satisfies these requirements. The number of employees that are hired must not be higher than what is necessary to achieve the identified purpose.
- Hiring healthcare personnel/pharmacy personnel for the execution of a particular assignment may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific drugs.
- Remuneration for work carried out must be reasonable and must reflect an accurate market value in relation to the content of the work and the time spent. Remuneration must be provided according to the health authority's collective agreements regarding travel and expenses. The above agreement shall stipulate how remuneration is regulated No other fringe benefits, remuneration, or gifts may be provided. Assignments performed by participants within the scope of their services shall be remunerated to the health authority.

- Pharmaceutical companies must prepare a list of consultants and, in an appropriate manner, use the information that is supplied through the assignment from the consultants.
- Conferences with pharmaceutical companies within the bounds of healthcare personnel's consulting activities may be held abroad if the majority of the participants are from a country other than Sweden.

In the written agreement between the employee, the healthcare management/the pharmacy company and the pharmaceutical company, the pharmaceutical company is recommended to indicate that there is an obligation for the employee to declare that he or she is a consultant for, or a part-time employee of, the company when he or she expresses an opinion in public, verbally or in writing, on the topic covered by the assignment.

A limited market study, such as an individual telephone interview or an e-mail/Internet enquiry, is not covered by that specified in the above paragraphs if the remuneration is minimal. The definition of "minimal" must be established on each occasion by LIF. However, the exceptions mentioned do not apply if the healthcare employee/pharmacy employee is consulted on a recurring basis (either through the number of telephone calls in general or telephone calls that refer to the same research).

That stated below under Events shall also cover employees who carry out assignments for a pharmaceutical company.

Product information

Article 33

Product information relates to conferences intended to provide information about the specific properties or handling of a drug.

The following shall be observed as regards product information:

- The pharmaceutical companies' product information may only take place upon agreement with the healthcare management or its appointed contact /with the pharmacy company's appointed contact person for one or several pharmacies. No other visits or contacts shall take place. For pharmacy companies, however, spontaneous visits that do not cover information about a drug's specific properties or handling can be implemented on the individual pharmacy's conditions. Visits may not deviate from their agreed purpose.
- Product information must be supplied to groups of healthcare personnel/groups of employees within pharmacy companies.

By way of exception, a single conference between employees and pharmaceutical companies may occur. Both group conferences and single conferences must be approved by the health authority. Information to individual employees may only refer to information of the same type as supplied to healthcare personnel in group. Individual meetings between employees and pharmaceutical companies, and the format of these, must always be approved of by the healthcare management/the appointed contact for the pharmacy company.

- Conferences shall be held during work hours at the participants' workplace. By way of exception, conferences after working hours may occur. Conferences carried out during working hours as well as after working hours must be approved by the health authority. Conferences targeting personnel from several workplaces may be held on locations other than the town or city where said healthcare personnel works, if specific educational, practical, economic or other similar reasons so dictate.
- Pharmaceutical companies shall contact the healthcare management or its appointed contact person/the superior within the pharmacy company if other contact person has not been appointed in good time and agree on the main content of the information, as well as the time and place. The healthcare management/the superior within the pharmacy company, if other contact person has not been appointed to, determines the format of the meeting and who may participate.
- The invite should specify:
 - (i) that the conference concerns product information
 - (ii) the content and the duration of the programme
 - (iii) the time and place

This is to enable the healthcare management/ the superior within the pharmacy company if other contact person has not been appointed to determine the relevance of the meeting for raising staff skill levels. Deviations from the agreed programme may not take place.

- It must be stated during the conference whether the product/the products are recommended by the affected counties' pharmaceutical committee.

Product information that is presented in exhibition stands or that is distributed at international scientific conferences or symposia may refer to drugs that are not registered in the country where the event is taking place, or that are registered in a different way, on the condition that:

- The event is an international scientific meeting with a majority of participants from countries other than the country where the event is taking place.

- Marketing material containing information about a drug that has not been granted marketing authorisation in the country where the meeting is taking place must include details about the countries in which the drug has received marketing authorisation, as well as the fact that it has not been granted such authorisation in the country where the event is taking place.
- Marketing material that refers to prescribing information (indication, warning texts, etc.) that has been approved in a country or countries, although not in the country where the event is taking place, but where the drug is registered, must be followed by information that the registration terms may differ internationally.
- Information must indicate the countries in which the drug has been approved, and specify that the drug has not been approved locally.

Therapy-oriented training

Article 34

Therapy-oriented training relates to conferences intended to give training in a particular field of treatment. The information shall give the participants current and relevant knowledge of general or specific facts and problems within the therapeutic field in question, i.e. it shall be problem-oriented and not product-oriented.

The following shall be observed for therapy-oriented training:

- Product information may be provided only if the product's use or the conditions for its use are relevant for the training. Product information may not occur during therapy-oriented training with pharmaceutical companies, if not agreed otherwise with the pharmacy company.
- If product information is provided this shall be made clear in the programme.
- The continuing education that pharmaceutical companies offer to the healthcare sector should be based on staff's competence needs. Consultation should therefore take place with the healthcare management in question/pharmacies about future continuing education activities. The healthcare management/pharmacies should be informed of planned education/conferences in good time, normally two months in advance,
- The invite should specify
 - (i) that the conference concerns therapy-oriented training
 - (ii) the content and the duration of the planned training,
 - (iii) time and place,

- (iv) the costs that the pharmaceutical company intends to pay for, and
- v) any incidental arrangements.

The purpose of this is to enable the health authority to determine the relevance of the training for raising the staff's skill levels.

- When the invitation is issued, it must be sent to the relevant healthcare management as well as to the drug therapeutic committee (as regards personnel within the healthcare) or manager within pharmacy company. The term invitation also includes advance invitations or advance notice of conferences. A copy of the invitation may be sent to individual employees at the workplace, in which case it must be sent to all employees.
- Therapy-oriented training aimed at physicians or groups of professionals including physicians, and which take place in Sweden, or abroad with physicians operating in Sweden as a target group, should be inspected and approved by IPULS. This should also be apparent in the invitation. This requirement applies to all training, irrespective of the organiser. Deviations from this may only take place in case of local training that is of once-only nature and carried out either by the healthcare management or a pharmaceutical company in collaboration with the healthcare management concerned.

Scientific meeting and congress

Article 35

Scientific meeting or congress are meetings arranged by pharmaceutical companies, or with the support of pharmaceutical companies, aiming to treat one or more medical or other scientific issues within one or more scientific fields.

The following shall be observed for a scientific meeting or congress:

- The health authority/the pharmacies shall be informed of a planned meeting or congress in good time, normally two months in advance.
- The invite shall specify:
 - (i) what type of meeting is contemplated, i.e. a scientific meeting or a congress
 - (ii) the content and the duration of the planned meeting or congress
 - (iii) time and place
 - (iv) the costs that the pharmaceutical companies intend to pay for, and
 - (v) any incidental arrangements

The purpose of this is to enable the health authority to determine the relevance of the meeting for raising the staff's skill levels.

- When the invitation is issued, it must be sent to the relevant healthcare management as well as to the drug therapeutic committee (as regards personnel within the healthcare) or manager within pharmacy company. The term invitation also includes advance invitations or advance notice of conferences. A copy of the invitation may be sent to individual employees at the workplace, in which case it must be sent to all employees.

Events

Article 36

All scientific meetings and congresses, therapy-oriented training, conferences, symposia and other similar events, including but not limited to visits to research and production facilities, advisory boards, planning, training and investigator meetings for clinical trials and non-interventional studies (each one an “**event**”) that are organised or financed by companies or on a company’s behalf, must be held in a suitable location that promotes the purpose of the arrangement.

Events shall normally be held at the participants’ workplace or in the same town or city or as near as possible. Events may be held at locations other than the town or city where the participants work if specific pedagogical, practical, economic or other similar reasons so dictate. Events outside Sweden are only permitted in direct connection with international training and scientific conferences or congresses (including satellite symposia) if the majority of participants are not from Sweden and equivalent knowledge cannot be acquired within the country. Study visits to internationally recognised scientific clinics/universities/laboratories etc. outside Sweden are only permitted if equivalent experience or information cannot be acquired within the country and the study visit can be considered relevant to the educational purpose of the activity.

Companies may arrange or provide financial support for arrangements that are held outside of their home country only if:

- (i) the majority of those invited come from countries other than the home country and, bearing in mind the origins of most of those invited, it is reasonable from a logistical or security perspective to organise the arrangement abroad, or
- (ii) bearing in mind the relevant resources or experts who are the subjects of the arrangement, it is rational to organise the arrangement in another country (“**international arrangement**”).

The choice of location for an arrangement must be reasonable in relation to the purpose of the arrangement. Leisure resorts during season and places known for their exclusivity shall be avoided, e.g. locations for winter sports during ski season. The same applies to locations at which major international events are being staged at the same time as or in connection with the arrangement, e.g. motor and golf competitions. Neither should companies contribute financially to arrangements, that are located in such places. LIF's Compliance Officer decides whether a location is acceptable or not. A decision made by the Compliance Officer can be appealed.

Refreshments, expenses and remuneration

Article 37

- At conferences, both domestic and abroad, any meals provided shall be very modest. For meals in Sweden, lunch and dinner expenses shall amount at most to the value per participant laid down by LIF at that time. For meals abroad, local rules must be followed where applicable. In the absence of such rules, the Swedish rules must be applied as far as possible. Food and drink etc. may only be offered at relevant times and in accordance with applicable rules, on the condition that
 - (i) only participants in the arrangement are invited. Accompanying individuals may not participate, and
 - (ii) the food is reasonable according to local standards. Alcoholic drinks in the form of wine and beer may only be offered in limited quantities and only as table drink. No spirits may be offered.
- Travel shall be arranged, insofar as possible, in economy class. Travel in first or business class is only permitted where the price difference is negligible. Moderation must also be observed regarding the choice of hotel. Travel should be planned so that the participants arrive at and depart from the conference as close to the opening and closing times of the arrangement as practically possible.
- At conferences, the work-related agenda shall be of such a duration and scope that there is no question of taxation on fringe benefits in accordance with applicable rules and guidelines from the Swedish Tax Agency.
- Pharmaceutical companies may pay for conference facilities, speakers, study materials and so forth that are necessary to carry out the conference.
- Pharmaceutical companies may partly subsidise the participants' costs for travel, food and accommodation, as well as the entire conference fee under the condition that the conference and such travel, food and accommodation are moderate and can be publicly examined. The participant or the participant's employer shall always be responsible for paying a reasonable

proportion of the above-mentioned costs. However, the pharmaceutical company may never be responsible for a larger proportion of the costs than the entire conference fee plus 50% of travel, food and accommodation costs. Pharmacy companies are responsible for its own employees' costs for travel and accommodation as well as the conference fee when participating in conferences. Accompanying individuals or relatives of participants may not participate in conferences arranged by the company.

- If the pharmaceutical company pays for conference fees and part of the travel, board and lodging, the healthcare management's decision on consent to participate in the conference shall be sent to the pharmaceutical company concerned; otherwise the participant's involvement shall not be accepted by the company.
- Independent social or leisure activities may not be offered by pharmaceutical companies or requested by healthcare/the pharmacies' staff, either in conjunction with conferences or other dealings. Simple social activities, such as background music or local performances, playing at the venue in connection with the meeting shall not be considered as offered by pharmaceutical companies provided that it has neither been organized, requested nor paid for by the pharmaceutical company.
- Conference participants may not be offered fees from pharmaceutical companies and said participants are not entitled to accept or demand fees for their participation. However, reasonable fees may be paid to healthcare and pharmacy personnel who have been hired to participate as speakers at scientific conferences or in advisory boards.
- Pharmaceutical companies may not offer, and healthcare/pharmacies' personnel may not demand or accept, fringe benefits, remuneration or gifts, nor demand any other action that is otherwise in contravention of that specified in this Chapter 2.
- Non-appropriate benefits in accordance with point 7 in the Anti-Bribery Institute's "Guiding ethical rules for benefits aimed at promoting contact and relationships in business activities" may not occur.

Sponsorship

Article 38

Sponsorship refers to financial or other support from pharmaceutical companies for activities/conferences not regulated otherwise in this chapter and that are targeted at employees within the healthcare sector/ pharmacies. Sponsorship also includes economic or other support to associations that organise employees within the public health service.

Sponsorship of activities/conferences within the operations of the public healthcare or pharmacy companies may not take place. This means for example that partial or full sponsorship of staff parties, planning conferences or individual clinic's education is not permitted. Neither is sponsorship of employees within the healthcare sector permitted to compensate purely for the time that the employee is present at an arrangement. Activities that are permitted under other sections of this chapter are not considered sponsorship and therefor are not comprehended of this provision.

Support from pharmaceutical companies of an activity/conference which is targeted at employees within the healthcare sector/pharmacies and which is not comprised by the prohibition in the second paragraph, shall fulfil the following requisites:

- (i) the sponsorship is done to support healthcare or research,
- (ii) the sponsor keeps a register of the sponsorship provided, and
- (iii) the sponsorship does not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific drugs.

The member companies are encouraged to publicly announce which sponsorships are provided.

Sponsorship of activities/conferences arranged by third parties (e.g. specialist associations) must be characterised by openness and may only be arranged if the following conditions are satisfied:

- (i) The activity/conference that is being sponsored must be for professional advancement and otherwise in accordance with this agreement.
- (ii) Pharmaceutical companies may not offer sponsorship in a sum exceeding the costs of the professional improving activity/conference. Professional improvement does not include for example performance of artists, expensive meals, travel and lodging.
- (iii) Sponsors placing resources at the disposal of the conference shall be named in the invitation.

LIF has entered into a separate agreement with the Swedish Medical Association regarding the sponsorship of trade associations (e.g. specialist associations) by pharmaceutical companies. From the agreement it is clear e.g. that the parties are in agreement that all sponsorship of trade associations must be characterised by openness, and that the information must be made available in a joint co-operation database. It is the duty of the member company concerned to enter the information in the co-operation database. The information is available at www.lif.se. The openness

concerns all agreements, regardless of whether the agreements are on-going, finished or concern future projects. LIF is responsible for quality control of the co-operation database with the aim of working preventatively and supportively to the parties, so that the database is kept updated and current.

Collaborative projects

Article 39

Collaborative projects between pharmaceutical company and healthcare that concern measures which are not referred to in other articles in chapter II, may be carried out provided that the conditions below are complied with. With collaborative project in this article means project which for example concerns:

- administration of drugs
- advanced home care
- educational programs for patients or the public
- development of support regarding prescription system or follow-up tools

The following shall be observed when a collaborative project are carried out:

- The collaboration between the pharmaceutical company and healthcare shall be governed by a written agreement between the healthcare management and the pharmaceutical company. The agreement shall, when needed, regulate the ownership of intellectual property rights.
- The agreement shall contain a project plan with, amongst other, information concerning how the collaborative project shall be evaluated. The agreement must be made public and available through the LIFs collaboration data base.
- The agreement may not involve exclusivity to provide certain types of services to one or more healthcare management.
- Both healthcare and the pharmaceutical company shall contribute to the collaboration project with resources as financial resources, material and labor.
- Contact search from the pharmaceutical company concerning offers to enter into collaborative project shall go through the head of the clinic and to the pharmaceutical committee as information.

It is desirable that the evaluation of decided collaborative project takes place before the corresponding activities are introduced on a large scale.

Gifts and aids

Article 40

No gifts or financial benefits may be supplied, offered or promised to healthcare personnel/pharmacy as an incentive to recommend, prescribe, purchase, supply, sell or administer drugs.

Gifts may only be distributed with considerable restraint, and may only refer to articles of little value and that are relevant (i.e. have a medical connection) to the professional. The term “little value” refers to no higher amount than at any time is determined by LIF’s Board.. Only the name of the pharmaceutical company or the name of the company’s representative in Sweden shall be specified on such articles, along with the name of the drug or its generic name or the trademark used by the company. No other printing may occur.

Donations and fringe benefits to institutions, organisations or associations comprising healthcare personnel and/or that supply healthcare or research are only permitted if:

- (i) this is done to support healthcare or research,
- (ii) the donor keeps a register of the donations or fringe benefits that are given, and
- (iii) the donations or fringe benefits do not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific drugs.

Member companies are encouraged to publicly make known which donations or fringe benefits are given.

Personal gifts or donations to those working within healthcare (e.g. tickets to entertainments, music CDs, DVDs, etc.) may not be offered or supplied.

Aids intended to facilitate the proper administration or use of a drug by healthcare personnel or patients – for example, dietary guides for diabetics, instructions for drug use, applicators, dosage containers and suchlike – may be distributed to the extent required by therapeutic considerations.

Aids intended to facilitate the prescription of drugs – such as rubber stamps for prescriptions, prescription pads, etc. – shall be distributed with restraint, and only upon order from persons licensed to prescribe. If such aids are sent by post, this shall be done in such a way that the consignment is only handed over in exchange for a receipt. Other aids with a medical connection may be offered or distributed free of charge on the condition that they have a professional value for the recipient or are important for patient care.

Aids must not be given a more lavish appearance than is necessary for the required purpose.

Clinical trials

Article 41

A separate agreement has been concluded between the Association of Local Authorities and Regions and the Association of the Pharmaceutical Industry (LIF)

regarding clinical trials; according to which agreements must be entered into between affected healthcare managements, investigators and pharmaceutical companies. The agreement has a standardised agreement form. The pharmaceutical companies must also comply with the publication of information on clinical trials databases and in scientific literature. See "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases" respectively "Joint Position on the Publication of Clinical Trial Results in the Scientific Literature".

Market research

Article 42

Market research encompass e.g. questionnaires, interviews and focus groups. These have different objectives, purposes and set-ups.

- The participation of individual healthcare employees in market researches should not be viewed as "consultation" in accordance with article 32 above, if the following criteria for the market research are satisfied.
- The company/institute that carries out the research has undertaken to conform to the ethical rules for market research in accordance with ICC/ESOMAR.
- The design of the research is intended solely to gather information or opinions and attitudes, not to influence respondents or convey sales-promotional contacts.
- The number of respondents does not exceed the number necessary to achieve reasonably secure results.
- The respondents are treated in the strictest confidence and in accordance with the Data Protection Act.
- If the market survey is conducted by an independent company/institute on behalf of a pharmaceutical company may the client company be kept anonymous in relation to the respondent if this is justified for methodological reasons.

The research does not have any inclusion criteria that entail prospective prescribing of selected medicines in a given therapeutic group.

Information gathering or interviews within the research must be carried out in such a way that this does not affect the respondents' work duties or infringe on their working hours. However, it is permitted to seek contact with the respondent by e-mail or fax during working hours.

Remuneration to the respondents in the market research is paid by the

company/institution that is carrying out the research. The level of the remuneration must not exceed that which is reasonable in relation to the time put in by the respondent, and at most SEK 1,000.

LIF is providing a market database in which the pharmaceutical company shall inform about the market survey which the pharmaceutical company have ordered, performed or have knowledge about in Sweden. The information can be found at www.lif.se.

General for chapter 2: Due to the extensive economic integration of the Öresund Region, Själland is comparable with Sweden.

Chapter III

3.1 Ethical rules as to co-operation between pharmaceutical companies and user organisations/interest groups.

3.2 Background and purpose

There has long been an important partnership and exchange of experience between pharmaceutical companies and various organisations. The pharmaceutical companies should maintain close contacts with organisations. The co-operation between the parties is all the more important since the pharmaceutical companies need to exchange knowledge and experience with those using pharmaceutical products so that the use and development of pharmaceutical products can be optimised. For their part, pharmaceutical companies possess knowledge which must be passed on to patients. All collaboration should take place within the constraints of these ethical rules.

The purpose of these ethical rules is to ensure that the co-operation between organisations and the pharmaceutical companies takes place in a responsible and meaningful manner, and that the co-operation, information and training are also conducted in such a manner that the parties' independence from one another is not jeopardised or questioned from either legal or ethical standpoints. This means that the chosen collaborative projects may not comprise an overwhelming share of the organisation's activity and/or economy.

The following principles serve as guidance for all collaboration between pharmaceutical companies and various organisations.

- ***Respect for each other and each other's roles***
- ***Reciprocity in relationships***
- ***Common responsibility for planning and implementation***
- ***Openness and transparency to the outside world***
- ***Restriction of the choice of collaborative fields***

The ethical rules are applicable to the pharmaceutical companies. Certain organisations and companies have set their own rules as to collaboration. Such rules are to be seen as complementary to these ethical rules.

In this document, organisations mean disability organisations, patient associations, relatives' associations and other patient networks/associations. Also included are other interest organisations which form opinion within the health service, such as pensioners' organisations, the 1.6 Million Club, the Swedish Cancer Society, the Swedish Red Cross, the Swedish Heart-Lung Foundation etc.

3.3 Ethical rules

Transparency and contract

Article 43

43.1 The co-operation between pharmaceutical companies and organisations should be regulated in written agreements.

43.2 Agreements should contain a project description, information about its financing and clearly state the rights and obligations of each party and the duration of the project. When using organisation's logos and name in information etc., the pharmaceutical company shall obtain the organisation's consent thereto prior to such use. When acquiring such consent, it shall be stated for which specific purposes and in which way the logo and name shall be used. The same shall apply to organisations who wish to use the pharmaceutical company's logo and name in information etc.

43.3 Contracts and agreements between organisations and pharmaceutical companies should also be kept available to third parties. Openness relates to all agreements, whether ongoing, concluded or regarding future projects.

43.4 Short versions of all contracts and agreements should also be available in the LIF Co-operation Database when activity is ongoing and at least for one month after the project is concluded. It is the responsibility of member companies to enter information into the Co-operation Database in accordance with current headings in the database. Information can be found on www.lif.se.

43.5 LIF's Compliance Officer is responsible for quality control of the Co-operation Database with the aim of working preventatively and supportively to the parties, so that the Database is kept updated and current.

43.6 If international co-operation is arranged by the company's foreign principal in Sweden, or is aimed at the Swedish market, it shall be incumbent upon the subsidiary in Sweden to ensure that the principal also respects the rules which apply in Sweden.

Economic and other support

Article 44

44.1 Economic or other support shall only be given to the specified collaborative projects or activities. The pharmaceutical companies may not supply economic funds or other support which:

- are intended to finance a user organisation's regular operations, or
- mean that a user organisation's operations cannot survive when the co-operative agreement ends, or

- mean that a dependency relationship arises between the parties, or
- exceeds the costs of the activity/conference

44.2 Companies may give economic support for personnel costs only in cases where the personnel costs are included in a temporary project. However, this does not mean that the company takes on employer's liabilities. This should be evident from the agreement made between the parties.

44.3 The pharmaceutical companies may pay the costs of such things as conference and educational activities as well as for travel, food and accommodation and educational materials necessary to conduct a joint activity in Sweden. Companies may also charge a fee corresponding to the company's costs for the arrangement. The choice of location for an event must be reasonable in relation to the purpose of the event. Locations at which major international events are being staged at the same time as, or in connection with, the arrangement shall be avoided. Neither should companies contribute financially to events that are located in such places. LIF's Compliance Officer decides whether a location is acceptable or not. A decision made by the Compliance Officer can be appealed.

If the collaboration relates to financing of the organization's participation in a meeting, activity or congress abroad, reference is made to what applies according to paragraph 44.5.

44.4 When a physician is invited to an activity, such as a lecture, and if the company is to be regarded as arranger or co-arranger, what is mentioned in chapter 2 regarding the interaction between the health care and representatives of the pharmaceutical industry, is also applicable. In this case, a contract is required with both the physician/his or her employer, as well as with the interest group concerned. Merely supplying a contribution for a specific project does not mean that the company is to be regarded as co-arranger.

44.5 If the collaboration relates to financing of the organization's participation in a meeting, activity or congress abroad, invitations should be addressed to the management of the organisation. It is then the organisation which determines first whether there is a need to participate, and secondly who from that organisation that will take part. Subsequently, provided there is participation, an agreement is made between the company and the organisation. However, the pharmaceutical company, or several companies part-financing the activity, may not be responsible for more than 50% of the total cost to the participant. As for the choice of location for events abroad, reference is made to what applies according to paragraph 44.3.

Companies may not arrange or provide financial support for arrangements that

are held outside of their home country unless:

- (i) the majority of those invited come from countries other than the home country and, bearing in mind the origins of most of those invited, it is reasonable from a logistical or security perspective to organise the arrangement abroad, or
- (ii) bearing in mind the relevant resources or experts who are the subjects of the arrangement, it is rational to organise the arrangement in another country (“international arrangement”).

44.6 A company may not pay fees which differ significantly from what other players must pay, e.g. membership dues, advertising costs, exhibitions or remunerations.

44.7 Travel should be planned so that the participants/consultant arrive(s) at and depart(s) from the conference/assignment as close to the opening and closing times of the arrangement as practically possible.

44.8 The activity as well as travel, food and accommodation shall be moderate and must be strictly related to the purpose of the activity.

44.9 Pharmaceutical companies may in exceptional cases, in cases of medical reasons, pay for conference fee, travel, food and accommodation for an accompanying person to a participant in connection with activities or congresses. If the activity or congress is held abroad, paragraph 44.5 shall be complied with as regards the extent of the financing.

44.10 Neither in connection with activities nor collaboration in general may separate social activities or leisure events be offered by pharmaceutical companies. In conjunction with meals or receptions may, however, a simpler social activity such as music entertainment be arranged as long as it is secondary to the activity as well as the meal or reception.

Consultation

Article 45

45.1 Representatives of organisations often form an important part of various activities to highlight the perspective of the patient, such as research, training, conferences, market studies, advisory boards or in product development of information material, articles etc.

The following must be taken into consideration when pharmaceutical companies wish to engage representatives of organisations for various assignments:

- The number of representatives that are hired must not be higher than what is necessary to achieve the identified purpose.
- There shall be a legitimate need for the assignment before it is inquired or initiated. The criteria for selecting consultation assignment shall be based upon identified needs. The inquiry regarding the assignment shall be made to the responsible persons within the organisation. The organisation decides if the inquiry shall be accepted or not. The extent of the assignment shall not be greater than is necessary in order to achieve the identified need. Before the assignment is initiated, it shall be agreed in writing between the organization that the representative represents and the pharmaceutical company in accordance with article 43.
- The pharmaceutical company shall appropriately make use of the information and the records that is provided through the assignment. The pharmaceutical company shall make known that the representative is a consultant for the company when the company expresses an opinion in public, verbally or in writing, on the topic covered by the assignment. In the written agreement it is recommended to indicate that an obligation for the organisation to declare that the representative is a consultant for the company when he or she expresses an opinion in public, verbally or in writing, on the topic covered by the assignment.
- Hiring representatives for the execution of a particular assignment may not constitute an incentive to recommend a specific drug, product or pharmaceutical company.
- Remuneration for work carried out must be reasonable in relation to the content of the work and the time spent. The above agreement shall stipulate how remuneration is regulated. The pharmaceutical company may pay for travel, board and lodging for the representative when performing the assignment under the condition that the costs are moderate. No other fringe benefits, remuneration, or gifts may be provided.

Rules for co-operation

Article 46

46.1 A basis for collaboration is that it should be in the interest of both parties. Collaboration should be jointly planned and implemented in a manner agreed by the parties. This should always take place openly, in a manner transparent to the public. Furthermore, it should always be clearly evident from any informational material and invitations that this is a collaborative project, so that the recipient understands who or which parties stands behind the material. The pharmaceutical companies are liable to observe the information rules and other applicable standards within what is known as the industry's self-regulatory

system.

46.2 These rules are applicable to the pharmaceutical company even if a company in collaboration with an organisation hires an external consultant (such as an advertising or PR agency).

46.3 A collaborative project may comprise more than one company and/or include public bodies. Choosing a primary partner is permissible in collaboration and in specific projects an exclusive right can be agreed. However, an exclusive right should not be included in any general contracts and/or agreements.

Monitoring IGM and NBL

The Pharmaceutical Industry's Information Examiner ("IGM") and the Information Practices Committee ("NBL") have the task of auditing and assessing any pharmaceutical company's violation of these rules.

CHAPTER IV

4.1 Rules for non-interventional studies

4.2 Background and purpose

Non-interventional studies mean all studies and projects which are not clinical trials according to the Swedish Medical Products Agency. The concept of non-interventional studies thus includes quality projects, follow-up studies, prescription studies etc. The rules given below also apply to participation in or support for the establishment or operation of various registers (e.g. quality registers). For those studies and projects covered by rules on non-interventional studies, agreements must be signed by all relevant responsible authorities, if staff in the public health service are participating, or where it concerns private healthcare if the study or project may entail costs to the responsible authority (i.e. in the form of prescribing drugs).

Studies are currently performed in the healthcare sector which are not clinical trials but which may be supported by pharmaceutical companies in some way. This might involve the mapping of therapeutic practice or costs, quality assurance of whether given guide-lines are being followed, or a follow-up of how a drug is being used or the health economics impact of a given drug therapy. The need for information provided by such studies is considerable and is growing at both regional and national level. The Medical Products Agency may require pharmaceutical companies to follow up drug use, and the formula committees may have wishes concerning the mapping of experience of drugs in an every-day clinical context.

4.3 Difference between non-interventional studies and clinical trials

The design of the study determines whether it is a clinical trial or a non-interventional study.

A clinical trial generally studies a selected group of patients (patients chosen on the basis of various exclusion and inclusion criteria) in a controlled manner. Patients are normally randomised to one or more treatments. These studies are always prospective and often take quite a long time to perform.

A non-interventional study includes patients on the basis of one or more selection criteria, e.g. by diagnosis or treatment received. Data is then collected retrospectively or prospectively using forms, or obtained from existing databases or medical records. In a cross-sectional study, information is obtained about the situation at a particular point in time. No study-related intervention is made.

4.4 When are non-interventional studies performed?

Which type of study should be chosen – clinical trial or non-interventional study – depends on its aim. Non-interventional studies are never a substitute for clinical trials, but may be a complement. We need the knowledge that is generated by both clinical trials and non-interventional studies. For example, epidemiological data cannot be studied in a clinical trial. Internationally Sweden has the advantage of being able to draw on national health data registers for epidemiological data. One example is the National Board of Health and Welfare's Prescribed Drug Register, which collects drug data from pharmacies.

Besides providing greater knowledge about drug effects, non-interventional studies can also be a good way of further mapping risks in the real world. Post-marketing surveillance (PMS) studies can in some cases be important in studying adverse effects after the introduction of a new pharmacological therapeutic principle.

Non-interventional studies allow information to be collected on the actual use of a particular drug. These studies can also provide epidemiological information about a particular disease, or even identify an unfulfilled medical need.

4.5 Criteria for non-interventional studies:

The study must be performed in the course of standard healthcare provision

Article 47

- The prescription of any drugs being studied must be clearly separated from the decision to include the patient in the study.
- The drug must be prescribed in the normal manner and in accordance with the terms of the marketing authorisation. The contribution of the medical representative may only be administrative in character and under the supervision of the medical department, which should also ensure that the representative has the relevant training. The representative's contribution may not be associated with the prescribing of drugs. For further information on the role of representative, see what is stated in chapter 1 article 22.
- The study is to be conducted so that the parties maintain full confidence and an independent standing in relation to one another. The study should not result in undertakings or expectations concerning prescribing or use of the pharmaceutical company's products.
- Financial compensation for extra resources for implementation of non-interventional studies should only be paid in cases where the workload within the framework of the study obviously exceeds the staff's ordinary daily operational responsibility/work duties.

Responsible health authority

Article 48

The study must be approved by responsible health authority. An agreement must be concluded between the healthcare provider, the responsible investigator and the pharmaceutical company. This also applies to studies which the investigator carries out in his/her "spare time", i.e. outside paid working hours for the healthcare provider or private healthcare subcontractor. Where financial re-muneration is payable, this must be reasonable in relation to the amount of work involved and specified in the agreement.

Regional ethical vetting board

Article 49

An application must be submitted to the regional ethical vetting board for assessment. The study must not be performed if the regional ethical vetting board is opposed to this.

Study plan/protocol

Article 50

There must be a study plan/protocol which approved and monitored by the pharmaceutical company's medical department and which contains:

- (i) **Background.** Motivation for performing the study.
- (ii) **Aim.** Description of what is to be studied (the scientific purpose).
- (iii) **Motivation for number of patients.** Total number of patients and number of patients per investigator.
- (iv) **Data collection.** How data is to be collected, patient information, questionnaires, etc.
- (v) **Data processing and collation.** Who is responsible for data processing, how it will happen, and when.
- (vi) **Adverse event reporting.** Reporting to the Medical Products Agency/company.
- (vii) **Study reporting.**

A summary of the report/publication should be analysed and, within a reasonable time, communicated to the pharmaceutical company's medical department. The medical department should keep a list of such reports which should be kept for a reasonable time. The report/publication is to be completed within 12 months of the end of the study and distributed to the participating clinics and, where necessary, the authority concerned. If the study indicates a result which is important from a risk or utility point of view, the summary of the report/publication should immediately be sent to the relevant authority.

Both the study plan/protocol and study report should be made available on demand to the Pharmaceutical Industry's Information Examiner (IGM) and the Information Practices Committee (NBL) as well as LIF's Compliance Officer.

The Swedish Data Protection Act (PUL)

Article 51

Patients must receive, where applicable, written information (including relevant provisions of the Personal Data Act) and give their written consent to take part in the study unless the regional ethical vetting board has permitted otherwise. In some cases the regional ethical vetting board may agree that consent need not be obtained from patients with reference to section 19 of the Personal Data Act.

Ownership of data

Article 52

The agreement between the parties must cover issues such as who owns the database and who holds the publication rights.

The company's internal process

Article 53

The company must have guidelines which describe the internal process for the performance of non-interventional studies. The company's medical department must approve these studies.

Quality assurance

Article 54

ICH Good Clinical Practice must be applied where applicable, and standard scientific methodology must be used. Monitoring (verification of source data) or auditing need not normally be performed, but there must be a process for quality assurance.

The Swedish Medical Products Agency

Article 55

An application need not normally be submitted to the Medical Products Agency. In case of uncertainty, the Medical Products Agency must be contacted.

Announcement

Article 56

As with clinical trials, pharmaceutical companies must publish the information given in the summary of the report/publication for non-interventional studies.

4.6. Financial support for National Quality Registers within the health service

4.6.1 Background and purpose

The National Healthcare Quality Registries hold data collected by healthcare personnel from clinics across Sweden. The registries contain individualised data on problems or diagnoses, treatments and outcomes. The fact that these registries are national means that data for all patients can be aggregated and analysed at patient, unit and national level. The health authorities have the main responsibility for the development, operation and funding of the registries, and for compliance with the Personal Data Act and Patient Data Act.

The Swedish Association of Local Authorities and Regions (SALAR) collaborates with the National Board of Health and Welfare at central level and provides financial and other support for the use of the National Healthcare Quality Registries. A total of 71 registries received financial support from SALAR in 2010. The registries are subject to a quality assurance system which requires annual reports, including a review of operations describing, among other things, how the registry's operations have contributed to local quality improvements.

The majority of National Healthcare Quality Registries currently receive financial support from pharmaceutical companies. All in all, support from the industry accounts for around a fifth of total funding for the registries. One recommendation is that the supporting pharmaceutical company should have access to anonymised, aggregated data from the registry in question on that company's own products.

It is important that collaboration between the parties is open, and one option is to register collaboration in LIF's collaboration database in the Healthcare Personnel section. To register, visit www.lif.se.

4.6.2 Criteria for financial support to National Quality Registers

Article 57

- (i) There should be a written partnership agreement between the parties (health authority, register manager and company) stating the parties' rights and liabilities as well as the duration of the partnership.
- (ii) The contents of the partnership agreement should be open and clarified in all contexts where the register is presented. E.g. via websites, publications annual reports

Statutes of the Swedish Pharmaceutical Industry's Information Examiner (IGM) and the Information Practices Committee (NBL)

GOVERNING BODIES AND AREA OF ACTIVITY

§ 1.1. The IGM and NBL are engaged in the system of self-regulation, which the Association of the Pharmaceutical Industry (LIF) has maintained in the pharmaceutical sector since 1969 for the purpose of realising the industry's aim of ensuring that the information supplied by pharmaceutical companies follows the Ethical rules for the pharmaceutical industry.

§ 1.2. LIF is the governing body of the two agencies.

§ 2. The IGM and NBL perform their duties independently and separately. The distribution of work between them is regulated in these statutes and by the rules of procedure established by the governing bodies.

DUTIES

§ 3. The task of the IGM and NBL is, in the forms stated in § 4 and on the basis of the work distribution between them stated in § 5, to endeavour to ensure that the pharmaceutical companies follow the Ethical rules for the pharmaceutical industry, observe legal statutory provisions and general non-statutory criteria for good business practice in industry, and otherwise comply with good industrial practice.

NATURE OF ACTIVITY

§ 4.1. The overall activity assigned to the IGM and NBL consists primarily of monitoring the market, assessing cases and pre-examination according to article 102.

§ 4.2. In addition, the NBL may issue advisory statements, i.e. explain what is or should be considered as good industry practice in any particular case.

§ 4.3. **Monitoring the market** entails first and foremost an ongoing monitoring of the product information provided by pharmaceutical companies, in respect of drugs for human and veterinary use. This monitoring also includes the pharmaceutical companies' compliance with LIF's quality labelling of websites. This task is performed by the IGM.

§ 4.4. **Assessment of cases** includes preparing and considering, and making decisions in, cases taken up for consideration in connection with monitoring the market or on receipt of a report. The assessment is performed by the IGM and/or the NBL. It focuses on whether a certain measure taken by a pharmaceutical company is objectively compatible with what is or should be considered as good industrial practice. The

intention behind the measure is not examined.

- § 4.5. Pre-examination includes examination of and making a decision regarding applications for pre-approval according to article 102.
- § 4.6 At the request of a pharmaceutical company, the IGM may provide general advice on measures that have not yet been implemented. Such advice does not constitute a binding advance statement.
- § 4.7 LIF's Compliance Officer decides, on his own initiative or upon notification or enquiry, if a location of a planned arrangement is acceptable.

DISTRIBUTION OF CASES

- § 5. Assessment of cases is distributed between the IGM and NBL, primarily as follows.

IGM

- § 5.1. The IGM's task is to try/examine:
- 1) measures that the IGM finds cause to question in the course of monitoring the market,
 - 2) measures that, in a report to the IGM, are questioned by a party that is entitled to take legal action in accordance with § 18,
 - 3) applications for pre-examination according to article 102 submitted by a pharmaceutical company.

NBL

- § 5.2. The NBL's task is to try/examine:
- 1) measures that the IGM, without taking a decision on its own, passes on to the NBL or which are reported by a public authority,
 - 2) measures that, in a report to the NBL, are questioned by a party with the right to take legal action in accordance with § 19,
 - 3) appeals against decisions taken by the IGM or LIF's Compliance Officer (cf. § 36).
- § 6. The NBL can issue advisory statements on issues of major importance, either in connection with consideration of a certain case, at the request of a party named in § 20 or at its own initiative, or when the NBL finds it necessary to make such a statement.

RULES OF PROCEDURE

- § 7. Detailed regulations concerning the IGM's and NBL's methods or working and the division of work between them can be found in the Rules of Procedure (cf. § 2).

ORGANISATION

IGM

- § 8. The IGM shall be a qualified physician with scientific competence, significant and comprehensive clinical experience and a good general overview of medical and pharmacological research. The appointment of an assistant IGM may be arranged. For the position of assistant IGM, the same skills requirements as for the IGM apply. In these statutes and in the rules of procedure, the term IGM refers to both the IGM and the assistant IGM.
- § 9. The IGM has at his disposal the assistance required for carrying out his activities effectively. The work is divided between the IGM and the assistant IGM according to the agreement between them.
- § 10. The IGM and assistant IGM are appointed by LIF's Board of Directors for a period of three calendar years; however, the first term may be of a shorter duration. The election takes place not later than the month of November before the start of the term. Re-election is permitted.

NBL

- § 11.1. The NBL comprises a chairman and eleven members.
- § 11.2. The chairman must be an experienced lawyer with certified expertise, and must not be engaged in the pharmaceutical sector.
- § 11.3. Six members must hold executive positions associated with pharmaceutical companies, and at least one of them must have specific experience in the area of self medication products. All of these members should possess knowledge of market law.
- § 11.4. Two members must represent medical expertise; they must be qualified physicians, have a clinical speciality or corresponding expertise and have clinical experience.
- § 11.5. Three members must represent public interests, one of them in particular consumer interests.
- § 12.1. There must be an alternate for the chairman – the deputy chairman.
- § 12.2. There must be four deputies for those members with corporate affiliations, of which at least one deputy must have experience of veterinary drugs; there must also be one deputy for the medical experts and two for the members representing public interests.
- § 12.3. The same skills requirements apply to the deputy chairman and the deputies as those that apply to the chairman and the members they are to

replace.

- § 13.1. LIF's Board of Directors elects the members with corporate affiliations and their deputies, as well as the chairman, deputy chairman and other members and deputies.
- § 13.2. The members with medical expertise and their deputy are appointed after consultation with the Swedish Medical Association.
- § 13.3. The representatives of public interests and their deputies are appointed in a corresponding manner following consultation with an appropriate body or authority.
- § 14. Members are elected for two calendar years, although the first term may be shorter. The election takes place not later than the month of November before the start of the term. Re-election is permitted.
- § 15.1. The NBL has one or more secretaries. Secretaries must be lawyers with a sound knowledge of market law.
- § 15.2. The secretary has the required assistance placed at his disposal.
- § 16. Secretaries are appointed by LIF's Board of Directors, in consultation with the chairman and deputy chairman, for two years at a time. Any other necessary assistance is arranged for a specific duration, for a specific task or until further notice.
- § 17. The NBL may co-opt members following consultation with LIF. The NBL may also co-opt experts if this is required for a particular case.

ENTITLEMENT TO TAKE LEGAL ACTION

IGM

- § 18. The right to complain to the IGM regarding measures that a pharmaceutical company itself has adopted, or that some other party has adopted on its behalf, lies with
 - 1) a private individual,
 - 2) a company or association (a public authority files complaints regarding such measures directly to the NBL, see § 19.1),
 - 3) LIF's Compliance Officer (regarding transgressions of decisions according to § 4.6).

NBL

- § 19.1. The right to complain to the NBL about adopted measures lies with

- 1) the IGM,
- 2) a private individual (appeal),
- 3) a company or association (appeal),
- 4) a public authority.

The right to complain to the NBL regarding an adopted measure concerning a *pre-approved website* and *pre-approved vaccination campaign* according to article 102 lies with

- 1) a private individual,
- 2) a company or association,
- 3) a public authority.

§ 19.2. The right to appeal to the NBL against a decision issued by the IGM lies with the defendant in a case that has been brought up by the IGM himself and with the parties in cases that have been reported to the IGM. In matters regarding pre-examination according to article 102, the right to appeal to the NBL against a decision issued by the IGM lies with the applicant.

§ 20. The right to request an advisory statement from the NBL lies with

- 1) LIF, Föreningen Innovativa Mindre Life Science Bolag (IML), Föreningen för Generiska Läkemedel (FGL), the IGM and pharmaceutical companies that are members of LIF, IML or FGL
- 2) Apoteket AB and associations of people working in the medical field,
- 3) courts of law and other public authorities.

Request for termination of a measure

§ 21. Competing pharmaceutical companies that submit a report to the IGM or NBL must enclose evidence that the company or companies against whom the representation is made has been encouraged to terminate or change the criticised measure but has/have failed to observe such request within two weeks of receiving it. The IGM and NBL may permit an exception to this requirement if the measure constitutes a serious disregard of good industrial practice or if a prompt intervention is required to prevent further damage caused by the measure.

QUORUM IN FINAL DECISIONS

IGM

§ 22.1. In cases dealt with by the IGM, decisions are taken by the IGM alone. The IGM is free to engage in confidential consultations with other experts

when the IGM considers this appropriate. For such consultation with regards to veterinary drugs, LIF places special experts at the IGM's disposal.

- § 22.2. The IGM may, without issuing a decision, dismiss a case if the case is of minor importance and the pharmaceutical company concerned has already terminated the measure when contacted by the IGM or if the company immediately rectifies the matter in an acceptable way. If the matter is a result of a complaint, it is a precondition that the complaint is withdrawn by the complainant. The IGM may also remove a case from the case list if a complaint to the IGM regards a matter which the NBL is simultaneously trying or has previously tried on the same grounds.

NBL

- § 23.1. The NBL constitute a quorum when the chairman or deputy chairman and at least five members are present. At least three of these members must have corporate affiliations, at least one must be a medical expert and at least one must represent public interests, in particular consumer interests.
- § 23.2. In dealing with cases concerning self medication products, at least one member with corporate affiliation, with special experience in this area, shall be present.
- § 24. Cases that are reported to the NBL and that the chairman judges to be simple in nature – in particular cases where the facts are unambiguous from a medical point of view where clear practice exists – may be settled by the chairman and one member with medical expertise.
- § 25. In cases relating to advisory statements, the NBL constitutes a quorum when the chairman or deputy chairman and at least seven members are present and take part in the decision. At least four members must have corporate affiliations and at least one must be a medical expert or represent public interests. If only one member with medical expertise can be present, this person must have consulted with either of the other two medical experts regarding the matter.
- § 26. At meetings of the NBL, all those who are not challengeable may participate in the deliberations (cf. § 32.3). Deputies for members who are present do not have voting rights. According to § 17, co-opted members or experts do not have the right to vote either.
- § 27. Decisions are taken by vote. The opinion shared by the majority constitutes the decision. In the event of an equal numbers of votes, the chairman has the casting vote.

INTERIM DECISIONS

- § 28. If, at an early stage, when a case is being prepared at the NBL, it is clear that a measure is obviously and seriously in conflict with good industrial practice, the NBL or the chairman acting on the NBL's behalf may urge the pharmaceutical company concerned through an interim decision to desist from the criticised measure until the NBL, at a meeting with the composition stated in § 23, has delivered a final decision in the case.
- § 29. The NBL can revoke an interim decision whenever it finds cause to do so.
- § 30. If, while dealing with a case, the IGM finds that the circumstances call for an interim decision, the IGM shall immediately pass the case on to the NBL.

DECISIONS IN DEALING WITH A CASE

- § 31.1. A decision during the handling of a case by the NBL, shall be taken by the chairman or the person appointed by the chairman.
- § 31.2. If a complaint or an appeal against a decision issued by the IGM is withdrawn, the matter is to be dismissed from further handling by the NBL. The decision to dismiss is taken by the chairman or the person appointed by the chairman.

CHALLENGE

- § 32.1. In case of a challenge to the IGM, the chairman of the NBL, deputy chairman, members and deputies, a co-opted member or expert, or the secretary, the challenge regulations in the Swedish Arbitration Act shall apply.
- § 32.2. In case of a challenge to the IGM as well as the assistant IGM, the case shall be transferred to the NBL.
- § 32.3. A person who is challengeable in a case may not be present when the case is considered.

FINAL DECISIONS AND ADVISORY STATEMENTS

IGM

- § 33.1. The IGM's final decision shall be stated in writing and be accompanied by the grounds for such decision and contain information about any charges payable according to §§ 42-44 and, where appropriate, a request to the company concerned to desist from repeating the measure after a certain date.

§ 33.2. Irrespective of whether an appeal has been lodged in accordance with § 36, the IGM's request shall be complied with until the NBL decides otherwise.

NBL

§ 34. The NBL's final decision shall be given in writing and contain

- 1) a description of the questioned or criticised measure,
- 2) the criticisms and the grounds on which they are based,
- 3) the objections of the defendant companies and the reasons for these,
- 4) the NBL's assessment of the measure, with reasons,
- 5) the NBL's conclusion,
- 6) information about any charges payable in accordance with §§ 42-44,
- 7) where appropriate, a request to the company to desist from repeating the measure after a certain date,
- 8) the names of those who took part in the decision and any dissenting opinions.

This paragraph shall not apply to decisions regarding pre-examination according to article 102.

§ 35. The NBL itself decides on the form of its advisory statements and decisions regarding pre-examination according to article 102.

APPEALS TO THE NBL

§ 36. An appeal against a decision taken by the IGM or LIF's Compliance Officer may be lodged with the NBL within three weeks of the date of the decision. Appeals that are received too late shall be dismissed by the NBL.

MINUTES AND ANNUAL REPORTS

IGM

§ 37.1. The IGM shall make appropriate notes of measures adopted.

§ 37.2. Twice a year, the IGM must submit a brief report to LIF and the NBL about the operation during the preceding half-year.

NBL

§ 38.1. Minutes shall be kept at NBL meetings and shall be approved by the chairman. The names of those present and which cases have been dealt with shall be noted therein. The decisions taken shall be appended to the minutes.

- § 38.2. No later than 1 April of each year, the NBL shall issue an annual report of operations for the preceding calendar year.

OPENNESS, CONFIDENTIALITY AND PROFESSIONAL SECRECY

- § 39. The IGM's and NBL's final decisions, the NBL's advisory statements and the IGM's and NBL's annual reports are accessible to the public.

Regarding matters of pre-approval, only such decisions which result in an approval are public. Such decisions will become public at such time that the IGM or the NBL decides. When deciding on the time for making such decisions public, consideration shall be paid to the applicant's interest for protection of non-available information and to the industry's interest in having an approved decision made public as soon as possible.

- § 40. In addition to that stated in § 39, documents in the possession of the IGM or NBL may not be handed over to outside parties without the permission of the IGM and NBL respectively. Nor may information in such documents be disclosed in any other way to outside parties without permission.

- § 41. A person who has taken part in dealing with a case at the IGM or NBL may not disclose to outside parties what has taken place during discussions regarding the case, nor the content of a decision not yet announced.

FEES

IGM and NBL fees

- § 42.1 In those cases specified in §§ 43-44 below, the IGM and NBL are entitled to determine fees for pharmaceutical companies.

- § 42.2 Fees determined by the IGM and NBL may not exceed SEK 500,000. In special circumstances, the IGM and NBL can refrain from setting a fee.

- § 42.3 When determining the size of a fee in individual cases, all circumstances must be taken into consideration. When good industry practice has been disregarded, particular consideration should be taken to whether the infringement is to be considered minor or serious. As regards pharmaceutical companies with an annual turnover of less than SEK 40,000,000 for the previous year according to "InformX Sellout National, Sellout OTC (Massmarket) and Vaccine", the fee is to be reduced to half the fee that would otherwise have been determined. However, this does not apply to late payment fees. If the fee relates to information measures for veterinary drugs, the charge must be reduced to half if the annual turnover from the company's veterinary drugs is less than SEK 40,000,000 for the previous year according to "InformX Sellout National, Sellout OTC (Massmarket) and Vaccine". In addition to this, the IGM and NBL can

determine late payment fees in accordance with § 45 below.

- § 43.1 If, in its final decision, the IGM determines that the pharmaceutical company in question has implemented a measure that is incompatible with good industry practice, the company must pay a fee determined by the IGM.
- § 43.2 If, in the final decision regarding a reported case, the IGM determines that complaints brought against the contested initiative are not justified, the complainant, if the complainant is or represents a competing pharmaceutical company, must pay a fee determined by the IGM.
- § 43.3 A pharmaceutical company's obligation to pay a fee determined by the IGM is cancelled if the NBL, after an appeal in accordance with § 36, finds in a final decision that the appeal is justified and the IGM's decision is overturned.
- § 43.4 If the IGM, in accordance with § 22.2, concludes a case without reaching a final decision, no fee is payable.
- § 44.1 If, after an appeal has been lodged, the NBL confirms the IGM's decision in accordance with § 43.1, the pharmaceutical company must pay a fee determined by the NBL in addition to the fee determined by the IGM. Similarly, if the NBL confirms a decision by the IGM in accordance with § 43.2, the complainant must pay a fee determined by the NBL in addition to the fee determined by the IGM.
- § 44.2 If, in an appeal case, the obligation to pay a fee determined by the IGM is cancelled in accordance with § 43.3, the opposite party, if the party is a pharmaceutical company, must instead pay a fee determined by the NBL.
- § 44.3 If a party submits an appeal regarding part of the IGM's decision, or if both parties submit an appeal, the NBL will reach a decision, impartially with regard to the outcome, as to whether the fee determined by the IGM is to be cancelled and whether and to what extent a fee is to be determined by the NBL.
- § 44.4 If the NBL, in a case other than one involving an appeal, finds that the measures undertaken is not in accordance with good industry practice, the pharmaceutical company concerned must pay a fee determined by the NBL.
- § 44.5 If the NBL, in a case other than one involving an appeal, finds that complaints made against the measures undertaken are unjustified, the pharmaceutical company making the complaint is to pay a fee determined by the NBL.

Late payment fees

§ 45 Should a pharmaceutical company exceed the prescribed period determined by the IGM or the NBL to reply to a charge, retort or other statements in the case, the company must pay a late payment fee for each instance of an amount not exceeding SEK 10,000. From the rules of procedure it is made clear that cases may be determined even if a party has not complied with a request from the IGM or NBL.

Payment

§ 46 The fees must be paid to Läkemedelsindustriföreningens Service AB as a contribution to the self-regulatory system.

ADVERTISING**Corrective advertisements**

§ 47 If the IGM or NBL finds that a pharmaceutical company has implemented a measure that is incompatible with good industry practice and that can be viewed as serious, the IGM or NBL is entitled, in addition to the fee, to request that the pharmaceutical company places a corrective advertisement in the media determined by the IGM or NBL. The corrective advertisement may include a summary of the implemented measure.

DISCIPLINARY MEASURES

§ 48. If a pharmaceutical company refuses to comply with the IGM's or NBL's decision, the IGM or NBL shall report this to LIF, and, as applicable, to the concerned industry association. It is dependant on LIF's Board of Directors to decide on any necessary disciplinary measures. The same applies if it has not been possible to persuade the pharmaceutical company to participate loyally in the preparation of the case.

ADMINISTRATIVE REGULATIONS

§ 49. The funds required for the IGM's and NBL's activities are supplied by Läkemedelsindustriföreningens Service AB.

§ 50. Remuneration is payable to the IGM and the following NBL members: the chairman, deputy chairman, the members with medical expertise and their deputy, the representatives of public interests and their deputy, as well as the secretary and co-opted members or experts. The members with corporate affiliations and their deputies do not receive any remuneration.

ADOPTION AND AMENDMENT OF STATUTES

§ 51. These statutes have been adopted by LIF's Board of Directors and will be

valid as of 1 January 2012. They will then replace the previously established statutes.

§ 52. Decisions on amendments to statutes follow the same rules as those applying to the adoption of statutes.

RULES OF PROCEDURE FOR THE IGM AND THE NBL

- p.1. These rules of procedure have been adopted by LIF's Board of Directors with the support of § 2 in the Statutes of the IGM and NBL (referred to here as "the Statutes"). The mode of operation of the two agencies – particularly the procedure to be followed in matters regarding pre-approval according to article 102, monitoring the market and dealing with cases – is determined in detail by these rules in the light of the regulations contained in the Statutes concerning the nature of activities and distribution of duties (§§ 4-7).

TERMINOLOGY

- p.2. In the rules of procedure, the following definitions are assumed

application for pre-approval, such an application which is submitted to the IGM by a pharmaceutical company regarding a decision for pre-approval in accordance with article 102.

Cases examined on own initiative: such cases that the IGM tries for examination in connection with its ongoing monitoring of the market.

Reported cases: such cases that the IGM or NBL tries after notification in accordance with § 18 or § 19 of the Statutes.

Cases referred by public authorities: those cases that the NBL takes up at the request of a court of law or other public authority or at the instance of another public authority.

PRE-APPROVAL

- p.3. An application for pre-approval regarding such a website referred to in article 102 of the Ethical rules for the pharmaceutical industry is handled by the IGM. The assessment shall primarily aim at the measure's compliance with articles 102, 112 and 117a. The measure's compliance with other rules in the Ethical rules for the pharmaceutical industry shall however also be observed. The recipients' interest and need for guidance shall be especially observed..
- p.4. An application for pre-approval regarding such a campaign referred to in article 102 of the Ethical rules for the pharmaceutical industry is handled by the IGM. The assessment shall primarily aim at the truthfulness and objectivity of the measure. The recipients' interest and need for guidance shall be especially observed. The measure's compliance with other rules in the Ethical rules for the pharmaceutical industry shall however also be observed.

MONITORING THE MARKET

- p.5. The task of monitoring the market is handled by the IGM. This activity shall first and foremost be aimed towards commercial information about drugs for human and veterinary use disseminated through advertisements and direct mail. Monitoring shall primarily be focused on the accuracy and reliability of the informational measures. Special attention shall be paid to the interests of the recipients and their need for guidance. Secondly, the activity should be aimed at measures covered by the Ethical rules for the pharmaceutical industry.
- p.6 Product information in FASS, FASS VET, and Fass.se are not covered by the IGM's monitoring of the market.

ASSESSMENT OF CASES

Pre-approval

- p.7. An application for pre-approval is made in writing to the IGM. Complete material shall be submitted with the application.
- p.8. The IGM may reject an application for pre-approval if it is so incomplete that a consideration of the application cannot be based on it. The IGM may however allow the applicant to supplement the application.
- p.9. The IGM shall decide on the matter as soon as possible upon receipt of the application.
- p.10. If the IGM finds that the application for pre-approval does not give rise to any criticism, the IGM shall grant the application for pre-approval. The pharmaceutical company shall be notified thereof in writing.
- p.11. If the IGM finds cause for criticism to the application for pre-approval, the IGM issues a written final decision in accordance with § 33 of the Statutes.

Assessment of cases by the IGM

Cases examined on own initiative

- p.12. If, when monitoring the market, the IGM finds cause to question the compability of an adopted measure with the Ethical rules for the pharmaceutical industry, the IGM may try the case on its own initiative.
- p. 13. Following registration, the IGM shall, as promptly as possible, communicate his inquiry with the liaison officer of the pharmaceutical company responsible for matters related to information and market ethics.

- p.14. Communication shall take place in writing in the form decided by the IGM. It must be clear from the communication what is being criticised and on what grounds. In the communication, the IGM shall state a fixed time-limit, normally a maximum of two weeks, within which the pharmaceutical company is required to submit a complete defence.
- p.15. The IGM shall take a decision in the case as soon as possible after receipt of the defence, normally not more than two weeks after expiry of the time-limit. The IGM is entitled to take a decision even if no defence has been received in the prescribed way.
- p.16. If the IGM finds that no criticism should be levelled against the measure in question, the IGM dismisses the case, normally without providing reasons for his decision. The pharmaceutical company must be notified of this in writing.
- p.17. If the IGM finds cause for criticism of the measure, the IGM issues a written final decision in accordance with § 33 of the Statutes. A form shall be appended to the decision urging the pharmaceutical company to confirm that it undertakes, after a certain date, to desist from repeating the criticised measure. The form, bearing confirmation of compliance, shall be returned to the IGM within a week from the date on which the company received the decision.

Reported cases

- p.18. A report to the IGM with a request to consider and take action against a measure is to be made in writing. The report shall clearly state what is being criticised and the circumstances on which the claim is based. The required investigative material must accompany the report.
- p.19. The IGM deals with reported complaints which, in accordance with § 18 of the Statutes, have been initiated by a party other than a competing pharmaceutical company, in the same way as cases undertaken on his own initiative. See p. 13, 14, 15 and 16. In reported cases, the IGM shall not supplement the comments made in the report with his own comments. These shall instead be taken up in a separate case undertaken on his own initiative.
- p.20. The IGM tries a reported case initiated by a competing pharmaceutical company only when the company has shown that a notice of termination of the criticised measure has been served in accordance with § 21 of the Statutes, unless the IGM has made an exception to this requirement in accordance with the same section of the Statutes. The case is then dealt with in the same way as other reported cases in accordance with point 19.
- p.21. The IGM may reject a report if it is obviously groundless or if it is so incomplete that consideration of the case cannot be based on it or if the required investigative material or notice stated in p.20 has not accompanied

the report. However, the IGM may grant the complainant an extension to supplement the report.

Referral to the NBL

- p.22. If the IGM finds, immediately or at a later stage when dealing with an application for pre-approval or with a case that the case is complicated or difficult to assess, or is important in principle or otherwise of great significance, the IGM shall refer the case to the NBL as soon as possible, without taking a decision.
- p.23. The IGM may proceed, in the same way as stated in p.22, in a case to be tried on his own initiative where the pharmaceutical company contests, in a reasoned defence, that there is cause for finding fault against the measure criticised by the IGM, and the IGM does not accept the company's standpoint and, for special reasons, finds that the case should be referred to the NBL.
- p.24. That stated in p.22 regarding the IGM's obligation and in p.23 regarding the potential for the IGM to refer a case to the NBL also applies with regard to reported cases.
- p.25. If a report to the IGM concerns a measure that the IGM has already tried on his own initiative and that are based on the same grounds the case shall be referred to the NBL. The same applies if the previous examination of the IGM regards case reported by another complainant. If the report is submitted by the same complainant as previously, it shall be rejected. If different grounds are cited in the report, the IGM may try the case.

Assessment of cases by the NBL

Institution of proceedings

- p.26. A report filed with the NBL containing a request to try a measure, must be submitted in writing. As regards a report to the NBL, that stated in p.18 shall apply, as well as that stated in p.20 and p.14 concerning a report to the IGM.
- p.27. If, without taking a decision of his own, the IGM refers an application for preapproval or a case to be tried on his own initiative to the NBL in accordance with p.22 and p.23, the IGM shall, if so required, state the reasons for the measure and also append the relevant documents in the case.
- p.28. Appeals must be submitted in writing to the NBL. The appeal shall clearly state the reasons for the appeal and the investigative material cited. Material not cited when the IGM considered the case may be cited before the NBL only if specific reasons are present. Regarding appeals on the IGMs decisions regarding an approved application for pre-approval to the NBL, that which is stated in p. 18 and p. 21 regarding a report to the IGM applies.

Preparation of cases

- p.29. In reported cases in accordance with p.26 and in cases that have been referred to the NBL by the IGM in accordance with p.27, the NBL must communicate all documents to the pharmaceutical company as soon as possible for written statements. This shall not apply to an application regarding pre-approval.
- p.30. In cases where a party lodges an appeal against the IGM's decision, the NBL shall notify the IGM and any possible opponents about the appeal and shall give them the opportunity to submit their comments on the matter. In cases where a party lodges an appeal against a decision made by LIF's Compliance Officer, the NBL shall notify LIF's Compliance Officer of the appeal and shall give him the opportunity to submit comments.
- p.31. When sending information for a statement in accordance with p.29 and p.30, a certain time-limit shall be set for a reply, normally not more than two weeks. Extension of the time-limit may not be permitted unless there are special reasons present. The NBL is entitled to determine the case even if no response has been received in the prescribed way.
- p.32. As soon as a statement in accordance with p.29 and p.30 has reached the NBL, it shall be sent to IGM and the party lodging the appeal as information and, where applicable, to LIF's Compliance Officer. The preparation of the case is thereby normally complete.

Consideration of cases and decision

- p.33. When the preparation of a case is complete or the time-limit for a statement set in accordance with p.31 has expired, the NBL shall consider the case and take a decision on the first suitable occasion.
- p.34. The NBL's decision, where appropriate taken in accordance with § 34 of the Statutes, should be forwarded promptly to the parties and should normally reach them within three weeks of the day of the meeting on which the NBL took a decision in the case.

Advisory statements

- p.35. If a request for an advisory statement in accordance with § 20 of the Statutes is presented in connection with a certain criticised measure, that stated in p.24 and pp.29-33 regarding the institution of proceedings, the preparation of cases and the consideration of cases and decisions shall apply where appropriate.
- p.36. If a request for an advisory statement is not connected to a particular criticised measure, the NBL shall, when required, itself attend to the investigation. The same applies if the NBL decides to issue an advisory statement on its own initiative.

Cases referred by public authorities

- p.37. Cases referred by public authorities are dealt with, where appropriate, in the same way as reports with a request for an advisory statement. See pp. 35-36.

NON-AFFILIATED COMPANIES

- p.38. If a pharmaceutical company that is not a member of LIF refuses to file a defence or to loyally assist in the consideration of a case by the IGM or the NBL, this shall promptly be reported by the IGM or the NBL to LIF.

These rules of procedure shall take effect as from 1 January 2012.

REGARDING CORRUPTION AND BRIBES

7 § Those who deliver, promise or offer bribes or other improper reward to employees or others included in paragraph 2 chapter 20 for the performance of services shall be condemned for bribery and sentenced to fines or prison for up to two years. In the event of a serious offence, the party will be sentenced to imprisonment for a minimum of six months and a maximum of six years. Law 2004:404.

Punishment for accepting bribes, see **20:2** forfeiture **36:1** – **H 1947:362** – For questions regarding bribery in connection to Christmas gifts which a company presented to municipal government employees **H 1981:477** – For questions of responsibility for a construction company offering municipal representatives and government employees from southern Sweden a study visit to Stockholm **H 1981:1174**.

(H= Holm, New judicial archive, dept. 1. (The numbers following H refer to year and page.))

17 § In certain instances of bribery, the prosecutor may indict only if the crime is reported by the employer or client of the person subjected to the bribes or if indictment is necessary from a general judicial viewpoint. This applies if bribes have been offered to someone who

1. is not an employee of the state or the municipality,
2. is not included in § 2 chapter 20 second paragraph 1-4, 8 or 9, and
3. is not a minister of a foreign state or a member of a foreign state's legislative assembly. Law 2004:404.

ETHICAL RULES FOR INTERACTION BETWEEN PHARMACEUTICAL COMPANIES AND VETERINARY CARE PERSONNEL

These ethical rules apply to interaction between pharmaceutical companies and veterinary care personnel.

In order to realize the pharmaceutical industry's ambition to retain responsibility itself for ensuring that pharmaceutical companies' information and other marketing activities comply with high ethical standards, LIF has established a so-called self-regulatory system.

When interaction between pharmaceutical companies and veterinary care personnel encompasses activities covered by the rules for pharmaceutical information or the pharmaceutical industry's self-regulatory system, the pharmaceutical companies are obliged to follow the information rules and other standards applied within the self-regulatory system. Moreover, the monetary limits and inappropriate places for meetings and scientific conferences as defined by the Board of Directors of LIF apply.

1. GENERAL CONDITIONS

There has long been an important collaboration between the pharmaceutical industry and veterinary care that touches on many areas. This collaboration is important to both the industry and veterinary care, as well as to the animal patients.

According to statutes and good business praxis, the industry is obliged to provide information about its products, such as their properties, effects, and suitable use, as well as any possible side effects. Correspondingly, in order to properly use the drugs, veterinary care has a need for such information. The collaboration comprises an important part of the further training of veterinary care personnel and provides wider opportunities to participate in the research and development of pharmaceuticals.

Within veterinary care, veterinary care personnel continually acquire broad knowledge of the properties and clinical use of drugs, and this knowledge needs to be conveyed to the pharmaceutical companies so as to provide a basis for the development of both existing and new drugs.

It is extremely important for collaboration to take place in such a manner that both veterinary care personnel and pharmaceutical companies retain full credibility and an independent position in relation to each other. Collaboration should be transparent and open to public examination. Subsequently, the purpose of these rules is to provide rules that promote collaboration pursued with good judgment, with retained credibility, and in compliance with applicable laws, agreements, and ethical rules. Good compliance with these rules may not, however, exonerate pharmaceutical companies and veterinary care personnel from any accusations of bribery and cor-

ruption. Such responsibility must always be tested individually and based on how strong the correlation is between the fringe benefit, the execution of duty, and the degree of influence.

2. THE CONTENT OF THE RULES

- Pharmaceutical companies hiring veterinary care personnel on a consultancy basis or for one-off remuneration.
- Provision of information and supply of training and scientific gatherings or the like, regardless of whether the activity is supplied by a pharmaceutical company or a third party, if a pharmaceutical company is the arranger or principal in whole or in part.
- Pharmaceutical company sponsorship of activities/meetings arranged by third parties (e.g. specialist associations) or by veterinary care operations.
- Gifts and aids

Any other collaboration or relations between veterinary care personnel and a pharmaceutical company not included in the above shall also be characterized by openness and shall follow this agreement in all essentials.

3. CONSULTATION

Veterinary care personnel often comprise an important part of different activities, such as research, training, conferences, advisory boards, and product development. Participation can entail an assignment falling under normal work duties or as a consultant, and can therefore comprise sideline employment.

The following shall be observed when a pharmaceutical company hires veterinary care personnel for assignments:

- The assignment should be agreed in writing between the employee and the pharmaceutical company.
- Remuneration for work carried out should be reasonable in relation to the content of the work and time expended. Compensation for expenses shall be in accordance with the pharmaceutical company's travel and expense allowance regulations. The above agreement shall stipulate how remuneration is regulated. No other fringe benefits, remuneration, or gifts may be provided.
- Meetings with pharmaceutical companies within the bounds of veterinary care personnel's consulting activities may be held abroad if the majority of the participants are from a country other than Sweden. Due to the extensive

economic integration of the Öresund Region, in this agreement Själland is comparable with Sweden.

That stated below under section 6 Events shall also cover employees who carry out assignments for a pharmaceutical company.

4. PRODUCT INFORMATION

Product information relates to meetings intended to provide information about the specific properties or handling of a drug (known as product information).

The following shall be observed as regards product information:

- Meetings shall normally be held at the participants' workplace. Meetings targeting veterinary care personnel from several workplaces may be held at locations other than the town or city where said personnel work if pedagogical, practical, economic, or other similar reasons so dictate.
- Pharmaceutical companies shall contact the personnel in good time and agree on the main content of the information meeting, as well as the time and place.
- The invitation shall clearly state the time and place of the gathering, as well as the duration and content of the work-related agenda.

Product information that is presented in exhibition stands or that is distributed at international scientific conferences or symposia may refer to drugs that are not registered in the country where the event is taking place, or that are registered in a different way, on the condition that:

- The event is an international scientific meeting with a majority of participants from countries other than the country where the event is taking place.
- Marketing material containing information about a drug that has not been granted marketing authorisation in the country where the meeting is taking place must include details about the countries in which the drug has received marketing authorisation, as well as the fact that it has not been granted such authorisation in the country where the event is taking place.
- Marketing material that refers to prescribing information (indication, warning texts, etc.) that has been approved in a country or countries, although not in the country where the event is taking place, but where the drug is registered, must be followed by information that the registration terms may differ internationally.

The information must indicate the countries in which the drug has been approved, and specify that the drug has not been approved locally.

5. THERAPY-ORIENTED TRAINING AND SCIENTIFIC CONFERENCES

Therapy-orientated training relates to meetings intended to mediate training in a particular field of treatment. The information shall give the participant current and relevant knowledge of general or specific facts and problems within the therapeutic field in question, that is, it shall be problem-oriented and not product-oriented.

Scientific conferences are meetings arranged by pharmaceutical companies, or with the support of pharmaceutical companies, aiming to address one or more medical or other scientific issue within one or more scientific fields.

The following shall be observed for the above conferences:

- Product information may be provided if the product's use or the conditions for its use are an integrated part of the training. If product information is provided this shall be made clear in the agenda.
- The in-service training offered should be based on the personnel's skill requirements.
- Conferences shall normally be held at the participants' workplace or in the same town or city or as near as possible. Conferences may be held at locations other than the town or city where the participants work if pedagogical, practical, economic, or other similar reasons so dictate. Conferences outside Sweden are only permitted in direct connection with international training and scientific conferences (including satellite symposia) if the majority of participants are not from Sweden and equivalent knowledge cannot be acquired within the country. Study visits to internationally recognized scientific clinics/universities/laboratories etc. outside Sweden are only permitted if equivalent experience or information cannot be acquired within the country and the study visit can be considered relevant to the educational purpose of the activity. Due to the extensive economic integration of the Öresund Region, in this agreement Själland is comparable with Sweden. Conferences may not be held in locations considered luxurious or that can be associated with leisure activities, such as winter sports, hotels adjacent to golf courses, or locations where a major sports event is underway at the same time.
- The time and place of the meeting, plus any incidental arrangements, shall be clearly stated in the invitation. The duration and content of the work-related agenda shall be clearly stated. If the conference is held at a location other than the employee's workplace, and if the pharmaceutical company finances a proportion of the costs of participation, the duration of the trip may not exceed the duration of the conference and any incidental arrangements.

6. Events

The choice of location for an event must be reasonable in relation to the purpose of the event. Locations that are known for leisure activities or other exclusivity shall be avoided, e.g. winter sports, motor and golf competitions. The same applies to locations at which major international events are being staged at the same time as, or in connection with, the arrangement. Neither should companies contribute financially to events that are located in such places. LIF's Compliance Officer decides whether a location is acceptable or not. A decision made by the Compliance Officer can be appealed.

7. REFRESHMENTS, EXPENSES, AND REMUNERATION

- At conferences, both domestic and abroad, any meals provided shall be very modest. For meals in Sweden, lunch and dinner expenses shall amount at most to the value per participant laid down by LIF at that time. For meals abroad, local rules must be followed where applicable. In the absence of such rules, the Swedish rules must be applied as far as possible. Food and drink etc. may only be offered at relevant times and in accordance with applicable rules, on the condition that
 - (i) only participants in the arrangement are invited. Accompanying individuals may not participate, and
 - (ii) the food is reasonable according to local standards. Alcoholic drinks in the form of wine and beer may only be offered in limited quantities and only with food. No spirits may be offered.
- Travel shall be arranged, insofar as possible, in economy class. Travel in first or business class is only permitted where the price difference is negligible. Moderation must also be observed in the choice of hotel.
- At conferences, the work-related agenda shall be of such a duration and scope that there is no question of taxation on fringe benefits in accordance with applicable rules and guidelines from the Swedish Tax Agency.
- Pharmaceutical companies may pay for conference facilities, speakers, study materials, and so forth that are necessary to carry out the conference.
- Pharmaceutical companies may partly subsidize the conference participants' travel, food, and accommodation costs and conference fees. The condition is that that the conference and such travel, food, and accommodation are moderate and can be publicly examined. The participant or the participant's employer shall always be responsible for paying a reasonable proportion of the above-mentioned costs. However, the pharmaceutical company may never be responsible for a larger proportion of the costs than the entire conference

fee plus 50% of travel, food, and accommodation costs. Accompanying individuals or relatives of participants may not participate in conferences arranged by the company.

- No separate social or recreational activities may be provided or offered by pharmaceutical companies, and nor may they be demanded by veterinary care personnel, in conjunction with conferences or interaction. However, simpler social activities, such as musical entertainment, are permitted in conjunction with meals or receptions as long as they are secondary to the actual conference and meal or reception.
- Conference participants may not be offered fees from pharmaceutical companies and said participants are not entitled to accept or demand fees for their participation.
- Pharmaceutical companies may not offer and veterinary care personnel may not demand or accept fringe benefits, remuneration, or gifts or demand any other action contravening these guidelines.

8. SPONSORSHIP

Here sponsorship refers to support, economic or otherwise, from pharmaceutical companies for activities/conferences intended for veterinary care personnel. Sponsorship also includes support, economic or otherwise, to professional associations that organize veterinary care employees.

Activities/conferences organized within regular operations may not be sponsored. This means, among other things, that partial or full sponsorship of staff parties is not permitted. Neither is sponsorship of employees within the veterinary care sector permitted to compensate purely for the time that the employee is present at an arrangement.

Sponsorship of activities/conferences arranged by third parties (e.g. specialist associations and students' associations) may only be arranged if the following conditions are satisfied:

- The sponsored activity/conference must be for professional improvement.
- Pharmaceutical companies may not offer sponsorship in a sum exceeding the costs of the activity/conference.
- Sponsors providing resources at the disposal of the conference shall be named in the invitation.

9. Gifts and aids

Gifts may only be distributed with considerable restraint, and may only refer to articles of little value to the professional. The term “little value” refers to the established value of articles at that time. Only the name of the pharmaceutical company or the name of the company’s representative in Sweden shall be specified on such articles, along with the name of the drug or its generic name; in addition or in place of that, the trademark used by the company may be specified. No other printing may occur.

Aids intended to facilitate the proper administration or use of a drug by veterinary care personnel or patients – for example, dietary guides for diabetics, instructions for drug use, applicators, dosage containers and suchlike – may be distributed to the extent required by therapeutic considerations.

Aids intended to facilitate the prescription of drugs – such as rubber stamps for prescriptions, prescription pads, etc. – shall be distributed with restraint, and only upon order from persons licensed to prescribe. If such aids are sent by post, this shall be done in such a way that the consignment is only handed over in exchange for a receipt. Other aids with a medical connection may be offered or distributed free of charge on the condition that they have a professional value for the recipient or are important for patient care.

Aids must not be given a more lavish appearance than is necessary for the required purpose.

General: Due to the extensive economic integration of the Öresund Region, Själland is comparable with Sweden.

10. SANCTIONS

The Information Examiner (*Informationsgranskningsmannen, IGM*) and the Practices Committee (*Nämnden för Bedömning av Läkemedelsinformation, NBL*) shall review any transgressions of the rules by pharmaceutical companies.

Stockholm in May 2008

The Swedish Association of the Pharmaceutical Industry, LIF

ETHICAL RULES FOR INTERACTION BETWEEN PHARMACEUTICAL COMPANIES AND POLITICIANS

1. BACKGROUND AND PURPOSE

Pharmaceutical companies and politicians conduct an on-going dialogue with the purpose of optimizing shared interests and creating a basis for increasing access to the best possible medical preventive measures and treatments for patients and other citizens. The ethical rules provide a framework for the dialogue between pharmaceutical companies and politicians, so as to ensure that the dialogue is always conducted with good judgement, maintained credibility and high ethical standard.

In applying this appendix, the word "politician" shall mean elected representatives, e.g. members of parliament and members of local government's and county council's decision making bodies. "Politician" also refers to ministers, county commissioners, local government commissioners, members and alternate members of boards and committees, and also politically appointed officials, e.g. under-secretaries of State, political experts and political secretaries.

2. CONSULTATION AND ASSIGNMENT

A pharmaceutical company may not remunerate politicians for services to the company. This, however, does not apply for remuneration to:

- a politician who is a permanent employee of the pharmaceutical company and the remuneration exclusively relates to the employment and the employment is not in any way related to the employee's political office, or
- a politician who performs a consultation assignment for the pharmaceutical company and in his or her assignment is not acting in his capacity as politician.

A pharmaceutical company may, within the scope of a specific and limited assignment, assign politicians to perform teaching, lectures or the like. No remuneration or reimbursement shall be paid for such assignment.

3. EVENTS

Politicians may be invited to scientific meetings, conferences, symposiums and other similar events.

4. REFRESHMENTS, EXPENSES AND REMUNERATION

Pharmaceutical companies may not cover travel expenses, overnight accommodation or conference fees for politicians who attend an event or offer politicians remuneration or any other form of compensation for the attendance. Pharmaceutical companies may, however, pay the costs for conference facilities, speakers, study materials and similar that are necessary in order to carry out an event that is wholly or partially targeting politicians. As regards meals and social or leisure activities, pharmaceutical companies shall apply article 37 paragraphs 1 and 7, regarding forms of collaboration with healthcare professionals and others, correspondingly.

5. GIFTS

Gifts to politicians may not be distributed.

6. CAMPAIGN CONTRIBUTIONS, OTHER BENEFITS ETC.

Pharmaceutical companies may not offer politicians benefits, remuneration or gifts other than what is allowed under this appendix. Pharmaceutical companies may not offer campaign contributions to individual politicians.

If a pharmaceutical company makes a campaign contribution to a political party, this shall be made public on the company's website.⁵

⁵ For example UK Bribery Act and The American "Foreign Corrupt Practices Act" (FCPA) as well as pharmaceutical companies' internal codes of conduct may contain provisions which constitute a more stringent regulation than what is stated here. The fact that the content of LER in this respect has a lesser strict content does obviously not mean that departure from other applicable and more stringent regulations may be made.



**The Danish Ethical Rules for
Promotion of Medicinal Products
towards Healthcare Professionals
2011**

1973-2011
38 years of self-regulation on medicinal products

The Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI)

Unauthorised translation
In case of doubt the Danish version
is always applicable and official

The Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI)

BACKGROUND

The Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI) was established in its current form by the Danish Association of the Pharmaceutical Industry (Lif), the Danish Generic Medicines Industry Association (IGL) and the Danish Association of Parallel Distributors of Pharmaceuticals (PFL) in April 2011 and aims, among other things, to ensure the control of the Danish Ethical Rules for Promotion of medicinal products towards Healthcare Professionals.

Before ENLI was established, the promotion activities of pharmaceutical companies concerning medicinal products were controlled by the industry committee NMI (the Danish Board of Drug Advertising) and later by the Danish Legal Board of Self-Regulation Concerning Pharmaceuticals (NSL).

As early as 1973, a code of practice was adopted to ensure a proper framework for the work of the industry. Since then, the code of practice has been updated, and in 2007, it was succeeded by the so-called "Co-operative Agreement", whose originators also included the Association of Danish Pharmacies, the Danish Medical Association, IGL and the Danish Association of Parallel Distributors, and which was controlled by NSL. The Co-operative Agreement was signed in 2007 and became effective in April 2008. The rules of the Co-operative Agreement were, however, quickly superseded to a large extent by "the Executive Order on Promotion of medicinal products" from 2007, which implements Directive 2001/83/EC of the European Parliament and of the Council, as these rules overlapped the agreement.

On the international scene, a significant development took place simultaneously. Where Denmark used to be in the lead:

- the EFPIA (European Federation of Pharmaceutical Companies and Associations):
 - in 2007 updated its code on the industry's promotion activities towards healthcare professionals, with regard to prescription-only medicines (which, like the Executive Order on Promotion, is based on the EU rules in force).
 - in 2006 updated its code on the industry's collaboration with patient groups.
- the IFPMA (the International Federation of Pharmaceutical Manufacturers & Associations):
 - in 2006 updated its Code of Pharmaceutical Marketing Practices.

Lif has, through its membership of the above-mentioned associations, decided to follow these international codes, which supplement the law and in many ways place higher demands on the industry than the law and the Co-operative Agreement did. It was not possible to incorporate the above-mentioned rules in the Co-operative Agreement and subject them to the control of NSL. At the same time, Lif had adopted several ethical rules such as "Lif's Ethical Rules for Dialogue and Negotiations with Decision-Makers" (Lif's code on lobbying activities), which also needed to be controlled, but could not be subjected to the control of NSL either.

On these grounds, Lif decided to terminate the collaboration, and together with IGL and PFL the industry established a new committee instead as of April 1, 2011, "The Ethical Committee for the Pharmaceutical Industry in Denmark" (ENLI), in order to bring the rules that follow from law and voluntary agreements etc. together in a more manageable system, in which all rules could be controlled by one regulatory body instead of having it spread out over several regulatory bodies, rules, agreements, etc. The hope is to create a better overview of the rules and practice in the field. It has also been wished to provide more guidance.

UNDERLYING RULES

ENLI ensures the control of the following rules:

- The Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals
- Ethical Rules for Collaboration between Patient Groups, etc. and the Pharmaceutical Industry
- Ethical Rules for Dialogue and Negotiations with Decision-Makers (code on lobbying activities)
- Parts of the Executive Order on Promotion concerning promotion of medicinal products towards healthcare professionals (ultimately controlled by the Danish Medicines Agency) and relevant parts of Chapter 7 of the Danish Medicines Act.
- Ethical Rules for Pharmaceutical Companies' Relations with the Danish Hospital Sector
- Ethical Rules for the Pharmaceutical Industry's Donations and Grants to Hospitals

COMPLAINTS

Complaints concerning the Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals can be filed to ENLI via www.ENLI.dk, as can complaints concerning the other codes of practice. Eligible to complain are the pharmaceutical companies subjected to the competency of ENLI.

All complaints are assessed by a legal and medical panel of investigators in the first instance, and appeals are handled by “the Board of Appeal” (ENLI).

Reports and cases are made public to the extent legally permitted, with regard to the Danish Act on Processing of Personal Data and other applicable laws and regulations, on the ENLI website: www.ENLI.dk.

All first instance and second instance decisions are forwarded to the Danish Medicines Agency for their information.

ORGANIZATION

Lif's Self-Regulating Instance (ENLI) consists of 2 instances:

- The first instance: the Legal and Medical Panel of Investigators (GP), comprising legal and medical investigators respectively, and
- The second instance: The Board of Appeal (ENLI), comprising:
 - Two lawyers (one is chairperson)
 - A medical doctor
 - A former employee of the pharmaceutical industry

The Legal and Medical Panel of Investigators is responsible for the handling of appeals in the first instance and for the control of filed cases. The panel is also responsible for providing guidance on and training in, i.a., “the Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals”.

The Board of Appeal handles cases, which are appealed from the first instance.

THE RELATIONS BETWEEN ENLI AND LIF, IGL AND PFL

ENLI works independently of Lif, IGL and PFL.

The relations between Lif, IGL, PFL and ENLI are regulated in the statutes of ENLI, which can be found on the ENLI website. Financial information on ENLI is published in ENLI's annual report.

Introduction to the Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals

Access to the best medical treatment

Lif, IGL and PFL work to provide the pharmaceutical industry with the best possible conditions to research, develop, market, distribute and inform about medicinal products *thus ensuring broad and fast access for patients to the best medical treatment.*

For this purpose, it is firstly required that relevant information about medicinal products is available to healthcare professionals etc., and secondly that the information is exchanged in an ethically responsible and transparent way. These ethical rules aim to ensure this.

Since 1973, the promotion activities of pharmaceutical companies have been regulated and controlled on a voluntary basis. These ethical rules complement and supplement Danish and international law in the field, and *place further and/or stricter demands on the activities of the pharmaceutical companies in a number of fields, than what follows from law and the previous co-operative agreement.*

The ethical rules are updated on a regular basis and regulate the members of the three associations (including affiliated companies) and their:

- Promotion of medicinal products towards healthcare professionals, also including printed promotion and information material
- Interaction with healthcare professionals

In general, companies must ensure that their promotion material (including websites etc.) contains appropriate, factual, balanced and verifiable information, and that all other activities are appropriate and fair.

Ensure high ethical standards

The very detailed rules ensure that pharmaceutical companies act in an ethically responsible and professional way. The pharmaceutical industry has a legitimate and statutory right to market medicine towards healthcare professionals, and the rules aim to balance the interests of patients, healthcare professionals and the general public in such information.

The rules are very much endorsed by the pharmaceutical industry, where substantial resources are allocated to ensure compliance with the rules. Any complaint of non-compliance is considered a serious matter. Sanctions are imposed for non-compliance, and the companies are obligated to ensure that relevant employees have received training in the rules.

These ethical rules incorporate the principles from:

- The European Federation of Pharmaceutical Companies and Associations' (EFPIA) Code on the Promotion of Prescription-only Medicines to, and interactions with, Healthcare Professionals.
- The International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Pharmaceutical Marketing Practices.
- Relevant parts of "Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC".
- Relevant parts of "the Executive Order on Promotion of Medicinal Products no. 272 of 21 March 2007" and appurtenant guideline 2007-05-24 no. 29 on promotion of medicinal products and relevant parts of Chapter 7 of the Danish Medicines Act.
- The World Health Organizations' Ethical criteria for medicinal drug promotion.

Who is subject to the rules?

The ethical rules only regulate the companies that are members of Lif, IGL and PFL, and the companies and associations that are not members of these associations, but have agreed to the ethical rules. A list of these companies and associations can be found on: www.ENLI.dk. Similarly, only these companies are subject to the control of ENLI.

Regardless of the above-mentioned, the healthcare professionals, who interact with the pharmaceutical industry, and the pharmaceutical companies, that are not yet affiliated with ENLI, are of course obligated to comply with the law in this field (e.g. the Executive Order on Promotion of Medicinal Products), which falls within the control of the Danish Medicines Agency.

It is noted that the ethical rules do not apply to the promotion of medical devices/medico, which is subject to other regulatory rules than medicinal products. The reason why these ethical rules only apply to the promotion of medicinal products is that Lif, IGL and PFL only represent the pharmaceutical industry – not the medico industry.

Supplementing rules

Apart from these ethical rules, ENLI controls a number of other rules concerning i.a. lobbying and collaboration with patient groups. Cf. the statutes for ENLI. See also the description in the introductory chapter on “the Ethical Committee for the Pharmaceutical Industry in Denmark” above.

Transparency

Lif, IGL, PFL and the affiliated companies and associations recognize transparency as an important means to ensure compliance with the rules and in that way maintain credibility and dispel any myths. These ethical rules, the right of appeal, and the obligation to report the companies’ promotion material and involvement in various activities, and the publication of decisions, reports etc. on: www.ENLI.dk all serve this purpose.

Sanctions

In cases, where ENLI finds, that the rules have not been complied with, the company concerned is ordered to issue a statement to ENLI that:

- 1) the illegal conduct is discontinued and
- 2) that the company guarantees, that the company has taken the necessary precautions to ensure that recurrence is prevented.

At the conclusion of the case and in case of non-compliance, the decision will be partially or fully published to the extent possible, subject to i.a. the Danish Act on Processing of Personal Data and rules laid down in another relevant statute, such as the Danish Competition Act. All decisions are also forwarded to the Danish Medicines Agency for their information.

In cases of serious non-compliance, sanctions may be imposed in addition to the above-mentioned. These sanctions include:

- Fines
- Withdrawal of illegal material
- Issuing of a corrected statement from the company
- Public reprimand
- Insertion of an advertisement in professional journals in cases, where a corrected statement or public reprimand is imposed, e.g. in the Journal of the Danish Medical Association (UfL), stating the characteristics of the case and specifying the name of the company and the nature of non-compliance.

Surveillance of activities and guidance and training

ENLI controls filed cases and also handle appeals. In addition to that, ENLI provides guidance on and training in the rules.

The associations behind ENLI

Lif – the Danish Association of the Pharmaceutical Industry is an industry association for the researching pharmaceutical industry in Denmark. The association was established in its current form in August 1997. Lif’s mission is to provide the pharmaceutical industry with the best possible conditions to research, develop, market, distribute and inform about medicinal products, thus ensuring broad and fast access for patients to the best medical treatment.

Lif has in a number of fields decided to follow stricter ethical rules, than what follows from law, as Lif finds it crucial, that we as a pharmaceutical industry act in a credible and ethically responsible way. For similar reasons, Lif has decided to lead the way in a number of fields – e.g. Lif adopted a code on lobbying activities as early as January 2010 and was the first industry in Denmark to do so.

See: www.lif.dk for further information on Lif, including information on the members of Lif.

IGL - The Danish Generic Medicines Industry Association (IGL) is an industry association established in 2002. Today, the association includes 13 member companies, which are all engaged in selling and promoting generic medicines to the Danish market. Some of these companies also manufacture generic medicines. IGL works to promote the sales of generic medicines in Denmark, thus limiting the medicine costs for consumers and society.

See: www.igldk.dk for further information on IGL, including information on the members of IGL.

PFL – The Danish Association of Parallel Distributors of Pharmaceuticals (PFL) works to ensure free access to import medicinal products on a parallel basis within the EU. Medicine imported on a parallel basis is original medicine, which has been imported from another EU country, in which it is less expensive than it is in Denmark. In the Danish system, the medicine with the lowest price of similar kind will receive grants from the Government. Medicine imported on a parallel basis thus accounts for 15% of the total use of medicine. Parallel import means that the importers monitor supply and prices on medicine in other countries, thus enabling them to offer Danish pharmacies and hospitals the medicine they demand at the lowest possible price.

The importer ensures that all information in the medicine packaging is written in Danish as laid down by the authorities, and medicine imported on a parallel basis is, similarly to any other legal medicine, distributed through wholesalers. I.e. through a pharmacy or a hospital.

See: www.pfldk.dk for further information on PFL.

Control of the Danish Ethical Rules

The Danish Ethical Rules (for Promotion of Medicinal Products towards Healthcare Professionals) are controlled by the Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI), which is also responsible for guidance on the rules, training in the rules and the complaint authority.

For further information, please see the paragraph on Lif's Self-Regulating Instance above or visit: www.ENLI.dk.

The Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals

CHAPTER 1 – PRELIMINARY PROVISIONS

Article 1 - Scope

Section 1.01. The scope of these ethical rules is to create a framework for the necessary and professionally responsible collaboration between the pharmaceutical industry and healthcare professionals, in such a manner that professional standards and ethics are given pride of place, and pressure opportunities and dependency between the parties are prevented. The ethical rules state a number of minimum standards, which must be complied with, in addition to the applicable laws and regulations.

Section 1.02. Pharmaceutical companies must maintain high ethical standards at all times. Promotion must:

- a) Never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry
- b) Be of a nature which recognises the special nature of medicinal products and the professional standing of the recipient(s) and
- c) Not be likely to cause offence.

Article 2 - Field of application

Section 2.01. These ethical rules are applicable to the activities of pharmaceutical companies inside and outside the borders of Denmark, concerning:

- a) Promotion of and communication about medicinal products towards healthcare professionals.
- b) Interaction with healthcare professionals concerning medicinal products.
- c) The rules are however only applicable in so far as to activities, which are partially or fully targeted at Danish healthcare professionals. The rules are however also applicable to activities, which are solely targeted at non-Danish healthcare professionals, provided that the activities are held in Denmark.

Section 2.02. The rules are not applicable to:

- a) Activities solely concerning products, which do not fall under the definition of a medicinal products, e.g. medical devices, skin care products and similar products,

- b) Activities not targeted at healthcare professionals, e.g.:
 - Dialogue and negotiations with decision-makers, including politicians and officials,
 - Collaboration between patient groups and the pharmaceutical industry,
 - Promotion of medicinal products towards the general public,
 - Press releases etc. and information to investors etc., and
 - Patients and citizens,
- c) Particulars of the exceptions to Art. 2 of the Executive Order on Promotion (i.e. particulars not included in the rules of Chapter 7 in the Executive Order on Promotion),
- d) Cases concerning clinical research filed to the scientific ethical committee system and/or the Danish Medicines Agency, except for Art. 13, sections 3-9, which also apply to meetings etc. in connection with clinical research.

Section 2.03. Promotion of the medicinal products mentioned in Art. 3, nos. 1-5 of the Executive Order on Promotion is not permitted.

Article 3 - Definitions

Section 3.01. "Promotion, "the general public" and "healthcare professionals" have the meaning set forth in Art. 1 of the Executive Order on Promotion. This applies to all activities, regardless of media, covered by the concept of promotion, which are undertaken, organized or sponsored by a pharmaceutical company or by authority of a pharmaceutical company.

Section 3.02. "Pharmaceutical companies" mean members of:

- a) The Danish Association of the Pharmaceutical Industry (Lif),
- b) The Danish Generic Medicines Industry Association (IGL)
- c) The Danish Association of Parallel Distributors of Pharmaceuticals (PFL) and
- d) "affiliated companies and associations", i.e. companies and associations, which are not members of the above-mentioned associations, but have decided to be bound by to these ethical rules, and
- e) Consultancy service companies etc., acting on behalf of the companies and associations mentioned in sub-sections a)-d).

Section 3.03. "medicinal products" means any product, which is:

- a) presented as having properties for treating or preventing disease in human beings, or
- b) may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis, or
- c) a medical device intended for administration of a medicinal product cf. litra a) or b) if the medical device and the medicinal product are marketed as an integrated product that solely is intended for use in the given combination and the medical device cannot be reused.

Section 3.04. With reference to the obligation to report in Art. 21, "Events" have the meaning set forth in section 21.02.

Section 3.05. "Danish healthcare professionals" means healthcare professionals employed in Denmark, or self-employed healthcare professionals in Denmark, i.e. general practitioners with a clinic in Denmark.

CHAPTER 2 – MARKETING AUTHORIZATION, REQUIREMENTS OF OBJECTIVITY, ETC.

Article 4 – Marketing authorization and requirements of objectivity

Section 4.01. It is prohibited to promote medicinal products:

- a) which cannot be legally sold or distributed in this country (Denmark)
- b) magistral medicinal products
- c) and the special medicinal products listed in Art. 3 of the Executive Order on Promotion.

Section 4.02. Promotion of a medicinal product must be sufficiently complete and objective, and it must not mislead or exaggerate the properties of the medicinal product. Information in promotion material must be consistent with the approved summary of product characteristics of the relevant medicinal product.

Section 4.03. Promotion material, which appears on exhibition stands or is distributed to participants at international events outside of Denmark may, without regard to section 4.01, unless prohibited or otherwise regulated by local laws and regulations, refer to medicinal products (or uses), which are not registered in the country where the event takes place, or which are registered under different conditions, so long as:

- a) Any such promotion material (except for promotional aids) is accompanied by a suitable statement indicating countries in which the medicinal products is registered and makes clear that the medicinal product or use is not registered locally, and
- b) Any such promotion material, which refers to the prescribing information (indications, warnings, etc.) authorized in a country or countries where the medicinal product is registered should be accompanied by an explanatory statement indicating that registration conditions differ internationally.

CHAPTER 3 – PROMOTION

Article 5 – Obligatory information

Section 5.01. All promotion material of medicinal products towards healthcare professionals must include the following information:

- 1) The trademark and the common name of the medicinal product or the international non-proprietary name, where this exists. The common name, or the non-proprietary name, must be indicated using the same font and same appearance as the proprietary name of the medicinal product. Promotion of combination medicinal products with no common name must include clear information on the common names of all active ingredients.

- 2) Name and permanent address of the marketing authorization holder.
- 3) Therapeutic indication area, consistent with the indication area listed in the summary of product characteristics. In promotion material solely targeted at a limited group of healthcare professionals, the indication area may be reduced to the extent relevant to the group concerned.
- 4) Contraindications.
- 5) Side-effects and risks.
- 6) Dosage.
- 7) Pharmaceutical forms.
- 8) Packaging sizes.
- 9) Dated price (registered price) incl. VAT as well as a reference to a current price on www.medicinpriser.dk, if the medicinal product is reserved to pharmacies only. The price may however be excluded from promotion material that is sent out for an extended period of time, if the promotion material is accompanied by a price list referring to the promotion material, or if the promotion material is solely targeted at students.
- 10) Dispensing group.
- 11) Reimbursement status.
- 12) The date on which the promotion material was generated or last revised.

Section 5.02. The information listed in section 5.01 must be clear and legible, thus enabling the natural target group of the promotion material to read it with minimal effort.

Section 5.03. If a medicinal product has been approved in several forms with different fields of application, and the promotion material solely concerns one of these forms, the promotion material must only include information on this pharmaceutical form. The promotion material must further state that the medicinal product is also available in other forms.

Article 6 - Reminders

Promotion solely targeted at healthcare professionals may not need to comply with Article 5 above, provided that the promotional material includes no more than the trademark and common name of the medicinal product.

Article 7 – Information material and substantiation

Section 7.01. Promotion of medicinal products must encourage the rational use of medicinal products by presenting them objectively and without exaggerating their properties. Claims must not imply that a medicinal product, or an active ingredient, has some special merit, quality or property unless this can be substantiated. Substantiation must be promptly provided in response to reasonable requests from healthcare professionals.

Section 7.02. Information material concerning medicinal products, which is sent out or distributed to healthcare professionals with a view to promote sales, must at least include the information listed in section 5.01, however see section 5.03, and the date on which the material was generated or last revised.

Section 7.03. All information in the information material listed in sections 7.01 and 7.02 must be adequate, objective, accurate, relevant, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned.

Section 7.04. Quotations, tables and illustrations from medical and scientific literature, which is used in the information material listed in sections 7.01 and 7.02, must be faithfully reproduced and the precise sources identified. Particular care must be taken to ensure that artwork included in promotion material does not mislead about the nature of a medicinal product (for example whether it is appropriate for use in children) or mislead about a claim or comparison (for example by using incomplete or statistically irrelevant information or unusual scales).

Section 7.05. Substantiation of information on medicinal products must, apart from the summary of product characteristics, only include scientifically substantiated research. The research must have been published in established and independent Danish or non-Danish publications, professional journals or the like. The research must prior to publication have been subjected to an independent assessment (peer review).

Section 7.06. The word "safe" must never be used to describe a medicinal product . The word "new" must not be used to describe any medicinal product or packaging which has been generally available or any therapeutic indication which has been generally promoted, for more than one year. It must not be stated that a medicinal product has no side-effects, toxic hazards or risk of addiction or dependency.

Article 8 – Comparative promotion

Section 8.01. If a promotion material includes a comparison of several medicinal products, including a price comparison, all medicinal products included in the comparison and their strengths, packaging sizes etc. must be clearly stated. The comparison must only include medicinal products, including their strengths and packaging sizes, which are relevant to compare from an objective point of view, i.e. medicinal products with the same field of application.

Section 8.02. Comparative promotion must be based on the information in the summaries of product characteristics of the medicinal products concerned.

Section 8.03. Comparison of various medicinal products must not be misleading or disparaging.

CHAPTER 4 - DISTRIBUTION OF PROMOTION, TRANSPARENCY AND PERSONAL ADVICES.

Article 9 –Distribution of promotion

Section 9.01. Promotion must only be directed at those, who's need for, or interest in, the particular information can reasonably be assumed.

Section 9.02. Mailing lists must be kept up-to-date. Requests by healthcare professionals to be removed from promotion mailing lists must be complied with.

Section 9.03. Subject to applicable national laws and regulations, the use of faxes, e-mails, automated calling systems, text messages and other electronic data communications for promotion is prohibited except with the prior permission, or upon the request, of the recipient.

Article 10 – Transparency

Section 10.01. Promotion must not be disguised.

Section 10.02. Clinical assessments, post-marketing surveillance and experience programs and post-authorization studies (including those that are retrospective in nature) must not be disguised promotion. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose.

Section 10.03. Where a pharmaceutical company pays for or otherwise secures or arranges the publication of promotion material in journals, such material must not resemble independent editorial matter.

Section 10.04. Material relating to medicinal products and their uses, whether promotional in nature or not, which is sponsored by a company must clearly indicate that it has been sponsored by that company.

Article 11 – No advice on personal medical matters

In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised to consult a healthcare professional.

CHAPTER 5 – FINANCIAL BENEFITS

Article 12 – General rule – prohibition against financial benefits and gifts

Section 12.01. Financial benefits must generally not be given or offered to healthcare professionals as part of marketing or otherwise with the intention of promoting the sales of a medicinal product, except as provided for in section 12.02, and section 13-15.

Section 12.02. The prohibition in section 12.01 does not extend to gifts of insignificant value, when such gifts are relevant to the practice of the recipient.

Section 12.03. Obligatory information need not to appear from the gift, if the gift is accompanied by the following information on the medicinal product:

- a) name and logo of the pharmaceutical company, identifying the sender,
- b) its common name or the international non-proprietary name, where this exists, and the trade mark.

Section 12.04. Gifts for the personal benefit of healthcare professionals (such as tickets to entertainment events), must not be offered or provided.

Section 12.05. Competitions must not be arranged and prizes must not be offered to healthcare professionals as part of marketing or otherwise with the intention of promoting the sales of a medicinal product.

Article 13 – Professional events, sponsorships and hospitality

Section 13.01. Pharmaceutical companies may give or offer a healthcare professional training and professional information related to medicinal products in the form of payment of direct expenses in connection with courses and other professional and scientific events, in which the healthcare professionals participate or arrange, including:

- a) As organizers or co-organizers of the events listed in section 13.01. Invitations for such events must only be targeted at healthcare professionals,
- b) As sponsors of the professional events listed in section 13.01, prepared by a third party responsible for the professional content, lecturers, educational method etc. Sponsorships must not be subject to the sponsor influencing on the professional content of the program. The preparation of the events must therefore be independent of the sponsorship given, as only events of a mere professional nature may be sponsored.

Section 13.02. It is a condition that the organizer and purpose of the events listed in section 13.01 appear from the invitation to the event, just as the invitation must state whether the event has been sponsored by one or more pharmaceutical companies. The pharmaceutical company is obligated to ensure this in the contract with any third party.

Section 13.03. All promotional, scientific or professional meetings, congresses, conferences, symposia and other similar events (including but not limited to advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an “event”) organized or sponsored by or on behalf of a pharmaceutical company must be held in an “appropriate” venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate.

Section 13.04. No pharmaceutical company may organize or sponsor any of the events listed in section 13.01 that take place outside its home country, unless:

- a) Most of the invitees are from abroad and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or
- b) Given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country.

Section 13.05. Hospitality extended in connection with the events listed in section 13.01 must be limited to travel, meals, accommodation and genuine registration fees.

Section 13.06. Hospitality must only be extended to persons who qualify as participants in their own right.

Section 13.07. All forms of hospitality offered to healthcare professionals must be "reasonable" in level and strictly limited to the main purpose of the event, and also, in terms of time, be a minor consideration to the promotional and professional event. As a general rule, the hospitality provided must not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

Section 13.08. Hospitality must not include sponsoring or organizing entertainment (e.g. sporting or leisure) events.

Section 13.09. Pharmaceutical companies must avoid using venues that are "renowned" for their entertainment facilities or are extravagant and/or luxurious.

Section 13.10. Funding must not be offered to compensate merely for the time spent by healthcare professionals in attending the events listed in section 13.01.

Section 13.11. In the case of international events, as listed in section 13.01, for which a company sponsors the participation of a healthcare professional, if any funding is provided to such healthcare professional, such funding is subject to the rules of the jurisdiction where such healthcare professional carries out his or her profession, as opposed to those in which the international event takes place. Danish law and any other mandatory statute must, at a minimum, always be complied with.

Article 14 - Donations and grants that support healthcare or research

Section 14.01. Donations, grants and benefits in kind to institutions, organizations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research (that are not otherwise covered by the EFPIA HCP Code or Lif's Ethical Rules for Collaboration between Patient Groups and the Pharmaceutical Industry) are only allowed if: (i) they are made for the purpose of supporting healthcare or research; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Section 14.02. Donations and grants to individual healthcare professionals are not permitted under this section, excluding company sponsorship of healthcare professionals to attend professional events, which is covered by section 13.01, or professional gifts of insignificant value, cf. section 12.02.

Section 14.03. Companies are encouraged to make available publicly information about donations, grants or benefits in kind made by them covered in this section 14.01.

Section 14.04. Contracts between pharmaceutical companies and institutions, organizations or associations of healthcare professionals under which such institutions, organizations or associations provide any type of services to companies (or any other type of funding from pharmaceutical companies not covered under these ethical rules) are only allowed if such services (or other funding):

- a) Are provided for the purpose of supporting healthcare or research; and
- b) Do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Article 15 – The use of consultants/professional services

Section 15.01. It is permitted to use healthcare professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel. The arrangements that cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- a) a written contract or agreement is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;
- b) a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- c) the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- d) the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need;
- e) the contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants;
- f) the hiring of the healthcare professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and
- g) the compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements should not be used to justify compensating healthcare professionals.
- h) Remuneration must only be offered in the form of actual payment, and not as a set-off, benefit in kind or by other indirect means.

Section 15.02. Employment arrangements of general practitioners and pharmacists with a pharmaceutical company require preceding permission from the Danish Medicines Agency, cf. Art. 3, sections 2-3, of the Danish Pharmacy Act.

Section 15.03. In their written contracts with consultants, pharmaceutical companies are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he or she is a consultant to the company whenever he or she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, a pharmaceutical company that employs, on a part-time basis, healthcare professionals that are still practicing their profession are strongly encouraged to ensure that such persons have an obligation to declare his or her employment arrangement with the company whenever he or she writes or speaks in public about a matter that is the subject of the employment or any other issue relating to that pharmaceutical company. The provisions of this section 15.03 apply even though these ethical rules do not otherwise cover non-promotional, general information.

Section 15.04. Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires is excluded from the scope of this Art. 15, except for section 15.01, sub-sections d), f), g)

and h), provided that the healthcare professionals are not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal and in proportion to the service, cf. section 15.01, sub-section g). Such research must not be disguised promotion.

Section 15.05. If a healthcare professional attends an event (an international event or otherwise) in a consultant or advisory capacity the relevant provisions of Art. 13 apply.

CHAPTER 6 – NON-INTERVENTIONAL STUDIES AND EXHIBITION

Article 16 – Non-interventional studies of marketed medicinal products

Section 16.01. A non-interventional study of a marketed medicinal product is defined as a study where the medicinal product (s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicinal product is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures are applied to the patients and epidemiological methods are used for the analysis of collected data.

Section 16.02. Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study must comply with all of the following criteria:

- a) The study is conducted with a scientific purpose
- b) There is a written study plan (protocol) and there are written contracts between healthcare professionals and/or the institutes at which the study will take place, on the one hand, and the pharmaceutical company sponsoring the study, on the other hand, which specify the nature of the services to be provided and, subject to clause c) immediately below, the basis for payment of those services;
- c) Any remuneration provided is reasonable and reflects the fair market value of the work performed; and the pharmaceutical company must, upon request, make information about how the remuneration was assessed available to ENLI.
- d) Study protocols concerning non-interventional studies (description of non-interventional studies) must be submitted to the Danish Medicines Agency for review and guidance.
- e) The Danish Act on Processing Personal Data (including the collection and use of personal data) must be complied with,
- f) The study must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product;
- g) The study protocol must be approved by the pharmaceutical company's scientific service as described in section 19.02, sub-section a).
- h) The study results must be analysed by or on behalf of the contracting company and summaries thereof must be made available within a reasonable period of time to the company's scientific

service (as described in section 19.02, sub-section a)). The scientific service must maintain records of such reports for a reasonable period of time. The pharmaceutical company must forward the summary report to all healthcare professionals that participated in the study and must make the summary report available to ENLI upon their request. If the study shows results that are important for the assessment of benefit-risk, the summary report must be immediately forwarded to the relevant competent authority; and

- i) Pharmaceutical sales representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.
- j) Pharmaceutical companies may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

Section 16.03. To the extent applicable, companies are encouraged to comply with section 16.02 for all other types of studies covered by section 16.01, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to section 16.02, sub-sections a), c) and f).

Article 17 – Exhibition etc.

Section 17.01. In connection with the holding of professional events, where pharmaceutical companies are given access to promotion and marketing of medicinal products, such promotion and marketing must be conducted separate from the rest of the event's professional content.

Section 17.02. The promotion and marketing set out in section 17.01 must only take place in connection with events that adhere to the professional standards in Art. 13.

Section 17.03. When pharmaceutical companies are given the opportunity to advertise, exhibit, display movies, inform about products etc., it must be conducted on the basis of a preceding agreement on the conditions, including the financial terms and program of the event.

Article 18 – Medical samples

Section 18.01. Samples of a medicinal product shall at most be supplied for two years after the date of introduction.

Section 18.02. The date of introduction for a new medicinal product shall be the date at which it is marketed for the first time, i.e. listed in Medicine Prices for the first time after grant of a marketing authorization. In the event of a new/amended marketing authorisation being granted for a change in indication or changes in strength /pharmaceutical form as a result of a new indication, the date of introduction should be the first date of marketing after the new/amended marketing authorisation has

been granted. Extensions to marketing authorizations as a result of additional strengths /pharmaceutical forms for existing indications - or new pack sizes - are not regarded as new medicinal products.

Section 18.03. The rules of s.1-2 shall apply to medical devices that are medicinal products pursuant to Art.3.03 (c). Other medical devices that are not covered by s.1 – 2. Samples of medicinal products may be supplied together with these devices insofar as required to test new or changed devices, and no more than two years after the introduction of the new /changed device, but otherwise not covered by s.1 - 2.

Section 18.04. In addition to the provisions of s 1-3, the executive order for the time being in force on the supply of samples of medicinal products shall apply, currently Executive Order No.1244 of 12 December 2005.

Section 18.05. (1–4) shall take effect from 1 January 2012 and shall cover all medicinal products introduced after 1 January 2012 on the basis of a new or amended marketing authorization, cf.(1 - 2). Samples of medicinal products introduced before 1 January 2012 may be supplied until 31 December 2013 in accordance with the rules applying hitherto.

CHAPTER 7 – STAFF, TRAINING, ETC.

Article 19 – Pharmaceutical company staff

Section 19.01. Each pharmaceutical company must ensure that its sales representatives, including staff retained by way of contract with third parties, and any other company representatives who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of medicinal products (each, a “pharmaceutical sales representative”) are familiar with the relevant requirements of the applicable code(s), and all applicable laws and regulations, and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the medicinal products they promote. Pharmaceutical sales representatives must for each medicinal product presented make the summary of product characteristics available to the person visited. The summary of product characteristics must be accompanied by information about prices (if the medicinal product is reserved to pharmacies) and reimbursement status.

- a) Pharmaceutical sales representatives must comply with all relevant requirements of the applicable code(s), and all applicable laws and regulations, and companies are responsible for ensuring their compliance.
- b) Pharmaceutical sales representatives must approach their duties responsibly and ethically.
- c) During each visit, pharmaceutical sales representatives must give the persons visited, or have available for them, a summary of the product characteristics for each medicinal product they present. The summary of product characteristics must be accompanied by information about prices (if the medicinal product is reserved to pharmacies) and reimbursement status.
- d) Pharmaceutical sales representatives must transmit to the scientific service of their companies forthwith any information they receive in relation to the use of their companies’ medicinal products, particularly reports of side-effects.

- e) Pharmaceutical sales representatives must ensure that the frequency, time and duration of visits to healthcare professionals, pharmacies, hospitals and other healthcare facilities, together with the manner in which they are made, do not cause inconvenience.
- f) Pharmaceutical sales representatives must not use unethical methods to gain an interview. In an interview, or when seeking an appointment for an interview, pharmaceutical sales representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.
- g) The provisions of section 16.02, sub-section (i) are also applicable to the activities of pharmaceutical sales representatives.

Section 19.02. All pharmaceutical company staff, and any staff retained by way of contract with third parties, who are concerned with the preparation or approval of promotional material or activities, must be fully conversant with the requirements of the applicable code(s) and relevant laws and regulations.

- a) Every pharmaceutical company must establish a scientific service in charge of information about its medicinal products and the approval and supervision of non-interventional studies. The pharmaceutical companies are free to decide how best to establish such service(s) in accordance with section 19.02 (i.e., whether there is one service in charge of both duties or separate services with clearly delineated duties), taking into account their own resources and organization. The scientific service must include a medical doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release. Such person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the applicable code(s) and any applicable information laws and regulations, is consistent with the summary of product characteristics and is a fair and truthful presentation of the facts about the medicinal product. In addition, the scientific service must include a medical doctor or, where appropriate, a pharmacist, who will be responsible for the oversight of any non-interventional study (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by pharmaceutical sales representatives). Such person must certify that he or she has examined the protocol relating to the non-interventional study and that in his or her belief it is in accordance with the requirements of the applicable code(s).
- b) Each pharmaceutical company must appoint at least one senior employee to be responsible for supervising the company and its subsidiaries to ensure that the standards of the applicable code(s) are met.

CHAPTER 8 – ENFORCEMENT, OBLIGATION TO REPORT AND PRE-APPROVAL

Article 20 - Enforcement

The rules are sanctioned as described in the statutes of ENLI, please refer thereto.

Article 21 – Obligation to report

Section 21.01. Pharmaceutical companies are obligated to report to ENLI activities:

- a) which are organized or co-organized by a pharmaceutical company, and the event is fully or partially targeted at Danish healthcare professionals.
- b) where a pharmaceutical company, not organizing or co-organizing the event, provides financial (sponsor) support to (i) a so-called third party event fully or partially targeted at Danish healthcare professionals or to (ii) the participation of Danish healthcare professionals.
- c) where a pharmaceutical company buys an exhibition stand at a congress in Denmark.

Section 21.02. "Event" has the meaning set forth in section 21.01, and includes all kinds of continuing training in the form of meetings, congresses, conferences, symposia, courses, end-of-day meetings or similar events with the participation of healthcare professionals. Not included are visits from pharmaceutical sales representatives and events, cf. section 21.01, sub-sections a) and b), where the healthcare professional provides a service in return.

Section 21.03. In addition, pharmaceutical companies are obligated to report all kinds of printed promotion material targeted at healthcare professionals on the Danish market, whether in printed advertisements, leaflets, handouts or the like. Electronic texts are comparable with printed texts. Texts on websites are thus comparable with printed promotion and must be reported, if access to the promotion is restricted in a way that makes it inaccessible to the general public (as described in Annex A) and the promotion is written in Danish. If access to the website text is not restricted, it is promotion to the general public and therefore not covered by these ethical rules.

Section 21.04. Companies are obligated to file a report online via: www.ENLI.dk and fill out the standard report form. The company is obligated to ensure that the report is fully cleared up and that all relevant documentation is submitted.

Section 21.05. Reports concerning the activities set out in section 21.01, sub-section a), must be filed no later than 10 working days prior to the opening day of the event. Reports concerning sponsorships etc., cf. section 21.01, sub-section b), must be filed no later than 10 working days after a binding promise to provide financial support has been made, or in the case of exhibition no later than 10 working days prior to the opening day of the event. Reports concerning promotion material must be filed no later than the same day as the printed promotion material, cf. section 21.03, is distributed (i.e. distributed or published as advertisement).

Section 21.06. The pharmaceutical company responsible for the event must ensure that the above-mentioned obligations to report are always complied with, even when the planning, distribution or other practical duties of the event are fully or partially managed by others.

Section 21.07. A pharmaceutical company, who wants a pre-publication vetting of an activity covered by these ethical rules and its compliance with the rules, may, subject to a fee, apply for a pre-approval. Applications are submitted online via: www.ENLI.dk.

Section 21.08. Pharmaceutical companies are in their event invitations to healthcare professionals obligated to write:

- a) that the event has been/will be reported to ENLI prior to the event and
- b) that the event in the organizers' opinion complies with the rules of the field, even if the event has not been pre-approved by ENLI or
- c) that the event in its current form and content has been pre-approved by ENLI.

ANNEX A (to "the Danish Ethical Rules for Promotion of medicinal products towards Healthcare Professionals"):

NB: ANNEX A IS NOT BINDING! UNDER REVIEW- PLEASE REFER TO APPLICABLE DANISH LAWS AND REGULATIONS!

[This is only a draft – and a translation of EFPIA’s corresponding annexes – must be carefully reviewed – to ensure that it follows Danish laws and regulations.]

GUIDELINES FOR INTERNET WEBSITES AVAILABLE TO HEALTHCARE PROFESSIONALS, PATIENTS AND THE PUBLIC IN THE EU

The guidelines for internet websites available to healthcare professionals, patients and the public in the EU set forth herein are intended as a supplement to the provisions of the European Federation of Pharmaceutical Industries and Associations Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the "EFPIA HCP Code") and the Danish Ethical Rules (for Promotion of Medicinal Products). Member associations and companies may find it necessary to adapt these guidelines to meet their particular requirements or needs and are encouraged to adopt additional measures which extend further than the provisions included in these guidelines.

In pursuance of Art. 9, section 1, of the Executive Order on Promotion, promotion on the internet must comply with the same rules as any other promotion of medicinal products. However, the rules must as required, cf. the guideline to section 8.1 of the Executive Order on Promotion, be read and interpreted with due consideration to the special nature of the internet. In accordance with the guideline to the Executive Order on Promotion, the rules apply to banner advertisements etc., clearly taking the form of promotion, and to information about medicinal products, e.g. on the websites of pharmaceutical companies, when such information must be assumed to fall under the definition of promotion.

Art. 9, sections 2 and 3, of the Executive Order on Promotion also state that promotion of medicinal products on the internet is considered promotion towards the general public, as the information is available to any and all. This is however not the case, if the access to such information is securely restricted to healthcare professionals through a personal password or by other effective means. The website stating that the material is targeted at healthcare professionals, or users merely having to type in a password to gain access to the website, is not sufficient. The minimum requirement is user identification in the form of a unique user name, license number or the like, combined with an associated personal password. This could be ensured by using the relevant website’s own special system or a general system, e.g. the user’s digital signature, cf. section 8.1 of the guideline to the Executive Order on Promotion.

Article 1. Transparency of website origin, content and purpose. Each website must clearly identify:

- (a) the identity and physical and electronic addresses of the sponsor(s) of the website;

- (b) the source(s) of all information included on the website, the date of publication of the source(s) and the identity and credentials (including the date credentials were received) of all individual/institutional providers of information included on the website;
- (c) the procedure followed in selecting the content included on the website;
- (d) the target audience of the website (e.g. healthcare professionals, patients and the general public, or a combination thereof) and
- (e) the purpose or objective of the website.

Article 2. Content of websites.

(a) Information included on the website must be regularly updated and must clearly display, for each page and/or item, as applicable, the most recent date as of which such information was updated.

(b) Examples of the information that may be included in a single website or in multiple websites are: (i) general information on the company; (ii) health education information; (iii) information intended for healthcare professionals (as defined in the EFPIA HCP Code), including any promotion; and (iv) non-promotional information intended for patients and the general public about specific medicinal products marketed by the company.

(iv) General information on the company. Websites may contain information that would be of interest to investors, the news media and the general public, including financial data, descriptions of research and development programs, discussion of regulatory developments affecting the company and its products, information for prospective employees, etc. The content of this information is not regulated by these guidelines or provisions of medicines advertising law. (v) Health education information. Websites may contain non-promotional health education information about the characteristics of diseases, methods of prevention and screening and treatments, as well as other information intended to promote public health. They may refer to medicinal products, provided that the discussion is balanced and accurate. Relevant information may be given about alternative treatments, including, where appropriate, surgery, diet, behavioural change and other interventions that do not require use of medicinal products. Websites containing health education information must always advise persons to consult a healthcare professional for further information. (vi) Information for healthcare professionals. Any information on websites directed to healthcare professionals that constitutes promotion (as defined in the EFPIA HCP Code) must comply with applicable codes (as defined in the EFPIA HCP Code) and any other industry codes of practice governing the content and format of advertisement and promotion of medicinal products. Such information must be clearly identified as information for healthcare professionals, but need not be encrypted or otherwise restricted.

(vii) Non-promotional information for patients and the general public. Subject to any applicable laws and regulations, websites may include non-promotional information for patients and the general public on products distributed by the company (including information on their indications, side-effects, interactions with other medicinal products, proper use, reports of clinical research, etc.), provided that such information is balanced, accurate and consistent with the approved summary of product characteristics. For each product that is discussed, the website must contain full, unedited copies of the current summary of product characteristics and patient leaflet. These documents should be posted in conjunction with other information about the products or be connected with that discussion by a prominent link advising the reader to consult them. In addition, the website may provide a link to the full, unedited copy of any public assessment report issued by the Committee for Medicinal Products for Human Use or a relevant national competent authority. Brand names should be accompanied by international generic names. The website may include links to other websites containing reliable information on medicinal products, including websites maintained by government authorities, medical research bodies, patient organizations, etc. The website must always advise people to consult a healthcare professional for further information.

Article 3. E-mail enquiries. A website may invite electronic mail communications from healthcare professionals and patients or the general public seeking further information regarding the company's products or other matters (e.g. feedback regarding the website). The company may reply to such communications in the same manner as it would reply to enquiries received by post, telephone or other media. In communications with patients or members of the general public, discussion of personal medical matters must be avoided. If personal medical information is revealed, it must be held in confidence. Where appropriate, replies shall recommend that a healthcare professional is consulted for further information.

Article 4. Links from other websites. Links may be established to a company-sponsored website from websites sponsored by other persons, but companies should not establish links from websites designed for the general public to company-sponsored websites that are designed for healthcare professionals. In the same manner, links may be established to separate websites, including websites sponsored by the company or by other persons. Links should ordinarily be made to the home page of a website or otherwise managed so that the reader is aware of the identity of the website.

Article 5. Website addresses in packaging. Subject to any applicable national laws and regulations, uniform resource locators (URLs) of company-sponsored websites that comply with these guidelines may be included in packaging of medicinal products.

Article 6. Scientific review. Companies should ensure that scientific and medical information prepared by them for inclusion in their websites is reviewed for accuracy and compliance with the applicable code(s). The scientific service established within the company pursuant to those provisions of the applicable code that adopt section 17.02 of the EFPIA Code may perform this function, or it may be entrusted to other appropriately qualified persons.

Article 7. Privacy. The website must conform to legislation and applicable codes of conduct governing the privacy, security and confidentiality of personal information.



CODE OF PRACTICE
for the
PHARMACEUTICAL
INDUSTRY

SECOND 2012 EDITION

PMCPA | Prescription Medicines
Code of Practice Authority



Bringing medicines to *life*

CODE OF PRACTICE
for the
PHARMACEUTICAL INDUSTRY

Second 2012 Edition

together with the

PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY
Constitution and Procedure

PMCPA | Prescription Medicines
Code of Practice Authority

This edition of the Code of Practice comes into operation on 1 July 2012. During the period 1 July 2012 to 31 October 2012, no promotional material or activity will be regarded as being in breach of the Code if it fails to comply with its provisions only because of requirements which this edition of the Code newly introduces.

THE PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

The Prescription Medicines Code of Practice Authority was established by the Association of the British Pharmaceutical Industry in 1993 to operate the Code of Practice for the Pharmaceutical Industry independently of the Association itself.

Complaints should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT, telephone 020-7747 8880, facsimile 020-7747 8881, email complaints@pmcpa.org.uk.

Complaints made under the Code are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on cases are published by the Authority and are available on request and on the Authority's website www.pmcpa.org.uk.

CODE OF PRACTICE

for the

PHARMACEUTICAL INDUSTRY

Second 2012 Edition

CONTENTS

	Page
CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY	
Introduction	4
1 Scope of Code and Definition of Certain Terms	6
2 Discredit to, and Reduction of Confidence in, the Industry	8
3 Marketing Authorization	9
4 Prescribing Information and Other Obligatory Information	10
5 Abbreviated Advertisements	12
6 Journal Advertising	13
7 Information, Claims and Comparisons	14
8 Disparaging References	16
9 High Standards, Format, Suitability and Causing Offence, Sponsorship	16
10 Provision of Reprints and the Use of Quotations	18
11 Distribution of Promotional Material	18
12 Disguised Promotion	19
13 Non - Interventional Studies of Marketed Medicines	19
14 Certification	20
15 Representatives	22
16 Training	24
17 Provision of Medicines and Samples	25
18 Items for Patients, Promotional Aids, the Provision of Medical and Educational Goods and Services, Agreements to benefit Patients such as Joint Working, Outcome Agreements and Patient Access Schemes	26
19 Meetings, Hospitality and Sponsorship	31
20 The Use of Consultants	33
21 Scientific Services	34
22 Relations with the Public and the Media	35
23 Relationships with Patient Organisations	36
24 The Internet	38
25 Compliance with Undertakings	38
PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY CONSTITUTION AND PROCEDURE	39
GUIDELINES ON COMPANY PROCEDURES RELATING TO THE CODE OF PRACTICE	51
LIST OF LEGISLATION, OTHER CODES & GUIDELINES	57
INDEX	58

In the Code of Practice, guidance on the interpretation of the Code appears as supplementary information to the text against a pale blue background.

CODE OF PRACTICE *for the* PHARMACEUTICAL INDUSTRY

INTRODUCTION

Promoting Appropriate Use of Medicines

The pharmaceutical industry in the United Kingdom is committed to benefiting patients by operating in a professional, ethical and transparent manner to ensure the appropriate use of medicines and support the provision of high quality healthcare. This commitment applies to all with whom the industry interacts. To demonstrate this commitment over 50 years ago, in October 1958, the Association of the British Pharmaceutical Industry (ABPI), which represents the UK industry, decided that certain activities should be covered in detail and thus agreed the first ABPI Code of Practice. The Code covers the promotion of medicines for prescribing to both health professionals and appropriate administrative staff. It also includes requirements for interactions with health professionals. In addition it sets standards for the provision of information about prescription only medicines to the public and patients, including patient organisations.

In addition to the Code there is extensive UK and European law relating to the promotion of medicines. The Code reflects and extends beyond the relevant UK law.

The aim of the Code is to ensure that the promotion of medicines to health professionals and to administrative staff is carried out within a robust framework to support high quality patient care. As well as covering promotional material, it controls samples, meetings, promotional aids, the provision of medical and educational goods and services, outcome or risk sharing agreements, patient access schemes, joint working between the pharmaceutical industry and the NHS, the conduct of non-interventional studies and the use of health professionals and administrative staff as consultants. The Code also sets standards relating to the provision of information to patients and the public as well as relationships with patient groups. The industry considers that provided the requirements of the Code are met, working with patients and patient organisations can bring significant public health benefits. These requirements also apply to working with all user groups, such as disability associations, relative and carer associations and consumer associations.

In summary, companies must ensure that their materials are appropriate, factual, fair and capable of substantiation and that all other activities are appropriate and reasonable.

Ensuring High Standards

The detailed provisions in the Code are to ensure that pharmaceutical companies operate in a responsible, ethical and professional manner. Whilst the industry has a legitimate right to promote medicines to health professionals, the Code recognises and seeks to achieve a balance between the needs of patients, health professionals and the public, bearing in mind the political and social environment within which the industry

operates and the statutory controls governing medicines. The availability of accurate up-to-date information is vital to the appropriate use of medicines. Pharmaceutical companies must ensure that enquiries about their medicines are answered appropriately in a timely manner.

Strong support is given to the Code by the industry with all companies devoting considerable resources to ensure that their activities comply with it. Any complaint made against a company under the Code is regarded as a serious matter both by that company and by the industry as a whole. Sanctions are applied against a company ruled in breach of the Code.

Companies must ensure that all relevant personnel are appropriately trained in the requirements of the Code and must have robust operating procedures under which all materials and activities covered by the Code are reviewed to ensure compliance both with the Code and with the appropriate legal requirements.

The Code incorporates the principles set out in:

- the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Practice
- The European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals
- The EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations
- The World Health Organisation's Ethical Criteria for Medicinal Drug Promotion
- Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC
- The Human Medicines Regulations 2012.

The Code covers the industry's activities only. However those interacting with industry as individuals or organisations also have a responsibility to ensure that their interactions comply with relevant legal requirements and are asked to follow the Code where relevant and not make requests that are not in accordance with the Code. Most of those interacting with the industry, other than patients, are covered by a selection of professional codes and guidance. For example, the General Medical Council 'Good Medical Practice', the General Pharmaceutical Council 'Standards of conduct, ethics and performance' and the Nursing & Midwifery Council 'Standards of conduct, performance and ethics for nurses and midwives'. Patient organisations are likely to be covered by Charity Commission rules as well as their own codes. The pharmaceutical industry takes note of all relevant codes and guidance as well as the ABPI Code.

Transparency

The industry recognises that transparency is an important means of building and maintaining confidence. The operation of the Code, including the complaints procedure, is a demonstration of the industry's commitment to transparency as are the requirement to declare pharmaceutical company involvement in activities and materials and the publication of detailed reports of cases considered under the Code. The industry's global agreement to disclose certain clinical trial data is another example of the industry's commitment to transparency. Companies also have to publish the summary details and results of non-interventional studies as well as the monetary value of certain support to patient organisations.

Other transparency changes will be effective in 2012 and 2013. These include disclosure of the total amount of fees paid to consultants for certain services and the total amounts paid to sponsor attendance at meetings organised by third parties.

Sanctions

In each case where a breach of the Code is ruled, the company concerned must give an undertaking that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the future. An undertaking must be accompanied by details of the action taken to implement the ruling. At the conclusion of a case a detailed case report is published.

Additional sanctions are imposed in serious cases. These can include:

- the audit of a company's procedures to comply with the Code, followed by the possibility of a requirement for the pre-vetting of future material
- recovery of material from those to whom it has been given
- the issue of a corrective statement
- a public reprimand
- advertising in the medical, pharmaceutical and nursing press of brief details of cases in which companies were ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand
- suspension or expulsion from the ABPI.

Monitoring of Activities and Guidance

The Prescription Medicines Code of Practice Authority (PMCPA) arranges for advertising and meetings to be regularly monitored. The PMCPA also provides informal guidance about the Code and its operation.

Promoting Health

The commitment of Britain's pharmaceutical industry to providing high quality effective medicines brings major benefits to both the nation's health and economy.

The National Health Service spends £12.9 billion a year on medicines, representing 9.8 per cent of its total expenditure. The pharmaceutical sector makes a greater contribution to the UK economy than any other industrial sector and generates an annual trade surplus of £6 billion. One fifth of the world's most popular prescription medicines were developed in the UK.

Investment into researching and developing new products in the UK is now running at over £4.6 billion a year and each new medicine takes an average of ten to twelve years to develop before it is authorized for use, with no guarantee of commercial success.

The Association of the British Pharmaceutical Industry and its Code of Practice

The Association of the British Pharmaceutical Industry (ABPI) is the trade association representing manufacturers of prescription medicines. It represents companies which supply 90 per cent of all medicines used by the National Health Service, and are researching and developing 90 per cent of the current medicines pipeline.

The Code has been regularly revised since its inception in 1958 and is drawn up in consultation with the British Medical Association, the Royal Pharmaceutical Society, the Royal College of Nursing and the Medicines and Healthcare products Regulatory Agency of the Department of Health. Anyone is welcome to send suggestions for amendments or additions to the Code to the PMCPA.

It is a condition of membership of the ABPI to abide by the Code in both the spirit and the letter. The Code applies to both members and affiliate members of the ABPI. Companies which are not members of the ABPI may give their formal agreement to abide by the Code and accept the jurisdiction of the PMCPA and over sixty have done so. Thus the Code is accepted by virtually all pharmaceutical companies operating in the UK.

Administering the Code of Practice

The Code is administered by the PMCPA which is responsible for the provision of advice, guidance and training on the Code as well as for the complaints procedure. The PMCPA operates independently of the ABPI itself. The relationship between the PMCPA and the ABPI is set out in a protocol of agreement. Financial information about the PMCPA is published in its Annual Report.

PMCPA publications can all be found on its website www.pmcpa.org.uk or are supplied on request.

Complaints under the Code are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on completed cases are published by the PMCPA in its Code of Practice Review and on its website. The PMCPA also publishes a list of ongoing cases on its website.

How to Complain

Complaints should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT, telephone 020-7747 8880, facsimile 020-7747 8881, email complaints@pmcpa.org.uk.

PROVISIONS OF THE CODE OF PRACTICE

Clause 1

Scope of the Code and Definition of Certain Terms

1.1 This Code applies to the promotion of medicines to members of the United Kingdom health professions and to appropriate administrative staff.

The Code also applies to a number of areas which are non-promotional, including information made available to the public about prescription only medicines.

It does not apply to the promotion of over-the-counter medicines to members of the health professions when the object of that promotion is to encourage their purchase by members of the public.

1.2 The term 'promotion' means any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

It includes:

- journal and direct mail advertising
- the activities of representatives including detail aids and other printed material used by representatives
- the supply of samples
- the provision of inducements to prescribe, supply, administer, recommend, buy or sell medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind
- the provision of hospitality for promotional purposes
- the sponsorship of promotional meetings
- the sponsorship of scientific meetings including payment of travelling and accommodation expenses in connection therewith
- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio or video recordings in any format, broadcast media, non-print media, the Internet, interactive data systems and the like.

It does not include:

- replies made in response to individual enquiries from members of the health professions or appropriate administrative staff or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry, are accurate and do not mislead and are not promotional in nature
- factual, accurate, informative announcements and reference material concerning licensed medicines and

relating, for example, to pack changes, adverse-reaction warnings, trade catalogues and price lists, provided they include no product claims

- price lists relating to unlicensed medicines, provided they include no product claims and they make clear that the products are unlicensed
- information supplied by pharmaceutical companies to national public organisations, such as the National Institute for Health and Clinical Excellence (NICE), the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC) is exempt from the Code provided the information is factual, accurate and not misleading
- measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993
- summaries of product characteristics
- European public assessment reports
- UK public assessment reports
- the labelling on medicines and accompanying package leaflets insofar as they are not promotional for the medicines concerned; the contents of labels and package leaflets are covered by regulations
- information relating to human health or diseases provided there is no reference, either direct or indirect, to specific medicines.

1.3 The term 'medicine' means any branded or unbranded medicine intended for use in humans which requires a marketing authorization.

1.4 The term 'health professional' includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine.

1.5 The term 'over-the-counter medicine' means those medicines or particular packs of medicines which are primarily advertised to the public for use in self medication.

1.6 The term 'representative' means a representative calling on members of the health professions and administrative staff in relation to the promotion of medicines.

1.7 The term 'promotional aid' means a non-monetary gift made for a promotional purpose.

1.8 Pharmaceutical companies must comply with all applicable codes, laws and regulations to which they are subject.

1.9 Each company must appoint a senior employee to be responsible for ensuring that the company meets the requirements of the Code.

Clause 1 Supplementary Information

Clause 1.1 Scope of the Code

For the purposes of the application of the Code, the United Kingdom includes the Channel Islands and the Isle of Man.

The Code applies to the promotion of medicines to members of the health professions and to appropriate administrative staff as specified in Clause 1.1. This includes promotion at meetings for UK residents held outside the UK. It also applies to promotion to UK health professionals and administrative staff at international meetings held outside the UK, except that the promotional material distributed at such meetings will need to comply with local requirements.

Some of the requirements of the Code are not necessarily related to promotion. Examples include declarations of sponsorship in Clause 9.10, non-interventional studies in Clause 13, certain aspects of the provision of medicines and samples in Clause 17, donations, grants and fees for services in Clauses 18.6 and 18.7, the use of consultants in Clause 20, the provision of information to the public in Clause 22 and relations with patient organisations in Clause 23.

The Code does not apply to the promotion of over-the-counter medicines to members of the health professions when the object of that promotion is to encourage their purchase by members of the public as specified in Clause 1.1. Thus, for example, an advertisement to doctors for an over-the-counter medicine does not come within the scope of the Code if its purpose is to encourage doctors to recommend the purchase of the medicine by patients. Where the advertisement is designed to encourage doctors to prescribe the medicine, then it comes within the scope of the Code.

Advertisements for over-the-counter medicines to pharmacists are outside the scope of the Code. Advertisements to pharmacists for other medicines come within the scope of the Code.

Clause 1.1 Market Extension

Activities which are designed to enlarge the market in a particular therapeutic area, such as disease awareness campaigns, are permitted, provided that these are carried out in a manner compatible with the Code.

Clause 1.1 Joint Working

Joint working with health authorities and trusts and the like is permitted if carried out in a manner compatible with the Code.

Joint working is where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery.

The Department of Health has issued to the NHS Best practice guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations. A toolkit, Moving beyond sponsorship: joint working between the NHS and the pharmaceutical industry has been issued by the Department of Health and the ABPI. The ABPI has produced guidance notes on joint working between pharmaceutical companies and the NHS and others for the benefit of patients.

The conduct of joint working is dealt with in Clause 18.5 and its supplementary information.

Clause 1.1 Journals with an International Distribution

The Code applies to the advertising of medicines in professional journals which are produced in the UK and/or intended for a UK audience. The identification of the country in which a journal is 'produced' is based on factors such as where it is compiled and edited, and where it is typeset, printed and bound, rather than on factors such as the location of the head office of the publisher.

International journals which are produced in English in the UK are subject to the Code even if only a small proportion of their circulation is to a UK audience. It is helpful in these circumstances to indicate that the information in the advertisement is consistent with the UK marketing authorization.

It should be noted that the Medicines and Healthcare products Regulatory Agency's guidance 'Advertising and Promotion of Medicines in the UK', The Blue Guide, differs from the above by advising that advertising material in professional journals intended primarily for circulation in the UK, whether or not in the English language, must comply with UK legislation and with the UK marketing authorization for the product.

Where a journal is produced in the UK but intended for distribution solely to overseas countries local requirements and/or the requirements of the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Practice should be borne in mind.

Clause 1.1 Advertising to the Public and Advertising Over-the-Counter Medicines to Health Professionals

The promotion of medicines to the public for self medication is covered by the Consumer Code of the Proprietary Association of Great Britain (PAGB) (www.pagb.co.uk). The PAGB also has a Professional Code which applies to advertising involving over-the-counter medicines aimed wholly or mainly at persons qualified to prescribe or supply and appropriate administrative staff, where the object of the advertising is to influence sales and/or recommendations to the public.

Clause 1.1 Promotion to Administrative Staff

The provisions of the Code apply in their entirety to the promotion of medicines to appropriate administrative staff except where the text indicates otherwise. For example, the prescribing information required under Clause 4 must be included in promotional material provided to administrative staff but it is not permissible to provide samples of medicines to them as this is proscribed by Clause 17.1.

Particular attention is drawn to the provisions of Clause 11.1 and the supplementary information to that clause, which concern the appropriateness of promotional material to those to whom it is addressed.

Clause 1.2 Replies Intended for Use in Response to Individual Enquiries

The exemption for replies made in response to individual enquiries from members of the health professions or appropriate administrative staff relates to unsolicited enquiries only. An unsolicited enquiry is one without any prompting from the company. In answering an unsolicited enquiry a company can offer to provide further information. If the enquirer subsequently requests additional information this can be provided and would be exempt from the Code

provided the additional information met the requirements of the exemption. A solicited enquiry would be one where a company invites a person to make a request. For example, material offering further information to readers would be soliciting a request for that information. Placing documents on exhibition stands amounts to an invitation to take them. Neither can take the benefit of this exemption.

Replies intended for use in response to enquiries which are received on a regular basis may be drafted in advance provided that they are used only when they directly and solely relate to the particular enquiry. Documents must not have the appearance of promotional material.

Clause 1.2 Price Lists for Unlicensed Medicines

Price lists of unlicensed medicines which include no product claims and make clear that the products are unlicensed can be sent to health professionals and appropriate administrative staff at reasonable intervals or in response to enquiries. They must not be used proactively in a manner which could be seen to be promoting unlicensed medicines, such as by displaying them on exhibition stands.

Clause 1.6 Representatives

'Medical representatives' and 'generic sales representatives' are distinguished in Clause 16.4 relating to examinations for representatives.

Clause 1.8 Applicability of Codes

Pharmaceutical companies must ensure that they comply with all applicable codes, laws and regulations to which they are subject. This is particularly relevant when activities/materials involve more than one country or when a pharmaceutical company based in one country is involved in activities in another country.

Activities carried out and materials used by a pharmaceutical company located in a European country must comply with the national code of that European country as well as the national code of the country in which the activities take place or the materials are used. Activities carried out and materials

used in a European country by a pharmaceutical company located in a country other than a European country must comply with the EFPIA Code as well as the national code of the country in which the activities are carried out and materials are used.

For example a company located in the UK carrying out an activity outside the UK but within Europe, such as in France, must comply with the UK Code and the French Code regardless of whether or not UK health professionals or appropriate administrative staff are involved. Conversely a company located in France carrying out an activity in the UK must comply with the ABPI Code regardless of whether or not UK health professionals or appropriate administrative staff are involved. Details of the various codes can be found at www.efpia.org or www.ifpma.org.

By 'company' is meant any legal entity that organises or sponsors promotion which takes place within Europe, whether such entity be a parent company (eg the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation.

In the event of a conflict of requirements the more restrictive requirements would apply.

All international events, that is to say events that take place outside the responsible pharmaceutical company's home country, must be notified in advance to any relevant local subsidiary or local advice taken.

Companies must take reasonable steps to ensure that any other parties that they commission to design, implement or engage in activities covered by the Code but which do not act on behalf of the company, and are therefore not covered by Clause 1.2, for example joint ventures or licensees, comply with the Code.

Clause 1.9 Responsible Person

There is an assumption that the responsible person is the managing director or chief executive or equivalent unless other formal arrangements have been made within the company.

Clause 2

Discredit to, and Reduction of Confidence in, the Industry

Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.

Clause 2 Supplementary Information

Clause 2 Discredit to, and Reduction of Confidence in, the Industry

A ruling of a breach of this clause is a sign of particular censure and is reserved for such circumstances.

Examples of activities that are likely to be in breach of Clause 2 include prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorization, conduct of company employees/agents that falls short of competent care and multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time.

Clause 3

Marketing Authorization

3.1 A medicine must not be promoted prior to the grant of the marketing authorization which permits its sale or supply.

3.2 The promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its summary of product characteristics.

Clause 3 Supplementary Information

Clause 3 Marketing Authorization

The legitimate exchange of medical and scientific information during the development of a medicine is not prohibited provided that any such information or activity does not constitute promotion which is prohibited under this or any other clause.

Clause 3 Promotion at International Meetings

The promotion of medicines at international meetings held in the UK may on occasion pose certain problems with regard to medicines or indications for medicines which do not have a marketing authorization in the UK although they are so authorized in another major industrialised country.

The display and provision of promotional material for such medicines is permitted at international meetings in the UK provided that the following conditions are met:

- the meeting must be a truly international meeting of high scientific standing with a significant proportion of the attendees from countries outside the UK in which the product is licensed
- the medicine or indication must be relevant and proportional to the purpose of the meeting
- promotional material for a medicine or indication that does not have a UK marketing authorization must be clearly and prominently labelled to that effect
- in relation to an unlicensed indication, UK approved prescribing information must be readily available for a medicine authorized in the UK even though it will not refer to the unlicensed indication
- the names must be given of countries in which the medicine or indication is authorized which must include at least one major developed country and it must be stated that registration conditions differ from country to country
- the material is certified in accordance with Clause 14, except that the signatories need certify only that in their belief the material is a fair and truthful presentation of the facts about the medicine.

Clause 3.1 Advance Notification of New Products or Product Changes

Health authorities and health boards and their equivalents, trust hospitals and primary care trusts and groups need to estimate their likely budgets two to three years in advance in order to meet Treasury requirements and there is a need for

them to receive advance information about the introduction of new medicines, or changes to existing medicines, which may significantly affect their level of expenditure during future years.

At the time this information is required, the medicines concerned (or the changes to them) will not be the subject of marketing authorizations (though applications will often have been made) and it would thus be contrary to the Code for them to be promoted. Information may, however, be provided on the following basis:

- i) the information must relate to:
 - (a) a product which contains a new active substance, or
 - (b) a product which contains an active substance prepared in a new way, such as by the use of biotechnology, or
 - (c) a product which is to have a significant addition to the existing range of authorized indications, or
 - (d) a product which has a novel and innovative means of administration
- ii) information should be directed to those responsible for making policy decisions on budgets rather than those expected to prescribe
- iii) whether or not a new medicine or a change to an existing medicine is the subject of a marketing authorization in the UK must be made clear in advance information
- iv) the likely cost and budgetary implications must be indicated and must be such that they will make significant differences to the likely expenditure of health authorities and trust hospitals and the like
- v) only factual information must be provided which should be limited to that sufficient to provide an adequate but succinct account of the product's properties; other products should only be mentioned to put the new product into context in the therapeutic area concerned
- vi) the information may be attractively presented and printed but should not be in the style of promotional material – product specific logos should be avoided but company logos may be used; the brand name of the product may be included in moderation but it should not be stylised or used to excess
- vii) the information provided should not include mock up drafts of either summaries of product characteristics or patient information leaflets
- viii) if requested, further information may be supplied or a presentation made.

Clause 3.2 Unauthorized Indications

The promotion of indications not covered by the marketing authorization for a medicine is prohibited by this clause.

Clause 4

Prescribing Information and Other Obligatory Information

4.1 The prescribing information listed in Clause 4.2 must be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements (see Clause 5).

The prescribing information must be positioned for ease of reference and must not be presented in a manner such that the reader has to turn the material round in order to read it, for example by providing it diagonally or around the page borders.

The prescribing information must form part of the promotional material and must not be separate from it.

4.2 The prescribing information consists of the following:

- the name of the medicine (which may be either a brand name or a non-proprietary name)
- a quantitative list of the active ingredients, using approved names where such exist, or other non-proprietary names; alternatively, the non-proprietary name of the product if it is the subject of an accepted monograph
- at least one authorized indication for use consistent with the summary of product characteristics
- a succinct statement of the information in the summary of product characteristics relating to the dosage and method of use relevant to the indications quoted in the advertisement and, where not otherwise obvious, the route of administration
- a succinct statement of common side-effects likely to be encountered in clinical practice, serious side-effects and precautions and contra-indications relevant to the indications in the advertisement, giving, in an abbreviated form, the substance of the relevant information in the summary of product characteristics, together with a statement that prescribers should consult the summary of product characteristics in relation to other side-effects
- any warning issued by the Medicines Commission, the Commission on Human Medicines, the Committee on Safety of Medicines or the licensing authority, which is required to be included in advertisements
- the cost (excluding VAT) of either a specified package of the medicine to which the advertisement relates, or a specified quantity or recommended daily dose, calculated by reference to any specified package of the product, except in the case of advertisements in journals printed in the UK which have more than 15 per cent of their circulation outside the UK and audio-visual advertisements and prescribing information provided in association with them
- the legal classification of the product

- the number of the relevant marketing authorization and the name and address of the holder of the authorization or the name and address of the part of the business responsible for its sale or supply
- the date the prescribing information was drawn up or last revised.

The information specified above in relation to dosage, method of use, side-effects, precautions and contra-indications and any warning which is required to be included in advertisements, must be placed in such a position in the advertisement that its relationship to the claims and indications for the product can be appreciated by the reader.

4.3 In addition, the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to the most prominent display of the brand name in bold type of a size such that a lower case 'x' is no less than 2mm in height or in type of such a size that the non-proprietary name or list of active ingredients occupies a total area no less than that taken up by the brand name.

4.4 In the case of audio-visual material such as films, DVDs and suchlike and in the case of interactive data systems, the prescribing information may be provided either:

- by way of a document which is made available to all persons to whom the material is shown or sent, or
- by inclusion on the audio-visual recording or in the interactive data system itself.

When the prescribing information is included in an interactive data system instructions for accessing it must be clearly displayed.

4.5 In the case of audio material, ie material which consists of sound only, the prescribing information must be provided by way of a document which is made available to all persons to whom the material is played or sent.

4.6 In the case of promotional material included on the Internet, there must be a clear, prominent statement as to where the prescribing information can be found.

In the case of an advertisement included in an independently produced electronic journal on the Internet, there must be a clear and prominent statement in the form of a direct link between the first page of the advertisement and the prescribing information.

The non-proprietary name of the medicine or the list of active ingredients, as required by Clause 4.3, must appear immediately adjacent to the brand name at its first appearance in a size such that the information is readily readable.

4.7 In the case of a journal advertisement where the prescribing information appears overleaf, at either the beginning or the end of the advertisement, a reference to where it can be found must appear on the outer edge of the other page of the advertisement in a type size such that a lower case 'x' is no less than 2mm in height.

4.8 In the case of printed promotional material consisting of more than four pages, a clear reference must be given to where the prescribing information can be found.

4.9 Promotional material other than advertisements appearing in professional publications must include the date on which the promotional material was drawn up or last revised.

4.10 All promotional material must include the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to [relevant pharmaceutical company]'.

4.11 When required by the licensing authority, all promotional material must show an inverted black triangle to denote that special reporting is required in relation to adverse reactions.

Clause 4 Supplementary Information

Clause 4.1 Prescribing Information and Summaries of Product Characteristics

Each promotional item for a medicine must be able to stand alone. For example, when a 'Dear Doctor' letter on a medicine is sent in the same envelope as a brochure about the same medicine, each item has to include the prescribing information. It does not suffice to have the prescribing information on only one of the items. The inclusion of a summary of product characteristics moreover does not suffice to conform with the provisions of this clause.

The prescribing information must be consistent with the summary of product characteristics for the medicine.

Clause 4.1 Legibility of Prescribing Information

The prescribing information is the essential information which must be provided in promotional material. It follows therefore that the information must be given in a clear and legible manner which assists readability.

Legibility is not simply a question of type size. The following recommendations will help to achieve clarity:

- type size should be such that a lower case letter 'x' is no less than 1 mm in height
- lines should be no more than 100 characters in length, including spaces
- sufficient space should be allowed between lines to facilitate easy reading
- a clear style of type should be used
- there should be adequate contrast between the colour of the text and the background
- dark print on a light background is preferable
- boldening headings and starting each section on a new line aids legibility.

Clauses 4.1 and 4.9 Date of Prescribing Information and Promotional Material

All prescribing information must include the date that the prescribing information was drawn up or last revised.

In addition, promotional material (other than journal advertising) must include the date that the material as a whole, ie the copy plus the prescribing information, was drawn up or last revised.

Clause 4.1 Electronic Journals

The first part of an advertisement in an electronic journal, such as the banner, is often the only part of the advertisement that is seen by readers. It must therefore include a clear, prominent statement as to where the prescribing information can be found. This should be in the form of a direct link. The first part is often linked to other parts and in such circumstances the linked parts will be considered as one advertisement.

If the first part mentions the product name then this is the most prominent display of the brand name and the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to the most prominent display of the brand name. The size must be such that the information is easily readable. If the product is one that is required to show an inverted black triangle on its promotional material then the black triangle symbol must also appear adjacent to the product name (see Clause 4.11). The size must be such that it is easily readable. The requirement of Clause 12.1 that promotional material and activities should not be disguised should also be borne in mind.

Clause 4.1 Advertisements for Devices

Where an advertisement relates to the merits of a device used for administering medicines, such as an inhaler, which is supplied containing a variety of medicines, the prescribing information for one only need be given if the advertisement makes no reference to any particular medicine.

Full prescribing information must, however, be included in relation to each particular medicine which is referred to.

Clause 4.1 Prescribing Information at Exhibitions

The prescribing information for medicines promoted on posters and exhibition panels at meetings must either be provided on the posters or panels themselves or must be available at the company stand. If the prescribing information is made available at the company stand, this should be referred to on the posters or panels.

Clause 4.3 Non-Proprietary Name

'Immediately adjacent to...' means immediately before, immediately after, immediately above or immediately below.

It should be noted that in a promotional letter the most prominent display of the brand name will usually be that in the letter itself, rather than that in prescribing information provided on the reverse of the letter.

Clause 4.4 Prescribing Information on Audio-Visual Material

Where prescribing information is shown in the audio-visual material as part of the recording, it must be of sufficient clarity and duration so that it is easily readable. The prescribing information must be an integral part of the advertisement and must appear with it. It is not acceptable for the advertisement and the prescribing information to be separated by any other material.

Clause 4.9 Date Drawn Up or Last Revised

This is in addition to the requirement in Clause 4.2 that the date of the prescribing information be included.

Clause 4.9 Dates on Loose Inserts

A loose insert is not regarded for this purpose as appearing in the professional publication with which it is sent and must therefore bear the date on which it was drawn up or last revised.

Clause 4.10 Adverse Event Reporting

A telephone number or email address for the relevant department of the company may be included. Text is more likely to be deemed to be prominent if it is presented in a larger type size than that used for the prescribing information.

Clause 4.11 Black Triangle Symbol

The agreement between the then Committee on Safety of Medicines and the ABPI on the use of the black triangle is that:

The symbol should always be black and its size should normally be not less than 5mm per side but with a smaller size of 3mm per side for A5 size advertisements and a larger size of 7.5mm per side for A3 size advertisements:

- the symbol should appear once and be located adjacent to the most prominent display of the name of the product
- no written explanation of the symbol is necessary.

Clause 5

Abbreviated Advertisements

5.1 Abbreviated advertisements are advertisements which are exempt from the requirement to include prescribing information for the advertised medicine, provided that they meet with the requirements of this clause.

5.2 Abbreviated advertisements may only appear in professional publications ie publications sent or delivered wholly or mainly to members of the health professions and/or appropriate administrative staff. A loose insert in such a publication cannot be an abbreviated advertisement.

Abbreviated advertisements may contain only the information specified in Clauses 5.4, 5.5, 5.6, 5.7 and 5.8 below.

Abbreviated advertisements are not permitted in audio-visual material or in interactive data systems or on the Internet, including journals on the Internet.

5.3 Abbreviated advertisements must be no larger than 420 square centimetres in size.

5.4 Abbreviated advertisements must provide the following information in a clear and legible manner:

- the name of the medicine (which may be either a brand name or a non-proprietary name)
- the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist
- at least one indication for use consistent with the summary of product characteristics
- a statement that prescribers are recommended to consult the summary of product characteristics before prescribing, particularly in relation to side-effects, precautions and contra-indications
- the legal classification of the product
- any warning issued by the Medicines Commission, the Commission on Human Medicines, the Committee on Safety of Medicines or the licensing authority which is required to be included in advertisements
- the name and address of the holder of the marketing authorization or the name and address of the part of the business responsible for its sale or supply

- the statement 'Information about this product, including adverse reactions, precautions, contra-indications and method of use can be found at [the address of the website referred to below]'.

The following information must be provided on the website referred to above:

either, the information set out in Clauses 4.2 and 4.3 above (except that the non-proprietary name of the medicine or the list of active ingredients, as required by Clause 4.3, must appear immediately adjacent to the most prominent display of the brand name in a size such that the information is readily readable),

or, the summary of product characteristics.

Information about cost as required by Clause 4.2 need not be included on the website where the abbreviated advertisement appears only in journals printed in the UK which have more than 15 per cent of their circulation outside the UK.

5.5 In addition, the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to the most prominent display of the brand name in bold type of a size such that a lower case 'x' is no less than 2mm in height or in type of such a size that the non-proprietary name or list of active ingredients occupies a total area no less than that taken up by the brand name.

5.6 In addition, abbreviated advertisements must include the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to [relevant pharmaceutical company]'.

5.7 When required by the licensing authority, abbreviated advertisements must show an inverted black triangle to denote that special reporting is required in relation to adverse reactions.

5.8 Abbreviated advertisements may in addition contain a concise statement consistent with the summary of product characteristics, giving the reason why the medicine is recommended for the indication or indications given.

5.9 Marketing authorization numbers and references must not be included in abbreviated advertisements.

Clause 5 Supplementary Information

Clause 5.2 Abbreviated Advertisements – Professional Publications

Abbreviated advertisements are largely restricted to journals and other such professional publications sent or delivered wholly or mainly to members of the health professions etc. A promotional mailing or representative leaflet cannot be an abbreviated advertisement and an abbreviated advertisement cannot appear as part of another promotional item, such as in a brochure consisting of a full advertisement for another of the company's medicines.

DVDs and suchlike sent to doctors etc may be considered professional publications and an abbreviated advertisement may be included on a box containing a DVD. The prescribing information must, however, be made available for any advertisement for a medicine appearing on audio-visual material or in an interactive data system or on the Internet, including journals on the Internet. Such advertisements cannot be deemed abbreviated advertisements.

Clauses 5.4, 5.5, 5.6, 5.7, 5.8 and 5.9 Abbreviated Advertisements – Permitted Information

The contents of abbreviated advertisements are restricted as set out in Clauses 5.4, 5.5, 5.6, 5.7, 5.8 and 5.9 and the following information should not therefore be included in abbreviated advertisements:

- dosage particulars
- details of pack sizes
- cost.

There may be exceptions to the above if the information provided, for example the cost of the medicine or the frequency of its dosage or its availability as a patient pack, is given as

the reason why the medicine is recommended for the indication or indications referred to in the advertisement.

Artwork used in abbreviated advertisements must not convey any information about a medicine which is additional to that permitted under Clauses 5.4, 5.5, 5.6, 5.7, 5.8 and 5.9.

Telephone numbers may be included in abbreviated advertisements.

Clause 5.5 Non-Proprietary Name

'Immediately adjacent to...' means immediately before, immediately after, immediately above or immediately below.

Clause 5.6 Adverse Event Reporting

A telephone number or email address for the relevant department of the company may be included.

Clause 5.7 Black Triangle Symbol

The agreement between the then Committee on Safety of Medicines and the ABPI on the use of the black triangle is that:

The symbol should always be black and its size should normally be not less than 5mm per side but with a smaller size of 3mm per side for A5 size advertisements and a larger size of 7.5mm per side for A3 size advertisements:

- the symbol should appear once and be located adjacent to the most prominent display of the name of the product
- no written explanation of the symbol is necessary.

It should be borne in mind that abbreviated advertisements must be no larger than 420 square centimetres in size. In abbreviated advertisements of no more than 310.8 square centimetres (A5) each side should be no less than 3mm. In abbreviated advertisements larger than A5 (but no larger than 420 square centimetres) each side should be no less than 5mm.

Clause 6

Journal Advertising

6.1 Where the pages of a two page advertisement are not facing, neither must be false or misleading when read in isolation.

6.2 No advertisement taking the form of a loose insert in a journal may consist of more than a single sheet of a size no larger than the page size of the journal itself, printed on one or both sides.

6.3 No issue of a journal may bear advertising for a particular product on more than two pages.

Clause 6 Supplementary Information

Clause 6 Journal Advertisements

See Clause 4 and in particular Clause 4.7 regarding the requirements for prescribing information in journal advertisements.

A two page journal advertisement is one where the pages follow on without interruption by intervening editorial text or other copy. Thus, for example, promotional material on two successive right hand pages cannot be a single advertisement. Each such page would need to be treated as a separate advertisement for the purposes of prescribing information.

Similarly, if promotional material appears on the outer edges of the left and right hand pages of a double page spread, and the promotional material is separated by intervening editorial matter, then again each page would need to be treated as a separate advertisement.

Clause 6.2 Advertising on the Outside of Journals

Advertising such as cards stapled to a journal and 'wraparounds' must not have a greater surface area than that outlined for loose inserts under Clause 6.2.

Clause 6.3 Limitation on Number of Pages of Advertising

Advertisements taking the form of inserts, whether loose or bound in, count towards the two pages allowed by Clause 6.3. An insert printed on both sides counts as two pages.

A summary of product characteristics is permitted as an

insert in addition to the two pages of advertising which is allowed.

Inserts and supplements which are not advertisements as such, though they may be regarded as promotional material, for example reports of conference proceedings, are not subject to the restrictions of Clauses 6.2 and 6.3.

Clause 7

Information, Claims and Comparisons

7.1 Upon reasonable request, a company must promptly provide members of the health professions and appropriate administrative staff with accurate and relevant information about the medicines which the company markets.

7.2 Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.

Material must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine.

7.3 A comparison is only permitted in promotional material if:

- it is not misleading
- medicines or services for the same needs or intended for the same purpose are compared
- one or more material, relevant, substantiable and representative features are compared
- no confusion is created between the medicine advertised and that of a competitor or between the advertiser's trade marks, trade names, other distinguishing marks and those of a competitor
- the trade marks, trade names, other distinguishing marks, medicines, services, activities or circumstances of a competitor are not discredited or denigrated
- no unfair advantage is taken of the reputation of a trade mark, trade name or other distinguishing marks of a competitor
- medicines or services are not presented as imitations or replicas of goods or services bearing a competitor's trade mark or trade name.

7.4 Any information, claim or comparison must be capable of substantiation.

7.5 Substantiation for any information, claim or comparison must be provided as soon as possible, and certainly within ten working days, at the request of members of the health professions or appropriate administrative staff.

The validity of indications approved in the marketing authorization can be substantiated by provision of the summary of product characteristics.

7.6 When promotional material refers to published studies, clear references must be given.

7.7 When promotional material refers to data on file, the relevant part of this data must be provided without delay at the request of members of the health professions or appropriate administrative staff.

7.8 All artwork including illustrations, graphs and tables must conform to the letter and spirit of the Code and, when taken from published studies, a reference must be given. Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.

7.9 Information and claims about side-effects must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no side-effects, toxic hazards or risks of addiction or dependency. The word 'safe' must not be used without qualification.

7.10 Promotion must encourage the rational use of a medicine by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.

7.11 The word 'new' must not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been generally promoted, for more than twelve months in the UK.

Clause 7 Supplementary Information

Clause 7 General

The application of this clause is not limited to information or claims of a medical or scientific nature. It includes, inter alia, information or claims relating to pricing and market share. Thus, for example, any claim relating to the market share of a product must be substantiated without delay upon request as required under Clause 7.5.

It should be borne in mind that claims in promotional material must be capable of standing alone as regards accuracy etc. In general claims should not be qualified by the use of footnotes and the like.

Clause 7.2 Misleading Information, Claims and Comparisons

The following are areas where particular care should be taken by companies:

- **claims for superior potency in relation to weight** are generally meaningless and best avoided unless they can be linked with some practical advantage, for example, reduction in side-effects or cost of effective dosage
- **the use of data derived from in-vitro studies, studies in healthy volunteers and in animals.** Care must be taken with the use of such data so as not to mislead as to its significance. The extrapolation of such data to the clinical situation should only be made where there is data to show that it is of direct relevance and significance
- **reference to absolute risk and relative risk.** Referring only to relative risk, especially with regard to risk reduction, can make a medicine appear more effective than it actually is. In order to assess the clinical impact of an outcome, the reader also needs to know the absolute risk involved. In that regard relative risk should never be referred to without also referring to the absolute risk. Absolute risk can be referred to in isolation
- **economic evaluation of medicines.** The economic evaluation of medicines is a relatively new science. Care must be taken that any claim involving the economic evaluation of a medicine is borne out by the data available and does not exaggerate its significance

To be acceptable as the basis of promotional claims, the assumptions made in an economic evaluation must be clinically appropriate and consistent with the marketing authorization

- **emerging clinical or scientific opinion.** Where a clinical or scientific issue exists which has not been resolved in favour of one generally accepted viewpoint, particular care must be taken to ensure that the issue is treated in a balanced manner in promotional material
- **hanging comparisons** whereby a medicine is described as being better or stronger or suchlike without stating that with which the medicine is compared must not be made
- **price comparisons.** Price comparisons, as with any comparison, must be accurate, fair and must not mislead. Valid comparisons can only be made where like is compared with like. It follows therefore that a price comparison should be made on the basis of the equivalent dosage requirement for the same indications. For example,

to compare the cost per ml for topical preparations is likely to mislead unless it can be shown that their usage rates are similar or, where this is not possible, for the comparison to be qualified in such a way as to indicate that usage rates may vary

- **statistical information.** Care must be taken to ensure that there is a sound statistical basis for all information, claims and comparisons in promotional material. Differences which do not reach statistical significance must not be presented in such a way as to mislead

Instances have occurred where claims have been based on published papers in which the arithmetic and/or statistical methodology was incorrect. Accordingly, before statistical information is included in promotional material it must have been subjected to statistical appraisal.

Clause 7.3 Comparisons

The Code does not preclude the use of other companies' brand names when making comparisons.

Clause 7.5 Data from Clinical Trials

Companies must provide substantiation following a request for it, as set out in Clause 7.5. In addition, when data from clinical trials is used companies must ensure that where necessary that data has been registered in accordance with the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases 2009.

Clause 7.6 References

Clause 7.6 applies to references to published material, including the use of quotations, tables, graphs and other illustrative matters.

Clause 7.8 Artwork, Illustrations, Graphs and Tables

Care must be taken to ensure that artwork does not mislead as to the nature of a medicine or any claim or comparison and that it does not detract from any warnings or contra-indications. For example, anatomical drawings used to show results from a study must not exaggerate those results and depictions of children should not be used in relation to products not authorized for use in children in any way which might encourage such use.

Particular care should be taken with graphs and tables to ensure that they do not mislead, for example by their incompleteness or by the use of suppressed zeros or unusual scales. Differences which do not reach statistical significance must not be presented in such a way as to mislead.

Graphs and tables must be adequately labelled so that the information presented can be readily understood. When taken from published studies, the source of the artwork must be given (see also Clause 7.6). If a graph, table or suchlike is taken from a published study it must be faithfully reproduced except where modification is needed in order to comply with the Code. In such circumstances it must be clearly stated that the material has been modified. Any such adaptation must not distort or mislead as to the significance of that graph, table etc. Care should be taken not to mislead when expressing data as percentages; patient numbers should be included wherever possible. It should also be noted that if a table, graph etc in a paper is unacceptable in terms of the requirements of the Code, because, for example, it gives a visually misleading impression as to the data shown, then it must not be used or reproduced in promotional material.

Clause 7.9 Use of the Word 'Safe'

The restrictions on the word 'safe' apply equally to grammatical derivatives of the word such as 'safety'. For example, 'demonstrated safety' or 'proven safety' are prohibited under this clause.

Clause 7.10 Benefit/Risk Profile

The benefit/risk profile of a medicine must be presented in promotional campaigns in such a way as to comply with the Code. Particular attention should be paid to Clauses 7.2, 7.9 and 7.10.

Clause 7.10 Superlatives

Superlatives are those grammatical expressions which denote the highest quality or degree, such as best, strongest, widest etc. A claim that a product was 'the best' treatment for a particular condition, for example, could not be substantiated as there are too many variables to enable such a sweeping claim to be proven. The use of a superlative is acceptable only

if it can be substantiated as a simple statement of fact which can be very clearly demonstrated, such as that a particular medicine is the most widely prescribed in the UK for a certain condition, if this is not presented in a way which misleads as to its significance.

Clause 7.10 Use of the Words 'The' and 'Unique'

In certain circumstances the use of the word 'the' can imply a special merit, quality or property for a medicine which is unacceptable under this clause if it cannot be substantiated. For example, a claim that a product is 'The analgesic' implies that it is in effect the best, and might not be acceptable under this clause.

Similarly, great care needs to be taken with the use of the word 'unique'. Although in some circumstances the word unique may be used to describe some clearly defined special feature of a medicine, in many instances it may simply imply a general superiority. In such instances it is not possible to substantiate the claim as the claim itself is so ill defined.

Clause 8

Disparaging References

8.1 The medicines, products and activities of other pharmaceutical companies must not be disparaged.

8.2 The health professions and the clinical and scientific opinions of health professionals must not be disparaged.

Clause 8 Supplementary Information

Clause 8.1 Disparaging References

Much pharmaceutical advertising contains comparisons with other products and, by the nature of advertising, such comparisons are usually made to show an advantage of the advertised product over its comparator. Provided that such critical references to another company's products are accurate, balanced, fair etc, and can be substantiated, they are acceptable under the Code.

Unjustified knocking copy in which the products or activities of a competitor are unfairly denigrated is prohibited under this clause.

Attention is drawn to the requirements for comparisons set out in Clauses 7.2 to 7.5.

Clause 9

High Standards, Format, Suitability and Causing Offence, Sponsorship

9.1 High standards must be maintained at all times.

9.2 All material and activities must recognise the special nature of medicines and the professional standing of the audience to which they are directed and must not be likely to cause offence.

9.3 The name or photograph of a member of a health profession must not be used in any way that is contrary to the conventions of that profession.

9.4 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.

9.5 Promotional material must not include any reference to the Medicines Commission, the Commission on Human Medicines, the Committee on Safety of Medicines, the Medicines and Healthcare products Regulatory Agency, the Medicines Control Agency or the licensing authority, unless this is specifically required by the licensing authority.

9.6 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.

9.7 Extremes of format, size or cost of promotional material must be avoided.

9.8 Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the public, contrary to Clause 22.1.

9.9 The telephone, text messages, email, telemessages, facsimile, automated calling systems and other electronic data communications must not be used for promotional purposes, except with the prior permission of the recipient.

9.10 Material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company.

The only exception to this is market research material which need not reveal the name of the company involved but must state that it is sponsored by a pharmaceutical company.

Clause 9 Supplementary Information

Clauses 9.1 and 9.2 Suitability and Taste

The special nature of medicines and the professional audience to which the material is directed require that the standards set for the promotion of medicines are higher than those which might be acceptable for general commodity advertising.

It follows therefore that certain types, styles and methods of promotion, even where they might be acceptable for the promotion of products other than medicines, are unacceptable. These include:

- *the display of naked or partially naked people for the purpose of attracting attention to the material or the use of sexual imagery for that purpose*
- *'teaser' advertising whereby promotional material is intended to 'tease' the recipient by eliciting an interest in something which will be following or will be available at a later date without providing any actual information about it*
- *the provision of rubber stamps to doctors for use as aids to prescription writing*
- *the provision of private prescription forms preprinted with the name of a medicine.*

Clause 9.5 MHRA Drug Safety Update

Where factual safety information given in promotional material is based on advice in the MHRA Drug Safety Update, the information can be referenced to that publication.

Clause 9.7 Extremes of Format, Size or Cost

Particular care needs to be taken in this regard in the first six months following the launch of a medicine to avoid criticism of the industry.

Clause 9.8 Reply Paid Cards

Reply paid cards which are intended to be returned to companies through the post and which relate to a prescription only medicine should not bear both the name of the medicine and information as to its usage but may bear one or the other.

Clause 9.9 Unsubscribing to emails

Where permission to use emails for promotional purposes has been given by a recipient, each email sent should inform the recipient as to how to unsubscribe to them.

Clause 9.9 Responding to emails

An enquiry received by email can be responded to by email without specific permission, consent to do so being implied in such circumstances. There is no need to inform recipients as to how to unsubscribe to an email response to an enquiry.

Clause 9.10 Declaration of Sponsorship

The declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset.

The wording of the declaration must be unambiguous so that readers will immediately understand the extent of the company's involvement and influence over the material. This is particularly important when companies are involved in the production of material which is circulated by an otherwise wholly independent party, such as supplements to health professional journals.

Clause 9.10 Market Research

Where market research is carried out by an agency on behalf of a pharmaceutical company, the agency must reveal the name of its client to the Prescription Medicines Code of Practice Authority when the Authority requests it to do so. When commissioning market research, a company must take steps to ensure that its identity would be so made known to the Authority should a request for that information be made.

Clause 10

Provision of Reprints and the Use of Quotations

10.1 Reprints of articles in journals must not be provided unsolicited unless the articles have been refereed.

10.2 Quotations from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required in order to comply with the Code) and must accurately reflect the meaning of the author. The precise source of the quotation must be identified.

10.3 Quotations relating to medicines taken from public broadcasts, for example on radio and television, and from private occasions, such as medical conferences or symposia, must not be used without the formal permission of the speaker.

10.4 The utmost care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.

Clause 10 Supplementary Information

Clause 10.1 Provision of Reprints

The provision of an unsolicited reprint of an article about a

medicine constitutes promotion of that medicine and all relevant requirements of the Code must therefore be observed. Particular attention must be paid to the requirements of Clause 3.

When providing an unsolicited reprint of an article about a medicine, it should be accompanied by prescribing information.

Clause 10.2 Quotations

Any quotation chosen by a company for use in promotional material must comply with the requirements of the Code itself. For example, to quote from a paper which stated that a certain medicine was 'safe and effective' would not be acceptable even if it was an accurate reflection of the meaning of the author of the paper, as it is prohibited under Clause 7.9 to state without qualification in promotional material that a medicine is safe.

Quotations can only be adapted or modified in order to comply with the Code. In such circumstances it must be clearly stated that the quotation has been amended.

Care should be taken in quoting from any study or the like to ensure that it does not mislead as to its overall significance. (See Clause 7.2 which prohibits misleading information, claims etc in promotional material.) Attention is drawn to the provisions of Clause 7.6 which requires that when promotional material refers to published studies clear references must be given to where they can be found.

Clause 10.4 Current Views of Authors

If there is any doubt as to the current view of an author, companies should check with the author prior to its use in promotional material.

Clause 11

Distribution of Promotional Material

11.1 Promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed.

11.2 Restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed.

11.3 Mailing lists must be kept up-to-date. Requests to be removed from promotional mailing lists must be complied with promptly and no name may be restored except at the addressee's request or with their permission.

Clause 11 Supplementary Information

Clause 11.1 Distribution of Promotional Material

Promotional material should be tailored to the audience to whom it is directed. For example, promotional material

devised for general practitioners might not be appropriate for hospital doctors and, similarly, material devised for clinicians might not be appropriate for use with National Health Service administrative staff.

Clause 11.2 Frequency of Mailings

The style of mailings is relevant to their acceptability to doctors and criticism of their frequency is most likely to arise where their informational content is limited or where they appear to be elaborate and expensive.

In the first six months following the launch of a new medicine, a health professional may be sent an initial mailing giving detailed information about its use, including, for example, the summary of product characteristics, the public assessment report, the package leaflet and the product monograph, and no more than three other mailings about the medicine.

No more than eight mailings for a particular medicine may be sent to a health professional in a year.

Mailings concerned solely with safety issues can be sent in addition to the above as can mailings about price changes which contain no product claims.

The limitations on frequency of mailings do not apply to emails as these can only be sent with the prior permission of the recipient.

Clause 12

Disguised Promotion

12.1 Promotional material and activities must not be disguised.

12.2 Market research activities, clinical assessments, post-marketing surveillance and experience programmes, post-authorization studies (including those that are retrospective in nature) and the like must not be disguised promotion. They must be conducted with a primarily scientific or educational purpose.

Clause 12 Supplementary Information

Clause 12.1 Disguised Promotional Material

Promotional material sent in the guise of personal communications, for example by using envelopes or postcards addressed in real or facsimile handwriting, is inappropriate. Envelopes must not be used for the dispatch of promotional material if they bear words implying that the contents are non-promotional, for example that the contents provide information relating to safety.

When a company pays for, or otherwise secures or arranges the publication of promotional material in journals, such

material must not resemble independent editorial matter. Care must be taken with company sponsored reports of meetings and the like to ensure that they are not disguised promotion. Sponsorship must be declared in accordance with Clause 9.10.

Clause 12.2 Non-Interventional Studies of Marketed Medicines

The conduct of non-interventional studies of marketed medicines is dealt with in Clause 13.

Clause 12.2 Market Research

Market research is the collection and analysis of information and must be unbiased and non-promotional. The use to which the statistics or information is put may be promotional. The two phases must be kept distinct.

Attention is drawn to the Legal & Ethical Guidelines for Healthcare Market Research produced by the British Healthcare Business Intelligence Association in consultation with the ABPI.

Market research material should be examined to ensure that it does not contravene the Code.

Where market research is carried out by an agency on behalf of a pharmaceutical company, the agency must reveal the name of its client to the Prescription Medicines Code of Practice Authority when the Authority requests it to do so. When commissioning market research, a company must take steps to ensure that its identity would be so made known to the Authority should a request for that information be made.

Clause 13

Non-Interventional Studies of Marketed Medicines

13.1 A non-interventional study of a marketed medicine is defined as a study where the medicine is prescribed in the usual manner in accordance with the terms of its marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided by a study protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures are applied to the patients and epidemiological methods are used for the analysis of collected data.

13.2 Companies must publish the summary details and results of non-interventional studies of marketed medicines in a manner consistent with their parallel obligations with respect to clinical trials.

13.3 Non-interventional studies that are prospective in nature and involve the collection of patient data must be conducted for a scientific purpose. They must comply with the following criteria:

- there must be a written protocol and written contracts between the health professionals and/or the institutes at

which the study will take place and the pharmaceutical company sponsoring the study, which specify the nature of the services to be provided and the payment for those services

- any remuneration must be reasonable and reflect the fair market value of the work
- in countries where ethics committees are prepared to review such studies, the study protocol must be submitted to the ethics committee for review
- data protection legislation must be complied with
- the study must not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine
- the company's scientific service must approve the protocol and must supervise the conduct of the study
- the study results must be analysed and summaries must be made available within a reasonable period of time to the company's scientific service, which service shall maintain records of such reports; the summary report should be sent to health professionals who participated in the study. If the study results are important for the assessment of benefit-risk, the summary report should be immediately forwarded to the relevant competent authority

- sales representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service which will also ensure that the representatives are adequately trained for the role; such involvement must not be linked to the promotion of any medicine.

Clause 13 Supplementary Information

Clause 13 EU Guidelines on Pharmacovigilance for Medicinal Products for Human Use

Attention is drawn to the EU Guidelines on Pharmacovigilance for Medicinal Products for Human Use.

Clause 13.2 Publication of Details and Results

This requirement applies to non-interventional studies completed on and after 1 May 2011 with which a UK

company has had any involvement. Companies are, however, encouraged to publish details and results of such studies completed prior to that date.

Clause 13.3 Other Studies Covered by Clause 13.1

Companies are encouraged to comply with Clause 13.3 for all other types of studies covered by Clause 13.1, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Clause 18.7.

Clause 13.3 Approval and Supervision

The approval and supervision of non-interventional studies are dealt with in Clause 21.2.

Clause 13.3 Date of Implementation

Companies must comply with Clause 13.3 in relation to non-interventional studies that are completed on or after 1 July 2008. Companies are encouraged to comply in relation to studies completed prior to that date.

Clause 14

Certification

14.1 Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by two persons on behalf of the company in the manner provided for by this clause. One of the two persons must be a registered medical practitioner or a UK registered pharmacist or, in the case of a product for dental use only, a registered medical practitioner or a UK registered pharmacist or a dentist.

Material referred to in Clause 14.3 below must be certified by two persons one of whom must be a registered medical practitioner or, in the case of a product for dental use only, a registered medical practitioner or a dentist.

The second person certifying on behalf of the company must be an appropriately qualified person or senior official of the company or an appropriately qualified person whose services are retained for that purpose.

14.2 All meetings which involve travel outside the UK must be certified in advance in a manner similar to that provided for by Clause 14.1.

14.3 The following must be certified in advance in a manner similar to that provided for by Clause 14.1:

- educational material for the public or patients issued by companies which relates to diseases or medicines but is not intended as promotion for those medicines
- material relating to working with patient organisations as described in Clause 23 and its supplementary information
- material prepared in relation to joint working between the NHS and the pharmaceutical industry as described in Clause 18.5 and its supplementary information

- material relating to patient support programmes involving the provision to health professionals of items to be passed on to patients as described in Clause 18.2 and its supplementary information
- non promotional material for patients or health professionals relating to the provision of medical and educational goods and services, including relevant internal company instructions, as described in Clause 18.4 and paragraph 8 of its supplementary information.

14.4 The names of those nominated, together with their qualifications, shall be notified in advance to the Advertising Standards Unit, Vigilance and Risk Management of Medicines of the Medicines and Healthcare products Regulatory Agency and to the Prescription Medicines Code of Practice Authority. The names and qualifications of designated alternative signatories must also be given. Changes in the names of nominees must be promptly notified.

14.5 The certificate for promotional material must certify that the signatories have examined the final form of the material and that in their belief it is in accordance with the requirements of the relevant regulations relating to advertising and this Code, is not inconsistent with the marketing authorization and the summary of product characteristics and is a fair and truthful presentation of the facts about the medicine.

The certificates for material covered by Clause 14.3 above must certify that the signatories have examined the final form of the material and that in their belief it complies with the Code.

Material which is still in use must be recertified at intervals of no more than two years to ensure that it continues to conform with the relevant regulations relating to advertising and the Code.

The certificate for meetings involving travel outside the UK must certify that the signatories have examined all the proposed arrangements for the meeting and that in their belief the arrangements are in accordance with the relevant regulations relating to advertising and the Code.

14.6 Companies shall preserve all certificates. In relation to certificates for promotional material, the material in the form certified and information indicating the persons to whom it was addressed, the method of dissemination and the date of first dissemination must also be preserved. In relation to certificates for meetings involving travel outside the UK, details of the programme, the venue, the reasons for using the venue, the audience, the anticipated and actual costs and the nature of the hospitality and the like must also be preserved.

Companies shall preserve certificates and the relevant accompanying information for not less than three years after the final use of the promotional material or the date of the meeting and produce them on request from the Medicines and Healthcare products Regulatory Agency or the Prescription Medicines Code of Practice Authority.

The certificates for material covered by Clause 14.3 above shall be preserved for not less than three years after the final use of the material and companies shall produce them on request from the Medicines and Healthcare products Regulatory Agency or the Prescription Medicines Code of Practice Authority.

Clause 14 Supplementary Information

Clause 14.1 Certification

An acceptable way to comply with Clause 14.1 is for the final proof to be certified but this is not obligatory provided that that which is certified is in its final form to which no subsequent amendments will be made. Companies may use validated electronic signatures for certifying material. Paper or electronic copies of certificates and the final form of material etc must be preserved in order to comply with Clause 14.6.

All promotional material must be certified in this way including audio and audio-visual material, promotional material on databases, interactive data systems and the Internet and representatives' technical briefing materials. Promotional aids must also be certified. Although not strictly promotional material they are used for a promotional purpose.

Account should be taken of the fact that a non-promotional item can be used for a promotional purpose and therefore come within the scope of the Code.

In certifying audio and audio-visual material and promotional material on databases, interactive systems and the Internet, companies must ensure that a written transcript of the material is certified including reproductions of any graphs, tables and the like that appear in it. In the event of a complaint, a copy of the written material will be requested. Alternatively companies may certify material on interactive systems by means of producing an electronic copy, for example on a CD Rom or data stick, if the electronic copy is write protected and unable to be changed.

The guidelines on company procedures relating to the Code which are on page 51 give further information on certification.

See also the supplementary information to Clause 3 on promotion at international conferences regarding the certification of such material.

Clause 14.1 Suitable Qualifications for Signatories

In deciding whether a person can be a nominated signatory, account should be taken of product knowledge, relevant experience both within and outwith the industry, length of service and seniority. In addition signatories must have an up-to-date, detailed knowledge of the Code.

Clause 14.1 Joint Ventures and Co-Promotion

In a joint venture in which a third party provides a service on behalf of a number of pharmaceutical companies, the pharmaceutical companies involved are responsible for any activity carried out by that third party on their behalf.

It follows therefore that the pharmaceutical companies involved should be aware of all aspects of the service carried out on their behalf and take this into account when certifying the material or activity involved. Similarly if two or more pharmaceutical companies organise a joint meeting each company should ensure that the arrangements for the meeting are acceptable.

Under co-promotion arrangements whereby companies jointly promote the same medicine and the promotional material bears both company names, each company should certify the promotional material involved as they will be held jointly responsible for it under the Code.

Clause 14.2 Meetings Involving Travel Outside the UK

When certifying meetings which involve travel outside the UK, the signatories should ensure that all the arrangements are examined, including the programme, the venue, the reasons for using that venue, the intended audience, the anticipated cost and the nature of the hospitality and the like.

Clause 14.3 Examination of Other Material

Other material issued by companies which relates to medicines but which is not intended as promotional material for those medicines per se, such as corporate advertising, press releases, market research material, financial information to inform shareholders, the Stock Exchange and the like, and written responses from medical information departments or similar to unsolicited enquiries from the public etc, should be examined to ensure that it does not contravene the Code or the relevant statutory requirements.

Clause 14.3 Non-Interventional Studies

The examination of non-interventional studies is dealt with in Clause 21.2 and is not covered by Clause 14.

Clause 14.4 Notification of Signatories

The names and qualifications of signatories and changes to them should be notified to the Medicines and Healthcare products Regulatory Agency by email to signatories.advertising@mhra.gsi.gov.uk.

Clause 14.6 Retention of Documentation

Companies should note that the Medicines and Healthcare products Regulatory Agency is entitled to request particulars of an advertisement, including particulars as to the content and form of the advertisement, the method of dissemination and the date of first dissemination, and such a request is not subject to any time limit. This does not apply to the certificates themselves in respect of which the three year limit in Clause 14.6 is applicable.

Clause 15

Representatives

15.1 Representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines which they promote.

15.2 Representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code.

15.3 Representatives must not employ any inducement or subterfuge to gain an interview. No fee should be paid or offered for the grant of an interview.

15.4 Representatives must ensure that the frequency, timing and duration of calls on health professionals, administrative staff in hospitals and health authorities and the like, together with the manner in which they are made, do not cause inconvenience. The wishes of individuals on whom representatives wish to call and the arrangements in force at any particular establishment, must be observed.

15.5 In an interview, or when seeking an appointment for one, representatives must at the outset take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.

15.6 Representatives must transmit forthwith to the scientific service referred to in Clause 21.1 any information which they receive in relation to the use of the medicines which they promote, particularly reports of side-effects.

15.7 Representatives must be paid a fixed basic salary and any addition proportional to sales of medicines must not constitute an undue proportion of their remuneration.

15.8 Representatives must provide, or have available to provide if requested, a copy of the summary of product characteristics for each medicine which they are to promote.

15.9 Companies must prepare detailed briefing material for medical representatives on the technical aspects of each medicine which they will promote. A copy of such material must be made available to the Medicines and Healthcare products Regulatory Agency and the Prescription Medicines Code of Practice Authority on request. Briefing material must comply with the relevant requirements of the Code and, in particular, is subject to the certification requirements of Clause 14.

Briefing material must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

15.10 Companies are responsible for the activities of their representatives if these are within the scope of their employment even if they are acting contrary to the instructions which they have been given.

Clause 15 Supplementary Information

Clause 15 Representatives

All provisions in the Code relating to the need for accuracy, balance, fairness, good taste etc apply equally to oral representations as well as to printed material. Representatives must not make claims or comparisons which are in any way inaccurate, misleading, disparaging, in poor taste etc, or which are outside the terms of the marketing authorization for the medicine or are inconsistent with the summary of product characteristics. Indications for which the medicine does not have a marketing authorization must not be promoted.

Attention is drawn to the provisions of Clause 9.9 which prohibit the use of the telephone, text messages, email, telemessages and facsimile etc for promotional purposes, except with the prior permission of the recipient.

Clause 15 Contract Representatives

Companies employing or using contract representatives are responsible for their conduct and must ensure that they comply with the provisions of this and all other relevant clauses in the Code, and in particular the training requirements under Clauses 15.1, 16.1, 16.3 and 16.4.

Clause 15.3 Hospitality and Payments for Meetings

Attention is drawn to the requirements of Clauses 18 and 19 which prohibit the provision of any financial inducement for the purposes of sales promotion and require that any hospitality provided is secondary to the purpose of a meeting, is not out of proportion to the occasion and does not extend beyond members of the health professions or appropriate administrative staff.

Meetings organised for groups of doctors, other health professionals and/or appropriate administrative staff which are wholly or mainly of a social or sporting nature are unacceptable.

Representatives organising meetings are permitted to provide appropriate hospitality and/or to meet any reasonable, actual costs which may have been incurred. For example, if the refreshments have been organised and paid for by a medical practice the cost may be reimbursed as long as it is reasonable in relation to what was provided and the refreshments themselves were appropriate for the occasion.

Donations in lieu of hospitality are unacceptable as they are inducements for the purpose of holding a meeting. If hospitality is not required at a meeting there is no obligation or right to provide some benefit of an equivalent value.

Clause 15.3 Donations to Charities

Donations to charities in return for representatives gaining interviews are prohibited under Clause 15.3.

Clause 15.3 Items Delivered by Representatives

Reply paid cards which refer to representatives delivering items to health professionals or appropriate administrative staff should explain that there is no obligation to grant the representative an interview when the items are delivered. This is to avoid the impression that there is such an obligation, which would be contrary to Clause 15.3 which prohibits the use of any inducement or subterfuge to gain an interview.

Clause 15.3 Health Professionals' Codes of Conduct

The General Medical Council is the regulatory body for doctors and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance, the Council advises doctors that 'You must act in your patients' best interests when making referrals and when providing or arranging treatment or care. You must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect the way you prescribe for, treat or refer patients'.

The General Pharmaceutical Council is the regulatory body for pharmacists and pharmacy technicians. The Council's Standards of conduct, ethics and performance state 'Do not ask for or accept gifts, rewards or hospitality that may affect, or be seen to affect, your professional judgement'.

The Code of the Nursing & Midwifery Council, Standards of conduct, performance and ethics for nurses and midwives, states 'You must not abuse your privileged position for your own ends' and 'You must ensure that your professional judgement is not influenced by any commercial considerations'.

Clause 15.4 Frequency and Manner of Calls on Doctors and Other Prescribers

The number of calls made on a doctor or other prescriber and the intervals between successive visits are relevant to the determination of frequency.

Companies should arrange that intervals between visits do not cause inconvenience. The number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. This does not include the following which may be additional to those three visits:

- attendance at group meetings, including audio-visual presentations and the like

- a visit which is requested by a doctor or other prescriber or a call which is made in order to respond to a specific enquiry
- a visit to follow up a report of an adverse reaction.

Representatives must always endeavour to treat prescribers' time with respect and give them no cause to believe that their time might have been wasted. If for any unavoidable reasons, an appointment cannot be kept, the longest possible notice must be given.

When briefing representatives companies should distinguish clearly between expected call rates and expected contact rates. Contacts include those at group meetings, visits requested by doctors or other prescribers, visits in response to specific enquiries and visits to follow up adverse reaction reports. Targets must be realistic and not such that representatives breach the Code in order to meet them.

Clause 15.8 Provision of Summary of Product Characteristics

The requirement to provide a copy of the summary of product characteristics can be met by the provision of an electronic copy if the recipient agrees.

If discussion on a medicine is initiated by the person or persons on whom a representative calls, the representative is not obliged to have available the information on that medicine referred to in this clause.

Clause 15.9 Briefing Material

The detailed briefing material referred to in this clause consists of both the training material used to instruct medical representatives about a medicine and the instructions given to them as to how the product should be promoted.

Clause 16

Training

16.1 All relevant personnel including representatives and members of staff (including persons retained by way of contract with third parties) concerned in any way with the preparation or approval of promotional material or of information to be provided to members of the UK health professions and to appropriate administrative staff or of information to be provided to the public and recognised patient organisations must be fully conversant with the requirements of the Code and the relevant laws and regulations.

16.2 All personnel (including persons retained by way of contract with third parties) must be fully conversant with pharmacovigilance requirements relevant to their work and this must be documented.

16.3 Representatives must pass the appropriate ABPI representatives examination, as specified in Clause 16.4. They must take the appropriate examination within their first year of such employment. Prior to passing the appropriate examination, they may be engaged in such employment for no more than two years, whether continuous or otherwise.

16.4 The Medical Representatives Examination is appropriate for, and must be taken by, representatives whose duties comprise or include one or both of:

- calling upon doctors and/or dentists and/or other prescribers
- the promotion of medicines on the basis, *inter alia*, of their particular therapeutic properties.

The Generic Sales Representatives Examination is appropriate for, and must be taken by, representatives who promote medicines primarily on the basis of price, quality and availability.

16.5 Persons who have passed the Medical Representatives Examination whose duties change so as to become those specified in Clause 16.4 as being appropriate to the Generic Sales Representatives Examination are exempt from the need to take that examination.

Persons who have passed the Generic Sales Representatives Examination whose duties change so as to become those specified in Clause 16.4 as being appropriate to the Medical Representatives Examination must pass that examination within two years of their change of duties. They must take the examination within one year of their change of duties.

16.6 Details of the numbers of medical and generic sales representatives who have passed the respective examinations above, together with the examination status of others, must be provided to the Prescription Medicines Code of Practice Authority on request.

Clause 16 Supplementary Information

Clause 16.1 Training

Extensive in house training on the Code is carried out by companies and by the Prescription Medicines Code of Practice Authority.

In addition, the Authority runs seminars on the Code which are open to all companies and personnel from advertising agencies, public relations agencies and the like which act for the pharmaceutical industry. Details of these seminars can be obtained from the Authority.

Clause 16.3 Time Allowed to Pass Examination

Prior to passing the appropriate ABPI examination, representatives may be engaged in such employment for no more than two years, whether continuous or otherwise and irrespective of whether with one company or with more than one company. A representative cannot, for example, do eighteen months with one company and eighteen months with another and so on, thus avoiding the examination.

In the event of extenuating circumstances, such as prolonged illness or no or inadequate opportunity to take the examination, the Director of the Prescription Medicines Code of Practice Authority may agree to the continued employment of a person as a representative past the end of the two year period, subject to the representative passing the examination within a reasonable time.

Similarly, in the event of failure to take the examination within the first year, the Director may agree to an extension, subject to the representative taking the examination within a reasonable time.

Service as a representative prior to 1 January 2006 by persons who were exempt from taking the appropriate examination by virtue of Clause 16.4 of the 2003 edition of the Code does not count towards the two year limit on employment as a representative prior to passing the appropriate examination.

Clause 16.4 Medical Representatives and Generic Sales Representatives – Examinations

The ABPI examinations for medical representatives and generic sales representatives are based on a syllabus published by the ABPI. The syllabus is complementary to, and may be incorporated within, the company's induction training which is provided to representatives as a prerequisite to carrying out their function.

Clause 16.5 Time Allowed to Pass Examination

The supplementary information to Clause 16.3 relating to the time allowed in which to take and pass the examination applies equally to persons who have passed the Generic Sales Representatives Examination but who now have to pass the Medical Representatives Examination.

Clause 17

Provision of Medicines and Samples

17.1 Samples of a product may be provided only to a health professional qualified to prescribe that product. They must not be provided to administrative staff.

17.2 No more than four samples of a particular new medicine may be provided to an individual health professional during the course of a year.

Samples of a particular new medicine may be provided to a health professional for no longer than two years after that health professional first requests samples of it.

17.3 Samples may only be supplied in response to written requests which have been signed and dated.

17.4 A sample of a medicine must be no larger than the smallest presentation of the medicine on the market in the UK.

17.5 Each sample must be marked 'free medical sample – not for resale' or words to that effect and must be accompanied by a copy of the summary of product characteristics.

17.6 The provision of samples is not permitted for any medicine which contains a substance listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the medicine is not a preparation listed in Schedule III to that Convention) or a substance listed in any of Schedules I to IV to the Psychotropic Substances Convention (where the medicine is not a preparation which may be exempted from measures of control in accordance with Paragraphs 2 and 3 of Article 3 of that Convention).

17.7 Samples distributed by representatives must be handed direct to the health professionals requesting them or persons authorized to receive them on their behalf.

17.8 The provision of medicines and samples in hospitals must comply with individual hospital requirements.

17.9 Companies must have adequate systems of control and accountability for samples which they distribute and for all medicines handled by representatives. Systems must clearly establish, for each health professional, the number of samples supplied in accordance with Clause 17.2 above.

17.10 Medicines which are sent by post must be packed so as to be reasonably secure against being opened by young children. No unsolicited medicine must be sent through the post.

17.11 Medicines may not be sold or supplied to members of the public for promotional purposes.

17.12 Samples must not be provided simply as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. Samples must not be given for the sole purpose of treating patients.

Clause 17 Supplementary Information

Clause 17 Definition of Sample

A sample is a small supply of a medicine provided to health professionals so that they may familiarise themselves with it and acquire experience in dealing with it. A sample of a medicine may be provided only to a health professional qualified to prescribe that particular medicine.

A small sample which is provided only for identification or similar purposes and which is not intended to be used in treatment may be provided to any health professional but is otherwise subject to the requirements of Clause 17.

Titration packs, free goods and bonus stock provided to pharmacists and others are not samples. This is because they are not for the purposes described above.

Titration packs are packs containing various strengths of a medicine for the purpose of establishing a patient on an effective dose.

The supply of a product which is not a medicine because it does not contain the active ingredient normally present is not regarded as the supply of a sample.

Clause 17 Starter Packs

The provision of starter packs is not permitted. Starter packs are small packs designed to provide sufficient medicine for a primary care prescriber to initiate treatment in such circumstances as a call out in the night.

Clause 17.2 Definition of 'New Medicine'

For the purpose of Clause 17.2 a 'new medicine' is a product for which a new marketing authorization has been granted, either following the initial application or following an extension application for a new indication that includes new strengths and/or dosage forms. Extension of a marketing authorization to include additional strengths and/or dosage forms for existing indications or to include additional pack sizes is not regarded as leading to new medicines.

Clause 17.2 Date of Implementation

Clause 17.2 applies with effect from 1 January 2012 in relation to new medicines launched on the UK market on or after that date.

In relation to medicines launched on the UK market prior to 1 January 2012, samples may be given in accordance with Clause 17.2 of the 2011 Code of Practice until 31 December 2013.

Clause 17.3 Sample Requests

This clause does not preclude the provision of a preprinted sample request form bearing the name of the product for signing and dating by the applicant.

All signed and dated written requests for samples should be retained for not less than one year.

Clause 17.9 Control and Accountability

Companies should ensure that their systems of control and accountability relating to medicines held by representatives cover such matters as the security of delivery to them, the security of medicines held by them, the audit of stocks held by them, including expiry dates, and the return to the companies of medicines no longer to be held by representatives.

Clause 18

Items for Patients, Promotional Aids, the provision of Medical and Educational Goods and Services, Agreements to Benefit Patients such as Joint Working, Outcome Agreements and Patient Access Schemes

18.1 No gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to administrative staff in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 18.2 and 18.3.

18.2 Health professionals may be provided with items which are to be passed on to patients and which are part of a formal patient support programme, the details of which have been appropriately documented and certified in advance as required by Clause 14.3.

The items provided must be inexpensive and directly benefit patient care. They may bear the name of the company providing them. They must not be given out from exhibition stands. They must not be given to administrative staff unless they are to be passed on to a health professional.

18.3 Health professionals and appropriate administrative staff attending scientific meetings and conferences, promotional meetings and other such meetings may be provided with inexpensive notebooks, pens and pencils for use at such meetings. They must not bear the name of any medicine or any information about medicines but may bear the name of the company providing them.

18.4 Medical and educational goods and services which enhance patient care, or benefit the NHS and maintain patient care, can be provided subject to the provisions of Clause 18.1. They must not be provided to individuals for their personal benefit. Medical and educational goods and services must not bear the name of any medicine but may bear the name of the company providing them.

18.5 Joint working between one or more pharmaceutical companies and health authorities and trusts and the like is acceptable provided that this is carried out in a manner compatible with the Code. Joint working must always benefit patients.

A formal written agreement must be in place and an executive summary of the joint working agreement must be made publicly available before arrangements are implemented.

18.6 The provision of medical and educational goods and services in the form of donations, grants and benefits in kind to institutions, organisations or associations that are comprised of health professionals and/or that provide healthcare or conduct research (that are not otherwise covered by the Code) are only allowed if:

- they comply with Clause 18.4 or are made for the purpose of supporting research

- they are documented and kept on record by the company
- they do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

Pharmaceutical companies must make publicly available details of donations and grants provided in accordance with Clause 18.6.

18.7 Contracts between companies and institutions, organisations or associations of health professionals under which such institutions, organisations or associations provide any type of services on behalf of companies (or any other type of funding by the company not otherwise covered by the Code) are only allowed if such services (or other funding):

- comply with Clause 18.4 or are provided for the purpose of supporting research
- do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

Clause 18 Supplementary Information

Clause 18.1 Health Professionals' Codes of Conduct

The General Medical Council is the regulatory body for doctors and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance, the Council advises doctors that 'You must act in your patients' best interests when making referrals and when providing or arranging treatment or care. You must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect the way you prescribe for, treat or refer patients'.

The General Pharmaceutical Council is the regulatory body for pharmacists and pharmacy technicians. The Council's Standards of conduct, ethics and performance state 'Do not ask for or accept gifts, rewards or hospitality that may affect, or be seen to affect, your professional judgement'.

The Code of the Nursing & Midwifery Council, Standards of conduct, performance and ethics for nurses and midwives, states 'You must not abuse your privileged position for your own ends' and 'You must ensure that your professional judgement is not influenced by any commercial considerations'.

Clause 18.1 Terms of Trade

Measures or trade practices relating to prices, margins and discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 are outside the scope of the Code (see Clause 1.2) and are excluded from the provisions of this clause. Other trade practices are subject to the Code. The terms 'prices', 'margins' and 'discounts' are primarily financial terms.

Schemes which enable health professionals to obtain personal benefits, for example gift vouchers for high street stores, in relation to the purchase of medicines are unacceptable even if they are presented as alternatives to financial discounts.

Clause 18.1 Package Deals

Clause 18.1 does not prevent the offer of package deals whereby the purchaser of a particular medicine receives with it certain associated benefits, such as apparatus for administration, the provision of training on its use or the services of a nurse to administer it. The transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine involved.

Clause 18.1 Outcome or Risk Sharing Agreements

Clause 18.1 does not preclude the use of outcome or risk sharing agreements where a full or partial refund of the price paid for a medicine, or some other form of recompense, is due if the outcome of the use of the medicine in a patient fails to meet certain criteria. That is to say its therapeutic effect does not meet expectations. Clear criteria as to when a refund or other recompense would be due must be settled in advance and set out in the agreement. Any refund or recompense must always go to a health authority or trust and the like and never to individual health professionals or practices etc.

Clause 18.1 Patient Access Schemes

Patient access schemes are acceptable in principle under the Code but they must be carried out in conformity with its requirements.

The 2009 Pharmaceutical Price Regulation Scheme describes patient access schemes as schemes proposed by a pharmaceutical company and agreed with the Department of Health (with input from the National Institute for Health and Clinical Excellence) in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines.

Clause 18.1 Donations to Charities

Donations to charities made by companies in return for health professionals' attendance at company stands at meetings are not unacceptable under this clause provided that the level of donation for each individual is modest, the money is for a reputable charity and any action required of the health professional is not inappropriate. Any donation to a charity must not constitute a payment that would otherwise be unacceptable under the Code. For example, it would not be acceptable for a representative to pay into a practice equipment fund set up as a charity as this would be a financial inducement prohibited under Clause 18.1. Donations to charities in return for representatives gaining interviews are also prohibited under Clause 15.3.

Any offer by a company of a donation to a charity which is conditional upon some action by a health professional must not place undue pressure on the health professional to fulfil that condition. At all times the provisions of Clauses 2 and 9.1 must be kept in mind.

Clause 18.1 Payments to Individuals

Any payment to an individual for an activity that is ruled in breach of Clause 12.2 and/or Clause 20 is likely to be viewed as an unacceptable payment and thus in breach of Clause 18.1.

Clause 18.1 Long term or Permanent Loan

The requirements of Clause 18.1 cannot be avoided by providing health professionals or practices etc with items on long term or permanent loan. Such items will be regarded as gifts and subject to the requirements of this clause.

Clause 18.1 Competitions and Quizzes

The use of competitions, quizzes and suchlike, and the giving of prizes, are unacceptable methods of promotion.

This does not preclude the use at promotional meetings of quizzes which are intended to gauge attendees' knowledge of the subject matter of the meetings, provided that such quizzes are non-promotional in nature and are bona fide tests of skill that recognise the professional standing of the audience and no prizes are offered. To be acceptable a quiz must form part of the meeting's formal proceedings. Exhibition stands must not be included in any way in the conduct of a quiz.

Clause 18.1 Promotional Aids

A promotional aid is defined as a non-monetary gift made for a promotional purpose. Promotional aids may be given to health professionals and administrative staff only in accordance with Clause 18.3. Health professionals may, however, be provided with items which are to be passed on to patients in accordance with Clause 18.2.

Items to be passed on to patients may bear the name of a medicine and/or information about medicines only if such detail is essential for the proper use of the item by patients.

Items for the personal benefit of health professionals or administrative staff must not be offered or provided.

Many items given as promotional aids in the past are no longer acceptable. These include coffee mugs, stationery, computer accessories such as memory sticks, diaries, calendars and the like.

Items for use with patients in the clinic, surgery or treatment room etc are also no longer acceptable. These include surgical gloves, nail brushes, tongue depressors, tissues and the like.

Items such as toys and puzzles intended for children to play with may no longer be provided.

Items for use in the home or car remain unacceptable. Examples include table mats, coasters, clocks, desk thermometers, fire extinguishers, rugs, thermos flasks, coffee pots, tea pots, lamps, travel adaptors, toolboxes, umbrellas, neck cushions, plant seeds, road atlases and compact discs of music.

Pharmaceutical companies can no longer give diaries and desk pads etc to health professionals and appropriate administrative staff but there is nothing to prevent them being given by other parties which are not pharmaceutical companies. In the past these have sometimes carried advertisements for prescription medicines but this is now not acceptable. Advertisements for prescription medicines must not appear on any items which pharmaceutical companies could not themselves give.

Literature such as leaflets, booklets and textbooks about medicines and their uses, which is intended for patients, can be provided to health professionals for them to pass on. They are not considered to be promotional aids but they must comply with relevant requirements of the Code, in particular Clause 22 and its supplementary information. A story-book for young patients about a product or a disease could be provided for relevant patients.

Clause 18.1 DVDs

Clause 18.1 does not preclude the provision to health professionals and appropriate administrative staff of DVDs etc which bear educational or promotional material compliant with the Code, provided that they cannot be used by the recipient to store other data.

Clause 18.1 Memory Sticks

Clause 18.1 does not preclude the provision to health professionals and appropriate administrative staff of memory sticks which bear educational or promotional material compliant with the Code, provided that their storage capacity is commensurate with the amount of data to be stored.

Clause 18.1 Textbooks

Textbooks must not be given to health professionals as promotional aids. In appropriate circumstances independently produced medical/educational publications such as textbooks could be given for health professionals to use in accordance with Clause 18.4 – Provision of Medical and Educational Goods and Services – but they must not be given to individuals.

Clause 18.2 Patient Support Items

Although items which are to be passed on to patients may not be given out from exhibition stands, they may be exhibited and demonstrated on stands and requests for them accepted for later delivery.

Patient support items may be provided to health professionals by representatives during the course of a promotional call and representatives may deliver such items when they are requested by health professionals, for example on reply paid cards.

Examples of items which might be acceptable include a peak flow meter as part of a scheme for patients to regularly record readings or a pedometer as part of a scheme to encourage exercise, perhaps for obese patients.

Provided that they have been appropriately documented and certified in advance as required by Clause 14.3, in limited circumstances patient support items may be made available for the use of health professionals even though they are not to be passed on to patients for them to keep. This is where their purpose is to allow patients to gain experience in using their medicines whilst under the supervision of a health professional. Examples include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject.

An 'inexpensive' item means one that has cost the donor company no more than £6, excluding VAT. The perceived value to the health professional and the patient must be similar.

Clause 18.2 Items Given to Patients

Items which may be made available to patients, for example by completing a request card enclosed with a medicine, should be inexpensive and related to either the condition under treatment or general health. Care must be taken that any such activity meets all the requirements of the Code and in particular Clause 22.

No item for use by patients must be given for the purpose of encouraging patients to request a particular medicine.

Companies cannot run or sponsor competitions or quizzes for patients if prizes are offered to individuals. A competition for patients where the prizes were health related and were given to a clinic or similar might be acceptable.

Clause 18.3 Notebooks, Pens and Pencils

Notebooks, pens and pencils are the only items that can be provided to health professionals and administrative staff for them to keep and then only at bona fide meetings. They

cannot be provided, for example, by representatives when calling upon health professionals.

The total cost to the donor company of all such items provided to an individual person attending a meeting must not exceed £6, excluding VAT. The perceived value to the recipient must be similar.

Clause 18.4 Provision of Medical and Educational Goods and Services

Clauses 18.1 and 18.4 do not prevent the provision of medical and educational goods and services. In order to comply with the Code such goods and services must be in the interests of patients or benefit the NHS whilst maintaining patient care. They must not be provided to individuals for their personal benefit.

The requirement in Clause 18.4 that medical and educational goods must not bear the name of any medicine does not apply where the goods involved consist of independently produced textbooks or journals which include as part of their texts the names of medicines.

Medical and educational goods and services may bear a corporate name. The involvement of a pharmaceutical company in such activities must be made clear to relevant health professionals and/or administrative staff receiving the service. In addition the involvement of a pharmaceutical company in therapy review services should be made clear to patients. However, if there are no materials for patients this would be a matter for the relevant health professional. If there are materials for patients the requirements for declaration of sponsorship set out in Clause 9.10 would apply.

The following guidance is intended to assist companies in relation to medical and educational goods and services.

1(i) The role of medical/generic representatives in relation to the provision of goods and services supplied in accordance with Clauses 18.1 and 18.4 needs to be in accordance with the principles set out below. In this context companies should consider using staff other than medical/generic representatives.

(ii) If medical/generic representatives provide, deliver or demonstrate medical and educational goods and services then this must not be linked in any way to the promotion of products.

In order to comply with this stipulation the representative must not carry out both activities at the same visit. Representatives may introduce a service by means of a brief description and/or delivering materials but may not instigate a detailed discussion about the service at the same time as a call at which products are promoted.

If, during a promotional visit by a representative, a change in medication to one of the company's products is agreed, the representative may not then offer a therapy review service to facilitate the change as this would be seen as a way for the company to ensure that the agreed change would in fact be made.

(iii) The acceptability of the role of medical/generic representatives will depend on the nature of the goods and services provided and the method of provision.

(iv) The nature of the service provider, the person associated with the provision of medical and educational goods and services, is important ie is the service provider a medical/generic representative or is the service provider some other appropriately qualified person, such as a sponsored

registered nurse? If the goods and services require patient contact, for example either directly or by identification of patients from patient records and the like, then medical/generic representatives must not be involved. Only an appropriately qualified person, for example a sponsored registered nurse, not employed as a medical/generic representative, may undertake activities relating to patient contact and/or patient identification. Medical/generic representatives could provide administrative support in relation to the provision of a screening service, but must not be present during the actual screening and must not discuss or help interpret individual clinical findings.

(v) Neither the company nor its medical/generic representatives may be given access to data/records that could identify, or could be linked to, particular patients.

(vi) Sponsored health professionals should not be involved in the promotion of specific products. Registered nurses, midwives and health visitors are required to comply with the Nursing & Midwifery Council Code - Standards of conduct, performance and ethics for nurses and midwives.

2 The remuneration of those not employed as medical/generic representatives but who are sponsored or employed as service providers in relation to the provision of medical and educational goods and services must not be linked to sales in any particular territory or place or to sales of a specific product or products and, in particular, may not include a bonus scheme linked to such sales. Bonus schemes linked to a company's overall national performance, or to the level of service provided, may be acceptable.

3 Companies must ensure that patient confidentiality is maintained at all times and that data protection legislation is complied with.

4 Service providers must operate to detailed written instructions provided by the company. These should be similar to the briefing material for representatives as referred to in Clause 15.9. The written instructions should set out the role of the service provider and should cover patient confidentiality issues. Instructions on how the recipients are to be informed etc should be included. The written instructions must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

5 Service providers must abide by the principle set out in Clause 15.5 that in an interview, or when seeking an appointment, reasonable steps must be taken to ensure that they do not mislead as to their identity or that of the company they represent.

6 A recipient of a service must be provided with a written protocol to avoid misunderstandings as to what the recipient has agreed. The identity of the sponsoring pharmaceutical company must be given. For example, a general practitioner allowing a sponsored registered nurse access to patient records should be informed in writing of any data to be extracted and the use to which those data will be put.

7 Any printed material designed for use in relation to the provision of medical and educational goods and services must be non-promotional. It is not acceptable for such materials to promote the prescription, supply, sale or administration of the sponsoring company's medicines. Nor is it acceptable for materials to criticise competitor products as this might be seen as promotional. All printed materials must identify the sponsoring pharmaceutical company.

8 Material relating to the provision of medical and educational goods and services, such as internal instructions, external instructions, the written protocol for recipients and other printed material, including material relating to therapy reviews, etc, must be certified by the Code of Practice signatories within companies to ensure that the requirements of the Code are met as required by Clause 14.3.

A copy of the materials must be made available to the Prescription Medicines Code of Practice Authority on request.

9 Companies are recommended to inform relevant parties such as NHS trusts, health authorities, health boards and primary care organisations of their activities where appropriate. This is particularly recommended where companies are proposing to provide medical and educational goods and services which would have budgetary implications for the parties involved. For example the provision of a screening service for a limited period might mean that funds would have to be found in the future when company sponsorship stopped. Another example might be the provision of diagnostic or laboratory services and the like, which the NHS trust, health authority, health board or primary care organisation would normally be expected to provide.

Clause 18.4 Switch and Therapy Review Programmes

Clauses 18.1 and 18.4 prohibit switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine is simply changed to another. For example it would be unacceptable if patients on medicine A were changed to medicine B, without any clinical assessment, at the expense of a pharmaceutical company promoting either or both medicines. It would be acceptable for a company to promote a simple switch from one product to another but not to assist a health professional in implementing that switch even if assistance was by means of a third party such as a sponsored nurse or similar. Such arrangements are seen as companies in effect paying for prescriptions and are unacceptable.

A therapeutic review is different to a switch service. A therapeutic review which aims to ensure that patients receive optimal treatment following a clinical assessment is a legitimate activity for a pharmaceutical company to support and/or assist. The result of such clinical assessments might require, among other things, possible changes of treatment including changes of dose or medicine or cessation of treatment. A genuine therapeutic review should include a comprehensive range of relevant treatment choices, including non-medicinal choices, for the health professional and should not be limited to the medicines of the sponsoring pharmaceutical company. The arrangements for therapeutic review must enhance patient care, or benefit the NHS and maintain patient care, and must otherwise be in accordance with Clause 18.4 and the supplementary information on the provision of medical and educational goods and services. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational grounds.

Clause 18.5 Joint Working

The Department of Health defines joint working between the NHS and the pharmaceutical industry as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or

resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery.

Each party must make a significant contribution and the outcomes must be measured. Treatments must be in line with nationally accepted clinical guidance where such exists. Joint working between the pharmaceutical industry and the NHS must be conducted in an open and transparent manner. Joint working must be for the benefit of patients but it is expected that the arrangements will also benefit the NHS and the pharmaceutical company or companies involved. Joint working differs from the situation where pharmaceutical companies simply provide funds for a specific event or programme.

The Department of Health has issued Best practice guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations. The Department of Health and the ABPI have jointly issued Moving beyond sponsorship: interactive toolkit for joint working between the NHS and the pharmaceutical industry.

The ABPI has produced guidance notes on joint working between pharmaceutical companies and the NHS and others for the benefit of patients. The ABPI Guidance refers to the requirements of the Code but goes well beyond them.

When considering joint working, companies should take account of the guidance which has been issued by the ABPI and the Department of Health. Joint working is acceptable in principle provided that it is carried out in conformity with the Code. In particular, it must not constitute an inducement to health professionals or administrative staff to prescribe, supply, recommend, buy or sell any medicine. It must therefore always be ensured that any and all of the benefits of joint working which are due to the NHS, go not to individuals or practices but to a health authority or trust and the like.

A joint working agreement can be based on the use by a health authority or trust etc of a particular medicine of a company party to the agreement, but only if the requirements below are complied with and only if the parties have satisfied themselves that the use of the medicine will enhance patient care. Goods and services provided by the company as part of the joint working agreement must be relevant to the medicines involved and the agreement as a whole must be fair and reasonable. Any goods and services provided by the company must themselves contribute to patient care.

The written agreement must cover the following points:

- the name of the joint working project, the parties to the agreement, the date and the term of the agreement
- the expected benefits for patients, the NHS and the pharmaceutical company; patient benefits should always be stated first and patient outcomes should be measured
- an outline of the financial arrangements
- the roles and responsibilities of the NHS and the pharmaceutical company and how the success of the project will be measured, when and by whom; all aspects of input should be included
- the planned publication of any data or outcomes
- if a pharmaceutical company enters into a joint working agreement on the basis that its product is already included in an appropriate place on the local formulary, a clear reference to this should be included in the joint working agreement so that all the parties are clear as to what has been agreed

- contingency arrangements to cover possible unforeseen circumstances such as changes to summaries of product characteristics and updated clinical guidance; agreements should include a dispute resolution clause and disengagement/exit criteria including an acknowledgement by the parties that the project might need to be amended or stopped if a breach of the Code is ruled
- publication by the company of an executive summary of the joint working agreement, for example on a clearly defined website or section of a website, such as on the company's or companies' website; the NHS organisation should also be encouraged to publish this.

The requirement to make the executive summary public applies to joint working projects started on or after 1 May 2011 or ongoing on that date.

Attention is drawn to the certification requirements set out in Clause 14.3 which apply to material prepared in relation to joint working including the joint working agreement.

Clause 18.6 is relevant to a joint working agreement between a pharmaceutical company and the NHS which does not involve the use and purchase of any of the company's medicines.

Although the ABPI Guidance is aimed principally at joint working between pharmaceutical companies and the NHS, it also covers joint working conducted through third party service providers and/or with suppliers of private healthcare.

More detail as to the requirements for joint working is provided in the ABPI Guidance which should be consulted when joint working is contemplated.

Joint working should be distinguished from straightforward sales where medicines are simply sold and there are no accompanying goods and services etc and from package deals and outcome or risk sharing agreements as defined in the supplementary information to Clause 18.1.

Clause 18.6 Donations, Grants and Benefits in Kind

Donations and grants to individual health professionals are not covered by this clause. Company sponsorship of health professionals to attend events is covered by Clause 19.

Details of each grant or donation must be disclosed, giving in each case the financial amount or value and the name of the recipient institution, organisation or association. Companies are also encouraged to ask recipients to make such funding public.

The information required by Clause 18.6 must be made publicly available in respect of donations and grants made in 2012 and each calendar year thereafter. Disclosure must be in the calendar year following that in which donations and grants were provided and the information must be made public within three calendar months of the end of the company's financial year.

All reasonable steps should be taken by the local operating company to similarly disclose donations and grants provided by overseas affiliates, head offices in the UK or overseas and UK based European offices.

Companies are encouraged to make publicly available information about benefits in kind provided by them which are covered by Clause 18.6.

Clause 19

Meetings, Hospitality and Sponsorship

19.1 Companies must not provide hospitality to members of the health professions and appropriate administrative staff except in association with scientific meetings, promotional meetings, scientific congresses and other such meetings, and training. Meetings must be held in appropriate venues conducive to the main purpose of the event. Hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting ie subsistence only. The level of subsistence offered must be appropriate and not out of proportion to the occasion. The costs involved must not exceed that level which the recipients would normally adopt when paying for themselves. It must not extend beyond members of the health professions or appropriate administrative staff.

19.2 Payments may not be made to doctors or groups of doctors or to other prescribers, either directly or indirectly, for rental for rooms to be used for meetings.

19.3 When meetings are sponsored by pharmaceutical companies, that fact must be disclosed in all of the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

19.4 Pharmaceutical companies must make publicly available financial details of sponsorship of UK health professionals and appropriate administrative staff in relation to attendance at meetings organised by third parties. Sponsorship in this context includes registration fees, costs of accommodation (both inside and outside the UK) and travel outside the UK.

Clause 19 Supplementary Information

Clause 19.1 Meetings and Hospitality

The provision of hospitality is limited to refreshments/subsistence (meals and drinks), accommodation, genuine registration fees and the payment of reasonable travel costs which a company may provide to sponsor a delegate to attend a meeting. The payment of travel expenses and the like for persons accompanying the delegate is not permitted. Funding must not be offered or provided to compensate merely for the time spent by health professionals in attending meetings. The payment of reasonable honoraria and reimbursement of out of pocket expenses, including travel, for speakers, advisory board members and the providers of other professional services, is permissible. The arrangements for meetings must comply with Clause 19.1 with regard to hospitality and venues.

Companies should only offer or provide economy air travel to delegates sponsored to attend meetings. Delegates may of course organise and pay at their own expense the genuine difference between economy travel and business class or first class.

Pharmaceutical companies may appropriately hold or sponsor a wide range of meetings. These range from small lunchtime audio-visual presentations in a group practice, hospital meetings and meetings at postgraduate education centres, advisory board meetings, visits to research and manufacturing facilities, planning, training and investigator meetings for clinical trials and non-interventional studies, launch meetings for new products, management training courses, patient support group meetings and satellite symposia through to large international meetings organised by independent bodies with sponsorship from pharmaceutical companies.

With any meeting, certain basic principles apply:

- *the meeting must have a clear educational content*
- *the venue must be appropriate and conducive to the main purpose of the meeting; lavish, extravagant or deluxe venues must not be used, companies must not sponsor or organise entertainment (such as sporting or leisure events) and companies should avoid using venues that are renowned for their entertainment facilities*
- *the subsistence associated with the meeting must be secondary to the nature of the meeting, must be appropriate and not out of proportion to the occasion*
- *any hospitality provided must not extend to a spouse or other such person unless that person is a member of the health professions or appropriate administrative staff and qualifies as a proper delegate or participant at the meeting in their own right*
- *spouses and other accompanying persons, unless qualified as above, may not attend the actual meeting and may not receive any associated hospitality at the company's expense; the entire costs which their presence involves are the responsibility of those they accompany.*

Administrative staff may be invited to meetings where appropriate. For example, receptionists might be invited to a meeting in a general practice when the subject matter related to practice administration.

A useful criterion in determining whether the arrangements for any meeting are acceptable is to apply the question 'would you and your company be willing to have these arrangements generally known?' The impression that is created by the arrangements for any meeting must always be kept in mind.

Meetings organised for groups of doctors, other health professionals and/or for administrative staff which are wholly or mainly of a social or sporting nature are unacceptable.

Meetings organised by pharmaceutical companies which involve UK health professionals at venues outside the UK are not necessarily unacceptable. There have, however, to be valid and cogent reasons for holding meetings at such venues. These are that most of the invitees are from outside the UK and, given their countries of origin, it makes greater logistical sense to hold the meeting outside the UK or, given the location of the relevant resource or expertise that is the object or subject matter of the meeting, it makes greater logistical sense to hold the meeting outside the UK. As with meetings held in the UK, in determining whether such a meeting is acceptable or not, consideration must also be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, subsistence provided and the like. As with any meeting it should be the programme that attracts delegates and not the associated hospitality or venue.

Promotional material which is displayed or provided at international meetings held outside the UK may, unless prohibited or otherwise regulated by local laws and regulations, refer to medicines or their indications which are not registered in the country where the event takes place, or which are registered under different conditions, so long as any such material is accompanied by a suitable statement indicating countries where the product is registered and making clear that the product is not registered locally. Any such promotional material which refers to the prescribing information authorized in a country or countries where the medicine is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally.

The requirements relating to international meetings held in the UK are set out in the supplementary information to Clause 3.

The requirements of the Code do not apply to the provision of hospitality other than to that referred to in Clauses 19.1 and 23.2 and the supplementary information to Clauses 20 and 22.2.

Clause 19.1 Meetings Organised by Affiliates Outside the UK

Companies should remind their affiliates outside the UK that the ABPI Code of Practice must be complied with if UK health professionals attend meetings which they organise regardless of whether such meetings occur in the UK or abroad.

Clause 19.1 Certification of Meetings

Pharmaceutical companies must ensure that all meetings which are planned are checked to see that they comply with the Code. Companies must have a written document that sets out their policies on meetings and hospitality and the associated allowable expenditure. In addition, meetings which involve travel outside the UK must be formally certified as set out in Clause 14.2.

Clause 19.1 Health Professionals' Codes of Conduct

The General Medical Council is the regulatory body for doctors and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance, the Council advises doctors that 'You must act in your patients' best interests when making referrals and when providing or arranging treatment or care. You must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect the way you prescribe for, treat or refer patients'.

The General Pharmaceutical Council is the regulatory body for pharmacists and pharmacy technicians. The Council's Standards of conduct, ethics and performance state 'Do not ask for or accept gifts, rewards or hospitality that may affect, or be seen to affect, your professional judgement'.

The Code of the Nursing & Midwifery Council, Standards of conduct, performance and ethics for nurses and midwives, states 'You must not abuse your privileged position for your own ends' and 'You must ensure that your professional judgement is not influenced by any commercial considerations'.

Clause 19.1 Continuing Professional Development (CPD) Meetings and Courses

The provisions of this and all other relevant clauses in the Code apply equally to meetings and courses organised or sponsored by pharmaceutical companies which are continuing professional development (CPD) approved, such as postgraduate education allowance (PGEA) approved meetings and courses. The fact that a meeting or course has CPD approval does not mean that the arrangements are automatically acceptable under the Code. The relevant provisions of the Code and, in particular, those relating to hospitality, must be observed.

Clause 19.2 Payment of Room Rental

This provision does not preclude the payment of room rental to postgraduate medical centres and the like.

Payment of room rental to doctors or groups of doctors or to other prescribers is not permissible even if such payment is made to equipment funds or patients' comforts funds and the like or to charities or companies.

Clause 19.3 Sponsorship and Reports of Meetings

Attention is drawn to Clause 9.10 which requires that all material relating to medicines and their uses, whether promotional or not, which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company.

It should be noted that where companies are involved in the sponsorship and/or distribution of reports on meetings or symposia etc, these reports may constitute promotional material and thus be fully subject to the requirements of the Code.

Clause 19.4 Sponsorship of Attendance

Meetings at which attendance is sponsored by companies must comply with Clause 19.1. The information required by Clause 19.4 must be made publicly available in respect of sponsorship for attendance at meetings held in 2012 and each calendar year thereafter. Disclosure must be in the calendar year following that in which the payments were made and the information must be made public within three calendar months of the end of the company's financial year.

The information which must be disclosed is the total amount paid in a calendar year in respect of all recipients and the total number of recipients. The total number of attendances at meetings sponsored in the year must also be given. The names of the recipients need not be disclosed.

Registration fees have to be included where the sponsorship of UK health professionals and appropriate administrative staff to attend meetings is paid by overseas affiliates, head offices in the UK or overseas and UK based European offices.

All reasonable steps should be taken by local operating companies to disclose their best estimates of the amounts for accommodation costs (both inside and outside the UK) and travel outside the UK for UK health professionals and appropriate administrative staff paid by overseas affiliates, head offices in the UK or overseas and UK based European offices.

Clause 20

The Use of Consultants

20.1 Health professionals and appropriate administrative staff may be used as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel. The arrangements which cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services
- a legitimate need for the services must be clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants
- the criteria for selecting consultants must be directly related to the identified need and the persons responsible for selecting the consultants must have the expertise necessary to evaluate whether the particular consultants meet those criteria
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need
- the contracting company must maintain records concerning, and make appropriate use of, the services provided by consultants
- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine
- the compensation for the services must be reasonable and reflect the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating health professionals and appropriate administrative staff
- in their written contracts or agreements with consultants, companies must include provisions regarding the obligation of the consultant to declare that he/she is a consultant to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, companies that employ, on a part-time basis, health professionals that are still practising their profession must ensure that such persons are obliged to declare their employment arrangement with the company whenever they write or speak in public about a matter that is the subject of the employment or any other issue relating to that company.

20.2 Pharmaceutical companies must make publicly available details of the fees paid to consultants in the UK, or to their employers on their behalf, for certain services rendered by them such as chairing and speaking at meetings, assistance with training and participation in advisory boards etc. It does not include payments to consultants in relation to research and development work, including the conduct of clinical trials. Nor does it include payment of UK travel costs or the cost of subsistence in relation to fees for services which are dealt with in Clause 20.3.

20.3 In addition to the information required to be made public by Clause 20.2, companies must make publicly available details of payments made to consultants in relation to market research (unless the company concerned is not aware of the identities of those participating in the market research) and payments in respect of accommodation (both in and outside the UK) and travel outside the UK in relation to fees for services as defined in Clause 20.2.

20.4 Fees, expenses and the like due to consultants in relation to Clauses 20.2 and 20.3 must be declared whether paid directly to them or to their employers or to companies or charities etc.

Clause 20 Supplementary Information

Clause 20 The Use of Consultants

The term 'consultant' in Clause 20 covers any health professional or administrative staff member consulted for the purposes described in Clause 20 regardless of their normal roles.

The administrative staff members covered by Clause 20 are those who could influence in any way the prescription, supply, administration, recommendation, purchase or sale of any medicine.

Clause 20 Patient Organisations

The provision of services to pharmaceutical companies by patient organisations is covered by Clause 23.8.

Clause 20.1 The Use of Consultants

The requirement that contracts or agreements with consultants must include provisions regarding their obligation to declare the arrangement whenever they write or speak in public applies to contracts entered into or renewed on or after 1 May 2011. Companies are encouraged to renegotiate existing contracts to include such provisions at their earliest convenience.

Limited market research, such as one-off telephone interviews or mail/email/Internet questionnaires is excluded from the scope of Clause 20.1, provided that the consultant is not consulted in a recurring manner (either with respect to the frequency of the calls generally or of calls relating to the same research) and that the remuneration is minimal. Following implementation of Clause 20.3 payments made in relation to this limited market research must be made publicly available in accordance with that clause.

If health professionals or appropriate administrative staff attend events in a consultant or advisory capacity the relevant provisions of Clause 19 apply.

Clause 20.2 Disclosure

The information required by Clause 20.2 must be made publicly available in respect of payments made to UK consultants in 2012 and each calendar year thereafter. Disclosure must be in the calendar year following that in which the payments were made and the information must be made public within three calendar months of the end of the company's financial year.

The information which must be disclosed is the total amount paid in a calendar year to all of the consultants who have provided services. The total number of consultants must be given. The names of the consultants need not be disclosed. Companies may of course give greater detail, for example by giving separate figures for different categories of service or by providing details of the maximum and minimum payments etc.

All reasonable steps should be taken by local operating companies to similarly disclose their best estimates of fees paid to UK consultants by overseas affiliates, head offices in the UK or overseas and UK based European offices.

Clause 20.3 Disclosure

Clause 20.3 relates only to market research using consultants whose identity is known to the pharmaceutical company. This is because the focus of the requirements concerning transparency is on areas where there are direct relationships between the parties and that is not so where the company does not know the identity of the participants. The names of the consultants need not be disclosed.

The information required by Clause 20.3 in respect of payments made to UK consultants in 2013 and each calendar year thereafter must be made publicly available by including it in the fees for service declaration required by Clause 20.2 and its supplementary information.

Clause 21

Scientific Services

21.1 Companies must have a scientific service to compile and collate all information, whether received from medical representatives or from any other source, about the medicines which they market.

21.2 Companies must also have a scientific service to deal with the approval and supervision of non-interventional studies. This scientific service must include a registered medical practitioner or, where appropriate, a pharmacist, who will be responsible for the oversight of non-interventional studies (including the review of any responsibilities relating to such studies, particularly those given to medical representatives). That person must state in writing that he or she has examined the protocol relating to the non-interventional study and that in his or her belief it is in accordance with the requirements of the Code.

21.3 Companies must disclose details of clinical trials in accordance with the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature..

Clause 21 Supplementary Information

Clauses 21.1 and 21.2 Scientific Services

Companies are free to decide whether there is one scientific service in charge of both responsibilities or separate services with clearly delineated duties.

Clause 14 does not apply to the examination of non-interventional studies.

Clause 21.3 Details of Clinical Trials

This clause requires the provision of details about ongoing clinical trials (which must be registered within 21 days of initiation of patients enrolment) and completed trials for medicines licensed for use in at least one country. Further information can be found in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases 2009 and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature 2010, both at <http://clinicaltrials.ifpma.org>.

Details about clinical trials must be limited to factual and non-promotional information. Such information must not constitute promotion to health professionals, appropriate administrative staff or the public.

Clause 22

Relations with the Public and the Media

22.1 Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination campaigns carried out by companies and approved by the health ministers.

22.2 Information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product.

Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

22.3 Requests from individual members of the public for advice on personal medical matters must be refused and the enquirer recommended to consult his or her own doctor or other prescriber or other health professional.

22.4 The introduction of a new medicine must not be made known to the public until reasonable steps have been taken to inform the medical and pharmaceutical professions of its availability.

22.5 Companies are responsible for information about their products which is issued by their public relations agencies.

Clause 22 Supplementary Information

Clause 22.1 Advertising of Medicines to the Public

The advertising of prescription only medicines to the public is also prohibited by the relevant regulations relating to advertising.

The promotion of medicines to the public for self medication purposes is covered by the Consumer Code of the Proprietary Association of Great Britain (PAGB).

Clause 22.2 Information to the Public

This clause allows for the provision of non-promotional information about prescription only medicines to the public either in response to a direct enquiry from an individual, including enquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities and the like. It also includes information provided by means of posters distributed for display in surgery waiting rooms etc and reference information made available by companies on their websites or otherwise as a resource for members of the public.

Any information so provided must observe the principles set out in this clause; that is, it should be factual, balanced and must not be made for the purpose of encouraging members of the public to ask their doctors or other prescribers to prescribe a specific prescription only medicine. It must not constitute the advertising of prescription only medicines to the public prohibited under Clause 22.1. The provisions of Clause 22.3 must be observed if an enquiry is from an individual member of the public.

Information to the public falls into one of three categories depending on its purpose, how it is supplied and how the public is made aware of the information.

Proactive information is supplied to the public without a direct request. This includes booklets on diseases and/or medicines supplied directly or via a health professional, press releases, briefings, conferences, mailings to patient organisations and disease awareness advertising.

Reference information is intended to provide a comprehensive up-to-date resource that companies should make available on their websites or by way of a link from their website or by some other means. The primary purpose of reference information is to be a library resource for members of the public giving information relating to prescription only medicines which have marketing authorizations. Pharmaceutical companies are not obliged to provide reference information but it is considered good practice to provide as a minimum the regulatory information comprising the summary of product characteristics (SPC), the package information leaflet (PIL) and the public assessment report (PAR) (UK or European) where such a document exists. Reference information may also include the registration studies used for marketing authorization applications and variations and any other studies published or not including those referred to in the SPC, PIL, EPAR or UKPAR or available on clinical trial databases. Reference information may also include material supplied for health technology assessments to bodies such as the National Institute for Health and Clinical Excellence (NICE), the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC).

Reference information may also include medicine guides where available, studies (published or not), information about diseases and information about specific medicines etc.

Where companies decide to make reference information available this must represent fairly the current body of evidence relating to a medicine and its benefit/risk profile.

Reactive information is supplied to the public in response to a direct request and must be limited to that information necessary to respond to the request.

It is good practice to include the summary of product characteristics with a press release or press pack relating to a medicine. Companies should also consider including references to other credible sources of information about a condition or a medicine.

Particular care must be taken in responding to approaches from the media to ensure that the provisions of this clause are upheld.

In the event of a complaint which relates to the provisions of this clause, companies will be asked to provide copies of any information supplied, including copies of any relevant press releases and the like. This information will be assessed to determine whether it fulfils the requirements of this clause.

Public assessment reports (European or UK), summaries of product characteristics and package leaflets may be provided to members of the public on request.

Companies may provide members of the health professions with leaflets concerning a medicine with a view to their provision to patients to whom the medicine has already been prescribed, provided that such a leaflet is factual and non-promotional in nature.

A company may conduct a disease awareness or public health campaign provided that the purpose is to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine. The use of brand or non-proprietary names and/or restricting the range of

treatments described in the campaign might be likely to lead to the use of a specific medicine. Particular care must be taken where the company's product, even though not named, is the only medicine relevant to the disease or symptoms in question.

Attention is drawn to the Disease Awareness Campaigns Guidelines produced by the Medicines and Healthcare products Regulatory Agency.

The requirements of Clause 7 relating to information (Clauses 7.2, 7.4, 7.5, 7.8, 7.9, 7.10 and 7.11) also apply to information to the public.

Meetings organised for or attended by members of the public, journalists and patient organisations must comply with Clause 19.

Items for patients or for use by patients are covered in Clause 18.2. and its supplementary information.

Clause 22.2 Financial Information

Information made available in order to inform shareholders, the Stock Exchange and the like by way of annual reports and announcements etc may relate to both existing medicines and those not yet marketed. Such information must be factual and presented in a balanced way. Business press releases should identify the business importance of the information.

Clause 22.2 Information to Current or Prospective Employees

Information about pharmaceutical companies provided to current or prospective employees may relate to both existing medicines and those not yet marketed. Such information must be factual and presented in a balanced way.

Clause 22.2 Approval of Information

Information on medicines made available under this clause other than responses from medical information departments or similar to unsolicited enquiries from the public must be certified in advance as required by Clause 14.3.

Clause 22.2 Health Technology Assessments

Companies may supply information to relevant patient

organisations, the public or patients in relation to forthcoming health technology assessments by public national organisations such as NICE, AWMSG or SMC, provided the information is accurate, not misleading, not promotional in nature and otherwise complies with Clause 22.2.

Clause 22.3 Requests for Information or Advice on Personal Medical Matters

This clause prohibits the provision of advice on personal medical matters to individual members of the public requesting it. The intention behind this prohibition is to ensure that companies do not intervene in the patient/doctor or patient/prescriber relationship by offering advice or information which properly should be in the domain of the doctor or other prescriber.

Pharmaceutical companies can provide information appropriate to support the use of medicines and enhance patient welfare. Emergency advice, for example action needed in the event of an overdose, can be provided. Other information may also be given, including information on medicines prescribed for the enquirer, provided that it complies with the requirements of Clauses 22.1 and 22.2 and does not impinge on the principle behind this clause. For example, answering requests from members of the public as to whether a particular medicine contains sucrose or some other inactive ingredient, or whether there would be problems associated with drinking alcohol whilst taking the medicine or whether the medicine should be taken before or after a meal, is acceptable. Particular care needs to be taken with regard to enquiries relating to side-effects, the indications for a medicine and suchlike.

All requests from members of the public must be handled with great care and a company should refer the enquirer to other sources where appropriate. These might include health professionals, NHS Direct and patient organisations, etc.

A request from a patient for information may in some instances best be handled by passing the information to the patient's doctor or other prescriber for discussion with them rather than providing the information direct to the patient concerned. This should not be done without the patient's consent.

Clause 23

Relationships with Patient Organisations

23.1 Pharmaceutical companies can interact with patient organisations or any user organisation such as disability organisations, carer or relative organisations and consumer organisations to support their work, including assistance in the provision of appropriate information to the public, patients and carers.

Companies must respect the independence of patient organisations.

23.2 When working with patient organisations, companies must ensure that the involvement of the company is made clear and that all of the arrangements comply with the Code. This includes the need to declare sponsorship (Clause 23.9) and the prohibition on advertising prescription only medicines to the public (Clause 22.1). The requirements of Clause 19, which covers meetings for health professionals and appropriate administrative staff, also apply to pharmaceutical companies supporting patient organisation meetings.

23.3 Companies working with patient organisations must have in place a written agreement setting out exactly what has been agreed, including funding, in relation to every significant activity or ongoing relationship.

23.4 No company may require that it be the sole funder of a patient organisation or any of its programmes.

23.5 A company must not make public use of a patient organisation's logo or proprietary material without the organisation's written agreement. In seeking such permission, the specific purpose and the way in which the logo or material will be used must be clearly stated.

23.6 A company must not seek to influence the text of patient organisation material in a manner favourable to its own commercial interests. This does not preclude a company from correcting factual inaccuracies.

23.7 Each company must make publicly available, at a national or European level, a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support, which must include a description of the nature of the support that is sufficiently complete to enable the average reader to form an

understanding of the significance of the support. The list of organisations being given support must be updated at least once a year.

The published information must include the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organisation receives.

23.8 Contracts between companies and patient organisations under which they provide any type of services to companies are only allowed if such services are provided for the purpose of supporting healthcare or research.

Patient organisations may be engaged as experts and advisors for services such as participation at advisory board meetings and speaker services. The arrangements that cover consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services
- a legitimate need for the services must be clearly identified and documented in advance of requesting the services and entering into the arrangements
- the criteria for selecting services must be directly related to the identified need and the persons responsible for selecting the service must have the expertise necessary to evaluate whether the particular experts and advisors meet those criteria
- the extent of the service must not be greater than is reasonably necessary to achieve the identified need
- the contracting company must maintain records concerning, and make appropriate use of, the services
- the engaging of patient organisations must not be an inducement to recommend a particular medicine
- the compensation for the services must be reasonable and not exceed the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating patient organisations
- in their written contracts with patient organisations, companies are strongly encouraged to include provisions regarding an obligation of the patient organisation to declare that they have provided paid services to the company whenever those concerned write or speak in public about a matter that is the subject of the agreement or any other issue relating to that company
- each company must make publicly available, at a national or European level, a list of patient organisations that it has engaged to provide significant contracted services, which must include a description of the nature of the services provided that is sufficiently complete to enable the average reader to form an understanding of the arrangement without the necessity to divulge confidential information. Companies must also make publicly available the total

amount paid per patient organisation over the reporting period. The list of organisations engaged must be updated at least once a year.

23.9 Companies must ensure that their sponsorship is always clearly acknowledged from the outset. The wording of the declaration of sponsorship must accurately reflect the nature of the company's involvement.

Clause 23 Supplementary Information

Clause 23.1 Other Codes and Guidelines

There are other codes and guidelines which cover patient groups, including Long-term Conditions Alliance guidelines and Charity Commission requirements etc.

Clause 23.2 Purpose of Materials and Activities

Companies should take into account the purpose of materials and/or activities. The purpose of information supplied to a patient organisation must be made clear. For example, there is a difference between providing information to be supplied to the members of a patient organisation and providing background information to enable a patient organisation to respond to a health technology assessment or similar.

Clause 23.2 Hospitality for Carers

Although the requirements in Clause 19 relating to the provision of hospitality at meetings apply where pharmaceutical companies support patient organisation meetings and their representatives, in exceptional circumstances, in the case of clear health needs such as disability, companies can pay for subsistence, accommodation, genuine registration fees and reasonable travel costs for an accompanying carer.

Clause 23.3 Written Agreements

The written agreement must include:

- the name of the activity
- the names of the organisations involved (pharmaceutical company, patient organisations and any third parties which will be brought in to help)
- the type of activity (eg unrestricted grant, specific meeting or publication etc)
- the objectives
- the respective roles of the company and the patient organisation
- the time-frame
- the amount of funding
- a description of significant indirect/non-financial support (eg the donation of public relations agency time or free training courses)
- a statement that all parties are fully aware that sponsorship must be clearly acknowledged and apparent from the start
- the code or codes of practice which will apply
- the signatories to the agreement
- the date of the agreement.

Attention is drawn to the certification requirements as set out in Clause 14.3.

Clause 23.5 Use of Patient Organisation Logos or Material

Even with the organisation's permission the use of its logo or material must not be such as to otherwise breach the Code.

Clause 23.7 Date of Implementation

A list of patient organisations including the monetary value of support regardless of its level must be made publicly available by the end of the first quarter of 2013 and cover activities commenced on or after 1 January 2012 or ongoing on that date.

Until that information is made publicly available, the requirements for disclosure set out in Clause 23.7 of the 2011 Code of Practice and its supplementary information remain applicable.

Clause 23.7 Further Information

An indication of the patient organisation's total income and/or the company's support as a percentage of the patient organisation's total income may be given. Neither is obligatory.

Companies are encouraged to be prepared to make available up-to-date information about such activities at any time in response to enquiries.

Clause 23.8 Date of Implementation

A list of patient organisations that have been engaged to provide significant contracted services must be published for the first time by the end of the first quarter of 2013 and cover activities commenced on or after 1 January 2012 or ongoing on that date.

Clause 24

The Internet

24.1 Promotional material about prescription only medicines directed to a UK audience which is provided on the Internet must comply with all relevant requirements of the Code.

24.2 Information or promotional material about medicines covered by Clause 24.1 above which is placed on the Internet outside the UK will be regarded as coming within the scope of the Code if it was placed there by a UK company or an affiliate of a UK company or at the instigation or with the authority of such a company and it makes specific reference to the availability or use of the medicine in the UK.

24.3 Information about medicines covered by Clauses 24.1 and 24.2 above which is provided on the Internet and which is intended for members of the public must comply with Clause 22.2.

24.4 A medicine covered by Clause 24.1 above may be advertised in a relevant independently produced electronic journal intended for health professionals or appropriate administrative staff which can be accessed by members of the public.

24.5 Public assessment reports (European or UK), summaries of product characteristics, package leaflets and reference material for prescription only medicines may be included on the Internet and be accessible by members of the public provided that they are not presented in such a way as to be promotional in nature.

24.6 It should be made clear when a user is leaving any of the company's sites, or sites sponsored by the company, or is being directed to a site which is not that of the company.

Clause 24 Supplementary Information

Clause 24.1 Access

Unless access to promotional material about prescription only medicines is limited to health professionals and appropriate administrative staff, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This is to avoid the public needing to access material for health professionals unless they choose to. The MHRA Blue Guide states that the public should not be encouraged to access material which is not intended for them.

Clause 24.4 Advertisements in Electronic Journals

It should be noted that the MHRA Blue Guide states that each page of an advertisement for a prescription only medicine should be clearly labelled as intended for health professionals.

Clause 24.5 MHRA Guidance

The MHRA Blue Guide states that the public should not need to access non-UK websites or non-UK parts of websites to obtain basic information about a company's products, such as patient information leaflets, summaries of product characteristics, public assessment reports and other non promotional material. It is good practice for each page of a company website to include a statement identifying the intended audience.

Clause 24.5 Information on Clinical Trials

Information on clinical trials as agreed in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases 2009 may be available at a UK or a non UK website.

Clause 24.6 Sites Linked via Company Sites

Sites linked via company sites are not necessarily covered by the Code.

Clause 25

Compliance with Undertakings

When an undertaking has been given in relation to a ruling under the Code, the company concerned must ensure that it complies with that undertaking.

PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

Constitution and Procedure

	Page
Introduction	40
Structure and Responsibilities	
1 Prescription Medicines Code of Practice Authority	40
2 Code of Practice Panel – Constitution and Procedure	40
3 Code of Practice Appeal Board – Constitution	42
4 Code of Practice Appeal Board – Procedure	42
Complaints Procedure	
5 Action on Complaints	43
6 Complaints Arising from Media Criticism	44
7 Code of Practice Panel – Rulings	45
8 Code of Practice Panel – Reports to the Code of Practice Appeal Board	46
9 Action on Complaints about Safety from the Medicines and Healthcare products Regulatory Agency	47
10 Code of Practice Appeal Board – Rulings	47
11 Reports to the Code of Practice Appeal Board	47
12 Code of Practice Appeal Board – Reports to the ABPI Board of Management	48
13 Case Reports	48
General Provisions	
14 Time Periods for Responding to Matters under the Code	49
15 Withdrawal of Complaints and Notices of Appeal	49
16 Code of Practice Levy and Charges	49
17 Scrutiny	49
18 Provision of Advice and Assistance with Conciliation	50
19 Amendments to the Code of Practice and Constitution and Procedure	50
20 Annual Report	50

PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY CONSTITUTION AND PROCEDURE

Operative on 1 January 2012.

INTRODUCTION

The Code of Practice for the Pharmaceutical Industry is administered by the Prescription Medicines Code of Practice Authority. The Authority is responsible for the provision of advice, guidance and training on the Code as well as for the complaints procedure. It is also responsible for arranging for conciliation between companies when requested to do so and for arranging for the scrutiny of advertising and meetings on a regular basis.

The Authority is not an investigatory body as such. It asks the respondent company for a complete response and may ask the parties to a case for further information in order to clarify the issues. It is essentially an adversarial process in which the evidence to be taken into account comes from the complainant and the respondent company, though the Authority can seek evidence from third parties where necessary. A complainant has the burden of proving their complaint on the balance of probabilities. Anonymous complaints are accepted and like all complaints are judged on the evidence provided by the parties. The weight to be attached to any evidence may be adversely affected if the source is anonymous and thus in some instances it will not be possible for such a complaint to proceed.

Complaints made under the Code about promotional material or the promotional activities of companies are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on cases are published by the Authority and are available on request and on the Authority's website www.pmcpa.org.uk.

The names of individuals complaining from outside the pharmaceutical industry are kept confidential. In exceptional cases it may be necessary for a company to know the identity of the complainant so that the matter can be properly investigated. Even in these instances, the name of the complainant is only disclosed with the complainant's permission.

Complaints about the promotion of medicines should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT, telephone 020-7747 8880, facsimile 020-7747 8881, email complaints@pmcpa.org.uk.

STRUCTURE AND RESPONSIBILITIES

1 Prescription Medicines Code of Practice Authority

1.1 The Prescription Medicines Code of Practice Authority (the 'Authority') is responsible for the administration of the Code of Practice for the Pharmaceutical Industry (the 'Code') including the

provision of advice, guidance and training on the Code. It is also responsible for arranging for conciliation between companies when requested to do so and for arranging for the scrutiny of advertising and meetings on a regular basis.

1.2 The Authority also administers the complaints procedure by which complaints made under the Code are considered by the Code of Practice Panel (the 'Panel') and, where required, by the Code of Practice Appeal Board (the 'Appeal Board').

1.3 The Authority is appointed by and reports to the Board of Management of the Association of the British Pharmaceutical Industry (ABPI) (the 'ABPI Board') and consists of the Director, Deputy Director, Secretary and Deputy Secretary.

Notwithstanding the above, the Director reports to the Appeal Board for guidance on the interpretation of the Code and the operation of the complaints procedure and to the President of the ABPI for administrative purposes.

In the absence of the Director, the Deputy Director is authorized to act on his behalf. In the absence of the Director and Deputy Director, the Secretary is authorized to act on the Director's behalf.

1.4 To facilitate the complaints procedure by ensuring that the requisite information is available, the Director may request copies of any relevant material from a pharmaceutical company, including copies of the certificates authorizing any such material and copies of relevant briefing material for representatives.

1.5 The Director may consult the Appeal Board upon any matter concerning the Code or its administration.

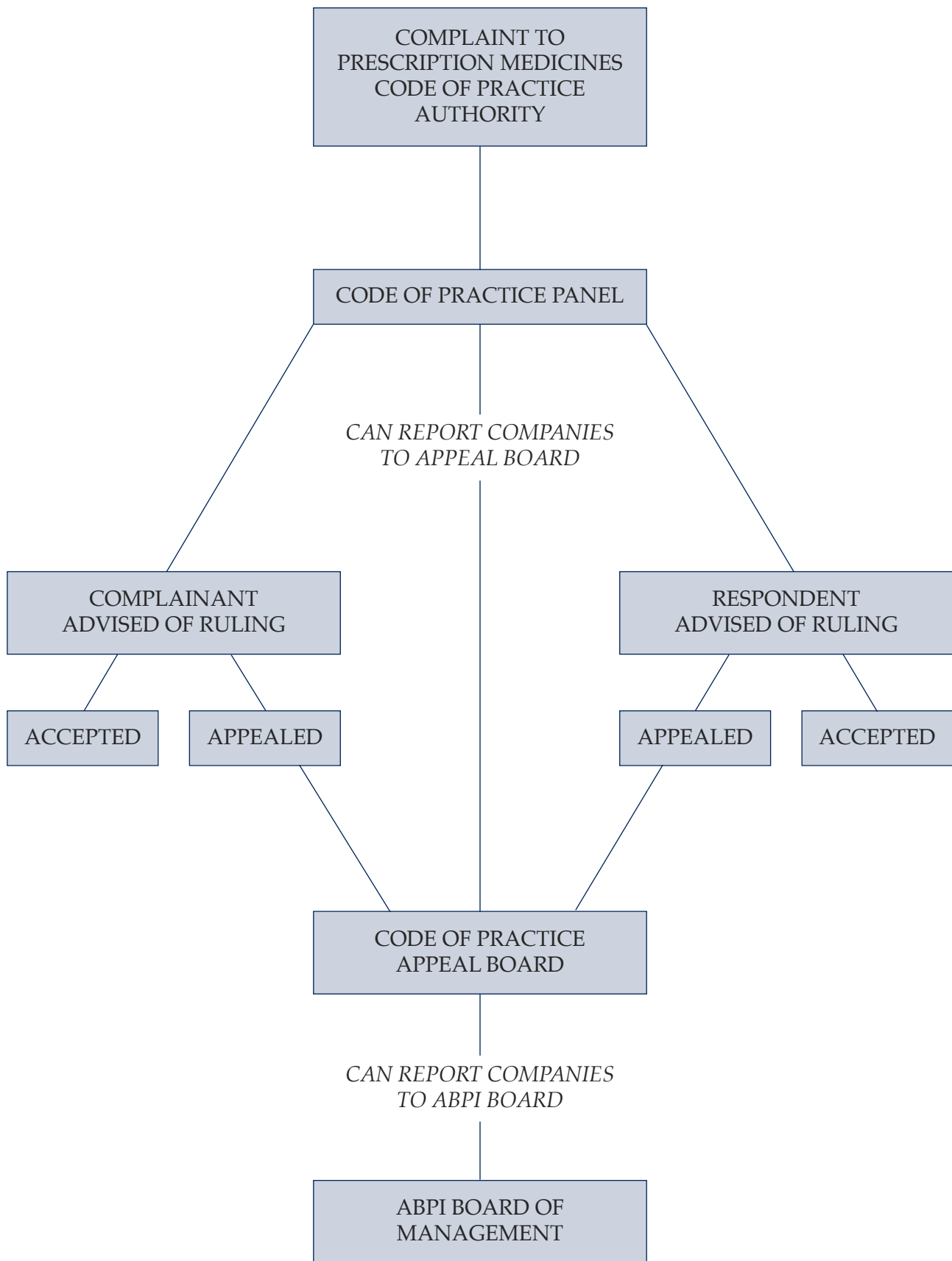
2 Code of Practice Panel – Constitution and Procedure

2.1 The Panel consists of the members of the Authority and meets as business requires to consider complaints made under the Code.

The member of the Authority who acted as case preparation manager for a particular case must not participate when the Panel considers it or be present when it does so.

The parties have no right to appear or be represented before the Panel.

2.2 Two members of the Authority form a quorum for a meeting of the Panel. Decisions are made by majority voting. The Director or, in his absence, the



Deputy Director or, in his absence, the Secretary, acts as Chairman of the Panel and has both an original and a casting vote.

Rulings are made on the basis that a complainant has the burden of proving their complaint on the balance of probabilities.

- 2.3 The Director may obtain expert assistance in any field. Expert advisers who are consulted may be invited to attend a meeting of the Panel but have no voting rights.

3 Code of Practice Appeal Board – Constitution

- 3.1 Vacancies for independent members of the Appeal Board, including the Chairman, are advertised in appropriate journals and/or the national press.

The Appeal Board and its Chairman are appointed by the ABPI Board. The appointment of independent members to the Appeal Board, including the Chairman, is made following consultation with the Medicines and Healthcare products Regulatory Agency.

- 3.2 The Appeal Board comprises:

- an independent, legally qualified Chairman
- three independent registered medical practitioners appointed following consultation with the British Medical Association, one with recent experience as a general practitioner and one with recent experience as a hospital consultant treating patients
- one independent practising registered pharmacist appointed following consultation with the Royal Pharmaceutical Society
- one independent registered nurse prescriber appointed following consultation with the Royal College of Nursing
- one independent member representative of the interests of patients
- one member from an independent body involved in providing information on medicines
- one independent lay member
- four registered medical practitioners who are medical directors or senior executives of pharmaceutical companies
- four directors or senior executives of pharmaceutical companies.

One of the members from pharmaceutical companies may be retired, provided that the initial appointment is made within one year of the date of retirement.

- 3.3 The Chairman of the Appeal Board is appointed for a term of five years which may be renewed.

Members of the Appeal Board are each appointed for a term of three years. Members may be reappointed but may serve for no more than two consecutive terms. In exceptional circumstances the Chairman may nominate a member who has served two terms

for reappointment for a third term. A member of the Appeal Board who has served two or, following the Chairman's nomination, three consecutive terms of service is eligible for reappointment after a minimum interval of one year.

A member of the Appeal Board appointed prior to 1 January 2006 is eligible to serve for two or, following the Chairman's nomination, three further consecutive terms following completion of their current term and is eligible for reappointment after a minimum interval of one year.

- 3.4 The Director is responsible for providing appropriate administrative support to the Appeal Board including the provision of case papers.

The Director, Deputy Director, Secretary and Deputy Secretary of the Authority may be present as observers at a meeting of the Appeal Board during the consideration of an appeal or a report under Paragraph 11 below only at the invitation of the Chairman and with the agreement of the party or parties involved in the appeal or report in question.

4 Code of Practice Appeal Board – Procedure

- 4.1 The Appeal Board meets as business requires to consider appeals under the Code and any other matter which relates to the Code. The Appeal Board receives reports on all complaints which have been submitted under the Code and details of the action taken on them.

- 4.2 The Chairman and seven members of the Appeal Board constitute a quorum. Four of those present, in addition to the Chairman, must be independent members, at least one of whom must be a registered medical practitioner, and there must also be present three members from pharmaceutical companies, at least one of whom must be a registered medical practitioner.

For the consideration of any particular case, or a report under Paragraph 11 below, independent members, including the Chairman, must be in a majority.

In the event that a quorum cannot be attained for the consideration of a case because of the number of members barred under Paragraph 4.4 below, or for any other reason, the Chairman may co-opt appropriate persons who are former members of the Appeal Board, or who are on a list of persons approved for co-option to the Appeal Board, so as to enable a quorum to be achieved. The list of persons approved for co-option is drawn up following procedures similar to those for appointing members of the Appeal Board. No one may be co-opted in relation to any case in which he has acted as a referee in accordance with Paragraphs 5.1, 5.2, 5.3, 7.2, 7.4, 7.5 and 7.6 below.

- 4.3 Decisions are made by majority voting. The Chairman has both an original and a casting vote.

Rulings are made on the basis that a complainant has the burden of proving their complaint on the balance of probabilities.

- 4.4 If a member of the Appeal Board is concerned in a case either as complainant or respondent, that member does not receive copies of the papers circulated in connection with the case and is required to withdraw from the Appeal Board during its consideration.

The complainant and the respondent are advised in advance of the membership of the Appeal Board, including potential co-optees, and asked if they have any objections to particular members and the grounds for such objections. Any member in respect of whom there are valid objections must withdraw from the Appeal Board during consideration of the case. The Chairman determines whether objections are valid.

Members of the Appeal Board must declare any other interest in a case prior to its consideration. Having consulted the representatives of the parties (if present), the Chairman determines whether it is appropriate for a particular member to remain for the consideration of the case.

- 4.5 The Chairman may obtain expert assistance in any field. Expert advisers may be invited to attend a meeting of the Appeal Board but have no voting rights.
- 4.6 When an appeal is considered by the Appeal Board, both the complainant and the respondent company are entitled to appear or be represented.

The first presentation in relation to a ruling which is appealed is made by the appellant.

A company may not be represented before the Appeal Board by a representative who is also a member of the Appeal Board except with the consent of the Chairman. Such consent may be given only if the member of the Appeal Board can satisfy the Chairman that no other person within his company can properly represent it in the case in question.

- 4.7 Where an appeal is brought which is concerned with an issue of fact between a complainant and the company concerned which cannot be properly resolved without the oral evidence of the persons directly involved, the Chairman may invite such persons to attend and give evidence.

COMPLAINTS PROCEDURE

5 Action on Complaints

- 5.1 When the Director receives information from which it appears that a company (being either a member of the ABPI or a company which, although not a member, has agreed to comply with the Code and

accept the jurisdiction of the Authority) may have contravened the Code, the Director must assign a member of the Authority (who may be the Director) to be the case preparation manager to process the matter and, if appropriate, prepare case papers for the Panel.

The case preparation manager must not divulge to other members of the Authority details of matters being processed until the formal case papers are provided to the Panel for consideration as provided for in Paragraph 5.5 below.

The Director is responsible for ensuring that the preparation of a case and the adjudication of it are carried out by different members of the Authority and must take steps to make certain that this separation is maintained in the event of absences of those involved.

The Director may delegate to a case preparation manager one or more of his responsibilities under this Constitution and Procedure when he considers it appropriate and necessary to do so.

The case preparation manager:

- determines whether a case should go before the Panel
- may invite evidence from third parties when considered to be appropriate even though the primary responsibility for the provision of evidence lies with the parties to a case
- may delay processing a complaint if the facts are essentially similar to those before an external forum, such as an employment tribunal; this does not apply to matters before the Medicines and Healthcare products Regulatory Agency
- may amalgamate a complaint with an ongoing complaint or complaints where two or more complaints are based on essentially the same evidence.

When a complaint is delayed or amalgamated, as above, the complainant may appeal against the delay or amalgamation to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

- 5.2 The managing director or chief executive or equivalent of the company concerned is requested to provide a complete response to the matters of complaint.

To assist companies in ensuring that a complete response is submitted the case preparation manager may suggest relevant supporting material to be supplied. It is nonetheless the responsibility of the respondent to ensure that a full response is

submitted. If the complainant is not a pharmaceutical company the case preparation manager may suggest the clauses of the Code to be addressed.

If a complaint is received about a company other than one of those referred to in Paragraph 5.1 above, it is invited by the case preparation manager to agree to comply with the Code and accept the jurisdiction of the Authority (unless it has previously declined to do so). In the absence of such agreement, the complaint is not proceeded with and the complainant is advised to refer the matter to the Medicines and Healthcare products Regulatory Agency.

Unless the information is disclosed in the complaint, a complainant other than a pharmaceutical company is asked whether or not they have any commercial, financial or other interest in the matter of complaint or in the company concerned, such as whether the complainant is an employee or ex-employee, or in a competitor.

Such interests will be disclosed to the respondent company and will normally be included in the case report.

If a complaint concerns a matter closely similar to one which has been the subject of a previous adjudication, it may be allowed to proceed at the discretion of the Director if new evidence is adduced by the complainant or if the passage of time or a change in circumstances raises doubts as to whether the same decision would be made in respect of the current complaint. The Director should normally allow a complaint to proceed if it covers matters similar to those in a decision of the Panel where no breach of the Code was ruled and which was not the subject of appeal to the Appeal Board.

If a complainant does not accept a decision of the Director that a complaint should not be proceeded with because a similar complaint has been adjudicated upon previously and nothing has changed in the meantime, then the matter is referred to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

If, in the view of the Director, a complaint does not show that there may have been a breach of the Code, the complainant will be so advised. If the complainant does not accept that view, the matter is referred to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

- 5.3 When the complaint is from a pharmaceutical company, the complaint must be signed or authorized in writing by the company's managing director or chief executive or equivalent and must state those clauses of the Code which are alleged to have been breached.

A complaint from a pharmaceutical company will be accepted only if the Director is satisfied that the company concerned has previously informed the company alleged to have breached the Code that it proposed to make a formal complaint and offered inter-company dialogue at a senior level in an attempt to resolve the matter, but that this offer was refused or dialogue proved unsuccessful. A formal statement detailing the actions taken must be provided. This requirement does not apply where the allegation is that a company has failed to comply with an undertaking that it has given and is in breach of Clause 25 of the Code.

If, in the view of the Director, that condition has not been met, the complainant shall be so advised. If the complainant does not accept that view, the matter is referred to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

Attention is drawn to the availability of conciliation prior to making a complaint as referred to in Paragraph 18.2 below. Information about conciliation is available from the Director.

- 5.4 Upon receipt of a complaint, the company concerned has ten working days in which to submit its comments in writing.
- 5.5 When the respondent company's response is received the case is referred to the Panel to determine whether or not there has been a breach of the Code.
- 5.6 When a company advises the Authority that it may have breached the Code, the Director will treat the matter as a complaint. The company's response is invited. The case preparation manager may suggest the clauses of the Code to be addressed. When the response is received the procedure under Paragraph 5.5 above will be followed.
- 5.7 The parties must be notified that a case has been referred to the Panel.

6 Complaints Arising from Media Criticism

- 6.1 When it appears to the Director from media reports (other than letters to the editor of a publication) that a company may have breached the Code, the matter is treated as a complaint.

The author of the article, or the editor where no author is named, is treated as the complainant.

The author, or editor, is asked if they want to be involved in the case and whether they have any additional information to submit. The consequences of not being involved (no right of appeal and no right to comment on a respondent's appeal or the proposed text of the case report) must be explained in writing. If the author or editor declines involvement, this is stated in the case report.

6.2 A published letter from which it appears that a company may have breached the Code is dealt with as a complaint with the author being treated as the complainant. The procedure set out in Paragraph 6.1 above will be followed.

7 Code of Practice Panel - Rulings

7.1 Where the Panel rules that there is a breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

If the promotional material or activity at issue is considered by the Panel to be likely to prejudice public health and/or patient safety, and/or it represents a serious breach of the Code, the Panel must decide whether, if there is subsequently an appeal by the respondent company, it would be required to suspend the use of the material or activity pending the final outcome of the case. If suspension would be required, the company must be so notified when it is advised of the Panel's ruling of a breach of the Code.

The respondent company has five working days to provide a written undertaking that the promotional activity or use of the material in question and any similar material (if not already discontinued or no longer in use) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. This undertaking must be signed by the managing director or chief executive or equivalent of the company or with his authority and must be accompanied by details of the actions taken by the company to implement the undertaking, including the date on which the promotional material was finally used or appeared and/or the last date on which the promotional activity took place.

In exceptional circumstances, an extension in the time allowed in which to respond may be granted at the discretion of the Director in accordance with Paragraph 14 below.

The company must also pay within twenty working days an administrative charge based on the number of matters ruled in breach of the Code.

7.2 Where the Panel rules that there is no breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision. Where the complaint is from a pharmaceutical company, the complainant must pay within twenty working days an administrative charge based on the number of matters alleged and ruled not to be in breach of the Code.

When advised of the outcome, the complainant will be sent a copy of the comments and enclosures submitted by the respondent company in relation to the complaint. If the respondent company objects to this because it regards part of the material as being confidential, and the matter cannot be settled by the Director, then it will be referred to an

independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

7.3 The complainant or the respondent company may appeal against a ruling of the Panel to the Appeal Board. Appeals must be accompanied by reasons as to why the Panel's ruling is not accepted. These reasons will be circulated to the Appeal Board.

Notice of appeal must be given within five working days of notification of the Panel's ruling and the appeal must be lodged within ten days of notification of the Panel's ruling.

If the Panel has so required in accordance with Paragraph 7.1 above, where the respondent company gives notice of appeal it must, within five working days of notification of the Panel's ruling, suspend the use of the promotional material or activity at issue, pending the final outcome of the case, and must notify the Authority that such action has been taken.

If the respondent company accepts one or more of the Panel's rulings of breaches of the Code, but appeals one or more other such rulings, then within five working days of notification of the Panel's rulings it must provide the undertaking required by Paragraph 7.1 above in respect of the ruling or rulings which it is not appealing.

In exceptional circumstances, an extension in the time allowed in which to respond may be granted at the discretion of the Director in accordance with Paragraph 14 below.

7.4 Where an appeal is lodged by the complainant, the respondent company has five working days to comment on the reasons given by the complainant for the appeal and these comments will be circulated to the Appeal Board.

The complainant has five working days to comment on the respondent company's comments upon the reasons given by the complainant for the appeal and these comments will be circulated to the respondent company and the Appeal Board.

Relevant material previously submitted to the Panel is provided to the Appeal Board. All additional material which the complainant and the respondent company want the Appeal Board to consider must be submitted in writing with the appeal, with the respondent company's comments on the reasons given by the complainant for the appeal or with the complainant's comments on the respondent company's comments on the reasons given by the complainant for the appeal. No new material may be introduced when the appeal is heard by the Appeal Board.

In the event that the respondent company objects to certain of its comments being made available to the complainant on the grounds of confidentiality, and the matter cannot be settled by the Director, then it

will be referred to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, who will determine whether those particular comments can be included in the evidence which goes before the Appeal Board. The referee's decision is final.

- 7.5 Where an appeal is lodged by the respondent company, the complainant has five working days to comment on the reasons given by the respondent company for the appeal and these comments will be circulated to the respondent company and the Appeal Board.

Relevant material previously submitted to the Panel is provided to the Appeal Board. All additional material which the complainant and the respondent company want the Appeal Board to consider must be submitted in writing with the appeal or with the complainant's comments on the reasons given by the respondent company for the appeal. No new material may be introduced when the appeal is heard by the Appeal Board.

In the event that the respondent company objects to certain details of its appeal being made available to the complainant on the grounds of confidentiality, and the matter cannot be settled by the Director, then it will be referred to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, who will determine whether those particular details can be included in the evidence which goes before the Appeal Board. The referee's decision is final.

Where an appeal is lodged by the respondent company, the complainant is sent a copy of the initial comments and enclosures submitted by the respondent company in relation to the complaint. If the respondent company objects to this because it regards part of the material as being confidential, and the matter cannot be settled by the Director, then it will be referred to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

- 7.6 Where the Panel rules no breach of the Code because it considers the matter of complaint is not within the scope of the Code the complainant and the respondent company are so advised in writing.

When advised of the outcome, the complainant will be sent a copy of the comments and enclosures submitted by the respondent company in relation to the complaint. If the respondent company objects to this because it regards part of the material as being confidential, and the matter cannot be settled by the Director, then it will be referred to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

The complainant may appeal against the Panel's ruling to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final. An appeal must be accompanied by reasons as to why the Panel's ruling is not accepted. These reasons will be provided to the referee. The appeal must be lodged within ten working days of notification of the ruling of the Panel.

The respondent company has five working days to comment on the reasons given by the complainant for the appeal and these comments will be provided to the referee.

The complainant has five working days to comment on the respondent company's comments upon the reasons given by the complainant for the appeal and these comments will be provided to the respondent company and the referee.

In the event that the respondent company objects to certain of its comments being made available to the complainant on the grounds of confidentiality, and the matter cannot be settled by the Director, then the referee must decide whether he can take those comments into consideration when making his determination.

In such an appeal, the referee must consider no more than whether or not the matter of complaint is within the scope of the Code.

If the referee determines that the matter is not within the scope of the Code the complainant and the respondent company are so advised in writing.

If the referee determines that the matter is within the scope of the Code the complainant and the respondent company are so advised in writing. The case is referred back to the Panel for it to be considered on its merits and the procedure in Paragraph 5.5 above will be followed.

No administrative charges apply in relation to proceedings under Paragraph 7.6 and there will be no case reports.

8 Code of Practice Panel - Reports to the Code of Practice Appeal Board

- 8.1 Failure to comply with the procedures set out in Paragraphs 5 and 7 above will be reported to the Appeal Board.
- 8.2 The Panel may also report to the Appeal Board any company whose conduct in relation to the Code, or in relation to a particular case before it, or because it repeatedly breaches the Code such that it raises concerns about the company's procedures, warrants consideration by the Appeal Board. Such a report to the Appeal Board may be made notwithstanding the fact that a company has provided an undertaking requested by the Panel.

9 Action on Complaints about Safety from the Medicines and Healthcare products Regulatory Agency

9.1 In the event of the Medicines and Healthcare products Regulatory Agency making a complaint which relates to the safety or proper use of a medicine, and requesting that an advertisement be withdrawn, the respondent company has five working days to respond with its comments.

9.2 If the Panel upholds the complaint, the company is required to suspend the advertisement or practice forthwith pending the final outcome of the case.

10 Code of Practice Appeal Board - Rulings

10.1 Where the Appeal Board rules that there is no breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

Where a complainant pharmaceutical company appeals and the Appeal Board upholds the ruling that there is no breach of the Code, the complainant pharmaceutical company must pay within twenty working days an administrative charge based on the number of matters taken to appeal on which no breach is ruled.

Where a respondent company appeals and the Appeal Board rules that there is no breach of the Code, the complainant pharmaceutical company must pay within twenty working days an administrative charge based on the number of matters taken to appeal on which no breach is ruled.

10.2 Where the Appeal Board rules that there is a breach of the Code, the respondent company is so advised in writing and is given the reasons for the decision. The respondent company then has five working days to provide a written undertaking providing relevant information as specified in Paragraph 7.1 above.

The company must also pay within twenty working days an administrative charge based on the number of matters ruled in breach of the Code.

10.3 Where the Appeal Board rules that there is a breach of the Code, it may require the company to take steps to recover items given in connection with the promotion of a medicine or non promotional items provided to health professionals and members of the public and the like. Written details of the action taken must be provided to the Appeal Board.

10.4 Where the Appeal Board rules that there is a breach of the Code, it may require an audit of the company's procedures in relation to the Code to be carried out by the Authority and, following that audit, decide whether to impose requirements on the company concerned to improve its procedures in relation to the Code. These could include a further audit and/or a requirement that promotional material be submitted to the Authority for pre-vetting for a specified period. The Authority

must arrange for material submitted for pre-vetting to be examined for compliance with the Code but it cannot approve such material. All of the costs of pre-vetting must be met by the company concerned.

The Appeal Board may also require an audit if a company repeatedly breaches the Code.

10.5 Where the Appeal Board rules that there is a breach of the Code, it may reprimand the company and publish details of that reprimand.

10.6 Where the Appeal Board rules that there is a breach of the Code, it may require the company to issue a corrective statement. Details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use.

11 Reports to the Code of Practice Appeal Board

11.1 Where the Panel reports a company to the Appeal Board under the provisions of Paragraphs 8.1 and 8.2 above, or where the Panel reports the failure of a company to comply with the procedure set out in Paragraph 9 above, or where the Authority reports the failure of a company to comply with the procedures set out in Paragraph 10 above, the procedures set out below shall apply. These procedures also apply if the Appeal Board, having received a report on a case completed at the Panel level, in accordance with Paragraph 4.1 above, considers that additional sanctions may be appropriate.

11.2 The company concerned is provided with a copy of the report prior to its consideration and is entitled to have a representative or representatives appear before the Appeal Board to state the company's case.

A company may not be represented before the Appeal Board by a representative who is also a member of the Appeal Board except with the consent of the Chairman. Such consent may be given only if the member of the Appeal Board can satisfy the Chairman that no other person within his company can properly represent it in the matter in question.

11.3 The Appeal Board may:

- reprimand the company and publish details of that reprimand
- require an audit of the company's procedures in relation to the Code to be carried out by the Authority and, following that audit, decide whether to impose requirements on the company concerned to improve its procedures in relation to the Code; these could include a further audit and/or a requirement that promotional material be submitted to the Authority for pre-vetting for a specified period; the Authority must arrange for material submitted for pre-vetting to be examined for compliance with the Code but it cannot approve such material; all of the costs of pre-vetting must be met by the company concerned

- require the company to issue a corrective statement; details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use
- require the company to take steps to recover items given in connection with the promotion of a medicine or non-promotional items provided to health professionals and members of the public and the like; written details of the action taken must be provided to the Appeal Board.

11.4 Where a company not in membership of the ABPI fails to comply with the procedures set out in Paragraphs 5, 7, 9 or 10 above and indicates that it no longer wishes to accept the jurisdiction of the Authority, the Appeal Board may decide to remove the company from the list of non member companies which have agreed to comply with the Code and advise the Medicines and Healthcare products Regulatory Agency that responsibility for that company under the Code can no longer be accepted.

The ABPI Board must be advised that such action has been taken.

12 Code of Practice Appeal Board - Reports to the ABPI Board of Management

12.1 Where the Appeal Board considers that the conduct of a company in relation to the Code or a particular case before it warrants such action, it may report the company to the ABPI Board. Such a report may be made notwithstanding the fact that the company has provided an undertaking requested by either the Panel or the Appeal Board.

12.2 Where such a report is made to the ABPI Board, the ABPI Board may suspend or expel the company from the ABPI.

In the case of a company not in membership of the ABPI, the ABPI Board may remove the company from the list of non member companies which have agreed to comply with the Code and advise the Medicines and Healthcare products Regulatory Agency that responsibility for that company under the Code can no longer be accepted.

To assist it in deciding whether to suspend or expel a company or, in the case of a company not in membership of the ABPI, to remove the company from the list of non member companies which have agreed to comply with the Code, the ABPI Board may require an audit of the company's procedures in relation to the Code to be carried out by the Authority.

12.3 If a member of the ABPI Board is concerned in a case which has led to the report, as either complainant or respondent, that member does not receive a copy of the report and is required to withdraw from the ABPI Board during its consideration.

The company concerned is advised in advance of the membership of the ABPI Board and asked if it

has any objections to particular members and the grounds for such objections. Any member in respect of whom there are valid objections must withdraw from the ABPI Board during consideration of the report. The President (or Chairman in the absence of the President) determines whether objections are valid.

Members of the ABPI Board must declare any other interest in a report prior to its consideration. Having consulted the company representative(s) (if present), the President (or Chairman in the absence of the President) determines whether it is appropriate for a particular member to remain for the consideration of the report.

12.4 Where a report is made to the ABPI Board under Paragraph 12.1 above, the company concerned is provided with a copy of the report prior to its consideration and is entitled to have a representative or representatives appear before the ABPI Board to state the company's case.

13 Case Reports

13.1 At the conclusion of any case under the Code, the complainant is advised of the outcome and a report is published summarising the details of the case.

13.2 The respondent company and the medicine concerned are named in the report.

In a case where the complaint was initiated by a company or by an organisation or official body, that company or organisation or official body is named in the report. The information given must not, however, be such as to identify any individual.

Where expert assistance has been obtained by either the Panel or the Appeal Board, the report will include the name and qualifications of the expert concerned.

Where a company has been required to issue a corrective statement, the report will reproduce its text and provide details of how the corrective statement was disseminated.

13.3 A copy of the report on a case is sent to both the complainant and the respondent company prior to publication. Any amendments to the report suggested by these parties are considered by the Director, consulting with the other party where appropriate. If either party does not accept the Director's decision as to whether or not a report should be amended, the matter is referred to the Chairman of the Appeal Board for his decision which is final.

13.4 Copies of all case reports are submitted to the Appeal Board prior to publication. Copies of the reports are sent to the ABPI Board for information following publication.

13.5 Full case reports in printed form are published each quarter by the Authority.

Copies of the reports are sent to the Medicines and Healthcare products Regulatory Agency, the Office of Fair Trading, the British Medical Association, the Royal Pharmaceutical Society, the Royal College of Nursing and the Editors of the BMJ, The Pharmaceutical Journal and the Nursing Standard. Copies are also available to anyone on request.

- 13.6 In addition to the printed reports, full case reports appear on the Authority's website. The website also carries brief details of all complaints which are currently under consideration but not yet resolved and the texts and modes of dissemination of any corrective statements that companies have been required to issue during the previous twelve months.

The Authority's website also carries interim case reports in respect of cases where publication of the final report is delayed because either the Appeal Board or the ABPI Board has required an audit of the respondent company's procedures in relation to the Code.

Access to the Authority's website is unrestricted.

- 13.7 Following publication of the relevant case reports, the Authority advertises in the medical, pharmaceutical and nursing press brief details of cases in which companies were ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand. Such advertisements also appear on the Authority's website. The companies concerned are required to contribute to the cost of the press advertisements.

GENERAL PROVISIONS

14 Time Periods for Responding to Matters under the Code

The number of working days within which companies or complainants must respond to enquiries etc from the Authority, as referred to in the above procedures, is counted from the date of receipt of the notification in question.

An extension in time to respond to such notifications may be granted at the discretion of the Director.

15 Withdrawal of Complaints and Notices of Appeal

- 15.1 A complaint may be withdrawn by a complainant with the consent of the respondent company up until such time as the respondent company's comments on the complaint have been received by the Authority, but not thereafter.
- 15.2 Notice of appeal may be withdrawn by a complainant with the consent of the respondent company up until such time as the respondent company's comments on the reasons for the appeal have been received by the Authority, but not thereafter.

- 15.3 Notice of appeal may be withdrawn by a respondent company at any time but if notice is given after the papers relating to its appeal have been circulated to the Appeal Board, then the higher administrative charge will be payable.

16 Code of Practice Levy and Charges

- 16.1 An annual Code of Practice levy is paid by members of the ABPI. The levy together with the administrative charges referred to in Paragraphs 7 and 10 above, the charges for audits carried out in accordance with Paragraphs 10.4, 11.3 and 12.2 above and the contributions to the cost of press advertisements referred to in Paragraph 13.7 above are determined by the ABPI Board subject to approval at a General Meeting of the ABPI by a simple majority of those present and voting.

- 16.2 Administrative charges are payable only by pharmaceutical companies and companies are liable for such charges whether they are members of the ABPI or not.

There are two levels of administrative charge.

The lower level is payable by a company which accepts either a ruling of the Panel that it was in breach of the Code or a rejection by the Panel of its allegation against another company. The lower level is also payable by a complainant company if a ruling of the Panel that there was a breach of the Code is subsequently overturned by the Appeal Board and by a respondent company if a ruling of the Panel that there was no breach of the Code is subsequently overturned by the Appeal Board.

The higher level is paid by a company which unsuccessfully appeals a ruling of the Panel.

- 16.3 Where two or more companies are ruled in breach of the Code in relation to a matter involving co-promotion, each company will be separately liable to pay any administrative charge which is payable.
- 16.4 Where a company advises the Authority that it may have breached the Code, and it is subsequently ruled in breach, any administrative charge payable will be one half of that which would otherwise have been due.
- 16.5 The number of administrative charges which apply in a case is determined by the Director. If a company does not agree with the Director's decision, the matter is referred to the Chairman of the Appeal Board for his decision which is final.
- 16.6 Failure to pay any of the charges provided for by this paragraph must be reported by the Director to the Appeal Board or the ABPI Board as appropriate.

17 Scrutiny

- 17.1 The Authority arranges for the scrutiny of samples of advertisements, detail aids, leavepieces, other promotional items and meetings on a continuing basis in relation to the requirements of the Code.

Members of the Authority must not carry out scrutiny.

To facilitate such scrutiny, the Director may request relevant material from pharmaceutical companies, including copies of the certificates authorizing such material, and companies must respond to such requests within ten working days.

- 17.2 Where a possible breach of the Code is identified under this procedure by the scrutineer, the company concerned is requested to comment in writing within ten working days of receipt of the notification.
- 17.3 If the company accepts that there is a breach of the Code, the company is requested to provide an undertaking providing the information specified in Paragraph 7.1 above. No administrative charge will be payable in these circumstances and there will be no case report on the matter in question.
- 17.4 If the company does not accept that there is a breach of the Code and, having considered the company's comments, the scrutineer decides that there is no case to answer under the Code, then the procedure is brought to a close. There will be no case report on the matter in question.
- 17.5 If the company does not accept that there is a breach of the Code but, having considered the company's comments, the scrutineer considers that a case has been established, the matter will be dealt with as a complaint.

18 Provision of Advice and Assistance with Conciliation

- 18.1 The Authority is willing and able to provide informal guidance and advice in relation to the requirements of the Code and, where appropriate, may seek the views of the Appeal Board.
- 18.2 Companies wishing to seek the assistance of a conciliator with the view to reaching agreement on inter-company differences about promotion may contact the Director for advice and assistance.

19 Amendments to the Code of Practice and Constitution and Procedure

- 19.1 The Code and this Constitution and Procedure may be amended by a simple majority of those present and voting at a General Meeting of the ABPI.

Notwithstanding the above, where a proposal to amend the Code or this Constitution and Procedure arises solely from the ABPI's obligation to comply with the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals and/or with the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations, both of the European Federation of Pharmaceutical Industries and Associations, then the ABPI Board may decide that formal approval at an ABPI General Meeting is not necessary. ABPI member companies must, nonetheless, be consulted in relation to the proposed texts of the changes.

- 19.2 The views of the Authority and the Appeal Board must be sought on any proposal to amend the Code or this Constitution and Procedure. The views of the Medicines and Healthcare products Regulatory Agency, the British Medical Association, the Royal Pharmaceutical Society and the Royal College of Nursing must also be invited.

Notwithstanding the above, where the ABPI Board has decided, in accordance with Paragraph 19.1 above, that formal approval of the proposal at an ABPI General Meeting is not necessary, then the bodies referred to above need only be informed of the changes which are to be made.

- 19.3 The Authority and the Appeal Board may, in the light of their experience, make recommendations for amendment of the Code and this Constitution and Procedure.

20 Annual Report

An annual report of the Authority is published each year with the approval of the Appeal Board. This report includes details of the work of the Authority, the Panel and the Appeal Board during the year and provides a list of all companies ruled in breach of the Code during the year which specifically identifies those ruled to have breached Clause 2.

GUIDELINES ON COMPANY PROCEDURES RELATING TO THE CODE OF PRACTICE

Paragraphs 10.4, 11.3 and 12.2 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority variously authorize the Code of Practice Appeal Board or the Board of Management of the Association of the British Pharmaceutical Industry to require an audit of a company's procedures in relation to the Code of Practice for the Pharmaceutical Industry to be carried out by the Prescription Medicines Code of Practice Authority.

Set out below are guidelines on company procedures which are regarded as representing good practice in this regard. They are minimum requirements and will need to be adapted to fit in with the arrangements at any particular company.

The guidelines also point out the most significant changes which have been made to the Code in the 2011, 2012 and Second 2012 editions.

The guidelines do not cover all aspects of the Code and are thus no substitute for a detailed study of the Code as a whole, including all of the supplementary information.

1) Scope of the Code

It should be borne in mind that the Code covers some matters that are not necessarily related to promotion. Companies should familiarise themselves with the detail of what is covered and ensure that their procedures are such as to ensure compliance at all times. The supplementary information to Clause 1.1 gives guidance in this regard as does Clause 14.3 which details materials to be certified even if they are non-promotional in nature.

Other material issued by companies which relates to medicines but which is not intended as promotion for those medicines, such as corporate advertising, press releases, market research material, financial information for shareholders and the Stock Exchange and responses to unsolicited enquiries from the public etc, should be examined to ensure that it does not contravene the Code or relevant statutory requirements.

Account should be taken of the fact that non-promotional material could be used or made available in such a way that it would be considered promotion and thereby come within the scope of the Code.

2) Co-Promotion

Adequate provision should be made in co-promotion agreements and the like to ensure compliance with the Code. Where companies jointly promote the same product and the promotional material bears both company names, each company must certify the promotional

material involved as the companies concerned will be held jointly responsible for it under the Code (supplementary information to Clause 14.1).

3) Breaches of the Code

In the event of a company being found in breach of the Code, procedures should provide that adequate steps are taken to ensure that relevant information about the matter is communicated internally to appropriate members of staff.

Procedures must be in place to ensure that promotional material found to be in breach of the Code, and any similar material in any format, is quickly and entirely withdrawn from use, not forgetting material stored electronically and/or in the hands of others, such as printers and agencies. It is important for the reputation of the industry that companies comply with undertakings. Inadequate action leading to a breach of undertaking is likely to be in breach of Clause 2.

Companies are advised to keep written records of the action taken to withdraw material.

4) Compliance

Companies should bear in mind that promotional material must be up-to-date at the time that it is sent or used or, in the case of a journal advertisement, at the publication date of the journal.

Each company must have a senior employee who is responsible for ensuring that it meets the requirements of the Code (Clause 1.9).

Unless other formal arrangements have been made by a company, it will be assumed that the responsible person is the managing director or chief executive or equivalent.

To assist with compliance, companies should have a comprehensive set of standard operating procedures (SOPs) covering all aspects of the Code. SOPs should set out high standards and relevant staff should be trained and validated on their content.

5) Price Lists for Unlicensed Medicines

The Second 2012 Code allows the use of price lists relating to unlicensed medicines provided that they include no product claims and make clear that the products are unlicensed (Clause 1.2 and its supplementary information). Such price lists can be sent to health professionals and appropriate administrative staff at reasonable intervals or in response to enquiries. They must not be used proactively in a manner which could be seen to be promoting unlicensed medicines, such as by displaying them on exhibition stands.

6) Abbreviated Advertisements

The Second 2012 Code makes significant changes in relation to abbreviated advertisements (Clause 5). Such advertisements must now refer to a website where further information about the product can be found. This further information can consist of the prescribing information, as set out in Clauses 4.2 and 4.3, or the summary of product characteristics. Companies should ensure that abbreviated advertisements published after 31 October 2012 comply with the new requirements in Clause 5.4.

7) Non-Interventional Studies of Marketed Medicines

A non-interventional study of a marketed medicine is a study where the medicine is prescribed in the usual manner in accordance with the terms of its marketing authorization (Clause 13). The assignment of the patient to a particular therapeutic strategy is not decided by a study protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures are applied to the patients and epidemiological methods are used for the analysis of collected data.

A company involved in non-interventional studies must have a scientific service to deal with their approval and supervision as required by Clause 21.2.

An important change was introduced in the 2011 Code. Companies must publish the summary details and results of non-interventional studies of marketed medicines completed on or after 1 May 2011 (Clause 13.2). This applies to studies with which a UK company has had any involvement. The 2008 Code encouraged companies to publish this information and this still applies to studies completed prior to 1 May 2011.

Clause 13.3, which sets out the criteria with which non-interventional studies must comply, applies to studies completed on or after 1 July 2008, though companies are encouraged to comply in relation to studies completed prior to that date.

8) Certification of Promotional Material

Procedures must ensure that:

- promotional material is not issued until its final form has been certified in accordance with Clause 14
- the names of signatories are notified in advance to the Advertising Standards Unit, Vigilance and Risk Management of Medicines of the Medicines and Healthcare products Regulatory Agency and to the Prescription Medicines Code of Practice Authority (Clause 14.4)
- the form of certificate encompasses at least the requirements of Clause 14.5

- material still in use is recertified at intervals of no more than two years (Clause 14.5); much more frequent recertification may be needed for some products and companies should ensure that the status of material continuing in use is kept under review
- paper or electronic copies of the certificates, together with the material in the form certified and information as to whom it was addressed, the method of dissemination and the date of first dissemination are preserved for at least three years after final use (Clause 14.6).

Each certificate should bear a reference number with the same reference number appearing on the promotional material in question so that there can be no doubt as to what has been certified. A particular reference number should relate to only one item of promotional material.

Different sizes and different layouts of a piece of promotional material should be separately certified and each should have its own unique reference number.

A change in the certification requirements made in the 2011 Code allows UK registered pharmacists to certify promotional material in lieu of a medical practitioner (Clause 14.1). Previously they could certify in this regard only to a limited extent and then only under the direction of a medical practitioner.

9) Certification of Representatives' Briefing and Training Materials

The certification requirements of Clause 14 apply also to briefing material prepared for representatives in accordance with Clause 15.9. Briefing material includes the training material used to instruct medical representatives about a medicine and the instructions given to them as to how the product should be promoted. Procedures must ensure that no such material is used or issued prior to certification.

10) Certification of Items to be Passed on to Patients

The 2011 Code introduced the certification of items which are provided to health professionals for them to pass on to patients (Clauses 14.3 and 18.2). Such items must be part of a formal patient support programme, the details of which must be appropriately documented and certified in advance.

11) Certification of Other Material

Clause 14.3 lists other material which needs to be certified and companies should familiarise themselves with what is covered. Additionally, Clause 14.2 requires the certification of all meetings which involve travel outside the UK. The Code now allows only very limited provision to health professionals of promotional aids for them to keep and these must be certified (supplementary information to Clause 14.1 and Clause 18.3).

12) Representatives' Expenses

There should be a clearly laid down procedure for approval and payment of representatives' expenses and expenditure on meetings and hospitality and the like. A system should be in place for an audit on a systematic or random basis which will check the nature of the expenditure which has been incurred and assess whether that expenditure was in accordance with the requirements of the Code.

13) Representatives' Training

Procedures must ensure that:

- representatives are aware that they must maintain a high standard of ethical conduct and comply with all relevant requirements of the Code (Clause 15.2)
- representatives (including contract representatives) are adequately trained in relation to every product which they are to promote (Clause 15.1)
- representatives are not employed as medical representatives or generic sales representatives unless they have passed the relevant examination as provided for in Clauses 16.3 and 16.4, or have been in such employment for less than two years (whether continuous or otherwise and irrespective of whether with one company or with more than one company)
- contract representatives are only employed or used if they comply with the requirements of Clauses 16.3 and 16.4 as regards examination status.

Representatives should be provided with written instructions on the application of the Code to their work even if they are also provided with an actual copy of it. It is recommended that each representative is given their own copy of the Code. Their instructions should cover such matters as the company's policies on meetings and hospitality, and the associated allowable expenditure, and the specific requirements for representatives in Clause 15. It should be made clear how reporting to the 'scientific service' of the company is to be carried out in relation to information about the medicines which they promote which comes to their notice, particularly reports of side-effects (Clause 15.6).

It should be made clear to representatives as to whether, and in what circumstances, they can themselves write letters (or prepare other written materials) which mention particular medicines and are thus almost certain to be considered promotional material.

Such items must be certified, either in advance by way of proforma letters or by certifying each individual letter or other item, and must bear prescribing information in accordance with Clause 4.1.

14) Training

It should be ensured that all relevant personnel,

including representatives and members of staff (including persons retained by way of contract with third parties) concerned in any way with the preparation or approval of promotional material or of information to be provided to members of the UK health professions or to appropriate administrative staff or of information to be provided to the public and recognised patient organisations, are fully conversant with the requirements of the Code and relevant legal requirements (Clause 16.1).

Appropriate arrangements should be in place for training on the requirements of the Code. These may be internal arrangements for appropriate staff members but it is recommended that key personnel attend one of the seminars organised by the Prescription Medicines Code of Practice Authority.

It should also be ensured that all personnel (including persons retained by way of contract with third parties) are fully conversant with pharmacovigilance requirements relevant to their work and that this is fully documented (Clause 16.2).

Adequate arrangements should be in place to ensure that any information as to changes to the Code etc, including reports of decided cases, are circulated to relevant personnel.

Companies should consider making knowledge of, and compliance with, their obligations in relation to both the Code and pharmacovigilance requirements part of the annual appraisal process for relevant employees.

Clauses 16.3 to 16.5 set out the requirements relating to the need for representatives to pass the relevant ABPI examination. Examination status is enquired into when a complaint is received about a representative. Companies should have appropriate procedures in place to ensure that representatives enter for the relevant examination on the earliest practicable date.

Representatives must take the examination in their first year of such employment and must pass it within two years of starting such employment.

15) Provision of Medicines and Samples

Companies should ensure that their procedures are such as to ensure compliance with Clause 17. They should be clear as to the distinctions between samples, identification samples, titration packs and free goods etc. which are described in the supplementary information to Clause 17.

Significant changes to the requirements relating to samples were made in the 2012 Code.

Not more than four samples of a particular new medicine may now be provided to an individual health professional during the course of a year and then for no longer than two years after that health professional first requests samples of it (Clause 17.2).

A definition of a 'new medicine' is given in the supplementary information to Clause 17.2.

The above applies to new medicines launched in the UK market on or after 1 January 2012. In relation to medicines launched in the UK prior to that date, samples may be given in accordance with Clause 17.2 of the 2011 Code until 31 December 2013.

Clause 17.9 requires companies to have adequate systems of control and accountability for samples and for all medicines handled by representatives. Similarly, there should be an adequate system to control the number of samples of a particular product given to a particular health professional (Clause 17.2).

The 2012 Code stated that samples must not be given for the sole purpose of treating patients (Clause 17.12).

The Second 2012 Code states that starter packs are not permitted (supplementary information to Clause 17). Starter packs are small packs designed to provide sufficient medicine for a primary care prescriber to initiate treatment in such circumstances as a call out in the night. Companies must ensure that no starter packs are provided to prescribers after 31 October 2012.

16) Items for Patients and Promotional Aids

The 2011 Code introduced considerable changes in this area.

The traditional forms of promotional aid, such as coffee mugs, stationery and calendars, can no longer be given to health professionals and nor can items for use in a clinic or treatment room, such as surgical gloves, tongue depressors and tissues and the like (supplementary information to Clause 18.1). Toys and puzzles for children to play with can no longer be provided either.

Items intended to be passed on to patients can be provided to health professionals if these are part of a patient support programme, the details of which have been appropriately documented and certified in advance (Clause 18.2). They must cost no more than £6, excluding VAT, and the perceived value to the health professional and the patient must be similar. They must directly benefit patient care. Such items can be provided to health professionals by representatives during the course of a promotional call but they must not be given out from exhibition stands.

In limited circumstances, patient support items can be provided to health professionals when they are not to be passed to patients for them to keep (supplementary information to Clause 18.2). This is where their purpose is to allow patients to gain experience in using their medicines whilst under the supervision of a health professional. Examples are inhalation devices devoid of active ingredients and devices to assist patients to learn how to self-inject.

The only items that can be provided to health professionals for them to keep are notebooks, pens and pencils for use at *bona fide* meetings and conferences etc. The total cost of such items provided to an individual must not exceed £6, excluding VAT, and the perceived value to the recipient must be similar. They may not bear the name of a medicine or any information about medicines (Clause 18.3). They must not be provided by representatives when calling upon health professionals.

There is much detail in the supplementary information to Clauses 18.1, 18.2 and 18.3 and it is essential that companies familiarise themselves with it.

17) Medical and Educational Goods and Services

The provision of medical and education goods and services must be carried out in compliance with Clause 18.4 and must be certified in accordance with Clause 14.3.

18) Agreements to Benefit Patients such as Joint Working, Outcome Agreements and Patient Access Schemes

Joint working between the NHS and the pharmaceutical industry is now dealt with in the Code in some detail (Clause 18.5 and its supplementary information). An executive summary of a joint working agreement must be made public in relation to joint working projects starting on or after 1 May 2011 or on-going on that date. Material relating to joint working must be certified (Clause 14.3)

The supplementary information to Clause 18.1 deals with outcome or risk sharing agreements, patient access schemes and package deals.

19) Donations and Grants to Institutions, Organisations and Associations

The 2011 Code required pharmaceutical companies to make publicly available details of grants and donations made to institutions, organisations and associations in accordance with Clause 18.6. This applies to donations and grants made in 2012 and each calendar year thereafter.

Companies should take steps to ensure that they are able to readily source the information to be published.

Contracts relating to services provided by such institutions must comply with Clause 18.7.

20) Meetings and Hospitality

A company must have a written document that sets out its policies on meetings and hospitality and the associated allowable expenditure and must ensure that all meetings that it plans are checked to see that they comply with Clause 19.

Meetings held outside the UK are not necessarily unacceptable but there have to be valid and cogent reasons for the use of a venue outside the UK (supplementary information to Clause 19.1).

Meetings which involve travel outside the UK must be formally certified as set out in Clause 14.2.

A company's procedures should cover its own meetings, those which it sponsors and the sponsorship of attendance at meetings.

Companies should remind their affiliates outside the UK that the ABPI Code of Practice must be complied with if UK health professionals attend meetings which they organise regardless of whether such meetings occur in the UK or abroad.

21) Sponsorship to Attend Meetings

An important change made in the 2011 Code was that financial details of sponsorship of UK health professionals and appropriate administrative staff to attend meetings organised by third parties must be made publicly available (Clause 19.4 and its supplementary information).

The information has to be made publicly available in respect of sponsorship to attend meetings in 2012 and each calendar year thereafter.

Companies should take steps to ensure that they are able to readily source the information to be published.

22) The Use of Consultants

Health professionals and appropriate administrative staff may be used as consultants and advisors for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel. The arrangements which cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil the criteria set out in Clause 20 and procedures should ensure that the requirements of that clause are complied with.

Significant changes were made in relation to the use of consultants in the 2011 Code. In particular, public disclosure of fees paid to consultants in the UK for certain services will be required for payments made in 2012 and each calendar year thereafter (Clause 20.2). No disclosure is required in relation to payments for research and development work, including the conduct of clinical trials. Additional information will have to be disclosed in relation to certain payments made in 2013 and each calendar year thereafter (Clause 20.3).

Companies should take steps to ensure that they are able to readily source the information to be published.

Contracts or agreements with consultants entered into or renewed on and after 1 May 2011 must include provisions regarding their obligation to declare the arrangement whenever they write or speak in public about the subject of the agreement or any issue relating to the company (Clause 20.1). The 2008 Code encouraged such provisions but they are now obligatory. Companies are encouraged to renegotiate existing contracts to include such provisions at their earliest convenience.

23) Scientific Services

Companies must ensure that they have an identifiable scientific service to compile and collate all information, from medical representatives or any other source, about the medicines which they market (Clause 21.1). Where relevant, they must also have a scientific service to deal with the approval and supervision of non-interventional studies (Clause 21.2). There can be one scientific service in charge of both responsibilities or separate services with clearly delineated duties.

Companies must disclose details of clinical trials (Clause 21.3). The Second 2012 Code details how this is to be done.

24) Relations with the Public and the Media

Prescription only medicines must not be advertised to the public but information about them can be provided either directly or indirectly. The provision of information to the public about prescription only medicines must be in accordance with Clause 22.

25) Relationships with Patient Organisations

Pharmaceutical companies can interact with patient organisations or any user organisation such as disability organisations, carer or relative organisations and consumer organisations to support their work, including assistance in the provision of appropriate information to the public, patients and carers.

When working with patient organisations, companies must ensure that all of the arrangements comply with the Code. This includes the prohibition on advertising prescription only medicines to the public (Clause 22.1). The requirements of Clause 19, which covers meetings for health professionals and appropriate administrative staff, also apply to pharmaceutical companies supporting patient organisation meetings.

Companies must ensure that the requirements of Clause 23 are complied with when working with patient organisations. In particular, written agreements must be in place in respect of every significant activity or ongoing relationship (Clause 23.3) and there has to be public disclosure of financial support or indirect/non financial support.

The 2011 Code required the disclosure of the monetary value of support with a value to the

organisation of £250 per project or more (excluding VAT) in relation to activities commenced on or after 1 May 2011 or ongoing on that date.

The 2012 Code changed this and required the published information to include the monetary value of financial support and of invoiced costs (Clause 23.7). The £250 minimum in the 2011 Code no longer applies. For significant non-financial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organisation receives.

A list of patient organisations including the monetary value of support regardless of its level must be made publicly available by the end of the first quarter of 2013 and cover activities commenced on or after 1 January 2012 or ongoing on that date. Until that information is made publicly available, the requirements for disclosure set out in Clause 23.7 of the 2011 Code and its supplementary information remain applicable. Companies should take steps to ensure that they are able to readily source the information to be published.

Companies must ensure that their support is clearly acknowledged from the outset. The wording of a declaration of sponsorship must accurately reflect the nature of a company's involvement.

A completely new requirement in the 2012 Code related to contracts under which patient organisations provide consultancy or other services to companies. Clause 23.8 specifies the criteria

which contracts for such services must meet, to the extent relevant to the particular arrangement. A list of patient organisations that have been engaged to provide significant contracted services must be published for the first time by the end of the first quarter of 2013 and cover activities commenced on or after 1 January 2012 or ongoing on that date.

Companies should ensure that such contracts comply with the criteria in Clause 23.8 and take steps to ensure that they are able to readily source the information to be published.

Under the 2012 Code hospitality can be provided in certain circumstances to patient carers (supplementary information to Clause 23.2).

26) The Internet

Companies should ensure that all relevant requirements of the Code, including Clause 24, are complied with in relation to promotional material for prescription only medicines which is provided on the Internet and directed to a UK audience.

If access to such material is not limited to health professionals and appropriate administrative staff, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections clearly separated and the intended audiences identified.

Material intended for the public which is provided on the Internet must comply with Clause 22.2.

LEGISLATION, OTHER CODES *and* GUIDELINES

LEGISLATION

The Human Medicines Regulations 2012
2012 No. 1916

The Consumer Protection from Unfair Trading
Regulations 2008
2008 No. 1277

Directive 2001/83/EC on the Community Code relating
to medicinal products for human use, as amended by
Directive 2004/27/EC

Bribery Act 2010

OTHER CODES

International

IFPMA Code of Practice (International Federation of
Pharmaceutical Manufacturers and Associations)

EFPIA Code on the Promotion of Prescription-Only
Medicines to, and Interactions with, Healthcare
Professionals

EFPIA Code of Practice on Relationships between the
Pharmaceutical Industry and Patient Organisations

(European Federation of Pharmaceutical Industries and
Associations – EFPIA)

WHO Ethical Criteria for Medicinal Drug Promotion,
Geneva 1988 (World Health Organisation)

IPCAA Healthcare Congress Guidelines (International
Pharmaceutical Congress Advisory Association)

United Kingdom

The UK Code of Non-broadcast Advertising, Sales
Promotion and Direct Marketing (Committee of
Advertising Practice/ Advertising Standards Authority)

Codes of Practice for Advertising Over-the-Counter
Medicines – the PAGB Consumer Code and the PAGB
Professional Code (Proprietary Association of Great
Britain – PAGB)

BMA ‘Medical ethics today’ (British Medical
Association)

General Medical Council ‘Good Medical Practice’

General Pharmaceutical Council ‘Standards of conduct,
ethics and performance’

Nursing & Midwifery Council ‘Standards of conduct,
performance and ethics for nurses and midwives’

Department of Health ‘Commercial sponsorship –
Ethical standards for the NHS’

Department of Health ‘Standards of Business Conduct
for NHS Staff’

GUIDELINES

Advertising and Promotion of Medicines in the UK
(2012) – The Blue Guide (Medicines and Healthcare
products Regulatory Agency). It includes Disease
Awareness Campaigns Guidelines and Medicines
which are promoted for use during pregnancy –
Guidance for the pharmaceutical industry

Best practice guidance on joint working between the
NHS and the pharmaceutical industry and other
relevant commercial organisations (Department of
Health)

Moving beyond sponsorship: interactive toolkit for
joint working between the NHS and the pharmaceutical
industry (Department of Health/ ABPI)

ABPI Guidance notes on joint working between
pharmaceutical companies and the NHS and others for
the benefit of patients

Joint Position on the Disclosure of Clinical Trial
Information via Clinical Trial Registries and Databases
2009 (<http://clinicaltrials.ifpma.org>)

Joint Position on the Publication of Clinical Trial Results
in the Scientific Literature 2010
(<http://clinicaltrials.ifpma.org>)

Guidelines on Standards in Medical Information
(Pharmaceutical Information & Pharmacovigilance
Association)

The Legal & Ethical Guidelines for Healthcare Market
Research (British Healthcare Business Intelligence
Association/ ABPI)

INDEX

Key

numbers refer to clauses in the Code

si refers to supplementary information to a clause in the Code

¶ followed by number refers to a paragraph in the Constitution and Procedure

abbreviated advertisements – 5

ABPI (the Association of the British Pharmaceutical Industry)

Board of Management – ¶ 1.3, ¶ 3.1, ¶ 11.4, ¶ 12, ¶ 13.4, ¶ 16.1 & ¶ 16.6

examinations – 16.3 to 16.6 & *si*

absolute risk, reference to – *si* to 7.2

administrative charges

appeals against number of – ¶ 16.5

determination of charges

in cases – ¶ 16.5

in relation to admissions – ¶ 16.4

in co-promotion – ¶ 16.3

levels of – ¶ 16.2

failure to pay – ¶ 16.6

payment of in relation to rulings

by Appeal Board – ¶ 10.1 & ¶ 10.2

by Panel – ¶ 7.1 & ¶ 7.2

administrative staff, promotion to – *si* to 1.1

admissions by pharmaceutical companies – ¶ 5.6 & ¶ 16.4

advance notification of new products – *si* to 3.1

adverse event reporting mechanisms – 4.10 & *si*, 5.6 & *si*

advertising to the public – 1.1 & 22.1 & *si*

advice on Code – ¶ 18.1

all-embracing claims – 7.10 & *si*

amendments to Code and Constitution and Procedure – ¶ 19

amount of advertising in journals – 6 & *si*

animal data, use of – *si* to 7.2

appeals against Panel rulings

appeals by complainants – ¶ 7.3 & ¶ 7.4

appeals by respondent companies – ¶ 7.3 & ¶ 7.5

appearance before Appeal Board – ¶ 4.6

withdrawal of appeals – ¶ 15

approval of promotional material – *see* certification

artwork, illustrations, graphs and tables

general – 7.8

abbreviated advertisements – *si* to 5.4, 5.5, 5.6, 5.7, 5.8 & 5.9

references to sources when taken from published studies – 7.8 & *si*

see also si to 7.2 on use of statistical information

audio, audio-visual material and interactive data systems etc

abbreviated advertisements not permitted – 5.2

certification – *si* to 14.1

prescribing information requirements – 4.4 & *si*, 4.5 & 4.6

audit of company's procedures – ¶ 10.4, ¶ 11.3 & ¶ 12.2 charges for – ¶ 16.1

automated calling systems – 9.9

benefit/risk profile – *si* to 7.10

benefits – 18.1 & *si* & 18.6 & *si*

black triangle symbol – 4.11 & *si* and *si* to 4.1 in abbreviated advertisements – 5.7 & *si*

Blue Guide – *si* to 1.1 & 24.1, 24.4 & 24.5 & page 57

bonus stock – *see* samples – *si* to 17

brand names, use of other companies' – *si* to 7.3

Bribery Act – page 57

briefing material for representatives – 15.9 & *si*

British Medical Association

case reports – ¶ 13.5

consultation with

on appointment of Appeal Board independent

registered medical practitioners – ¶ 3.2

on Code – ¶ 19.2

Medical Ethics Today – page 57

carers, hospitality to – *si* to 23.2

case preparation manager – ¶ 2.1, ¶ 5.1, ¶ 5.2, & ¶ 5.6

case reports – ¶ 13

certification

general – 14

audio and audio-visual material etc – *si* to 14.1

content of certificate – 14.5

educational material relating to diseases or medicines – 14.3

Internet – *si* to 14.1

joint working material – 14.3

meetings held outside UK – 14.2

non-promotional material relating to the provision of medical and educational goods and services – 14.3

notification of signatories – 14.4

patient organisation material – 14.3

patient support programme material – 14.3

preservation of certificates – 14.6 & *si*

promotional aids – *si* to 14.1

promotional material – 14.1

promotional material at international conferences in UK – *si* to 3

qualifications and experience of signatories – 14.1 & *si*

children in advertisements – *si* to 7.8

- clinical assessments – 12.2
- clinical and scientific opinion
 - current views of authors – 10.4 & *si*
 - disparaging clinical and scientific opinion – 8.2
 - emerging opinion – *si* to 7.2
- clinical trials, disclosure of details – 21.3 & *si*
- clinical trial data, use of – *si* to 7.5
- Codes of Practice for Advertising Over-the-Counter Medicines of the PAGB – *page* 57
- Code of Practice Appeal Board
 - Constitution and Procedure – ¶ 3 & ¶ 4
 - independent members to be in a majority – ¶ 4.2
 - membership – ¶ 3.2
 - power to publicly reprimand – ¶ 10.5 & ¶ 11.3
 - power to require audit – ¶ 10.4 & ¶ 11.3
 - power to require a corrective statement – ¶ 10.6 & ¶ 11.3
 - power to require pre-vetting – ¶ 10.4 & ¶ 11.3
 - power to require recovery of items – ¶ 10.3 & ¶ 11.3
 - reports from Code of Practice Panel – ¶ 4.1 & ¶ 8
 - reports to ABPI Board – ¶ 12.1
 - reports to, consideration of – ¶ 11
 - rulings – ¶ 10
- Code of Practice levy – ¶ 16.1
- Code of Practice Panel
 - Constitution and Procedure – ¶ 2
 - membership – ¶ 2.1
 - power to suspend advertising on complaints from Medicines and Healthcare products Regulatory Agency – ¶ 9.2
 - power to suspend material or activities in certain circumstances pending an appeal – ¶ 7.1
 - reports to Appeal Board – ¶ 4.1 & ¶ 8
 - rulings – ¶ 7
- Commission on Human Medicines, references to – 9.5
- Committee on Safety of Medicines, references to – 9.5
- comparisons
 - general – 7.2 & 7.3 & *si*
 - disparaging references, prohibition on – 8.1 & *si*
 - hanging comparisons – *si* to 7.2
 - price/cost comparisons – *si* to 7.2
- competitions & quizzes – *si* to 18.1
- complaints procedure
 - complaints from Medicines and Healthcare products Regulatory Agency – ¶ 9
 - confidentiality of complainants – *see introduction to Constitution and Procedure – page* 40
 - dealing with complaints – ¶ 5 to ¶ 13
 - making complaints
 - general – *see introduction to Constitution and Procedure – page* 40
 - by pharmaceutical companies – ¶ 5.3
 - withdrawal of complaints – ¶ 15
- conciliation between companies – ¶ 18.2
- conferences – *see meetings*
- confidence in the industry – 2 & *si*
- consultants
 - disclosure of payments to – 20.2 & 20.3 & *si*
 - from patient organisations – 23.8 & *si*
 - use of – 20 & *si*
- continuing professional development meetings and courses – *si* to 19.1
- contracts with institutions etc – 18.7
- co-promotion – *si* to 14.1
- corporate advertising, examination of – *si* to 14.3
- cost comparisons – *si* to 7.2
- criticism in media – ¶ 6
- current views of authors – 10.4 & *si*
- data on file, provision of – 7.7
- date of prescribing information – 4.2
- date of promotional material – 4.9
- delivery of items by representatives – *si* to 15.3
- discounts – *see* trade practices
- discredit to the industry – 2 & *si*
- disease awareness campaigns – *si* to 22.2
 - Disease Awareness Campaigns Guidelines – *si* to 22.2 & *page* 57
- disguised promotion – 12 & *si*
- disparaging references, prohibition on – 8 & *si*
- distribution of promotional material – 11 & *si*
- doctors, use of names and photographs – 9.3
- donations
 - in lieu of hospitality – *si* to 15.3
 - to charities – *si* to 15.3 & 18.1
 - to institutions etc – 18.6 & *si*
 - see also* prohibition on financial inducements – 18.1
- DVDs for health professionals – *si* to 18.1
- economic evaluation of medicines – *si* to 7.2
- educational goods and services, provision of – 18.4 & *si*
- EFPIA Code on the Promotion of Prescription – Only Medicines to, and Interactions with, Healthcare Professionals – *see introduction to Code & page* 57
- EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations – *see introduction to Code & page* 57
- electronic data communications – 9.9
- email, use of – 9.9 & *si* & *si* to 15
- employee responsible for ensuring compliance with Code – 1.9 & *si*

- employees, current and prospective, information for – *si to 22.2*
- European Directive – *see introduction to Code & page 57*
- exaggerated or all-embracing claims – 7.10 & *si*
- examinations for representatives – 16.3 to 16.6 & *si*
- exhibitions and exhibition panels, prescribing information requirements – *si to 4.1*
- experience programmes – 12.2
- extremes of format, size & cost of promotional material – 9.7 & *si* – *see also si to 11.2*
- facsimile, use of – 9.9 & *si to 15*
- films – *see audio, audio-visual material and interactive data systems etc*
- financial inducements, prohibition of – 18.1
- free goods – *see samples – si to 17*
- frequency
of mailings – 11.2 & *si*
of mailings for new medicines – *si to 11.2*
of calls by representatives – 15.4 & *si*
- General Medical Council – *si to 15.3, 18.1 & 19.1 & page 57*
- General Pharmaceutical Council – *si to 15.3, 18.1 & 19.1 & page 57*
- gifts – 18.1 & *si*
- grants to institutions etc – 18.6 & *si*
- graphs – *see artwork, illustrations, graphs and tables*
- guidelines on company procedures relating to the Code of Practice – *page 51*
- hanging comparisons – *si to 7.2*
- health professionals, use of names and photographs – 9.3
- health professions, criticism of – 8.2
- healthy volunteer studies, use of data from – *si to 7.2*
- high standards, maintenance of – 9.1
- Human Medicines Regulations – *see introduction to Code & page 57*
- IFPMA Code of Practice – *see introduction to Code & page 57*
- illustrations
see artwork, illustrations, graphs and tables
- inducements – 18.1
- information to the public – 22 & *si, 24 & si*
- inserts in journals
cannot be abbreviated advertisements – 5.2
size of – 6.2
see also si to 6.3
- interactive data systems
see audio, audio-visual material and interactive data systems etc
- international conferences, symposia and meetings
see meetings
- international journals, advertising in – *si to 1.1*
- Internet
general – 24
abbreviated advertisements not permitted – 5.2
access to promotional material by public – *si to 24.1*
certification – *si to 14.1*
journals – 24.4
prescribing information requirements – 4.6
- in-vitro* data, use of – *si to 7.2*
- items delivered by representatives – *si to 15.3*
- joint ventures & co-promotion – *si to 14.1*
- joint working with the NHS – *si to 1.1 & 18.5 & si*
- journal advertising
advertising in international journals – *si to 1.1*
specific requirements – 4.7 & 6
see also abbreviated advertisements in professional publications – 5.2 & si
- ‘knocking copy’ – 8.1 & *si* – *see also 7.3*
- labelling
labelling of medicines – 1.2 under ‘It does not include’
labelling of samples – 17.5
- legislation – *page 57*
- levy
failure to pay – ¶ 16.6
level of – ¶ 16.1
- licensing authority, references to – 9.5
- limitations on journal advertising – 6 & *si*
- loans, long term or permanent – *si to 18.1*
- mailings
frequency and number of – 11.2 & *si*
mailed medicines – 17.10
mailing lists – 11.3
- margins – *see trade practices*
- market extension – *si to 1.1*
- market research
disclosure of payments – 20.1 & *si* – 20.3 & *si*
general – 12.2 & *si*
guidelines – The Legal & Ethical Guidelines for Healthcare Market Research – *si to 12.2 & page 57*
- market share claims – *si to 7*
- marketing authorization – 3 & *si*
- media
complaints arising from – ¶ 6
relations with – 22 & *si*

- medical and educational goods and services, provision of – 18.4 & *si*
- medicines
 distributed in hospitals – 17.8
 handled by representatives – 17.9
 posted – 17.10
- Medicines and Healthcare products Regulatory Agency
 case reports – ¶ 13.5
 complaints from – ¶ 9
 consultation with
 on appointment of Appeal Board independent members – ¶ 3.1
 on Code – ¶ 19.2
 Disease Awareness Campaigns Guidelines – *si to 22.2 & page 57*
 MHRA Drug Safety Update – *si to 9.5*
 references to – 9.5
 submission of briefing material – 15.9
 submission of certificates – 14.6
 submission of names of signatories for promotional material – 14.4
 The Blue Guide Advertising and Promotion of Medicines in the UK – *si to 1.1, 24.1, 24.4 & 24.5 & page 57*
- Medicines Commission, Commission on Human Medicines, Committee on Safety of Medicines, Medicines and Healthcare products Regulatory Agency, Medicines Control Agency and licensing authority, references to – 9.5 & *si*
- meetings general – 19
 attendance by administrative staff – *si to 19.1*
 certification of meetings held outside the UK – 14.2
 continuing professional development (CPD) meetings and courses – *si to 19.1*
 exhibitions and exhibition panels, prescribing information requirements – *si to 4.1*
 held outside the UK – *si to 19.1*,
 certification of – 14.2
 hospitality, provision of – 19.1 & *si*
 involving travel outside the UK – *si to 19.1*,
 certification of – 14.2
 organised by affiliates – *si to 19.1*
 payment of room rental – 19.2 & *si*
 payment of travelling and accommodation expenses – 18.1 & 19 & *si*
 postgraduate education allowance (PGEA) meetings and courses – *si to 19.1*
 prohibition on inducements and payments for interviews – 15.3 & 18.1 & *si*
 promotion at international meetings – *si to 3 & 19.1*,
see also si to 1.1
 reports on meetings – *si to 19.3*, *see also 10.3*
 sponsorship of attendance at meetings, disclosure of – 19.4 & *si*
 sponsorship of meetings, disclosure of – 19.3
 subsistence, provision of – 19.1 & *si*
 venue, suitability of – 19.1 & *si*
- membership
 of Code of Practice Appeal Board – ¶ 3.2
 of Code of Practice Panel – ¶ 2.1
- memory sticks for health professionals - *si to 18.1*
- MHRA Drug Safety Update - *si to 9.5*
- naked or partially naked people, use of in advertising – *si to 9.1 & 9.2*
- National Health Service, joint working with – *si to 1.1 & 18.5 & si*
- new medicines
 advance notification of new products – *si to 3.1*
 avoidance of extremes of format, size or cost – *si to 9.7*
 introduction of a new medicine – 22.4
 limitations on mailings – 11.2 & *si*
 samples – 17.2 & *si*
 use of the word ‘new’ – 7.11
- non - interventional studies of marketed medicines
 approval and supervision of – 21.2
 disclosure of – 13.2 & *si*
 general – 13
- non-proprietary name, size and position – 4.3 & 5.5
- Nursing & Midwifery Council – Standards of conduct, performance and ethics for nurses and midwives – *si to 15.3, 18.1, 18.4 & 19.1 & page 57*
- offence, causing – 9.2
- official documents, reproduction of – 9.6
- outcome agreements – *si to 18.1*
- over-the-counter medicines
 definition of term – 1.5
 scope of the Code – 1.1 & *si*
- package deals – *si to 18.1*
- package leaflets – 1.2 *under ‘it does not include’*
 on the Internet – 24.5
 provision to the public – *si to 22.2 & 24.5*
- patient access schemes – *si to 18.1*
- patient carers, hospitality to – *si to 23.2*
- patient information leaflets
 provision by doctors to patients – *si to 22.2*
see also package leaflets
- patient organisations
 relationships with – 23 & *si*
 disclosure of support – 23.7 & *si*
 services provided by – 23.8 & *si*
- patients, items given to – 18.2 & *si*
- patient support items – 18.2 & *si*
- payments for interviews – 15.3 & *si & 18.1 & si*
- pecuniary advantage, offer or provision of – 18.1 & *si*
- pharmacovigilance – personnel’s knowledge of – 16.2
- post - authorization studies – 12.2 & 13
- postcards, use of – 9.8
- posted medicines – 17.10
- postgraduate education allowance (PGEA) meetings and courses – *si to 19.1*

- post-marketing surveillance studies – 12.2 & 13
- potency per weight claims – *si to 7.2*
- pre-printed private prescription forms – *si to 9.1 & 9.2*
- prescribing information
 - general – 4
 - date of – 4.2
 - exemptions – 4.1 & 5.1
 - legibility – 4.1 & *si*
 - provision on
 - audio, audio-visual etc – 4.4 & *si* & 4.5
 - exhibitions and exhibition panels – *si to 4.1*
 - Internet – 4.6
 - journal advertisements – 4.7
 - multi-page advertisements other than journal advertisements – 4.8
 - requisite information – 4.2
 - size of non-proprietary name – 4.3
 - typesize – *si to 4.1*
- prescription forms
 - pre-printed private prescription forms – *si to 9.1 & 9.2*
 - reproduction of official documents – 9.6
- Prescription Medicines Code of Practice Authority
 - annual report – ¶ 20
 - material to be supplied to Authority
 - authority of Director to require material – ¶ 1.4
 - copies of certificates – 14.6
 - examination status of representatives – 16.6
 - material required for scrutiny – ¶ 17.1
 - medical representatives briefing material – 15.9
 - names of signatories – 14.4
 - scrutiny – ¶ 17
 - structure and responsibilities – ¶ 1
- press conferences and press announcements – 22.2 & *si*
- pre-vetting
 - cost of – ¶ 10.4 & ¶ 11.3
 - power of Appeal Board to require – ¶ 10.4 & ¶ 11.3
- price comparisons – *si to 7.2*
- price lists – 1.2 under ‘it does not include’
- prices – *see* trade practices
- prizes – *si to 18.1*
- private prescription forms, preprinted – *si to 9.1 & 9.2*
- professional publications – 5.2 & *si* for definition of term
- promotional aids – 1.7 & 18.1 & *si*
- public assessment reports (European & UK)
 - outside scope of the Code – 1.2 under ‘It does not include’
 - provision of
 - on the Internet – 24.5
 - to the public – *si to 22.2 & 24.5 & si*
- public health campaigns – *si to 22.2*
- public relations activities – 22 & *si to 22.2*
 - responsibility for – 22.5
- public, relations with
 - advertising to – 1.1 & 22 & *si*
- disease awareness campaigns – *si to 22.2*
- enquiries from – 22.3 & *si*
- exposed mailings – 9.8 & *si*
- Internet – 24
- provision of information to – 22 & *si*, 24 & *si*
- provision of samples to not allowed – 17.11
- public health campaigns – *si to 22.2*
- quizzes – *si to 18.1*
- quotations – 10.2 & *si*, 10.3 & 10.4 & *si see also 7.6*
- referee, independent – ¶ 5.1, 5.2, 5.3, 7.2, 7.4, 7.5 & 7.6
- references
 - prohibition in abbreviated advertisements – 5.9
 - references to published studies – 7.6 & *si*, 7.8 & *si*
- relative risk, reference to – *si to 7.2*
- reminder advertising
 - see* abbreviated advertisements
- replies to individual enquiries – 1.2 & *si*
- reply paid cards – *si to 9.8*
 - reply paid cards offering items to be delivered by representatives – *si to 15.3*
 - see also* samples, request forms – 17.3 & *si*
- representatives
 - general – 15
 - briefing material – 15.9 & *si*
 - contract representatives – *si to 15*
 - definition of term – 1.6
 - delivering items – *si to 15.3*
 - examinations – 16.3 to 16.6
 - frequency & manner of calls on doctors – 15.4 & *si*
 - hospitality and payments for meetings – *si to 15.3*
 - identifying themselves – 15.5
 - items delivered by representatives – *si to 15.3*
 - prohibition on payments for interviews – 15.3 & *si*
 - provision of summary of product characteristics by representatives – 15.8 & *si*
 - training, general – 15.1, 16.1, 16.3 to 16.5 & *si*
- reprints of articles, distribution of – 10.1 & *si*
- reproduction of official documents – 9.6
- risk/benefit profile – *si to 7.10*
- risk, relative and absolute – *si to 7.2*
- risk sharing agreements – *si to 18.1*
- room rental, payment – 19.2 & *si*
- Royal College of Nursing
 - case reports – ¶ 13.5
 - consultation with
 - on appointment of Appeal Board independent registered nurse prescriber – ¶ 3.2
 - on Code – ¶ 19.2
- Royal Pharmaceutical Society
 - case reports – ¶ 13.5
 - consultation with
 - on appointment of Appeal Board independent registered pharmacist – ¶ 3.2
 - on Code – ¶ 19.2

- rubber stamps as aids to prescription writing – *si to 9.1 & 9.2*
- rulings
 - by Appeal Board – ¶ 10
 - by Panel – ¶ 7
- ‘safe’, use of the word – 7.9 & *si*
- samples
 - general – 17
 - definition of – *si to 17*
 - distribution
 - in hospitals – 17.8
 - to the public not allowed – 17.11
 - identification samples – *si to 17*
 - labelling – 17.5
 - maximum number of – 17.2
 - posted – 17.10
 - request forms and their retention – 17.3 & *si*
 - size – 17.4
 - starter packs – *si to 17*
 - system of control and accountability – 17.9
 - titration packs – *si to 17*
 - use as inducement – 17.12
 - use for patient treatment – 17.12
 - which medicines can be sampled? – 17.2 & *si*
- sanctions
 - audit of company’s procedures – ¶ 10.4, ¶ 11.3 & ¶ 12.2
 - case reports – ¶ 13
 - corrective statements – ¶ 10.6 & ¶ 11.3
 - pre-vetting – ¶ 10.4 & ¶ 11.3
 - publication in medical, pharmaceutical and nursing press - ¶ 13.7
 - recovery of items – ¶ 10.3 & ¶ 11.3
 - reports to Appeal Board and ABPI Board – ¶ 8, ¶ 11 & ¶ 12
 - reprimand and publication – ¶ 10.5 & ¶ 11.3
 - suspension/expulsion from ABPI – ¶ 12.2
 - special provision for non ABPI companies – ¶ 11.4 & ¶ 12.2
 - undertakings from companies ruled in breach – ¶ 7.1, 7.3 & ¶ 10.2
- scientific service in charge of information
 - general – 21.1
 - reports on side effects by representatives – 15.6
- scientific service in charge of non-interventional studies of marketed medicines – 21.2
- scope of the Code – 1 & *si*
- scrutiny – ¶ 17
- sexual imagery, use of – *si to 9.1 & 9.2*
- side-effects
 - claims about – 7.9
 - need to consult SPC – 4.2 & 5.4
 - references to in prescribing information – 4.2
 - reporting by representatives – 15.6
- size of promotional material
 - abbreviated advertisements, size of – 5.3
 - journal advertisements, size of – 6
 - see also* extremes of format
- sponsorship of material and meetings, disclosure of – 9.10 & 19.3
- sponsorship of meeting attendance, disclosure of – 19.4 & *si*
- starter packs – *si to 17*
- statistical information, use of – *si to 7.2*
see also *si to 7.8* on artwork, illustrations, graphs and tables
- subsistence, provision of – 19.1 & *si*
- substantiation of information, claims and comparisons – 7.4 & 7.5
- suitability and taste – 9.1 & 9.2 & *si*
- summaries of product characteristics
 - outside scope of the Code – 1.2 under ‘It does not include’
 - need to consult – 4.2 & 5.4
 - provision of
 - by representatives – 15.8 & *si*
 - on the Internet – 24.5
 - to the public – *si to 22.2 & 24.5 & si*
 - with press releases and press packs – *si to 22.2*
 - with samples – 17.5
 - summary in prescribing information – 4.2
- superlatives – 7.10 & *si*
- suspension of advertising on complaints from Medicines and Healthcare products Regulatory Agency – ¶ 9.2
- suspension of material or activities pending appeal when required by Panel – ¶ 7.1 & ¶ 7.3
- switch and therapy review programmes – *si to 18.4*
- symposia – *see* meetings
- tables – *see* artwork, illustrations, graphs and tables
- taste in advertising – *si to 9.1 & 9.2*
- ‘teaser’ advertising – *si to 9.1 & 9.2*
- telemessages, use of – 9.9 & *si to 15*
- telephone and text messages, use of – 9.9 & *si to 15*
- terms of trade – *see* trade practices
- textbooks, provision of – *si to 18.1*
- text messages, use of – 9.9 & *si to 15*
- ‘the’, use of the word – *si to 7.10*
- therapy review programmes – *si to 18.4*
- timing under complaints procedure
 - general – ¶ 14
 - appeals – ¶ 7.3
 - commenting on appeal by complainant – ¶ 7.4
 - commenting on appeal by respondent – ¶ 7.5
 - extensions – ¶ 7.1, ¶ 7.3 & ¶ 14
 - payment of administrative charge – ¶ 7.1, ¶ 7.2, ¶ 10.1 & ¶ 10.2
 - providing an undertaking on rulings by Appeal Board – ¶ 10.2

Panel – ¶ 7.1 & ¶ 7.3
responding to complaint – ¶ 5.4
suspension pending appeal when required by
Panel – ¶ 7.1 & ¶ 7.3

titration pack – *see* samples – *si* to 17

trade practices, prices, discounts, margins, etc – *si* to
18.1

training

training on Code – 16.1 & *si*

training of representatives – 15.1, 16.1, 16.3 to 16.5 & *si*

travelling expenses – 18.1 & 19 & *si*

unauthorized medicines and unauthorized indications
– 3 & *si* – *see also* unlicensed medicines

undertakings by companies ruled in breach – ¶ 7.1,
¶ 7.3 & ¶ 10.2

undertakings, breach of – 25

‘unique’, use of the word – *si* to 7.10

unlicensed medicines, price lists of – 1.2 & *si*

volume of promotional material – 11.2 & *si*

voluntary admissions by pharmaceutical companies
– ¶ 5.6 & 16.4

WHO Ethical criteria for medicinal drug promotion –
see introduction to Code and page 57

withdrawal of complaints and appeals – ¶ 15

‘wraparounds’ on journals – *si* to 6.2

yellow cards – 4.10 & 5.6



**Spanish Code of Good Practices
for the Promotion of
Medicines and Interaction
with Healthcare Professionals**



Spanish Code of Good Practices
for the Promotion of Medicines and Interaction
with Healthcare Professionals

1

Spanish Code of Good Practices for the Promotion of Medicines and Interaction with Healthcare Professionals

Introduction	3
Definition and purpose of the Code	4
Scope of the Code	4
Provisions of the Code	5
1. Marketing authorization	5
2. Information to be made available	6
3. Information and its rationale	6
4. Acceptability of material	7
5. Transparency of promotion	8
6. Use of reference quotations	8
7. Distribution of promotional material	8
8. Promotion via the internet	8
9. Scientific service and review of promotional material	9
10. Incentives	9
11. Hospitality and meetings	10
12. Pharmaceutical company staff	11
13. Samples	12
14. Studies	13
15. Donations and grants	15
16. Services rendered by entities integrated by healthcare professionals	15
17. Services provided by healthcare professionals	16
18. Rules of application of the code	17
19. Request for queries	18
20. Control of code compliance	18
21. Infringements and sanctions	19
22. Implementation guides and collaboration agreements	20
23. Disclosure and compilation of rulings	21
24. Entry into force of the code	21



Introduction

In 1991, Farmaindustria, conscious of the importance of providing accurate, fair and objective information about medicinal products to allow taking rational decisions on their use, adopted as Spanish Code the European Code of Practice of the Promotion of Medicines approved by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Subsequently, in 1992, the Spanish Code was appropriately adapted to make it fully consistent with the provisions introduced by Directive 92/28/ECC of 31 March 1992 on the advertising of medicinal products for human use. The revised version of the Code took effect on January 1, 1993.

On March 2002, FARMAINDUSTRIA's General Assembly approved a much more stringent and precise new version of the Code, and on January 2004 additional measures were taken to reinforce this self-regulation system on promotion of medicinal products by (i) preparing and approving implementation guides, (ii) implementing the query system, published in a question and answer format, and (iii) making an in-depth reform of the Rules of Procedure, including the start-up of the Code of Practice Surveillance Unit as the body responsible for active monitoring of Code compliance.

A new version of the Code, of the Rules of Procedure for the Control Bodies of the Spanish Code and of the Implementation Guides which came into force in June 2005, and incorporated

elements of the new version of the European Code approved in November 2004, and strengthened the self-regulation system.

Subsequently, following approval of a new version of the European Code in October 2007, adapting the Spanish Code had become necessary, culminating in the approval of a new text on 26 June 2008.

The recent amendment of Law 3/1991, of 10 January, of Unfair Competition, made by Law 29/2009 is of great importance, insofar as it promotes preparing Codes of Conduct by companies, associations, or commercial organizations, professionals and consumers in accordance with the provisions of Article 37.

The self-regulation system for the promotion of medicines of the pharmaceutical industry fully complies with the provisions of the Law of Unfair Competition. It collaborates with and belongs to Autocontrol, which is entrusted with the resolution of controversies, Autocontrol being the only Spanish private agency attached to the EJE-Net (European Extra-judicial Network) of the Commission.

Given the foregoing, resulting from the need to adapt the Code to applicable legislation to this issue and from pharmaceutical companies continuous commitment to provide self-regulation system with the higher level of credibility and transparency arises this new version of the Code, approved by the General Assembly of FARMAINDUSTRIA, during its meeting held on October 26th, 2010.

Definition and purpose of the code

This Code represents the ethical rules which, using its self-regulation power and according to the provisions of article 97, paragraph 5 of Directive 2001/83/EC, on the Community code relating to medicinal products for human use, FARMAINDUSTRIA has agreed to comply as regards promotion of medicines for human use as well as with regards in the field of interactions with the healthcare professionals, with the desire to guarantee that both are carried out in the respect of the strictest ethical principles of professionalism and responsibility. For this purpose, an Agreement was signed with the Association for Self-regulation of Commercial Communication (Autocontrol).

Compliance with the principles contained in the Code will ensure that the information made available to healthcare professionals when promoting the medicines they prescribe or supply is complete, up-to-date and accurate. This will be beneficial to the interests of both the Health Administration and the pharmaceutical industry, and to protect and improve public health. Both the content and nature of promotional activities or materials as well as the interaction with the healthcare professionals must contribute to strengthening confidence in the pharmaceutical industry.

Scope of the code

The Code covers all the forms of promotion of medicines and interactions between the Pharmaceutical companies and the healthcare professionals or any other person who, in the practice of his/her professional activity, may carry out or determine the activities of prescribing, buying, distributing, dispensing or administering a medicine.

The term 'promotion' refers to any activity undertaken, organized, or sponsored by a pharmaceutical company

or under its control –subsidiaries, foundations, associations, institutes, agencies, etc.- designed to directly or indirectly promote the prescription, dispensing, sale or consumption of its medicines.

To the effects of this Code, without prejudice to what is established by the current legislation in this matter, any member of the medical, dentist related, pharmaceutical or nursing profession, or any other person who, in the practice of his/her professional activity, can carry out or determine the activities of prescribing, buying, distributing, dispensing or administering a medicine, will be considered a healthcare professional.

The Code covers all promotional methods, including journal and direct mail advertising, the activities of medical representatives, the sponsorship of scientific congresses and scientific or professional meetings attended by health care professionals, the Internet, the use of audiovisual systems such as films, video recordings, data storage systems, and others that could arise in the future, and the provision of samples, gifts and hospitality.

Likewise, the Code covers all the forms of interaction between the Pharmaceutical companies and healthcare professionals, as well the ones derived from research agreements (clinical trials, studies) and other types of agreements (collaboration, Consulting, etc.).

This Code is not intended to inhibit the exchange of medical and scientific information during the development phase of a product nor to limit the relationship between the pharmaceutical companies and the healthcare professionals, but to establish rules of conduct that the entire pharmaceutical industry agrees to adhere to.

The Code does not cover:

- I) The labeling of medicinal products and accompanying package leaflets.
- II) Correspondence, possibly accompanied by material of a non-promotional nature

(e.g. scientific articles), needed to answer a specific question about a particular medicinal product, but only if it relates solely to the subject matter of the enquiry, is accurate and not misleading.

- III) Specific information and reference material relating, for example, to pack changes, warnings on adverse reactions in the setting of drug surveillance, trade catalogues and price lists, provided they include no information on the medicinal product. It also does not cover the information that the doctor may provide to a patient regarding certain medicines which, due to the complexity of their dosage, route of administration, etc., require the provision of additional information, as long as this information is intended to improve compliance with treatment.

- IV) Information on human health or diseases provided there is no reference, even indirect, to specific medicinal products.

- V) Corporate advertising of pharmaceutical companies, except as stated in article 17.3.

- VI) Promotion of non-prescription medicinal products, except as stated in article 10 and article 11.

Non-prescription medicines shall be excluded from the scope of the Code, as stated in Articles 10 (incentives) and 11 (hospitality and meetings), when established by a collaboration agreement between FARMAINDUSTRIA and ANEFP, regulating the promotion of these medicines and their control procedures, for the companies belonging to both Associations.

- VII) Originals, reprints, literal translations of scientific articles and abstracts published in scientific sources of recognized prestige are acceptable, provided they do not contain printed, stamped or electronically-linked trademarks or trade names of medicines, advertising slogans or other advertising material, related or not to this

information. This type of scientific information may be accompanied by publicity of the company, but regardless of the mass medium used (journals, bulletins, books or the like, or audiovisual materials stored on optical, magnetic, electronic or other supports), it shall have no connection with that scientific information, so that its handling, reading, display, listening or the like will be separate.

- VIII) Texts written or prepared by journalists as part of their professional work in regular editions, supplements, special issues or editions, etc. of newspapers, magazines, television or radio programs, etc., in which information about drug therapies, specific treatments or 'new' medicines, scientific studies or papers or references to a specific medicine, lines of research or product launchings, press conferences, publications, etc. is presented as a news item, an interview, a debate, an editorial or in another similar format, are permissible, provided that a contractual relationship does not exist between the research laboratory or owner of the trade mark or medicinal products and the firm responsible for the edition or the author of the information.

The companies adhered to the Code must comply with its spirit and letter, maintaining the same conduct standards in their relationship with all types of healthcare professionals.

Provisions of the code

1. MARKETING AUTHORIZATION

- 1.1. A medicinal product cannot be promoted prior to the grant of the marketing authorization allowing

its commercialization. This prohibition also covers medicines authorized in another country, which have not obtained marketing authorization in Spain. This regulation, however, does not imply a limitation to the right of the scientific community to be fully informed about medical and scientific progress, nor it intended to restrict complete and adequate exchange of scientific information related to medicines or medicinal substances, including appropriate and objective dissemination of research findings in the scientific communication media and scientific congresses.

1.2. All parts of the advertising of a medicinal product must be consistent with the information contained in the applicable summary of product characteristics and with the approved indications.

2. INFORMATION TO BE MADE AVAILABLE

2.1. All printed promotional material should include the following information in a clear and legible form:

- a)** Essential information consistent with the data in the summary of product characteristics, specifying the date on which it was prepared or last revised.
- b)** The prescription and dispensing conditions of the medicinal product.
- c)** The different presentations of the medicinal product and, when appropriate, the dosage and/or pharmaceutical form.
- d)** The selling price, the conditions for reimbursement by the National Health System and, when appropriate and feasible, the estimated cost of the treatment.

2.2. For audiovisual material such as films, video recordings and the like, and for interactive data systems, the information may be provided:

- a)** In a document which is made available to all persons to whom the material is shown or sent.

- b)** By inclusion on the audio-visual recording or in the interactive data system itself. In this case, the information shall be included in the manner technically feasible and adapted to the chosen medium, but guaranteeing rapid and comprehensible access to information in the applicable summary of product characteristics. When the information is included in an interactive data system, instructions for accessing it must be clearly stated.

2.3. In accordance with national law, where the advertising is intended only as a reminder and the medicinal product has been authorized for at least two years, the requirements of paragraph 2.1. above need not be complied with, provided the advertising includes no more than the name of the product. In this case, the name of the medicinal product must be included and, if this is a brand name or an invented name and the product contains a single drug substance, it must be accompanied by the Spanish Official Name or, if unavailable, the International Non-proprietary Name. The product logo and the name and logo of the pharmaceutical company may also be included, but no other information.

2.4. Printed information or documentation supplied by pharmaceutical companies to doctors to be given to patients regarding certain medicines which, due to the complexity of their dosage, route of administration, etc. require the provision of additional information, will not be considered promotional material, provided that this information is intended to improve treatment compliance.

3. INFORMATION AND ITS RATIONALE

3.1. Information about medicinal products should be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the concerned medicine. It should be based on an up-to-date evaluation of scientific evidence and clearly reflect that evidence; it should not mislead by distortion, undue emphasis, omission or in any other way.



3.2. All artwork, including illustrations, graphs and tables, must conform to the letter and spirit of the Code. Graphs and tables should be presented in such a way as to give a clear, fair, balanced view of the topics covered, and should not be included unless they are relevant to the claims or comparisons being made.

Special care should be taken to ensure that all graphic material included in the promotion is not misleading about the nature of the medicine (e.g. if the product is appropriate for use in children) or because of an argument or comparison (e.g. when incomplete or statistically non-relevant information, or unusual scales are used).

3.3. Information and statements about untoward reactions should reflect the available evidence. It cannot be stated that a product has no adverse effects, or toxicity or addiction risks.

3.4. To avoid adaptations in presentations of data that may introduce biases or cause confusion, when promotional material refers to published studies, these should be quoted exactly. In the case of tables or figures, they should be reproduced literally. In accordance with the rules on data publication, the reference of the published work should be added.

As an example of this, when the efficacy, safety or other properties of different drug substances are compared in promotional material, information such as the statistical significance of the results cannot be omitted, nor can the results of different clinical studies or trials be compared in the same table or graph, except when the source is a meta-analysis. Statistics, conclusions or any other data from different studies conducted using different methodologies cannot also be mixed or compared, unless they come from systematic reviews or meta-analyses in which homogeneity criteria are specified.

3.5. Exaggerated or all-embracing statements should not be made. Statements should not imply that a medicine or a drug substance has some

special merit, quality or property unless this can be substantiated.

3.6. The word new cannot be used to describe any medicine or presentation which has been generally available, or any indication which has been generally promoted, for more than two years in Spain.

3.7. Trademarks or trade names of medicinal products from other companies may only be quoted if their ownership is clearly indicated.

3.8. Comparative advertising must always comply with the regulations on fair competition. It cannot be disparaging, and comparisons must be based on relevant and comparable aspects. At any rate, and particularly as regards comparative advertising, care must be taken to ensure that the sources on which statements are based are valid and immediately accessible to the competitor.

3.9. Any information, statement, or comparison included in promotional materials should be well founded. Such foundation (or rationale) should be provided to physicians and all other healthcare professionals on request. In particular, any comparison made between different medicines must be scientifically verified. Such rationale need not be provided, however, for statements related to the indications approved in the summary of product characteristics.

4. ACCEPTABILITY OF MATERIAL

4.1. Any promotional activity or material should respect the special nature of the medicinal product and the professional standing of the target audience, and must not be likely to cause any offence or decrease the confidence in the pharmaceutical industry.

4.2. Promotional material should not imitate the products, slogans, presentation, or general layout adopted by other companies in a way that is likely to mislead or confuse.

4.3. Postcards, other exposed mailings, envelopes, or wrappers should not carry anything that



could be regarded as advertising to the general public.

4.4. All material relating to medicines and their uses that is sponsored by a pharmaceutical company must clearly state that it has been sponsored by that company.

5. TRANSPARENCY OF PROMOTION

5.1. Promotional material and activities should not be designed to disguise their actual purpose or nature.

5.2. Whenever a company finances, ensures, or directly or indirectly organizes publication of promotional material in newspapers or magazines, it should be expressly stated that such material is not included as an independent editorial topic, and the sponsoring company should be included in a visible place.

5.3. Any material related to medicines and their uses, whether promotional or not, that is sponsored by a company should clearly state that it has been sponsored by such company.

5.4. In consultations from the general public asking for advice on medical topics of a personal nature, a recommendation to consult a physician must be given.

6. USE OF REFERENCE QUOTATIONS

6.1. Quotations from medical and scientific literature or from personal communications should accurately reflect the opinion of the author.

6.2. Quotations relating to medicines taken from public broadcasts, for example on radio and television, and from private events, such as medical conferences or symposia, should not be used without the formal authorization of the speaker.

7. DISTRIBUTION OF PROMOTIONAL MATERIAL

7.1. Promotional material should be sent or distributed to those healthcare professionals for whom the particular information may be relevant.

Except authorization from the competent Health Authority (e.g. vaccination campaigns), promotion directed to the public in general will not be allowed for medicines which can only be dispensed through facultative prescription.

7.2. Mailing lists for shipment of promotional material must be regularly updated. Requests by healthcare professionals to be removed from promotional mailing lists must be complied with.

7.3. All promotional activities will be conducted in accordance with applicable regulations concerning personal data protection.

7.4. In the international congresses and meetings organized by third parties where numerous healthcare professionals from other countries assist, those shall be informed regarding some medicines or indications without marketing authorization in Spain, only if:

- (I) The information carried out or delivered is written in English or in any language pertaining to the countries where it is authorized, and
- (II) some text or warning such as “this medicine is not commercialized in Spain or in the following countries...” or “it is only authorized in ...” or “it is not authorized in Spain for the following indication ...” should be indicated or signalled at least in Spanish with emphasized letters, clearly visible, in a continuous, lasting and readable way on the item or any commercial material.

8. PROMOTION VIA THE INTERNET

8.1. Promotional materials for medicines directed to healthcare professionals to be disseminated through the Internet must have a primarily technical-scientific or professional content.



8.2. In addition, measures must be taken to ensure that this advertising is only accessible to these professional groups.

8.3. Promotional material must include a prominent and clearly legible warning indicating that the information contained on the web page is intended only for healthcare professionals qualified to prescribe or dispense medicines, and specialized training is therefore required for its adequate interpretation.

9. SCIENTIFIC SERVICE AND REVIEW OF PROMOTIONAL MATERIAL

9.1. Pharmaceutical companies must have a scientific service to compile and collect all information, whether received from medical representatives or from any other source, and to inform about the medicines which they market.

9.2. Promotional material should not be issued unless its final form, to which no subsequent amendments will be made, has been reviewed and checked by the scientific service of the company.

The scientific service should guarantee that it has examined the final version of the material and that in their opinion it is in accordance with the applicable rules regulating advertising and with this Code, is consistent with the marketing authorization, and particularly with the information included in the approved summary of product characteristics and patient leaflet, and is a fair and faithful presentation of the data about the medicine.

10. INCENTIVES

10.1. To ensure the independence of the decisions related to the prescribing, dispensing, or administering of medicines with regard to business interests, no gifts, bonuses, pecuniary advantages or benefits in kind may be granted, offered, or promised by those who have direct or indirect interests in the manufacture, production or commercialization of medicines to healthcare professionals or to any person who, in the

practice of his/her professional activity, can carry out or determine the activities related to the medicine prescription, dispensation or administration cycle, including their relatives, with the exception of inexpensive gifts related to the practice of medicine or pharmacy. Therefore, the provision of gifts such as items for professional use in the practice of medicine or pharmacy or office items of insignificant value is permissible.

Discounts for early payment or volume of purchase carried out by distributors (wholesaler or pharmaceutical company if it directly carries out the distribution) to pharmacies are considered an exception from the previously stated prohibition. These may make up to a maximum of 5% for the medicines reimbursed by the National Health System, which may be extended up to 10% in the case of generic drugs, provided that:

- a) They do not induce the purchase of a product against those of its competitors.
- b) Such practices remain recorded in the pertaining invoice.

10.2. Gifts will be considered to be inexpensive when their market price does not exceed 10 Euros. Market price refers to the amount that a recipient would normally pay for the purchase of one unit of said product in Spain.

10.3. The provision of objects such as books or other materials on optical, magnetic, electronic or similar supports on medicine or pharmacy topics sponsored by the company is excepted, provided that they comply with applicable legal requirements.

10.4. The provision of gifts of higher value or which are not of a scientific or technical nature is not permissible. It is also not permitted to provide directly or indirectly portable electronic devices susceptible to personal use, even if they may have a professional use.

10.5. These gifts must include all the information specified in article 2.1. However, when the

medicinal product has been authorized for at least two years and reminder advertising is thus allowed, only the information specified in article 2.3 can be included.

11. HOSPITALITY AND MEETINGS

The following standards shall apply to every type of event (congresses, conferences, symposia, meetings or any type of similar activity, including but not limited to expert meetings, investigator meeting, training meetings, etc.) organized or sponsored by a pharmaceutical company or under its control, and to all the participants therein, whether they might be healthcare professionals, or any other person who, in the practice of his/her professional activity, can carry out or determine the activities of prescribing, buying, distributing, dispensing or administering a medicine.

11.1. Pharmaceutical companies may organize or collaborate in events of a purely scientific-professional nature. It is not permitted to organize or collaborate in events containing elements or activities of an entertainment or recreational nature. This prohibition does not include welcome cocktails, work lunches and dress dinners that are usually included in the official programs of congresses and scientific meetings, provided they are reasonable and moderate and do not include additional elements (cultural, leisure or entertainment, etc.).

11.2. Hospitality at professional and scientific events should be reasonable at all times, and its cost cannot exceed what recipients would normally be prepared to pay for themselves in the same circumstances. The concept of hospitality includes the payment of actual travel, inscription and subsistence expenses by the company, which must be reasonable and not out of proportion, and be limited to the days on which the scientific meeting is planned to be held. Hospitality cannot be extended beyond a reasonable period after the event, nor will it include the sponsorship or organization of recreational events (sports, leisure activities, etc.).

Hospitality must always be secondary to the main purpose of the meeting. The scientific goals must represent the main focus in the organization of such meetings. Hospitality provided by a pharmaceutical company should be limited to include the strictly necessary logistic means—in all cases reasonable and moderate—that allows the healthcare professional to attend the event, and no other expense.

11.3. Hospitality should not be extended to persons other than healthcare professionals.

11.4. Payments may not be made to physicians or groups of physicians, either directly or indirectly, for rental for rooms to be used for meetings, unless it is duly accredited that such rooms are intended for scientific or professional meetings.

11.5. When meetings, congresses, symposia and similar events are sponsored by pharmaceutical companies, that fact must be disclosed in all of the papers relating to the meetings and in any published paper, speech, or document related to such meetings.

11.6. The payment of reasonable fees and reimbursement of out of pocket expenses, including travel, for speakers and moderators at meetings, congresses, symposia, and similar scientific or professional events, is permissible.

11.7. Pharmaceutical companies established in Spain which belong to international corporations with headquarters or subsidiaries or other associated companies located in foreign countries shall be responsible for compliance with this Code by these associated companies with regard to promotional activities directed to healthcare professionals practicing in Spain, when they are invited to events held in foreign countries or in the Spanish territory.

11.8. Scientific and promotional meetings and events organized or sponsored by pharmaceutical companies must be notified previously in accordance with the provisions in the Rules of Procedure of the Control Bodies of the Code.



11.9. Failure to notify a scientific and promotional meeting or event, when such notification is obligatory, shall constitute an infringement of this Code.

11.10. Companies cannot organize or promote events held outside Spain (international events) unless this makes more sense from a logistic viewpoint because:

- a) the majority of participants invited are foreigners; or
- b) a resource or expertise that is relevant and the main object of the event is located outside Spain. This case (b) shall have the previous authorization of the Code of Practice Surveillance Unit.

If international events are organized or sponsored, in addition to the Spanish Code, companies must also respect the specific provisions of the Code of Practice for the Promotion of Medicines of the country where the event is held, as set forth at article 18.4.

11.11. Companies should meet the criteria stated in the applicable codes as regards selection and sponsorship of healthcare professionals for their attendance to events.

11.12. In no case can money be offered to merely compensate the time used by healthcare professionals to attend the event.

12. PHARMACEUTICAL COMPANY STAFF

12.1. Medical representatives should be adequately trained by or on behalf of the company which employs them, and shall have an adequate scientific knowledge to present information on their company's products in an accurate and responsible manner.

12.2. Medical representatives should approach their duties responsibly, complying with the applicable law and ethical rules, as well as the provisions in this Code.

12.3. Medical representatives should not use any incentive or subterfuge to gain an interview. No fee shall be paid or offered for the grant of an interview.

12.4. Medical representatives should ensure that the frequency, timing and duration of visits to healthcare professionals, administrative staff in hospitals, and health authorities and the like, together with the manner in which they are made, do not cause inconvenience.

12.5. Both when interviews are agreed and conducted, medical representatives should from the very outset take any reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.

12.6. Medical representatives must notify to the scientific service of the pharmaceutical company any information they receive from the professionals about the use of the medicines they promote, with particular reference to any untoward reactions reported to them by the persons they visit.

12.7. At each visit, medical representatives will provide to the person visited, or have available for him/her if requested, the current summary of product characteristics for each medicinal product they promote, accompanied by information on the different pharmaceutical forms and dosages, the prescription and dispensing conditions of the medicinal product, price information, the conditions of reimbursement by the National Health System, if applicable, and when feasible, the estimated cost of the treatment.

12.8. Companies shall take effective measures to ensure that their medical representatives and all company personnel related in any way with the preparation or approval of promotional material or of information intended for healthcare professionals are fully conversant and comply at all times with the provisions in this Code and the relevant regulations on the advertising and promotion of medicines.



Likewise, they shall adopt efficient measures and watch so the interactions between the medical representatives and other pharmaceutical company staff with the healthcare professionals (including any other person who, in the practice of his/her professional activity, can carry out or determine the activities of prescribing, buying, distributing, dispensing or administering a medicine), complies with this Code and the applicable regulation provisions at any given time.

12.9. Medical representatives must have adequate training to disseminate the characteristics of the medicinal products. It is the responsibility of each company to ensure (through tests, additional training, joint work, etc.) on a regular basis that the training of their representatives is adequate.

12.10. The same rules as for medical representatives will be applicable for representatives who call on retail pharmacies, who should comply with the applicable law on the promotion of medicines and with ethical principles and provisions of this Code.

12.11. Each company should appoint at least one adequately qualified employee or manager, who will be responsible for internal supervision of Code compliance. An implementation guide shall explain the basic principles and mechanisms for internal control to be respected by all pharmaceutical companies. In any case, the existence of persons responsible for internal supervision does not exempt the maximum representatives of the companies from their responsibilities.

13. SAMPLES

13.1. In accordance with national law, a limited number of free samples may be supplied to healthcare professionals qualified to prescribe medicinal products, to familiarize themselves with new medicines, provided they are requested by the professionals.

13.2. Samples can be provided for a maximum of two years from the date of marketing authorization of the medicinal product.

13.3. A sample of a medicine should be no larger than the smallest presentation of the medicine available on the national market.

13.4. Each sample must bear the statement "free sample-sale forbidden", and the coupon of the medicinal product must be suppressed or cancelled. Whenever samples are provided, a copy of the current summary of product characteristics must always be given, together with updated price information, conditions of reimbursement in the National Health System, if applicable, and when feasible, an estimate of the cost of treatment.

13.5. No samples of medicinal products containing psychotropic or narcotic substances, as defined in international agreements, medicines that may cause dependency or give rise to public health problems from improper use, and any other medicinal products as determined by the relevant authorities may be given.

13.6. Samples distributed through medical representatives will be directly provided to healthcare professionals qualified to prescribe medicinal products who have requested them or persons authorized to receive them on their behalf.

13.7. Sample distribution in hospitals must comply with individual hospital requirements and procedures.

13.8. Companies must have adequate systems for control and accountability of samples they distribute.

14. STUDIES

14.1. Clinical trials. The term clinical trial comprises all the research carried out on human beings in order to determine or confirm the clinical, pharmacological and/or other pharmacodynamic effects, and/or to detect the adverse reactions, and/or to study the absorption, distribution, metabolism and excretion of one or various medicines under investigation, with a view to determining their safety and/or their efficacy.



Pharmaceutical companies shall carry out this kind of trials in accordance with applicable regulation, thus obtaining prior agreement of the Clinical Research Ethics Committee, the approval of each one of the Centers where it will take place and the authorization from the Spanish Agency for Medicinal Products and Medical Devices (AEMPS).

14.2. Post-authorization studies. A post-authorization study is any epidemiological or clinical study carried out during the marketing of a medicinal product in accordance with the conditions authorized in the summary of product characteristics or under normal conditions of use, in which the medicinal product(s) of interest are the main factor of exposure investigated. This type of study may take the form of a clinical trial (art 14.1) or an observational study.

An observational study is a study in which the medicinal products are prescribed in the usual manner in accordance with the conditions established in the marketing authorization. The assignment of a patient to a given therapeutic strategy shall not be decided beforehand by a trial protocol, but by the standard practice of medicine, and the decision to prescribe a given medicinal product shall be clearly dissociated from the decision to include the patient in the study. No diagnostic or follow-up intervention shall be applied to patients other than such as are standard in clinical practice, and epidemiological methods shall be used to analyze the data collected.

Post-authorization observation studies shall be those epidemiological studies that meet the conditions of being post-authorization and observational. These must be conducted in accordance with the requirements of applicable legislation, among others, submission of the documentation to the AEMPS for registration and classification, submission to a Clinical Research Ethics Committee for evaluation, etc. These studies should in no case be undertaken as a procedure to promote a product or to induce prescription by healthcare professionals.

Legislation also covers conducting observational studies that are not post-authorization studies (non-

PAS). These are observational studies in which the main factor of exposure investigated are not medicines, as is the case, for instance, of studies on incidence or prevalence of diseases. These observational studies should also be conducted in compliance with the requirements of applicable legislation.

14.3. Market research studies. Market research (including social and opinion research) consists of the systematic collection and interpretation of information on individuals or organizations, using statistical and analytical methods and techniques of the social sciences, applied to obtain new perceptions or provide elements of support for decision-making.

In these studies, the identity of respondents is not revealed to the user of the information without their specific consent, nor are respondents contacted for sales actions as a direct result of having provided the information.

Without prejudice to the applicable regulation, there is a general framework for ethical action in which market research should be conducted, embodied in the ICC/ESOMAR International Code of Marketing and Social Research Practice of the European Society of Marketing and Opinion Research (ESOMAR). In the specific case of the pharmaceutical industry, the framework of self-regulation in this area comprises the Code of Conduct of the European Pharmaceutical Marketing Research Association (EphMRA).

The present regulation does not seek to replace the EphMRA Code, but only for arranging certain mechanisms guaranteeing adequate conduct of these studies within the scope of this Code. The EphMRA Code shall be of subsidiary application for correct interpretation of this Code.

All market research studies that are carried out at the initiative of a pharmaceutical company, at the initiative of several pharmaceutical companies that share marketing strategies of a product or when a pharmaceutical company acquires the study from a third party (research institute, scientific society, etc.) that has undertaken the work on its own

initiative shall be subject to the provisions of this article.

Market research studies must meet the following requirements:

- I) Ignorance of the identity of the individuals participating in the study. Pharmaceutical companies shall not be able to know before, during or after its conduct, the identity of the individuals who took part in the study.
- II) Anonymous nature of the information collected. Pharmaceutical companies shall not have the possibility of linking by name each of the study participants with the data or opinions obtained.
- III) Pooled processing of the responses or data obtained.
- IV) Proportionality between the universe and the sample. Quantitative market research studies pursue a level of representativeness of the universe. When to calculate sample size, parameters are used other than those generally accepted in market research (simple random sample, a margin of error of 5%, 95% confidence and 50% heterogeneity level), prior authorization by the Code of Practice Surveillance Unit shall be required.
- V) The individual who participates in the study does not know and has no opportunity to link its conduct with a pharmaceutical company or a specific product. Therefore, the sales network of the pharmaceutical company cannot play any role in the conduct and implementation of study.
- VI) The study results and the data obtained will not be advertised or used in promotional material.

Any exception to these requirements should have prior approval of the Code of Practice Surveillance Unit. In particular, requirements i, ii and v will be developed in the guide for market research studies linked to a product.

In addition, to ensure that market research studies do not represent an inducement to prescription or contain an incentive prohibited by the Code, pharmaceutical companies undertake to:

- I) Communicate them prior to their start, in accordance with the Rules of Procedure of the Control Bodies of the Code.
- II) Ensure the study does not modify the physicians' prescriptions habits or the pharmacists' dispensing habits.
- III) Have a written protocol in which its objectives, methodology, expected results and its use are clearly established.

In this respect, written agreements shall be signed with the professionals and/or the entities with which the studies will be carried out on one hand, and the company sponsoring the study on the other hand, specifying the nature of the services to be provided, the professionals' participation and payment conditions, etc.

- IV) Payment to participating professionals must be based on market criteria and be proportionate to the time devoted, the work done, and the responsibilities assumed, and must be adequately documented.

Payment shall be monetary. Exceptionally, and with prior authorization of the Unit, some payments may be made in kind.

- V) Guarantee that conduct of the study does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.
- VI) Be approved prior to their conduct by the pharmaceutical company scientific service or by the compliance officer foreseen in Article 12.11 of the Code.

These requirements shall be applicable irrespective of the methodologies, sources, or techniques applied for its conduct, for example: survey method, observation, experimental designs, ethnographic techniques, expert groups, qualitative techniques, etc.

Failure to communicate the studies referred to in article 14.3, when such communication is compulsory, shall constitute an infringement to this Code.

14.4. Any other type of activity, practice, or initiative for information collection not foreseen in the foregoing paragraphs or in articles 16 and 17 of the Code and intended to involve directly or indirectly payment to healthcare professionals, will be considered a promotional action and, as such, shall be subject to the provisions in this Code, particularly in Article 10 (Incentives).

15. DONATIONS AND GRANTS

Donations, grants and benefits in kind to institutions, organizations or associations that are composed of healthcare professionals and/or that provide social or humanitarian assistance services or conduct research education or training (that are not otherwise covered by this Code or the Spanish Code of Practice on Interactions between the Pharmaceutical Industry and Patient Organizations) are only allowed if:

- (I)** they are made for the purpose of supporting healthcare, research, education/training or social or humanitarian assistance;
- (II)** they are documented and kept on record by the donor/grantor; and
- (III)** they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Donations and grants to individual healthcare professionals are not permitted under this section, except companies' sponsorship of healthcare professionals to attend international events which is covered in Article 11. Hence, in accordance with article

10.4, direct or indirect donation of portable electronic devices susceptible to personal use, even if they may have professional use, is not permitted.

To encourage transparency, companies are encouraged to make publicly available information about donations, grants or benefits in kind made by them, covered in this Section.

16. SERVICES RENDERED BY ENTITIES INTEGRATED BY HEALTHCARE PROFESSIONALS

16.1. Contracts between companies and institutions, organizations or associations of healthcare professionals under which such institutions, organizations or associations provide any type of services to companies (or any other type of agreement from which funding not covered by this Code arises) are only allowed if such services:

- I)** are provided for the purpose of supporting health assistance, research, teaching and training, or the organization of professional or scientific events;
- II)** are gathered on a document of which the contracting pharmaceutical company keeps a record;
- III)** do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products; and
- IV)** are approved, prior to the contract, by the pharmaceutical company scientific service or by the compliance officer foreseen in article 12.11 of the Code.

16.2. Agreements with these entities involving paid participation of at least 20 healthcare professionals must be notified by pharmaceutical companies which organize or sponsor them in their majority, prior to their start, in accordance with the Rules of Procedure of the Control Bodies of the Code.

Failure to notify these agreements will constitute an infringement of this Code.

17. SERVICES PROVIDED BY HEALTHCARE PROFESSIONALS

17.1. It is permitted to use healthcare professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel and boarding expenses. The arrangements covering legitimate provision of such services must meet the following conditions:

- a) a written contract or agreement is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;
- b) a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- c) the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- d) the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need;
- e) the contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants;
- f) the hiring of the healthcare professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and

- g) Payment to participating professionals must be based on market criteria and be proportionate to the time devoted, the work done, and the responsibilities assumed, and must be adequately documented.

Payment shall be monetary. Exceptionally, and with prior authorization of the Unit, some payments may be made in kind.

- h) are approved, prior to the contract, by the pharmaceutical company scientific service or by the compliance officer foreseen in article 12.11 of the Code.

17.2. When the contracting of this kind of service for a single project or activity involves paid participation of at least 20 healthcare professionals, the pharmaceutical company must notify it before it begins, in accordance with the Rules of Procedure of the Control Bodies of the Code.

Failure to notify these services shall constitute an infringement of this Code.

17.3. In their written contracts with consultants, companies are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he/she is a consultant to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company.

Similarly, companies that employ, on a part-time basis, healthcare professionals that are still practicing their profession are strongly encouraged to ensure that such persons have an obligation to declare his/her employment arrangement with the company whenever he/she writes or speaks in public about a matter that is the subject of the employment or any other issue relating to that company.

This section applies in all cases, even though the Code does not cover corporate advertising of pharmaceutical companies.



17.4. If a healthcare professional attends an event in a consultant or advisory capacity, the relevant provisions of Article 11 shall apply.

18. RULES OF APPLICATION OF THE CODE

18.1. The companies that are members of FARMAINDUSTRIA or adhered to the Code have agreed to abide by the principles contained in this Code in the conduct of their promotional activities and in their interaction with healthcare professionals or with any other person who, in the practice of her professional activity, can carry out or determine the activities of prescribing, buying, distributing, dispensing or administering a medicine.

The companies that are members of FARMAINDUSTRIA or adhered to the Code which also belong to other Associations whose goals and objectives match some of the objectives stated in the bylaws of FARMAINDUSTRIA, must apply, as a priority, the provisions of this Code as opposed to other self-regulation systems which can be applicable in medicines promotion, all in accordance with what is stated in Article 18.4.

In the case of Groups of Companies, the companies belonging to such groups that are individual members of FARMAINDUSTRIA or adhered to the Code at an individual level shall be held responsible for any possible infringements of the Code committed by companies of their Group that are not members of FARMAINDUSTRIA or adhered to the Code.

Likewise companies that are members of FARMAINDUSTRIA or adhered to the Code at an individual level shall be held responsible for any possible infringements of the Code committed by third parties acting in their name or representation, or under their control, or according to a subscribed agreement (examples: external sales networks, marketing studies companies, travel agencies, advertising agencies, etc.).

The companies adhered to the Code that are not members of FARMAINDUSTRIA shall contribute to operating expenses and application of the self-regulation system by means of a financial contribution, at least in the same proportion as companies that are members of FARMAINDUSTRIA.

18.2. In addition, as a national association that is a member of the EFPIA, FARMAINDUSTRIA shall comply with the provisions in the European Code of Practice for the Promotion of Medicines and Interactions with Healthcare Professionals (hereinafter EFPIA Code) as adopted in 1991 and subsequently amended in November 2004 and October 2007, particularly with regard to its Rules of Application and Procedure detailed in Annex A to said Code.

18.3. Pursuant to the provisions of the EFPIA Code, the member companies of such Federation must comply with the applicable codes in the different countries where they operate, and enforce compliance of the code by their respective subsidiary and related companies.

The companies members of the EFPIA shall comply with the Codes and regulations which apply to them. In conformity with what is stated in the bylaws of said Federation, the companies members of the EFPIA shall: (i) in the countries where they operate – directly or through a subsidiary – in which the EFPIA code is applicable, belong to a member association, or (ii) accept in writing with each member association, its submission—or its subsidiary's—to the Code of this association (including the applicable sanctions which could apply in virtue of it).

18.4. As established in the EFPIA Code, the applicable codes for promotion and interaction with healthcare professionals in Europe (that is in the countries where the EFPIA member associations Codes apply) are as follows:

- a)** (i) for promotion conducted, sponsored, organised or under the control of a company sited in Europe, the code of the national association of the country where the company is sited; (ii) if promotion is

conducted by a company not sited in Europe, the EFPIA Code; and

- b) the code of the national association of the country where the promotion is conducted.

If a conflict should arise between the rules of the different codes applicable in a given promotional activity or an activity of interaction with healthcare professionals, the most strict or stringent rule will prevail.

The term “company” as used in the EFPIA Code refers to any legal entity, whether the company headquarters, control company, marketing company, subsidiary, or any other form of legal entity organizing or sponsoring promotional activities in Europe.

19. REQUEST FOR QUERIES

19.1. The companies subject to the Code provisions in accordance with articles 18.1 and 18.3 may submit queries on the conformity to the Code of a given promotional activity or of interaction with healthcare professionals, or request for clarifications of a more general nature related to the Code. Queries on the content of specific promotional materials are excluded.

19.2. Queries must be addressed to the Code of Practice Surveillance Unit following the procedure established for this purpose in the Rules of Procedure of the Control Bodies of the Code and shall be resolved by the Code of Practice Committee. Queries will be binding for both the Unit and the Committee.

19.3. Neither the queries submitted nor their outcome can be mentioned in promotional activities or of interaction with healthcare professionals.

19.4. Queries of general interest for the whole industry shall be published, at Board of Governors criteria, in the form of questions-answers, maintaining the anonymity of the company that submitted the query.

20. CONTROL OF CODE COMPLIANCE

20.1. Control of compliance with the regulations on the promotion of medicines set out in this Code shall be the responsibility of the Code of Practice Surveillance Unit, the Code of Practice Committee of the Pharmaceutical Industry in Spain (hereinafter the Code of Practice Committee) and the Jury of the Association for Self-Regulation of Commercial Communications (hereinafter the Jury).

20.2. In this regard, companies that are subject to Code provisions in accordance with articles 18.1 and 18.3, without prejudice to the request for cessation that may be sent to the pharmaceutical company against whom the complaint has been alleged, agree to initially submit to the Code of Practice Committee any eventual complaints against the promotional practices of other companies subject to code provisions, prior to lodging an appeal with the courts of justice or health authorities, and to obey and comply immediately with the mediation agreements reached and the content of the Jury's decisions.

20.3. Both the complainant and the respondent companies agree to preserve the confidentiality in the processing of the complaint and its resolution, refraining from disclosing any information about it, until the decision on the conflict has been published, if applicable.

20.4. For effective application of this Code, and processing and resolution of any eventual complaints that may be submitted against promotional activities of companies or activities of interaction with healthcare professionals that are subject to the Code provisions in accordance with articles 18.1 and 18.3, the Code of Practice Surveillance Unit, the Code of Practice Committee, and the Jury shall abide by the provisions of their respective Rules of Procedure.

20.5. Failure to cooperate with the Control Bodies of the Code by a company subject to the Code provisions in accordance with article 18.1 and 18.3 shall represent an infringement in accordance with the provisions in article 21.

20.6. The rejection or unjustified failure to collaborate with the investigation procedure stated in Article 13 of the Rules of Procedure of the Control Bodies of a company subject to the provisions of the Code in accordance with Article 18.1 and Article 18.3 shall constitute a serious or very serious infringement in accordance with Article 21.

21. INFRINGEMENTS AND SANCTIONS

21.1. Infringements will be classified as minor, serious and very serious based on the following criteria:

- a) Magnitude of the infringement, particularly its potential risk for the health of patients.
- b) Impact on the scientific or medical community of the practice resulting in Code infringement.
- c) Unfair competition.
- d) Generalization of the infringement.
- e) Repetition of the infringement.
- f) Damage to the image of the pharmaceutical industry.

After the infringement has been qualified as minor, serious, or very serious based on previous criteria, there may be aggravating circumstances that shall be taken into account by the Jury for imposing the appropriate penalties based on the scale in paragraph 2 of this article. Accumulation of aggravating circumstances may change the initial qualification from “minor” to “serious”, or from “serious” from “very serious”. Such aggravating circumstances are as follows:

- I) Degree of intentionality.
- II) Failure to comply with previous warnings.
- III) Concurrence of several infringements for the same action or promotional activity

IV) Financial benefit for the pharmaceutical company derived from the infringement.

21.2. Based on the aforementioned criteria, the Jury and the Board of Governors of FARMAINDUSTRIA, if applicable—in accordance with provisions in paragraph 3 of this article—, can agree to impose the following monetary sanctions:

- a) Minor offences: 6,000 to 120,000 Euros.
- b) Serious offences: 120,001 to 240,000 Euros.
- c) Very serious offences: 240,001 to 360,000 Euros.

For infringements described in article 11.9, 14.3, 16.2 and 17.2 the first two infringements will lead to an admonition by the Code of Practice Surveillance Unit, while for the third and subsequent infringements occurring within one year, the applicable sanctions will be 1,000 Euros for each activity requiring mandatory notification that has not been timely and duly reported to the Code of Practice Surveillance Unit.

For complaints lodged by the Code of Practice Surveillance Unit, the Jury can impose the infringing pharmaceutical company, as non-monetary sanctions, any corrective or rectifying actions proposed by the Unit in the conciliation meeting, depending on the seriousness of the facts, and always intended to repair the damage caused and to prevent recurrence in the future.

In cases where the Jury finds that an infringement has been committed, but the company has acted in good faith based on a query made by the company itself as per article 19 of the Code, and provided there is an identity between the facts and the terms of the query, the Jury will decide to urge the company to stop that promotional conduct, but will not impose any other sanction.

21.3. FARMAINDUSTRIA shall execute the sanctions imposed by the Jury. The amounts collected from monetary sanctions shall be used to set up a special fund in FARMAINDUSTRIA for promotion of the

rational use of medicines. The Board of Governors of FARMAINDUSTRIA, at the proposal of the Code of Practice Committee or the Code of Practice Surveillance Unit, shall also be responsible for the imposition and execution of sanctions for failure to comply with the provisions in articles 11.9, 14.3, 16.2, 17.2, 20.5 and 21.8 of this Code. In these cases, companies belonging to the Board of Governors that are directly affected by the matter in question shall abstain from taking part in its deliberations and agreements.

21.4. In the event of serious or very serious infringements or failure to comply with the content of a decision issued by the Jury, the Code of Practice Committee and the Code of Practice Surveillance Unit –in cases where the latter acts as complainant– can propose to the Steering Committee that FARMAINDUSTRIA reports the company against whom the complaint has been made to the relevant health authorities and/or propose to the Board of Governors of the Association withdrawal of membership of the company following the procedure stated in FARMAINDUSTRIA By-laws. If the company is withdrawn from the Association for this reason, readmission cannot be considered for at least one year.

21.5. Readmission of the company to the Association will only occur if, once this period has elapsed, the company expressly agrees not to carry out the promotional practices prohibited by the Code and has paid all fees corresponding to the period its membership was discontinued.

21.6. In any case, the decision taken by the Jury will determine which party or parties will pay the administrative expenses incurred by the claim procedure before Autocontrol. All fees due to Autocontrol for the procedure, and also any costs from the expert support decided by the Jury –by itself or at the request of a party–, if applicable, will be paid by the part whose claims have been totally rejected. If claims are partly accepted or rejected, each party will pay its own expenses and half of the abovementioned administrative expenses.

21.7. If repeated, clearly ungrounded complaints are submitted, the Jury may impose the monetary sanction it deems appropriate. The amount of this sanction will be proportional to the seriousness of practiced denounced.

21.8. The Board of Governors may also impose sanctions, at the proposal of the Code of Practice Surveillance Unit, in the event of repeated, ungrounded reporting of alleged breaches to the Code of Practice Surveillance Unit.

22. IMPLEMENTATION GUIDES AND COLLABORATION AGREEMENTS

By agreement of the Board of Governors of FARMAINDUSTRIA, implementation guides of this Code may be prepared in order to provide guidance to pharmaceutical companies on adequate compliance with the rules contained in the Code.

The Board of Governors can also authorize the signing of collaboration agreements with other bodies or organizations for an improved development of the self-regulation system.

23. DISCLOSURE AND COMPILATION OF RULINGS

23.1. The Jury may agree to make public or disclose its decisions using the means it deems appropriate.

23.2. At the discretion of the Board of Governors of FARMAINDUSTRIA, a complete compilation of all the decisions adopted during the year, as well as the summaries of the achieved matters and mediation agreements will be published annually.

24. ENTRY INTO FORCE OF THE CODE

This Code enters into force on October 27th, 2010, and supersedes the Code applicable to this date. The Code of Practice Surveillance Unit is authorized to establish by means of a circular periods of adaptation for practical application of the novelties introduced in this new Code, which under no circumstances shall exceed June 30th, 2011.

Code of Ethics



PHARMA INDUSTRY FINLAND (PIF)
2008

CONTENTS

I	Introduction	3
II	Code for the marketing of medicinal products	4
III	Code for the good medical sales representation practices	12
IV	Code for the co-operation between the pharmaceutical industry and patient organisations	14
V	Code for health awareness information and other information on health and diseases targeted at consumers	15
VI	Monitoring of the compliance with the codes, preliminary inspection, sanctions and other stipulations	18

Code of Ethics

Pharma Industry Finland (PIF) 2008

I INTRODUCTION

Correct information on pharmaceuticals promotes their correct use. The purpose of marketing activities, sales promotion and advertising is to provide healthcare professionals with updated information on medicines for the prevention, alleviation and cure of diseases. As a result, there is less need for more expensive medical treatments, people are able to maintain their ability to work or restore it more quickly, and as medicines help to maintain better health, the overall healthcare expenditure is smaller. The marketing of non-prescription medicines to consumers provides them with information about the available treatment options in cases where the treatment of the illness does not call for medical attention, directing the consumers towards the correct and safe use of medicines.

The objective of the voluntary guidance is to increase the reliability of the marketing of medicines and to promote the information value of the marketing message vis-à-vis the consumers and healthcare professionals, thus contributing to an appropriate use of medicines. The research, development and production of medicinal products meet the highest quality standards. The same objective also applies to the marketing of medicinal products.

The pharmaceutical industry performs research on medicines, introducing them to the market for the pharmacy professionals as well as physicians, dentists and veterinarians to dispense, prescribe or use for the treatment of the patients. The healthcare professionals also play a core role in the collecting of the pharmaceutical research and other information. In order to guarantee pharmaceutical development and proper use of medicines, the co-operation between the pharmaceutical industry and the healthcare professionals is of vital importance. The co-operation must take place in the framework of unambiguous and transparent guidelines.

Representing the medicine users and their close ones, the patient organisations play a significant role.

The co-operation between patient organisations and pharmaceutical companies is necessary but it must be transparent by nature, conducted in the framework of clear guidelines so that the autonomy of both parties is safeguarded.

The consumers and patients have an increasing need to obtain information on various diseases. The pharmaceutical industry can also provide such information, having substantial information on various diseases as well as on their prevention, diagnosis and treatment. The information disseminated by the pharmaceutical companies is complementary to that given by, among others, the healthcare professionals and the Authorities, and it has to meet the high ethical requirements related to the quality and objectivity of the information.

The legislator and the medicines control authorities regulate and monitor some of the themes covered by the present Code of Ethics. The voluntary ethical control by the pharmaceutical industry is complementary to their work.

The present Code of Ethics incorporates the following guidelines and instructions regarding pharmaceutical marketing and other information distributed by the pharmaceutical companies, as well as the co-operation between the pharmaceutical industry and its various stakeholder groups.

- Code for the Marketing of Medicinal Products
- Code for the Good Medical Sales Representation Practices
- Code for the co-operation between the pharmaceutical industry and patient organisations
- Code for health awareness information and other information on health and diseases targeted at consumers

Moreover, the Code of Ethics also includes a section on the monitoring of the compliance of the above codes, on preliminary inspection operations, on the sanctions following from non-compliance as well as on certain other stipulations.

The Code of Ethics sets forth generally accepted operative principles which the pharmaceutical companies shall comply with in their operations. In particular, the purpose of the Code of Ethics is to ensure that the healthcare professionals and consumers receive correct information on the medicines and their use and that the co-operation between the pharmaceutical industry and its co-operation partners is transparent, respecting the autonomy of both parties.

Distributing information on medicines is the responsibility and social obligation of any pharmaceutical company. Without it, the information about new medications would spread slowly which would be a disadvantage, especially for patients awaiting treatment. The pharmaceutical companies play a central role in the production and distribution of information on medicines.

The principles behind the Code for the Marketing of Medicinal Products are based on legislation relating to medicinal products, marketing, consumer protection and competition, on the International Code of Marketing Practice as well as on the Codes of Pharmaceutical Marketing Practice published by EFPIA (European Federation of Pharmaceutical Industries and Associations) and IFPMA (International Federation of Pharmaceutical Manufacturers Associations). In formulating the Code, the following EU legislation has also been taken into account: the Directives 2001/83/EC and 2004/27/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use; the Council Directive 89/552/EEC and 2007/65/EC on the coordination of certain provisions laid down by law, Regulation or administrative action in Member States concerning the pursuit of television broadcasting activities; the Directive 2005/29/EC of the European Parliament and of the Council concerning unfair business-to-consumer commercial practices in the internal market; as well as the Council Directive 84/450/EEC relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising.

The Code for the Good Medical Sales Representation Practices is a recommendation jointly issued by Pharma Industry Finland and Association of Finnish Local and Regional Authorities. In preparing the above document, the recommendation for quality criteria for sales promotion of medicines issued by National Agency for Medicines in 2007 was also taken into consideration.

The instructions regarding the co-operation between the pharmaceutical industry and patient organisations have been prepared in line with the corresponding EFPIA Code of practice from 2007, in particular.

II CODE FOR THE MARKETING OF MEDICINAL PRODUCTS

SCOPE OF APPLICATION

1 § *Relationship to other regulations.* In the marketing of medicinal products, the companies must comply not only with legislation and guidance given by the Authorities but also with this Code. In their international marketing operations, the pharmaceutical companies must meet, at a minimum, the requirements imposed by the EFPIA and IFPMA Codes.

The present Code must also be followed in marketing targeted to Finns abroad or in international conferences. In these cases, the marketing operations must also be in line with the rules and regulations issued by the local Authorities.

The Supervisory Committee for the Marketing of Medicinal Products and the Inspection Boards only apply the present Code.

2 § *Definitions.* The term 'pharmaceutical company' refers to an enterprise engaged in the marketing or importation of medicines, to a holder of a marketing authorisation or to other business enterprise involved in marketing of medicinal products.

'The marketing of medicinal products' refers to any information, order acquisition or incentive measures, with the purpose of promoting the prescription, supplying, purchase or use of medicines. Such measures include, for instance, advertising targeted at consumers as well as the advertising and sales promotion targeted at healthcare professionals, the operation of medical sales representatives and the distribution of free samples of medicinal products.

'Healthcare professionals' refers to persons who in their work prescribe, handle, distribute or in practice administer medicines to patients or who otherwise need medicine-related information in their work.

'Consumers' refers to all persons other than the healthcare professionals.

3 § *Scope of application.* The Code applies to all forms of marketing utilised by the pharmaceutical companies in their marketing operations, from person-to-person marketing to the operations taking place through the media. As appropriate, the Code also applies to the marketing of veterinary medicines.

The following does not fall within the scope of application of the Code

- a) products other than those meeting the definition of medicines set forth in the Medicines Act (395/1987);
- b) the summary of product characteristics, the package leaflets and labelling;

- c) the replies to specific questions about the medicine and the non-commercial material eventually related to the reply;
- d) informative notices regarding, for example, changes in packaging or warnings about adverse effects;
- e) product and price lists which do not contain any claims related to the medicinal product;
- f) general statements related to health and diseases if the direct objective of such statements is not the promotion of the sales of a medicine;
- g) scientific material published by the pharmaceutical industry, if the direct objective of such material is not the promotion of the sales of a medicine;
- h) information focusing primarily on the operations of the company, as well as corporate image marketing and business entertainment, with no direct objective of promoting the sales of a medicine;
- i) press releases based on the statutory information liability of the pharmaceutical companies; and
- j) distribution of free starter packs to a healthcare unit by the personnel of a pharmaceutical company.

GENERAL PRINCIPLES

4 S *Responsibility for compliance with the Code.* The pharmaceutical company is always responsible for the compliance of its marketing with this Code. The pharmaceutical company is also responsible for the marketing if it has assigned its marketing operations to a third party.

5 S *Precondition related to the marketing authorisation.* It is not permissible to market medicines other than those with valid marketing authorisations.

6 S *Nature of marketing.* Pharmaceutical marketing and the information on the medicine given in marketing contexts must be matter-of-fact, presenting the various effects of the medicine in a comprehensive manner, thus conducive to a correct and safe use of the medicine. The information on the medicine must be updated and based on the latest knowledge. The commercial nature of pharmaceutical marketing must not be hidden, and the marketing must be designed so that the recipient easily recognises it as pharmaceutical marketing.

The marketing of a medicine must be based on the most recent adopted summary of product characteristics.

Minor deviations from the summary of product characteristics are acceptable in case of serious diseases, if there is clear proof that the treatment according to the latest knowledge is superior to earlier treatments. Such marketing must, however, highlight the valid summary of product characteristics.

The marketing material must not fail to mention such material facts, the omission of which may give an erroneous impression of the medicine, its composition, origin, medical significance or quality.

Marketing may not refer to a clinical trial in such a way as to give an erroneous impression of the outcome, scope or significance of the trial.

Without justified reason, the marketing of medicinal products must not use the word 'safe' or maintain that the product has no adverse effects or that its use is not associated with the risk of dependency.

A medicine must not be marketed as a novelty after one year of its introduction to the market. Likewise, the change in the price, reimbursement status, indication, package size or other similar aspect must not be marketed as a novelty after one year from the implementation of such changes.

The information on the medicine given in marketing contexts must be reliable, and it must not contain such verbal or visual presentations or other effects as may be misleading.

The information on a medicine must be given in such a manner as to allow for the recipients to familiarise themselves with the information in the advertisement without difficulty.

It is not the purpose of this Code to prevent the exchange of medical or other scientific information.

7 S *Reminder advertisements.* If the only purpose of a medicine advertisement is to be a reminder of the name of the medicine, the advertisement may contain only the name or trade name of the medicine, the name of its active substance and the trademark of the medicine, as well as the name of the holder of the marketing authorisation, the marketer, importer or manufacturer and its company logo. The name of the medicine refers to its trade name, accompanied by the strength and pharmaceutical form.

8 S *Good practices of the marketing of medicinal products.* The marketing of medicinal products must comply with good practices in a way that inspires trust and respect. Insulting or tasteless expression are not allowed, and the marketing must not contain such verbal or visual presentations as may denigrate or offend any professional group, patient group, product or pharmaceutical company or cast a suspicion on them. The marketing must not contain violence, sexual behaviour or criminal

actions, or any reference to them without a direct association with the approved indication of the medicine.

The marketing of medicinal products must promote the good public image of the pharmaceutical industry. Such marketing must not jeopardise the public's trust in the impartiality of prescribing or dispensing of medicines.

9 § Comparisons. The comparisons between different medicines, active substances, excipients or other characteristics must be matter-of-fact and reliable. The visual and price comparisons between products must be clearly justified. The objects of comparison must be clearly specified.

The price comparisons must include mutually comparable packages and dosages. Price comparisons must clearly indicate the medicines involved and their trade names.

Comparisons between active substances must be based on scientific evidence.

If comparisons are used, the time when the comparison was made or a study report was published must be indicated.

The requirement of matter-of-factness and correctness of information are particularly underlined as far as comparisons are concerned.

In the marketing of non-prescription medicines to consumers, special attention must be paid to the limitation under Article 13, Paragraph 1 b) of the present Code.

10 § Scientific service unit. The pharmaceutical companies must have a scientific service unit responsible for the information distributed on the medicines of the company and for the correctness of such information as well as on the control of the non-interventional studies under Article 37 hereunder.

The scientific service unit must employ at least one physician or pharmacist with a Master's or Bachelor's Degree, with adequate conversance and experience, responsible for the approval of the company's marketing measures before their publication, including events, advertisement gifts and market studies. This person must ensure that the final form of the marketing measure complies with the present Code and the legislation on pharmaceuticals marketing. Moreover, he or she must control the implementation of the non-intervention studies under Article 37, ensuring that the study plan complies with the present Code and the applicable legislation.

Any company staff member involved in the marketing of medicinal products or non-intervention studies must be fully aware of the rules contained in the present Code.

INSTRUCTIONS FOR GOOD CONSUMER MARKETING PRACTICE

11 § Pharmaceuticals marketed to consumers. Only non-prescription medicines can be marketed to consumers.

However, it is permissible to distribute public information on a vaccination campaign approved by the competent Authorities.

According to this Code, it is not prohibited to target information on prescription-only medicines at consumers if such information only contains information that is equal to the details included in the summary of product characteristics or the package leaflet.

According to this Code, it is neither prohibited to target impartial and matter-of-fact information at consumers on the characteristics of diseases or issues related to their prevention, diagnosis and treatment. Such health information can also refer to prescription-only medicines if the information is of impartial and matter-of-fact nature, covering all alternative medicines on the market. In such cases, sufficient information on non-medicinal forms of treatment must also be given.

In questions related to personal health, the consumers must be advised to turn to their physician or other healthcare professionals.

It is prohibited to market medicinal products containing narcotics or psychotropic substances (as referred to in the international conventions on narcotics and psychotropic substances) to consumers.

Disguised advertising of medicines is prohibited.

12 § Minimum information in an advertisement for a medicine. An advertisement for a medicine must contain at least the following information:

- a) name of the medicine and the active substance if the medicine in question only contains one active substance;
- b) indication of the medicinal product;
- c) necessary information for the correct and safe use of the medicine as well as any special precautions of use, interactions and adverse effects significant for the safe use of the medicine;
- d) explicit advice to read the package leaflet or the user instructions contained in the package;
- e) name of the marketing authorisation holder, importer or marketer; and
- f) in the marketing of veterinary medicines, also the approved target species of the medicine, as well as the maximum residue limits.

As an exception to the above, reminder advertisements referred to under Article 7 above are permitted.

13 § Prohibited information. A pharmaceutical advertisement must not give information or impression which

- a) gives an impression that consulting a physician or the treatment recommended by the physician is not necessary for a disease that would normally require medical care;
- b) suggests that the effects of the medicine are guaranteed and that they are not associated with any adverse effects, or that the effects are equal or superior to those of another treatment or medication;
- c) suggests that the medicine would improve the users' normal good health, or claim without justification that their health would deteriorate without the use of the medicinal product;
- d) is targeted at children;
- e) suggests that the medicinal product is a nutritive product, cosmetic product or other consumer good;
- f) suggests that the efficacy or safety of the medicinal product is based on its natural origins;
- g) is liable to lead, in self-medication use, to wrong diagnosis or treatment due to a detailed case report contained in it;
- h) refers to recovery allegations through inappropriate, intimidating or misleading expressions;
- i) uses inappropriate, intimidating or misleading expressions or visual presentations of the changes caused by the disease or trauma in the body, or of the effects of the medicinal product in the body or in a part thereof; or
- j) contains a reference to the medicine having a marketing authorisation.

Misleading or inappropriate expressions are allegations or other expressions or advertisement elements which

- emphasise the presence or lack of such ingredients in the product as have no material pharmacological or health-promotional significance;
- exaggerate or over-dramatise symptoms or their alleviation;
- give a misleading or one-sided picture of the efficacy of the product; or
- strongly divert the consumer's attention from the subject matter of the advertisement.

14 § Use of study results and the use of sources. The study results and their sources used in pharmaceutical marketing must be reliable, and they must not be used to give a wrong or misleading impression of the medicine or its medical significance. Reference to the source material must be made so that the source can be identified without difficulty.

15 § Special groups. Pharmaceutical marketing must not exploit the non-expertise or distress of consumers or consumer groups.

Special prudence must be applied to the use of children in pharmaceutical advertisements. Marketing of medicines intended for children's use must be targeted at adults.

16 § Use of prestige or celebrity. Pharmaceutical marketing must not contain direct and active recommendations to use the medicine, given by scientists, healthcare professionals or celebrities.

17 § Sponsorship. A company can engage in sponsorship only through its business name or logo.

Sponsorship comprises any operations the purpose of which is to support one or several persons, company or event, or part thereof, financially or otherwise, in such person's or party's scientific, artistic, sport-related or other pursuit and which entail rights conferred to the sponsor to promote its own business operations by using the sponsored person or party.

When sponsoring TV or radio broadcasts, the sponsorship element must be clearly and understandably separate from the rest of the programme offer or programme intros through the showing of the company name or logo. The name or logo of the company must be shown immediately before the programme or at its end (sponsor logo).

Sponsorship must not encourage the viewers to purchase the sponsor's or a third party's products.

For the rest, sponsorship is subject to the marketing instructions contained in the present Code.

18 § Co-operation with patient organisations. Pharmaceutical companies can collaborate with patient organisations. Such co-operation must be transparent and in line with the stipulations of this Code, and in international co-operation, also with the stipulations of the applicable EFPIA Code. Moreover, the co-operation must comply with the Code for the co-operation between the pharmaceutical industry and patient organisations issued by Pharma Industry Finland.

19 § Forbidden measures in consumer marketing. Pharmaceutical marketing to consumers must not involve competitions with prizes.

If the consumer buying a non-prescription medicine will receive another commodity or other benefit (the so-called giveaway) at the same price, such an offer must not entice the consumer to purchase or use the medicine unnecessarily, and it must not endanger the appropriate dissemination of the information on the correct and safe use of medicines to consumers.

It is forbidden to distribute free samples of medicinal products to consumers.

INSTRUCTIONS FOR GOOD PRACTICE IN MARKETING TARGETED AT HEALTHCARE PROFESSIONALS

20 § *Objective of information on a medicine.* The objective of the information given on a medicine is to maintain and promote the professional expertise of the healthcare professionals related to the use of medicines, as well as to promote patient safety.

21 § *Targeting of pharmaceutical marketing measures.* Non-prescription medicines can be marketed to all healthcare professionals. The marketing of prescription-only medicines must be targeted at such persons authorised to prescribe or supply medicines as can reasonably be expected to need the information on the medicine in question. As regards the prescription-only medicines, the other groups of healthcare professionals can only be subject to guidance and training related to the correct and safe use of the medicine.

A pharmaceutical company must not deliver advertising or other direct marketing material to persons who have declared they do not want it.

22 § *Contents of information on a medicine.* All information on a medicine must contain, at least, the information which is consistent with the most recent adopted summary of product characteristics of the product and which is essential for the physician to be able to prescribe the medicine. The information on a medicine will contain the legal conditions of supply as well as health insurance reimbursement criteria, average medication costs as well as the retail prices of different package sizes, if possible.

As an exception to the above, reminder advertisements referred to under Article 7 above are permitted.

Marketing material made available at exhibition stands or distributed to the participants in international events may refer to medicinal products or indications of products with no marketing authorisation in the country where the event is organised if

- a) this material is accompanied with information on the countries where the product or indication has a marketing authorisation, and the material clearly shows that the product or indication has no marketing authorisation in the country where the event takes place;
- b) the information on the medicine is accompanied with a clarifying notice specifying that the information differs in accordance with the marketing authorisations in force in each separate country; and
- c) this is permitted by the national legislation of the place where the event takes place.

23 § *Special requirements related to information on a medicine.* The information on a medicine must

- be accurate, correct and verifiable;
- give objective and impartial information on the beneficial and adverse effects of the medicine;
- be clear and easily understandable; and
- be sufficiently complete so that the reader can form an opinion on the therapeutic value of the medicinal product.

24 § *Dating of marketing material.* Pharmaceutical marketing material must indicate the date (month and year) in which the material was compiled, or the latest revision was made.

25 § *Results of clinical trials.* Any study results included in the material for the marketing of medicinal products must have been published in article form in a scientific journal. Moreover, it is permissible to include in the material for the marketing of medicinal products articles which have been accepted for publication in a scientific journal, as well as the results of trials or studies submitted to the regulatory Authorities in association with marketing authorisation applications.

The use of unpublished materials, such as abstracts, posters or similar materials which have not been published in scientific journals, is prohibited.

As an exception to the above, reference can be made to such study results which do not meet the criteria in Paragraph 1, if they can be deemed to have material significance for the medication of patients. New information has material significance if it refers to a serious disease and if there is clear proof that the new treatment is superior to the earlier treatments.

The unpublished study results must meet the same quality criteria applied to published results. The use of unpublished study results is subject to the

consent of the responsible investigator. If the pharmaceutical marketing refers to unpublished study results, additional information on the contents must be given upon request.

The reference to study results must be associated with explicit information on the trial arrangements (e.g., *in vivo*, *in vitro*, animal testing).

26 § Sources of information in the marketing of medicinal products. Reference to the materials used as the source of the information in the marketing of medicinal products must be made in a manner allowing the identification of the source without difficulty. Quotations, tables, figures and other corresponding illustrative material must be reproduced accurately so that the subject contents are not changed.

If the information is based on material related to another medicine or pharmaceutical form, the information must not unjustly lead to the assumption that the material would refer to the medicine or pharmaceutical form being marketed.

As concerns the use of results of clinical trials in the marketing of medicinal products, see Article 25 of the Code for detailed instructions.

27 § Information liability. If the clinical use of the medicine reveals new important aspects, information thereof must be given in an appropriate manner.

Pharmaceutical information on new serious adverse effects, contraindications, limitations of indications or withdrawal of production lots or medicines, must be given in writing. The expression "Erittäin tärkeä – Mycket viktigt" (Extremely important) or similar phrases can be used only in such contexts.

28 § Medical sales representatives. In order to ensure the distribution of correct information, the pharmaceutical company must ensure that a person giving verbal information in the context of medicinal product marketing meets, or he/she will be trained, no later than within one year from the start of medical sales representative work, to meet at least the level of a registered medical sales representative (RLE) or registered medical sales representative of self-care medicines (ILE). Verbal information must meet the criteria imposed in the Code on any information and it must be based on written documents.

Moreover, the specific Code for the Good Medical Sales Representation Practices must be followed in medical sales representation events taking place in the public healthcare units. The guidance in question must also be followed, as applicable, in the sales representation events taking place in pharmacies and in

the framework of private healthcare, targeted at persons entitled to prescribe or supply medicines.

During their visits, the medical sales representatives must provide their clients with the summary of product characteristics of each medicine presented as well as the respective price and reimbursement data, or make the information available to them through other means.

All the significant information given to the medical sales representatives in relation to the clinical use of the medicine they are presenting, and especially to the possible adverse effects of the same, must be forwarded by them to the scientific service unit referred to under Article 10 above.

At the request of the Secretary of the Inspection Board or the Supervisory Commission, the company must provide these bodies with the presentation material used by the medical sales representative.

29 § Events organised or sponsored by the pharmaceutical industry. The emphasis of the events must be related to pharmaceutical information or research or other medical education so that most of the time spent by the participants involves a scientific programme or training. The participants must always be provided with a written programme of the event.

When the company organises or sponsors an event, this must always be made clear.

Pharmaceutical companies can participate in the expenses of further or complementary training only if the company is provided with sufficient conditions to actively distribute information.

Such events must be organised in a place that is appropriate in view of the demands of scientific or training programme implementation. The events must not be organised in venues that are renowned for their entertainment facilities or are extravagant. The event can be organised abroad if there is a valid scientific or training-related justification to do so.

The event itself and the travels must be organised so that, excluding the travelling days, most of the time spent by the participants involves a scientific programme or training.

The target group of the events must be constituted by healthcare professionals, and the expenses incurred for the events must be materially related to the scientific programme or training.

If persons employed by the public healthcare are provided with the opportunity to participate, during working hours, in events organised or sponsored by the pharmaceutical industry, the invitation to the event must be addressed to the healthcare unit in question, considering the instructions and rules which apply to the allocation of support by external parties within that healthcare unit.

30 § Hospitality. In events or sessions organised or sponsored by the pharmaceutical industry, the usual local norms of hospitality will be followed. The hospitality can extend only to the registration costs related to a scientific or training event, as well as to the travelling, accommodation and meal expenses. Hospitality must be reasonable, matched to the circumstances and secondary in view of the purpose of the event, and it must not be extended to parties other than the healthcare professionals.

An exception to the stipulations in Paragraph 1, the representatives of pharmaceutical companies can, however, participate as guests in the evening programmes organised in association with medical events, training sessions of specialist societies and corresponding scientific or training events, the daytime scientific or training programmes of which the pharmaceutical companies have sponsored, if

- a) there is more than one company sponsoring the scientific or training programme;
- b) the sponsorship allocated to the organisation of the scientific or training programme is justified in extent;
- c) the hospitality related to the evening programme is reasonable and suitable in view of the situation, and the eventual entertainment element is secondary;
- d) the eventual participation fee charged for the evening programme is the same for each participant;
- e) no single company is the designated sponsor of the evening programme; and
- f) no medicines are marketed during the evening programme.

The healthcare professionals must not be offered or paid a compensation merely for their use of time to participate in an event arranged or sponsored by a pharmaceutical company.

The obligation to arrange for hospitality or for other benefits, such as economic compensations, must not constitute the precondition for the organisation of an appropriate information event.

The hospitality must not extend beyond the expenses a typical guest of the event would be prepared to cover themselves, should they pay for their own expenses.

31 § Incentives, advertising gifts and other support measures. The distribution and offer of advertising gifts related to the marketing of medicinal products must be reasonable. The advertising gifts must have minor economic significance for the recipient, and they must have a bearing on their professional operation.

Healthcare professionals must not be offered or otherwise provided with direct or disguised economic incentives or inducements.

It is prohibited to support the leisure activities of healthcare professionals or their associations.

32 § Market research. Market research can be used to obtain information, e.g., about medicinal behaviour, use of medicines and treatment practices, with the objective of promoting the correct use of medicines and patient safety. In organising market research, special attention must be paid to the protection of the privacy of the patients and those who are the objects of the research. The questions must respect the objectiveness principle. Market research must not have an impact on the treatment of individual patients.

Market research must be of limited scope, such as one-off telephone interviews or questionnaires sent by mail, email or the Internet, and the opinion of the healthcare professionals must not be asked repeatedly, considering the frequency of the contacts in general and the contacts related to a specific research project in particular.

The compensation paid for the participation of the research must be of reasonable economic value.

33 § Competitions. The competitions organised for marketing purposes must be associated with the company or the product. The prizes must be of reasonable economic value and associated with the professional activities of the participants.

34 § Free samples of medicines. Free samples of medicines can be given only to persons who are authorised to prescribe or supply them, who factually prescribe or supply the medicinal product in question, and therefore benefit from the opportunity to familiarise themselves with the product in question. A free sample of medicine refers to the smallest marketed package size of the medicinal product, given for free to the recipients to allow them to familiarise themselves with the product. Each recipient can be given only one free sample of each medicinal product, strength and pharmaceutical form in one calendar year.

A prescription-only medicine sample can only be given to a person authorised to prescribe such medicines. If the prescription of a medicine is subject to a supply limitation, such sample can only be given to a physician who is entitled to prescribe such medicines. Dosage devices can also be given to other persons. Narcotics, including psychotropic substances as well as substances with primary effects on the central nervous system, must not be distributed as free samples.

Free starter packages must not be used in the marketing of medicinal products.

A free medicine sample will be delivered against a written request provided with a signature and date. Each sample must be accompanied with a respective summary of product characteristics.

The pharmaceutical company must keep records of the free samples of medicines given in each calendar year. These records must be kept until the end of the year following the calendar year to which the record liability refers. On request, the records must be submitted to the Supervisory Commission for the Marketing of Medicinal Products or to Inspection Board II subject to it.

35 § *Donations and grants for the support of healthcare or research.* Donations, grants and benefits in kind to institutes, organisations or associations, the members of which are constituted by healthcare professionals or which provide healthcare or are engaged in research and which do not otherwise fall within the scope of application of the present Code, are permissible only if their purpose is to support healthcare or research and the donor or the party giving the grant documents the respective information, keeping records of them. The donations or grants must not constitute an incentive for the recommendation, prescription, purchase, supply, sales or administration of a particular medicinal product.

Making donations or giving grants to individual healthcare professionals is not permitted, with the exception of grants for investigator-initiated clinical trials with an appropriate study protocol, which have been approved by the regulatory Authorities and ethics committee and which otherwise comply with the requirements set in the legislation for clinical trials.

The pharmaceutical companies are encouraged to publish the information on the donations, grants and benefits in kind in line with the present Article.

36 § *Use of consultants.* The use of healthcare professionals as a group or as individual consultants or advisers is admissible. For example, they can act as speakers or chairpersons in meetings or training events, participate in medical or scientific studies or clinical trials or participate in the meetings of advisory committees or participants of market research in cases where compensation is paid for their participation or their travelling costs are reimbursed.

The arrangements related to such consultant or other services must meet the following criteria:

- a) Before the services start, a written contract is made with the person in question or the company owned by the person, specifying

the nature of the services offered and the criteria for the fee payable for them in line with Paragraph g) hereunder;

- b) The service need must be identified clearly before the request for the services and the signing of the eventual contracts made with the consultants;
- c) The selection criteria of the consultants are directly related to the identified service needs, and the persons responsible for the selection of the consultants have sufficient expertise to evaluate whether the healthcare professionals in question meet such criteria;
- d) The number of the healthcare professionals retained for the job must not exceed the reasonable number required to meet the service need;
- e) The pharmaceutical company constituting a party to the contract keeps records of the services provided by the consultants;
- f) The use of healthcare professionals as service providers does not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product;
- g) The fee payable for the services is reasonable and in line with the valid market price of such services. Nominal consultant arrangements must not be used as a pretext for the compensations paid to healthcare professionals.

In their written consultant contracts, the pharmaceutical companies must include a term whereby the consultant is liable to disclose his or her consultation relationship to the company whenever he or she writes or speaks in public about the issue constituting the object of the contract or otherwise related to the company. Likewise, the companies providing part-time employment to healthcare professionals who continue to exercise their profession, are invited to ensure that such a person is obliged to disclose his/her employment relationship with the company whenever he/she writes or speaks in public about the issue constituting the object of this employment relationship or otherwise related to the company. The stipulations under this Paragraph also apply to written or oral presentations other than the marketing or sales promotion of medicines.

This stipulation does not apply to the market research referred to under Article 32.

If a healthcare professional participates as a consultant in an event, the stipulations under Article 29 and 30 regarding the events arranged and sponsored by the pharmaceutical industry and the respective hospitality also apply.

37 § Non-interventional studies on medicines with a marketing authorisation. Non-interventional studies refer to trials where the medicinal product is prescribed in the usual manner in line with the conditions of the marketing authorisation. The treatment strategy chosen for an individual patient is not determined in advance in the study protocol but is based on the normal treatment practice. The decision on the prescription of a medicine is independent of the inclusion of the patient in the study. No additional diagnostic or other monitoring procedures are applied to the patients. Epidemiological methods are used for the analysis of the information collected.

Prospective non-interventional studies, whereby individual healthcare professionals collect patient data, are permitted under the following conditions:

- a) The study is made for a scientific purpose;
- b) The study is accompanied with a written study protocol and with written contracts between the healthcare professionals or the units at which the study will take place and the company financing the study. The contracts must specify the nature of the services provided and the criteria of the compensation payable for the services;
- c) The compensation payable for the services is reasonable, reflecting the fair market price of such services;
- d) Whenever possible, the study protocol is approved by an ethics committee;
- e) The Personal Data Act is followed in connection with the study;
- f) The study does not constitute an incentive for the recommendation, prescription, purchase, supply, selling or administration of a particular medicinal product;
- g) The company's scientific service unit has approved the study protocol, monitoring the progress of the study;
- h) The company must analyse, or have another party analyse, the results of the study, and the scientific service unit must be provided with the respective summary within a reasonable time. The scientific service unit maintains records of these summaries, stored for a reasonable period of time. The summary report must be sent to all healthcare professionals participating in the study, and, upon request, also to the use of the competent bodies of the Supervisory Commission for the Marketing of Medicinal Products. If the results of the study are important for the evaluation of the risk-benefit relationship of the medicinal product, the summary report must also be

sent immediately to the competent Authorities;

- i) The medical sales representatives can participate in the implementation of the study in an administrative capacity only, under the control of the scientific service unit. The scientific service unit must ensure that the medical sales representatives have received proper training for the implementation of the study.

Corresponding principles must also be followed, as applicable, to the epidemiological studies, register studies and other studies of retrospective nature.

III CODE FOR THE GOOD MEDICAL SALES REPRESENTATION PRACTICES

38 § Medical sales representations. The term 'medical sales representation' refers to the meetings, mainly taking place on the initiative of the pharmaceutical companies, between their medical sales representatives and physicians. Their objective is to disseminate information on the medicinal product presented, in order to promote the sales of the product in question. At its best, medical sales representation provides the actively practicing physicians and pharmacists with updated state-of-the-art information on medicines and their correct use. In addition to marketing, the medical sales representative transmits information on the results of the clinical trials on the medicine being presented, to promote the correct use of the medicinal product in question.

39 § Purpose of the Code. The purpose of the present Code is to provide instructions for the healthcare units using medicines and the pharmaceutical companies marketing them, regarding the medical representation taking place during the physicians' working hours. However, the ultimate decision on the implementation of medical sales representation events is taken by the management of the healthcare unit in question.

40 § Enhancing proper pharmacotherapy. The activities of the medical sales representatives must be fitted in as a flexible part of the working day of the healthcare unit and the physicians working there, so that they enhance proper pharmacotherapy without disturbing the operation of the unit or the patients.

41 § Medical sales representation related to prescription-only medicines. Medical sales representation events to promote the sales of prescription-only medicines can be targeted only at persons entitled to

prescribe or dispense such medicines. However, the principles of this Code must also be followed, as applicable, in situations in which the representatives of pharmaceutical companies instruct and train nurses in the correct and safe use of the medicine.

42 § *Good medical sales representation practices.* The pharmaceutical companies and healthcare units should respect the following principles of good medical sales representation practices in the respective events:

- a) The medical sales representative must possess the necessary basic knowledge in order to be able to provide as complete information about the medicinal product as possible. The medical sales representative must have the registered medical sales representative (RLE) or registered medical sales representative of self-care medicines (ILE) diploma, or otherwise possess the knowledge required for the proper performance of the work.
- b) The medical sales representations must be based on advance agreements on the visit timetable.
- c) The healthcare unit compiles clear instructions regarding the procedure for the pharmaceutical companies to book medical sales representation visits, also indicating respective contact persons. The instructions are based on solutions that are purposeful from the perspective of the unit's operation. The instructions contain information as to the person and the procedure (by phone, by email) and times of booking the medical sales representation visits. Instructions specific to each unit should be given to the pharmaceutical companies, for example, through Pharma Industry Finland. The pharmaceutical companies must follow the instructions given by the healthcare unit regarding the booking of the visits in order to avoid unnecessary contacts that might disturb the operation of the unit.
- d) The medical sales representation activities taking place in the healthcare unit premises must be arranged in the physician's consulting room, the medical staff's common room or other similar premises assigned by the healthcare unit for presentation purposes, to allow for the presentation to take place in privacy, without disturbing the other activities of the healthcare unit. The medical sales representations can also be arranged in premises other than those of the healthcare unit.

- e) Reasonable time must be reserved for the medical sales representations, and the parties should, as far as practicable, respect the agreed starting and ending hours. Eventual cancellations of the visits must be made in good time.
- f) Medical sales representation must be based on the therapy-approach: the medicines presented must be necessary in view of the work of the physicians participating in the event, considering their experience and speciality, the novelty of the medicinal product being presented or the new research data on the medicine. In their work, the medical sales representatives must focus primarily on the medicinal product scheduled for the event in question.
- g) The information about the medicine given at the medical sales representation event must correspond to the latest adopted summary of product characteristics and be accurate, correct, reliable as well as sufficiently complete and clear. The material used in the presentation must give a true and fair overall picture of the medical significance of the medicinal product being presented.

The marketing material must always contain information in line with the adopted summary of product characteristics, indicating the correct and safe use of the medicine. Moreover, the information on the medicinal product must contain the legal dispensing conditions, health insurance reimbursement criteria, average medication costs as well as the retail prices of different package sizes, if possible.

The adverse effects, interactions and contraindications of the medicine as well as other aspects related to the safe use of the medicinal product must be presented in a sufficiently clear manner.

The study results presented by the medical sales representative, not included in the summary of product characteristics, must correspond to or support the information in the summary of product characteristics.

Any quotes, figures and tables from literature or research reports must correspond to the original. Different study results must not be combined, for example, for purposes of comparisons between different products.

The origins of the information used in the presentation must be indicated accurately, and the sources used must be

available to those participating in the event. If reference is made to unpublished research material, it must be provided for the participants if so requested.

- h) The hospitality offered at the medical sales representation events must be reasonable, suitable for the situation and secondary to the scientific and training contents of the medical sales representation in question. As far as hospitality is concerned, the general instructions related to the accepting of hospitality by officials as well as the Code for the Marketing of Medicinal Products of Pharma Industry Finland must be followed.
- i) Free samples of pharmaceuticals can be given only to persons who are authorised to prescribe or supply them, and as regards prescription-only medicines, only to those who are entitled to write prescriptions. The sample must correspond to the smallest marketed package size of the product in question. In one year, each recipient can be given one sample package of each strength and pharmaceutical form of each medicinal product. The free sample is delivered against a written, signed and dated request, accompanied by the product's summary of product characteristics.
- j) The use of starter packs in the marketing of medicinal products is prohibited. However, during their presentation visits, the medical sales representatives can provide the healthcare unit with the necessary starter packs.
- k) The member companies of Pharma Industry Finland are committed to following the Code for the Marketing of Medicinal Products, a part of which the current Code constitutes. Responsible for following the respect of the Code, the Supervisory Commission for the Marketing of Medicinal Products and the Inspection Boards subject to it, may impose sanctions defined in the Code on companies breaking the Code.

43 § *Presentation events during the physicians' free time.* Physicians are free to decide whether or not they intend to participate in medical sales representation events at their free time. When organising such events, the stipulations of the obligations of civil servants and employees of public corporations must be taken into consideration. Hospitality or other benefits that are offered must not jeopardise the public trust in the Authorities, civil servants or employees of public corporations.

44 § *Responsibility for compliance with the Code.* In addition to the activities of its own staff, the pharmaceutical company is also responsible for the activities of assisting parties, such as the subcontractors providing medical sales representation services.

IV CODE FOR THE CO-OPERATION BETWEEN THE PHARMACEUTICAL INDUSTRY AND PATIENT ORGANISATIONS

45 § *Patient organisations.* The term 'patient organisations' refers to organisations of public utility, including their local and regional associations and central organisations, constituted around a certain illness, disease or injury or a group thereof, with the majority of the members being patients or their close ones taking care of them. The patient organisations represent or promote the interests of the patients or their close ones.

46 § *Prohibition of marketing of prescription-only medicines.* The marketing of prescription-only medicines to consumers is prohibited. This prohibition also applies to the co-operation with the patient organisations.

47 § *Agreement on support provided.* A written agreement between the pharmaceutical company and patient organisation must be made on the financial support or any other significant sponsorship, direct or indirect. The agreement must specify the amount of the funding provided or describe the other type of support, indicating the purpose of the sponsorship. The pharmaceutical company must have a clear procedure for the approval of such agreements.

48 § *Patient organisation's logo and other materials.* The pharmaceutical company can use the patient organisation's logo or other material in its own operations only upon a written consent of the patient organisations, covering the purpose and means of use of the materials.

49 § *Materials published by the patient organisation.* The pharmaceutical company must not try to influence the contents of the materials published by the sponsored patient organisation in a way promoting its own commercial interests.

50 § *List of the sponsored organisations.* The pharmaceutical company must publish an annual list of the sponsored patient organisations. The list must be accompanied by a brief description of the nature of

the sponsorship. The information published must be readily accessible to those looking for such data.

51 § Transparency. The pharmaceutical company must ensure that its sponsorship to the patient organisation is public by nature, and that such support is clearly disclosed, as applicable, on the occasion of the sponsored activities.

52 § Principle of multiple sponsorship. A pharmaceutical company cannot be the only founding member of a patient organisation or require that it should act as the sole funder of a patient organisation or a significant form of its activities.

53 § Events. An event sponsored or organised by a pharmaceutical company must be held in a place that is appropriate from the point of view of the materialisation of the main purpose of the event. The events must not be organised in venues that are renowned for their entertainment facilities or are extravagant. The event can be organised abroad if the majority of the participants come from countries other than Finland or if the purpose or theme of the event calls for resources or expertise justifying the organisation abroad.

54 § Hospitality. The hospitality offered at events sponsored or organised by a pharmaceutical company must be of a reasonable level, secondary to the main purpose of the event. The hospitality can extend only to the registration costs related to the event, as well as to the travelling, accommodation and meal expenses.

55 § Responsibility for compliance with the Code. The pharmaceutical company is responsible for the compliance with the Code when co-operating with the patient organisation. The pharmaceutical company is responsible for the compliance with the Code also when using the assistance of third parties.

V CODE FOR HEALTH AWARENESS INFORMATION AND OTHER INFORMATION ON HEALTH AND DISEASES TARGETED AT CONSUMERS

HEALTH AWARENESS INFORMATION

56 § Objectives and nature of health awareness information. The aim of health awareness information is to encourage the consumers to maintain a good state of health both personally and among

those close to them, to help them identify diseases, their symptoms and risks and to guide them in the search for further information for health promotion and treatment of diseases. The premise of the disease-awareness information must be the disease itself and its diagnostics, rather than the presentation of various therapy options.

Health awareness information must be matter-of-fact by nature, reliable, high-quality and in good taste so that the information supports the positive image of the pharmaceutical industry. Written in clear terms and expressions, the language used must be comprehensible to the consumers. The premise must be the targeting information at an audience possessing the knowledge of an average reader. The information must cover the essential factors related to the disease.

57 § Balanced picture of the disease. In health awareness information, the impacts of the disease must be described realistically. The consumers should not be frightened and the consequences of the diseases must not be overly dramatised. Health awareness information must not entice the consumers to unjustified use medicines or to seek unnecessary treatment.

58 § Prohibition of marketing of prescription-only medicines. Health awareness information must not contain marketing of medicines to consumers. In other words, it must not promote the use of any particular medicinal product or products. The marketing of prescription-only medicines, including disguised advertising, is categorically prohibited.

59 § Impartial presentation of therapy options. Information on the various therapy options can be given as part of the health awareness information. In that case, the information must cover all therapy options, including the eventual pharmacotherapies and other factors potentially influencing the treatment or prevention of the disease in question, such as changes in living habits.

No therapy option must be presented in such a way as to encourage the consumers to turn to a physician for a particular medicine prescription. Therapy options must be presented in an equal and neutral manner, without highlighting any specific option. The choice of the therapy best suited to an individual patient always takes place as collaboration between the patient and the physician. Health awareness information must in no way direct the choice between different therapy options.

Health awareness information may also include information about the prescription medicines used

for the treatment of diseases. Should information about pharmacotherapies be given, all medicines used for that particular disease must be mentioned. If the trade names of medicinal products are mentioned, the names of all products must be given in an equitable manner.

The criteria for neutral and unbiased presentation of the therapy options include the following:

- a) No comparisons between various therapy options are made;
- b) No single therapy option is accentuated, for example, through the choice of words, colours or images, or by using different fonts, highlights or other similar tools and elements;
- c) The positive features of no single therapy option are accentuated, highlighting the negative features of the other options;
- d) No categorisation of the therapy options is made without justifiable cause, for example by classifying them into leading or most recent products that are widely presented and into other or older options with a more limited presentation;
- e) No single therapy option is recommended in the articles written by healthcare professionals or in patient narratives; and
- f) The technical user instructions, such as dosing information, are either given for all products or not given at all.

If there is only one therapy option for the disease in question, the health awareness information must be realised with special care, in order not to interpret such information as disguised marketing of a prescription-only medicine to consumers. The description of dosage devices usable for the medicinal products of one single pharmaceutical company only can also qualify as disguised marketing.

60 § Correctness of information and use of research findings. The information given must always be updated and true, and never apt to mislead the consumers.

If the health awareness information include reference to study results, such data must always come from articles in scientific publications. References to sources must be given in an appropriate manner.

The sources for general health and disease information must primarily include research other than that by the pharmaceutical company.

The information given together with the study results must be impartial and neutral. Therefore, the health awareness information must not include research-based data that would direct the choice towards a particular therapy option. Moreover, the

eventual references to Current Care Guidelines must be neutral so that they would not direct towards a particular therapy option. When referring to particular Current Care Guidelines, the source must be indicated, always giving the latest updated version in the quotation.

61 § Use of tests. The use of various tests measuring the consumers' state of health is allowed in health awareness information if such tests are scientifically validated and have been published in a scientific publication.

62 § Use of prestige and celebrity. Health awareness information must not contain direct and active recommendations to use the medicine, given by scientists, healthcare professionals or celebrities.

63 § Use of children and other special groups. Special prudence must be applied to the use of children in health awareness information. Health awareness information must not be targeted at children, not even when paediatric diseases are concerned.

Health awareness information must not exploit the non-expertise or distress of consumers.

64 § Competitions. If competitions are associated with health awareness information, the eventual prizes must be of reasonable value. When organising the competitions, the stipulations and instructions of the Consumer Protection Act and ensuing orders must be taken into account.

65 § Visual image of health awareness information. The visual image (including illustrations or colours) of health awareness information must not be the same as the image used in the marketing of the prescription-only medicine used for the treatment of the disease in question to healthcare professionals. The use of the same visual image is seen as disguised marketing of the prescription-only medicine to consumers. Moreover, the use of package images is prohibited.

66 § Reference to further information. Health awareness information may refer the consumers to further information on the disease in question (including the Authorities, physicians, healthcare nurses and other healthcare professionals, pharmacies or other healthcare units as well as patient organisations).

67 § Health awareness campaigns. If health awareness information is channelled through several media, or the material is composed of various elements, for

example one single TV spot or outdoor advertisement may be limited in content, if the necessary additional information is available from other sources, such as the Internet or patient guidebook, and the more limited material makes reference to such additional information. If, for example, the TV spot refers to an Internet site, such a site must meet the criteria imposed on health awareness information. This also applies to all other materials and events associated with the health awareness campaign.

68 § *Special stipulations concerning Internet sites.* If the Internet site containing health awareness material includes links, the following principles must be followed:

- a) The link must not lead directly to information including pharmaceutical marketing;
- b) There can either be links to the sites of all parties offering pharmacotherapy options, or alternatively, no links to any such parties' sites;
- c) The links must always lead to the home page of the company, not to their product pages;
- d) No links to foreign pages must be given, with the exception of the company's international homepage with no prescription-only medicine marketing;
- e) If the material includes a link to the summary of product characteristics or package leaflet of one medicine, there must also be links to the summaries of product characteristics or package leaflets of all medicinal products used for the treatment of the disease in question; and
- f) The links to the homepages of patient organisations and similar parties are allowed if they do not include marketing of prescription-only medicines to consumers.

All Internet sites targeted at Finns, with the address formulated as "www.disease.fi" (such as www.migraine.fi), must always meet the criteria for the dissemination of health awareness information as defined in the present Code. This will also apply to the health awareness sites accessible through a link from the homepage of the pharmaceutical company.

69 § *Name and responsibility of the company.* The health awareness information must always clearly indicate the pharmaceutical company responsible for such information. The company's contact data can also be given.

As far as the material produced is concerned, the pharmaceutical company is always responsible for

the compliance with the present Code, including any operations of an assisting third party. For example, no articles written by healthcare professionals or their interviews or patient narratives must advertise any particular therapy option.

Health awareness information can give neutral general information about the pharmaceutical company in question.

PATIENT INSTRUCTIONS DISTRIBUTED AS SUPPORT MATERIAL WITH THERAPIES PRESCRIBED BY PHYSICIANS

70 § *Purpose of patient instructions.* Pharmaceutical companies can produce patient instructions about the use of a particular prescription-only medicine, distributable by physicians and other healthcare professionals to patients with prescriptions of said medicines. The patient instructions act as support material for the pharmacotherapy prescribed for the patient, and are not deemed to be consumer marketing of prescription-only medicines, provided that the principles under Articles 71–73 are respected.

71 § *Contents of patient instructions.* The information contained in the patient instructions must be neutral, unbiased, true and matter-of-fact. The patient instructions may contain general information about the disease in question and about its treatment, as well as "package-leaflet-like" information about the prescription-only medicine and its correct and safe use. Patient instructions must not contain any marketing elements, such as comparisons of different therapy options or advertising-type highlighting of the medicinal product or its properties.

72 § *Visual image of patient instructions.* The patient instructions may use the same colours as the package of the medicinal product in question, or show its image.

73 § *Distribution of patient instructions.* Patient instructions must always be delivered by the company to physicians or other healthcare professionals, and they must not be generally available to consumers, for example in physicians' waiting rooms or the pharmaceutical companies' homepages. When delivering the material, the recipient must be informed clearly that the patient instructions are merely intended for particular patients to support the treatment prescribed for them, and are not generally distributable to all patients.

VI MONITORING OF THE COMPLIANCE WITH THE CODES, PRELIMINARY INSPECTION, SANCTIONS AND OTHER STIPULATIONS

THE SUPERVISORY COMMISSION FOR THE MARKETING OF MEDICINAL PRODUCTS AND THE INSPECTION BOARDS

74 § Competence. The Supervisory Commission for the Marketing of Medicinal Products, hereinafter "the Supervisory Commission" as well as two Inspection Boards subject to it, are charged with the task of monitoring and directing the matter-of-factness and compliance with the respective Codes of pharmaceutical marketing, medical sales representation activities, co-operation between the pharmaceutical companies and patient organisations as well as the health awareness information and other information on health and diseases.

At the request of Pharma Industry Finland, the Supervisory Commission can also issue opinions on marketing or on individual marketing measures on the basis of the EFPIA or IFPMA Codes, in force at each given time.

The Supervisory Commission issues the opinions to outside parties.

75 § Inspection Boards. The Supervisory Commission acts as an umbrella for two Inspection Boards: Inspection Board I, involved in pharmaceutical marketing targeted at consumers, the co-operation between pharmaceutical companies and patient organisations as well as health awareness information and the distribution of other information on health and diseases, and Inspection Board II, which focuses on pharmaceutical marketing to healthcare professionals and the operations of medical sales representatives.

Joint rules covering the procedure at the Supervisory Commission and Inspection Boards

76 § General rules on the initiation of cases. The cases examined by the Inspection Boards are initiated through the board's own control initiatives, complaints or preliminary inspections.

The cases examined by the Supervisory Commission are initiated on the basis of appeals by a party to the case, referrals by one of the Inspection Boards, or requests of opinion.

If a case has already been initiated and is being examined by the Authorities, the Supervisory Com-

mission or Inspection Boards cannot issue a decision until such proceedings have been finalised. After a final and legally valid decision by the Authorities has been issued, the case can be decided in the manner referred to under Article 74, Paragraph 1, considering the dimensions of the decision by the Authorities as well as the eventual sanctions imposed.

Any disputes between pharmaceutical companies should be resolved primarily between the interested companies. The companies can only agree to end an incorrect action, not to approve of an action contrary to the Code. In situations referred to in Article 107, Paragraphs 4 and 5 of the present Code of Ethics, or in cases of marketing of non-prescription medicines to consumers, the dispute needs not be solved between the companies in question before submitting the case to the Inspection Board.

When a company contacts another pharmaceutical company to solve a dispute, it must specify the points in the marketing or other measure which it requests to be deleted or changed, as well as the rules in the present Code which underpin its request. The contact must be taken in the language used in the marketing or other measure in question. The eventual reply given as a result of the contact must also be compiled in the language used in the marketing or other measure in question.

Should the companies not be able to find a solution in the case within seven working days from the first verifiable contact, the dispute can be submitted to the Inspection Board. The dispute must be submitted to the Inspection Board within 30 days from the first verifiable contact, on pain of the case otherwise lapsing. Before filing the complaint, the other company must be notified, in a verifiable manner, about the case being submitted to the Inspection Board, unless the situation at hand is one referred to in Article 107, Paragraph 4 or 5 of the present Code of Ethics, or if the case relates to the marketing of non-prescription medicines to consumers.

A complaint to the Inspection Board or appeal to the Supervisory Commission must be made in writing, and signed by a person/s who is/are authorised to sign for the business name of the company. The complaint or appeal must be written, except for the attachments, in the language used in the marketing measure in question. The complaint or appeal must be clear and sufficiently specified, containing all relevant information related to the complaint or appeal. If the complaint or appeal is ambiguous or incomplete, the applicant must be asked to complete the complaint or appeal at the preparatory phase, within five days of the date in which the notice of the request was served.

If the complaint or appeal is not supplemented despite the request to that effect, and it remains so ambiguous or incomplete that it cannot constitute the basis for further examination, the complaint or appeal will be dismissed without examining its merits. A separate decision will be made regarding the dismissal.

A dispute between pharmaceutical companies related to a violation of the present Code of Ethics must be solved following the order and system prescribed by the Code of Ethics, before submitting the case to the Authorities.

The Inspection Boards can take up the case on their own initiative under circumstances described in Articles 90 and 91 of the present Code.

The documents submitted to the Inspection Boards or Supervisory Commission can be sent by mail, fax or email.

77 § *Limitation period.* Any violation against the present Code must be submitted to the complaint system described in the Code within one year of the violation.

78 § *Hearing of experts and requests for opinions.* The Supervisory Commission and the Inspection Boards can hear experts and ask for opinions.

79 § *Minutes and decisions.* Minutes will be kept of the meetings, recording the meeting participants, agenda, decisions and relevant motivations in matters other than those related to the compliance with the present Code of Ethics, disagreeing opinions as well as a list of documents attached to the Minutes.

As regards issues related to the compliance with the present Code of Ethics, a separate decision will be written on each issue, including the complaint made, the marketing measure examined or its written description, replies, opinions obtained, motivations, names of those participating in the decision-making, as well as any disagreeing opinions.

The Minutes and the decisions will be signed by the Chairperson of the Supervisory Commission or Inspection Board (or if the Chairperson is impeded, the Vice Chairperson) and the Secretary. The decisions will be sent to the parties involved by mail.

No appeal can be lodged against the decisions of the Supervisory Commission.

80 § *Disqualification.* As concerns the disqualification of the Chairmen and Members of the Supervisory Commission and Inspection Board, the stipulation on the bias of Arbitrators will apply. Moreover, in order to maintain reliability, the Chairperson or Member must disqualify themselves if they

have been employed full-time in one of the companies involved in the case during the past five years. Persons employed by a pharmaceutical company must not participate in the examination of a case if they or their employers could draw special benefits from the decision.

If the Supervisory Commission returns an issue to the examination of the Inspection Board, the Members of the Board that had earlier participated in the discussion of this case in subsequent supervision must refrain from examining it again, if the case can still be solved respecting the quorum criteria.

The Supervisory Commission can examine the request to correct its own decision in the same composition that made the original decision.

81 § *Confidentiality commitment.* The Board of Directors of Pharma Industry Finland must request from the Chairmen, Members and Secretaries of the Supervisory Commission and the Inspection Boards a commitment of confidentiality regarding the documents involved in the examination of a case, and the documents or copies thereof must not be given to anyone other than those participating in the discussion of the case or the parties to the case, without the consent of the party to whom the document refers. Moreover, the Members or Secretaries of the Supervisory Commission and Inspection Board must not disclose – apart from the decision or opinion issued – anything of the matters that have come up during the discussion of the case.

82 § *Complementing the Supervisory Commission or the Inspection Boards.* If a Member resigns from the Supervisory Commission or Inspection Board in the middle of the term, or is otherwise permanently impeded from fulfilling his/her responsibilities, the appointing party, Pharma Industry Finland, will nominate a new Member to act as a substitute until the end of the term.

83 § *Financial administration.* The Secretary of the Supervisory Commission is in charge of its finances and administration. The Secretary has the sole right to make all decisions related to the finances of the Commission.

The expenses incurred for the operation of the Supervisory Commission will be covered primarily by the funds accumulated from processing and preliminary inspection charges, sanction payments and contractual penalties. Pharma Industry Finland will cover the eventual deficit in the Commission's accounts, and is entitled to receive the surplus, if any.

The Supervisory Commission constitutes a unit which is financially independent of Pharma Industry Finland. Constituting a part of Pharma Industry Finland's overall budget, the Supervisory Commission will present its own budget for the following calendar year for Pharma Industry Finland's approval. The operating result of the Supervisory Commission will be recorded and specified under Pharma Industry Finland's Income Statement.

The outside experts heard by the Supervisory Commission and the Inspection Boards will receive a reasonable compensation for the work performed. The expenses incurred for the hearing of experts or for other clarifications may also be imposed on the companies involved.

The Supervisory Commission will issue an annual report on its operation. The annual report will be sent to the major stakeholders of the Supervisory Commission for their information.

Supervisory Commission

84 § *Composition of the Supervisory Commission.* The Supervisory Commission is constituted by its Chairperson, five Members and Secretary.

The Board of Pharma Industry Finland appoints the Supervisory Commission, nominating its Chairperson, Vice Chairperson, four ordinary Members and their personal substitutes. Moreover, the Board of Pharma Industry Finland also appoints five persons employed by pharmaceutical companies, among whom one person, with no impediments, will be separately chosen to join the examination of the case at hand at any given time.

The substitute of the Member employed by a pharmaceutical company is the Director General of Pharma Industry Finland.

Pharma Industry Finland also appoints the Secretary of the Commission, and the substitute of the Secretary.

The term of the Chairperson and Members of the Commission is three calendar years so that every year two Members, with substitutes, will resign in turn. The Chairperson, Vice Chairperson, Member or substitute can be re-elected for the maximum of three subsequent terms.

85 § *Secretary of the Supervisory Commission.* The Secretary of the Supervisory Commission acts as the presenting official, keeps the Minutes of the Commission meetings and administers the Commission's finances. The Secretary has no vote in decision-making. If the Secretary is disqualified or impeded from examining a case, the respective functions – includ-

ing the financial administration – will be covered by the Secretary's substitute.

86 § *Supervisory Commission meetings and quorum.* The Supervisory Commission will be convened by the Chairperson, or if he is impeded, by the Vice Chairperson.

The Secretary of the Supervisory Commission will propose to the pharmaceutical companies which are parties to the case, a non-biased person employed by a pharmaceutical company to be adopted as a Member to discuss the case. If the pharmaceutical company, party to the case, is opposed to the proposal of the Secretary, a substitute Member will be convened.

The summons to the meeting must be sent to the Members no later than seven days prior to the meeting. A Member recognising his own bias must inform the Secretary of the Supervisory Commission of such circumstances without delay, and the Secretary will summon the substitute Member.

The Supervisory Commission constitutes a quorum when the Chairperson or Vice Chairperson and at least two Members or the substitute Members are present.

The decisions of the Supervisory Commission will be taken by simple majority. In case of an even vote, the Chairperson will cast the deciding vote.

87 § *Main responsibilities of the Supervisory Commission.* The Supervisory Commission shall

- a) examine the appeals against the decisions made by the Inspection Boards as well as the issues submitted by the Boards under Article 107, Paragraphs 4 or 5 of the present Code;
- b) if necessary, discuss and issue opinions on questions which are related to pharmaceutical marketing, good medical sales representation practices, co-operation between pharmaceutical companies and patient organisations as well as health awareness information and the distribution of other information on health and diseases, in principle, or which set guidance for the work of the Inspection Boards.

88 § *Hearing.* Before issuing its opinion, the Supervisory Commission shall hear the parties, the rights of which are involved in the case and which have not yet had the opportunity to express their views in this context, and, at the discretion of the Secretary of the Supervisory Commission, the Inspection Board involved. The hearing can take place by letter, fax or email.

The reply must be given within a short timeframe determined by the Secretary of the Supervisory Commission. The deadline must not be shorter than seven days or exceed 14 days, save for exceptional reasons. Failure to give a reply does not constitute an obstacle to the examination of the case by the Supervisory Commission. The reply must be written, except for the attachments, in the language used in the marketing measure in question.

The replies given will be sent to the other parties for their information.

89 § Scope of the examination. The Supervisory Commission will make the decisions on the appeals and on the issues submitted by the Inspection Boards on the basis of the material provided by the parties or the Inspection Board, and is not liable to acquire any further information on the case at hand. At its discretion, the Supervisory Commission can also examine the marketing or other measure beyond the scope defined in the appeal, as far as the case concerns issues taken up by the Inspection Board on its own initiative.

Inspection Boards

90 § Competence of Inspection Board I. Inspection Board I controls pharmaceutical marketing targeted at consumers, co-operation between the pharmaceutical industry and patient organisations as well as health awareness information and other information on health and diseases targeted at consumers. Inspection Board I can take up a marketing or other measure of a pharmaceutical company under examination on its own initiative or on the basis of a complaint.

91 § Competence of Inspection Board II. Inspection Board II controls the marketing targeted at health-care professionals as well as medical sales representative activities, and, on request, resolves marketing-related disputes. In matters of principle, Inspection Board II can initiate proceedings under the present Code on its own initiative.

92 § Composition of the Inspection Boards. Inspection Board I has five Members or their personal substitutes and the Secretary, as well as a veterinary medicine expert member or a personal substitute who will only participate in the discussion of cases which are related to the marketing of veterinary medicines. Inspection Board II has four Members or their personal substitutes and the Secretary, as well as a veterinary medicine expert member or a personal substitute who will only participate in the discus-

sion of cases which are related to the marketing of veterinary medicines. The Board of Pharma Industry Finland will appoint the Members of the Inspection Boards. Both Inspection Boards elect the Chairperson and Vice Chairperson for the term among their ordinary Members. Pharma Industry Finland will appoint the Secretaries of the Inspection Boards.

The term of the Members of Inspection Board I is three calendar years so that every year two Members, with substitutes, will resign in turn. The term of the Members of Inspection Board II is four calendar years so that every year one Member, with substitute, will resign in turn and every four years the veterinary medicine expert member, with substitute, will resign. The Member or substitute can be re-elected for the maximum of three subsequent terms.

93 § Meetings. The Inspection Board is convened by the Chairperson as is necessary. A written complaint must be taken up without delay.

94 § Hearing. Before issuing a request to abstain from incorrect marketing or other measures or imposing a sanction payment, the Inspection Board must reserve the parties the opportunity to be heard.

The Inspection Board must ask a reply to a written complaint from the parties, the rights of which are involved in the case and which have not yet had the opportunity to express their views in this context. The reply can be requested by letter, fax or email. The reply must be given within a short timeframe determined by the Inspection Board or its Secretary. The deadline must not be shorter than seven days or exceed 14 days, save for exceptional reasons. Failure to give a reply does not constitute an obstacle to the examination of the case by the Inspection Board. The reply must be written, except for the attachments, in the language used in the marketing or other measure in question.

If the reply contains such new facts as have a bearing on the decision, the Inspection Board or its Secretary must request an opinion – to be given within a short period of time either in written or spoken form – from the party which had made the original complaint. The deadline must not exceed seven days, save for exceptional reasons.

95 § Scope of the examination. In resolving a case related to the marketing targeted at consumers, the co-operation between the pharmaceutical industry and patient organisations, or the health awareness information and other information on health and diseases targeted at consumers, Inspection Board I must examine the marketing measure as a whole, and form its opinion of the

compliance of the marketing with the present Code.

In resolving a case related to the marketing targeted at healthcare professionals or medical sales representative activities, Inspection Board II must examine the marketing measure or the medical sales representation activity to the extent complained against. At its discretion, Inspection Board II may also examine a marketing measure more thoroughly than was requested in the complaint. In matters of principle, in which Inspection Board II initiates proceedings under the present Code on its own initiative, it can examine the marketing measure to the extent it finds appropriate.

The Inspection Boards will make the decisions on the complaints on the basis of the material provided by the parties, and they are not liable to acquire any further information on the cases at hand.

96 § Principles and the interpretation of the Code. The Inspection Board can request the Commission's opinion on the principles to follow in the case at hand as well as on the correct interpretation of the present Code of Ethics. After receiving the opinion, the Inspection Board must make the decision in the case without delay.

97 § Decision-making. The Inspection Board constitutes a quorum when the Chairperson or Vice Chairperson plus two Members or substitute Members are present.

The decisions of the Inspection Board will be taken by simple majority. In case of an even vote, the Chairperson will cast the deciding vote.

However, the Chairperson and Secretary of the Inspection Board may decide on the lapsing of the case under Article 76, Paragraph 6 after the expiry of the 30-days deadline.

98 § Temporary request to abstain from incorrect activity. If a material mistake is identified in the marketing or other activities of the pharmaceutical company, the Chairperson and Secretary of the Inspection Board may together issue a temporary request to abstain from the incorrect marketing or other incorrect activities. The decision must be adhered to without delay and until the Inspection Board makes the decision in the case. In order to keep the temporary request to abstain from incorrect marketing or other incorrect activity in force, the Inspection Board must convene within 30 days to make a decision in the case which constituted the subject for the temporary request.

99 § Appeal. Appeal against the decision taken by the Inspection Board or by the Chairperson and Sec-

retary under Article 97 Paragraph 3 can be lodged with the Supervisory Commission through an application to that effect. The period of appeal is 14 days of the date in which notice of the written decision was served. The Supervisory Commission must examine the appeal without delay.

The appeal addressed to the Supervisory Commission or the reply given to an appeal must not make reference to such materials as were not presented for the examination of the Inspection Board, unless there are particularly weighty reasons to do so.

Despite the appeal or application for enforcement ban, the decision of the Inspection Board must be adhered to until the Supervisory Commission has issued its decision in the case. The Chairperson and the Secretary of the Supervisory Commission can together order, upon the request of the party involved and for particular reasons, that the decision of the Inspection Board must not be enforced until the Supervisory Commission has made a decision in the case (enforcement ban).

A particular reason may, for example, be that the decision of the Inspection Board is based on an evident misinterpretation of the Code or that the Inspection Board has otherwise followed an incorrect procedure in its decision-making.

PRELIMINARY INSPECTION

100 § Preliminary inspection. A pharmaceutical company can request from Inspection Board I a preliminary inspection of the marketing or other measure targeted at the consumers.

The Inspection Board must be supplied with the marketing or other measure to be inspected as well as the basic information on the medicinal product approved by the Authorities.

The basic information will include the summary of product characteristics, package leaflet, and if necessary, also the package itself. If the marketing or other measure refers to other material, the Inspection Board must also be supplied with that material.

If the advertisement is a spot that can be shown on the TV or radio, the applicant must also complement the application with the manuscript of the planned spot or the finalised spot.

101 § Exceptional order related to preliminary inspection of spots. An exception to the rule of voluntary action under Article 100, Paragraph 1, radio and TV spots of medicines must be submitted to preliminary inspection. The pharmaceutical company is liable to organise the preliminary inspection referred to hereunder.

If the radio or TV spot covered by the obligatory preliminary inspection rule refers to an Internet site, the Internet site in question is not covered by the preliminary inspection obligation.

102 § *Broadcasting of TV and radio spots.* The liability to comply with the preliminary inspection decision lies with the pharmaceutical company which is conducting the marketing operations.

103 § *Procedure in the preliminary inspection of radio and TV spots.* During preliminary inspection of radio and TV spots, the Inspection Board can

- a) approve the planned spot without changes; or
- b) fail the planned spot.

If necessary, the Inspection Board can hear the applicant before making the decision.

If the Inspection Board is presented with a version other than the final spot, the opinion expressed by the Board in relation to a non-finalised spot will not constitute the Board's final opinion on the completed spot. However, the Inspection Board is tied to its opinions related to the compliance of the spot manuscript with the present Code.

The Inspection Board will provide the applicant with a separate motivated decision on the preliminary inspection of the spot, marking the date of the decision. Notice of the decision must be served to the applicant immediately.

A spot that has undergone the preliminary inspection and approval procedure at the Inspection Board can be broadcasted for the maximum of three years from the date of the respective approval.

104 § *Procedure in other preliminary inspections.* As concern marketing and other measures, other than radio or TV spots, the preliminary inspection may focus on the question whether the measure in question complies with the present Code of Ethics and whether it would be prohibited in subsequent supervision. If only a part of a larger marketing or other measure is submitted for preliminary inspection, the preliminary inspection decision does not signify the final approval of the measure as a whole but it only constitutes an opinion related to the aspects that have come up in that context. The preliminary inspection decision must specify the reasons for which the measure does not comply with the present Code.

If the Inspection Board notices that a finalised marketing or other measure is either contrary to the decision made during preliminary inspection, or otherwise in violation against this Code, the Inspection Board can examine the case in terms of normal subsequent supervision.

105 § *Preliminary inspection charge.* The Supervisory Commission will impose a preliminary inspection charge on the applicant, the amount of which will be decided by the Board of Pharma Industry Finland annually when adopting the budget for the Supervisory Commission.

SANCTIONS

106 § *Sanctions.* The Inspection Board or Supervisory Commission can decide to give an admonition to the pharmaceutical company for future reference, or request the interested company to abstain from incorrect marketing or other activities contrary to the present Code ("request to abstain from incorrect activity"), decide on the processing charge, the compensation payable for unfounded complaint and the sanction payment as well as order the company to correct its incorrect activity. Moreover, the Supervisory Commission can impose a contractual penalty.

A sanction can be imposed due to the violation of the present Code, even though the pharmaceutical company in violation thereof would already have given up such measures.

The sanctions under the present Code do not impact one pharmaceutical company's obligation to compensate the other company for the damages caused by the violation of the Code.

107 § *Decisions related to marketing and other actions contrary to the present Code.* If the marketing or other measure is found to be contrary to the present Code, the pharmaceutical company in question can be issued an admonition for future reference, or the said company can be requested to abstain from the incorrect activity (request to abstain from incorrect activity).

The admonition for future reference can be given when the violation of the Code is of minor importance. The admonition for future reference must be associated with a reasonable deadline by which time the advertisement or other material must be revised. In this case, the pharmaceutical company can, within the set timeframe, complete an agreed campaign or finish the printed materials.

The request to abstain from incorrect activity can be given when the violation of the Code is not of minor importance. In this case, the pharmaceutical company must abstain from its incorrect activity immediately once it has been served oral or written notice of the request to abstain. Moreover, the eventual material must be immediately withdrawn from the market.

If the company violates an admonition for future reference, continues operations which do not comply with the Code despite the request to abstain, violates the decision made during the preliminary inspection of radio or television advertisements, circumvents the system referred to in the Code, violates a contract made amicably with another pharmaceutical company in relation to the discontinuation of incorrect activity, or neglects to correct its incorrect activity as ordered by the Inspection Board or the Supervisory Commission, the Inspection Board must submit the case to the Supervisory Commission. If the case has already been initiated at the Supervisory Commission, the latter will directly examine the case which could be submitted to it.

If the company continues its incorrect activity despite the temporary request to abstain from it, the Inspection Board must submit the case to the Supervisory Commission. In this case, the violation against the temporary request to abstain is equal to the violation of the actual request to abstain from incorrect activity.

108 § Processing charge. The Supervisory Commission or Inspection Board can impose on the company that has caused the proceedings a charge per each handling necessary in the case. As a general rule, the charge is imposed on the party that has been found to engage in activity that is contrary to the Code. If the activity focused on is found to violate against the present Code, no charge can be imposed on the company that has made the complaint. However, the processing charge may also be imposed on the complainant company if the complaint has been unfounded or the complainant company has requested that the case be dismissed.

The amount of the processing charge will be decided annually as Pharma Industry Finland adopts the budget for the Supervisory Commission. The purpose of the processing charge is to cover the expenses incurred for the processing, which must be taken into account when the amount is being determined. The charge can be diminished or augmented for a particular reason related to the expenses incurred for the processing. Moreover, the processing charge may be multiplied to five times the original if the complaint is found to be completely unfounded. Besides the processing charge, the company will be obliged to reimburse the direct expenses incurred by the Supervisory Commission for the clarifications in the case. Preliminary inspections are subject to separate charges determined on the occasion of the adoption of the budget.

109 § Compensation payable for unfounded complaint. Upon the request of the interested party, the

Inspection Board or the Supervisory Commission can, at their discretion, impose a € 5,000 compensation payment on the company behind a completely unfounded complaint, made merely for the purpose of harming the competitor, payable to the company suffering from the complaint to cover the costs incurred for the reply to the unfounded complaint.

110 § Sanction payment. At their discretion, the Inspection Board or the Supervisory Commission can impose a sanction payment ranging from the minimum of € 1,000 to the maximum of € 50,000 on a company that has violated against the present Code of Ethics. The sanction payment must be proportional to the quality and extent of the violation as well as to the eventual benefits gained by the company through such violation. The sanction payment associated with a request of abstaining from incorrect activity must be bigger than the one on an admonition for future reference. If the case is about the marketing of veterinary medicines, this constitutes a factor diminishing the sanction payment.

The sanction payment cannot be imposed in the same case which results in a contractual penalty.

111 § Correction of incorrect measures. The Inspection Board or Supervisory Commission can order that an incorrect marketing or other measure be corrected using the same method as the one used for distributing the incorrect information, if such correction can be deemed possible. The Inspection Board or Supervisory Commission can also issue this order on their own initiative. The order must specify the aspects which must, at least, be contained in the correction as well as the timeframe in which the correction must be made. In considering the correction of incorrect measures, the Inspection Board or the Supervisory Commission must consider the extent and quality of the incorrect operation as well as the eventual negligence vis-à-vis the present Code of Ethics shown by such incorrect operation.

112 § Contractual penalty and other sanctions. If the company neglects an admonition, request or temporary request to abstain from incorrect activity and continues to operate in a way that does not comply with the present Code, violates the decision made during the preliminary inspection of radio or television advertisements, circumvents the system referred to in the Code, violates a contract made amicably with another pharmaceutical company in relation to the discontinuation of incorrect activity, or neglects to correct its incorrect measures as ordered by the Inspection Board or by the Supervisory Commission, the Supervisory Commission can

- a) submit the case to the regulatory Authorities for their eventual measures, or
- b) at its discretion, impose a contractual penalty ranging from a minimum of € 20,000 and maximum of € 200,000 on the company that has violated the Code.

When determining the amount of the contractual penalty, the Supervisory Commission must consider the extent of the incorrect measures, the media used, the eventual negligence vis-à-vis the Code shown by such incorrect activity, as well as any other relevant issues. If the incorrect marketing takes place on television, this constitutes a particular factor increasing the amount of the contractual penalty.

113 § Conciliation. The sanction can be conciliated if, determined under the present Code, it would lead to an unreasonable situation. When assessing the unreasonableness of the sanction, the following aspects must be taken into consideration: the entire contents of the measure under examination; the status of the party; the circumstances during the measure and thereafter; the eventual benefit gained by the party through the measures; and other relevant aspects.

OTHER STIPULATIONS

114 § Publicity. The decisions and opinions of the Supervisory Committee and Inspection Boards on issues concerning subsequent supervision are public information. Preliminary inspection decisions are not public.

Correction of mistakes in decisions

115 § Correction of an error in the substance matter or in the procedure. If the decision of the Inspection Board or Supervisory Commission is based on clearly erroneous or incomplete information or on evidently wrong interpretation of the Code, or if a procedural error has taken place in the decision-making process, the Inspection Board or Supervisory Commission can, at the request of the interested party, cancel the erroneous decision and take up the case for further examination.

The decision can be corrected either for or against the interested party. Correcting the decision against the interested party calls for the consent of the interested party to submit the decision for correction. However, the consent of the interested party is not necessary if the error is evident and it has been caused by the interested party's own action.

116 § Correction of typos. The Chairperson and Secretary of the Inspection Board or Supervisory Commission must correct an evident miscalculation or typo or other similar clear mistake in the decision taken by these instances.

However, the mistake must not be corrected if such correction would lead to an unreasonable result from the interested party's point of view, and the mistake is not due to the interested party's own action.

117 § Initiation and processing of correction issues. The Inspection Board or Supervisory Board will process the correction issues on their own initiative or at the request of the interested party. The initiative concerning the correction must be made within 30 days of the decision. The correction request must be made within 30 days from the date in which the interested party was served written notice of the decision.

The correction of a mistake in a substance matter or procedure calls for new processing and decision in the case. A typo will be corrected by replacing the decision document containing the mistake by a corrected version of the same. The interested party must be reserved the opportunity to be heard before the correction of the typo, unless it is unnecessary.

118 § Complementary stipulations concerning the correction procedure. While discussing the corrections of substance-matter mistakes or typos, the Inspection Board or Supervisory Board can ban execution until further notice.

If a complaint against a decision by the Inspection Board, to be corrected, has been lodged with the Supervisory Commission, the Inspection Board must inform the Supervisory Commission about the correction, supplying the corrected decision to the latter. The processing of a correction issue does not influence the period of appeal against the decision by the Inspection Board.

Special provisions

119 § Notice. The notice of withdrawal from the agreement on the compliance with the present Code of Ethics must be given in writing to Pharma Industry Finland. The period of notice is six months. The notice does not prevent the processing of violations that have taken place before the end of the period of notice, in line with the system under this Code of Ethics.

120 § Entry into force. This Code of Ethics will enter into force on 1 July 2008. The Code for the Market-

ing of Medicinal Products, in force since 1 February 2007, will be repealed as the companies commit themselves to the new Code, however no later than 31 December 2008.

121 § Transitional provisions. Any violations that take place before 1 July 2008 and the respective sanctions will be examined under the Code for the Marketing of Medicinal Products, in force since 1 February 2007, while the rules and regulations of the new version of the Code will be applied for the procedure.

The Members of the Supervisory Commission and Inspection Boards will continue as bodies under the new Code until the end of their term determined earlier. However, the composition of Inspection Board I must be complemented in line with the present Code as from 1 July 2008.

The stipulations under Articles 84 and 92 of the present Code, related to the term and re-election of the Members of the Supervisory Commission and the Inspection Boards, will be applied to the Members in office at the moment of the entry into force of the present Code as from 1 January 2010.

The approved broadcasting period of a spot, adopted by the Inspection Board I before 1 July 2008 in preliminary inspection, will continue unaltered after the entry into force of the new version of the Code.

The stipulations under Article 37 on the non-interventional studies will be applied only to the new studies launched after the entry into force of the present Code.

The pharmaceutical companies must publish the list of sponsored patient organisations, referred to in Article 50, no later than 31 March 2009. The published list must cover the sponsorship in 2008.

122 § Pharmaceutical companies agree to abide by the resolutions taken in accordance with the present Code. It is not possible to seek compensation from the Supervisory Commission or Pharma Industry Finland for the damages resulting from the sanctions imposed under the present Code or from other decision entailed by the Code.

Admonition for future reference	106, 107, 110 and 112	Disguised advertising	11
Agreement on sponsorship	47	Disputes between companies	76
Appeal	99	Donations	35
Business entertaining	3	Enforcement ban	99 and 118
Business gifts	31	Entry into force	120
Celebrity	16 and 62	Events	29–30 and 53
Children	13, 15 and 63	Exploitation of celebrity	16 and 62
Circumventing the system	107 and 112	Free medicine samples	34 and 42
Commercial nature	6	Giveaways	19
Company logo	7 and 17	Good medical sales representation practices	42
Company name	69	Good pharmaceutical marketing practice	8
Comparisons	9	Grants	35
Compensation for unfounded complaint	109	Health awareness information	3, 11 and 56–69
Competitions	19, 33 and 64	Healthcare professionals	2
Complaint	76, 90, 91, 93 and 108	Hearing of experts	78
Conciliation	113	Hospitality	30 and 54
Confidentiality commitment	45	Inappropriate expression	13
Consumer	2	Incentives	31
Contents of information	12, 22 and 59	Information in international events	22
Contractual penalty	106 and 112	Information liability	27
Correction of an erroneous decision	115–118	Information on company operations	3
Correction of incorrect measures	111	Informative notifications	3
Dating of marketing material	24	Inspection Board	
Disease awareness campaign	56–69	– appeal	99

– competence	75 and 90–91	Scope of application	1–3
– completing	82	Sources of information	14, 26 and 60
– composition	92	Special groups	15 and 63
– decision	79	Sponsorship	17
– decision-making	97	Study results	6, 9, 14, 24, 25 and 60
– disqualification	80	Summary of product characteristics	3, 6, 11, 22, 28 and 100
– hearing	94	Supervisory Commission	
– initiation of a case	76	– competence	74
– meetings	93	– completing	82
– Minutes	79	– composition	84
– reply	94	– decisions	79 and 88
– scope of the examination	95	– disqualification	80
Internet sites in health awareness communications	68	– finances	83
Labelling	3	– hearing	88
Legislation	1	– initiation of a case	76
Limitation period	77	– meetings	86
List of recipients of sponsorship	50	– Minutes	79
Market research	32	– quorum	86
Marketing abroad	1, 22, 29 and 30	– reply	88
Marketing	1–3	– responsibilities	87
Medical sales representation	28 and 38–44	– scope of the examination	89
Medical sales representative	28	– Secretary	85
Medicines marketed to consumers	11	Targeting of pharmaceutical marketing measures	11 and 21
Minimum information	12 and 22	Temporary request to abstain from incorrect activity	98, 107 and 112
Misleading information	6, 13, 14 and 60	Tests	61
Nature of information	6, 23 and 56	Transitional provisions	121
Nature of marketing	6	Transparency	51
Non-intervention study	37	TV spot	100–104, 107 and 112
Novelty	6	Unpublished studies	25
Objective of information	20 and 56	Updatedness	6 and 22
Orders by the Authorities	1	Use of consultants	36
Package leaflets	3, 11, 12 and 100	Use of prestige or celebrity	16 and 62
Patient instructions	70–72	Vaccination campaign	11
Patient organisations	18 and 45–55	Veterinary medicines	3, 12 and 110
Pharmaceutical company	2	Visual image	65
Precondition related to marketing authorisation	5		
Preliminary inspection	100–105, 107, 112 and 114		
Presenting therapy options	9		
Prizes	19 and 33		
Processing charge	106 and 108		
Product and price lists	3		
Prohibited information	13		
Prohibition of marketing of prescription-only medicines	11, 46 and 58		
Publicity	114		
Radio spot	101–104, 107 and 112		
Reference to further information	66		
Reminder advertisements	7, 12 and 22		
Request to abstain from incorrect activity	98, 106, 107, 110 and 112		
Responsibility for compliance	4, 44 and 55		
Sanction payment	106 and 110		
Sanctions	70–71 and 75–77		
Scientific material	3		
Scientific service unit	10		

Sources:

Medicines Act (395/1987) and Medicines Decree (693/1987), www.finlex.fi
National Agency for Medicines: The recommendation for quality criteria for sales promotions of medicines (2007), www.nam.fi
Association of Finnish Local and Regional Authorities: Aspects regarding travelling and other economic benefits offered by outsiders to municipal employees and elected officials (circular letter 21/80/2005), www.kunnat.net
EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals and EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations, www.efpia.eu
IFPMA Code of Pharmaceutical Marketing Practices, www.ifpma.org



PHARMA INDUSTRY FINLAND

Pharma Industry Finland (PIF)
Eteläranta 10, P.O. Box 109, FI-00131 Helsinki, Tel. +358 9 6150 4900, Fax +358 9 6150 4940
www.pif.fi