







Agreement on voluntary commitment for the pharmaceutical sector for the period 2012-2014

Between

The Ministry for Ecology, Sustainable Development, Transport and Housing,

The Ministry for Work, Employment and Health, of the first part

<u>And</u>

The French Pharmaceutical Companies Federation (LEEM), of the second part





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Background

Since 2006, LEEM and its members have been resolutely committed, across all their roles and activities, to carrying out projects and actions to promote Corporate Social Responsibility (CSR). They want to make their CSR programmes part of their strategic objectives to promote therapeutic innovation, efficiency of healthcare expenditure and attractiveness of France. They are making progress by combining the efforts of all their employees and stakeholders.

Drug companies are represented by LEEM, a business association with nearly 270 member companies, that make more than 93% of the total sales turnover for pharmaceutical products in France.

The drug industry is an eminently strategic sector for France. In 2010, drug companies achieved sales of 27.3 billion Euros in France, to which were added 24.1 billion Euros in exports, making pharmaceutical products the 4th largest source of foreign currencies for the French economy. In 2008 the industry invested 5 billion Euros in research and development, equivalent to 12.5% of turnover. The pharmaceutical products sector is the second largest sector investing in R&D. In 2012, companies in the sector employed 103,900 people. The total number of people employed in the entire pharmaceutical product chain is 297,700, including employees in SMEs in biotechnology and the active ingredients industry, wholesale distributors, agents, dispensing pharmacies, etc.

Drug companies are involved in healthcare, research and more broadly the industrial, social and economic life of France.

General principles of the Agreement

Companies are committed to improving their environmental and social performance, and to using tools to assess the measures implemented. They will use the necessary human resources so that drug companies implement action plans consistent with the 'Grenelle Environment'.

The objectives of this agreement are to renew the commitments made when signing the 'Progress Agreement under the Grenelle Environment for the period 2009-2011' in March 2009 and to go further than current regulations and at least achieve the Grenelle commitments.

In particular this agreement is justified by the following reasons:

Drug companies consider their activities serving patients as based on values of ethics and transparency, which this agreement recognises as being the basis for sustainable development of the sector in the service of all its stakeholders. They intend to set themselves ambitious objectives that go beyond regulatory measures in order to increase the number of ways to implement the Grenelle Environment.

Five joint action programmes

This agreement falls under the framework of ISO 26000. The approach for Progress in Social Responsibility in the pharmaceutical products sector in the coming 3 years, from 2012 to the end of 2014, will be based particularly on the following five programmes:

- To implement governance of CSR in companies
- To promote diversity and continuous improvement of working conditions
- To develop environmental action programmes throughout the drug product life cycle (combat climate change, reduce waste, preserve natural resources and protect the environment)
- To promote an ethical and transparent approach in regard to the society's expectations
- To promote access to pharmaceutical products to the greatest number of people and to be involved locally in sustainable development

1. CORPORATE SOCIAL RESPONSIBILITY

1.1. To implement governance of CSR in companies

CSR combines economic strategy, social responsibility and eco-responsibility. For companies the approach will consist of taking account of the social and environmental impacts of their activity in order to adopt the best possible practices and so contribute to improving society and protecting the environment.

Objective: To implement a CSR policy, in particular by promoting the use of best practices

- Companies will undertake to include CSR as a component of their strategy and organisation.
 - Management bodies (executive committee, board of directors) of companies will progressively consider questions relating to CSR by putting these subjects on the agenda once per year in order to include them in the strategic plan of companies.
 - Objective 2014: to double the number of companies that put CSR on the agenda for their management bodies at least once per year
 - Performance indicator: number of companies that put CSR on the agenda for their management bodies at least once per year in 2012, 2013, 2014
 - > Companies will appoint one (or more) 'CSR coordinator(s)' responsible for the CSR/SD programme, to coordinate actions.
 - Objective 2014: all companies will have appointed CSR coordinators
 - Performance indicator: number of companies having a CSR coordinator in 2012, 2013, 2014
- Training tools regarding best CSR practices will be made available to companies, particularly in the form of a joint-working platform. Through LEEM, best CSR practices will be listed and reproduced during an annual meeting of CSR coordinators. In addition, they will be highlighted every year in the LEEM CSR report.

Objective: To encourage companies to take part in dialogue with stakeholders

- The sector will encourage companies to develop cooperative strategies with stakeholder committees
 - > To encourage companies to take part in dialogue with stakeholders on behalf of the sector and to create their own stakeholder committees (panels) at national (head office or subsidiary) or local (site) level
 - ➤ To submit strategic policies to stakeholders and to examine the conclusions and recommendations arising from the dialogues established.

- LEEM will provide technical support (creating tools) and/or procedural support to companies to set up these dialogues.
 - Objective 2014: to double the number of companies that have set up formal dialogue with their stakeholders (based on 2011)
 - Performance indicator: number of companies that have set up formal dialogue with their stakeholders in 2012, 2013, 2014
- Companies will inform employee representatives of the CSR policy
 - Organisations representing employees (ORE) will be kept informed of the company's CSR policies.
 - Objective: once a year the sector will inform the OREs about the CSR policy in the sector.
 - Performance indicator: number of companies that have informed OREs about their CSR policy in 2012, 2013 and 2014

Objective: to make sector employees aware of CSR

- Companies offer their employees awareness / training programmes about CSR issues and its specific integration in healthcare issues.
- LEEM will provide its members specific training tools to help companies engage their employees on these topics.
 - Objective: to increase the number of employees made aware or trained in sustainable development / CSR by 10% (based on 2011)
 - Performance indicator: number of employees that have taken awareness / training programmes in sustainable development / CSR in 2012, 2013, 2014

1.2. To promote diversity and continuous improvement of working conditions

Objective: to ensure professional equality and increase the proportion of women in senior positions

- Companies will also encourage more balanced representation of women in senior positions and boards of directors
 - Performance indicator: percentage of women in management positions in 2012, 2013, 2014

Objective: to promote access to jobs for young people

- Companies will set up support programmes to give young people access to jobs (tutelage, placements, etc.) and will strengthen their partnerships with universities.
 - Objective 2016: to double the number of placement contracts signed with young people in 5 years
 - Performance indicator: number of placement contracts signed with young people in 2012, 2013, 2014

Objective: increase the proportion of seniors in recruitment: 4.10% at the end of 2012

- LEEM will encourage pharmaceutical companies, according to provisions specified by the
 collective agreement dated 3 November 2009, to adopt active age management and include
 more seniors in their human resources management, in order to enable progressive
 improvement in the level of recruitment for people aged 50 and over in the sector.
 - Objective 2012: to increase the proportion of seniors in recruitment and so increase from 3.25% to 4.10% by the end of 2012 across the entire sector.

This objective may be revised based on renegotiation of the collective agreement

Performance indicator: proportion of seniors in recruitment during 2012, 2013, 2014

Objective: encourage recruitment of disabled people: 400 people at the end of 2014

• Companies, as defined by the amended collective agreement dated 25 October 2008, will

conduct a policy to promote recruitment and maintenance of people affected by a handicap in employment. This policy will result in companies in the sector employing close to 400 people by the end of 2014.

- Objective 2014: recruitment of 400 disabled people under the following conditions: 50 people in 2010, 60 in 2011; 70 in 2012; 110 in 2013 and 110 in 2014.
- Performance indicator: number of disabled people recruited in 2012, 2013, 2014
- Each company will also appoint a disabled persons' coordinator
 - Objective 2014: 100% of companies will have appointed a disabled persons' coordinator
 - Performance indicator: number of disabled persons' coordinators in 2012, 2013 and 2014

Objective: to make healthcare a daily priority

- In accordance with the collective agreement dated 6 July 2011, companies will work to improve the health of all employees, so that they can be identified as belonging to a company that pays particular attention to these matters. They will deal with the prevention of working risks including psychosocial risks as well as managing accidents at work and working illness. Prevention of working risks will require all those involved in healthcare in the company (employer, HSE department, etc.) to take part in evaluating working risks, classifying these risks and implementing preventive and, if appropriate, curative actions.
 - Objective: performance indicators allowing this agreement to be monitored will be developed in 2012.

2. THEMED COMMITMENTS OF THE SECTOR

2.1. To develop environmental action programmes throughout the life cycle of the drug

2.1.1. Contribute to combatting climate change

Objective: to voluntarily reduce greenhouse gas emissions from the sector as well as energy consumption

- LEEM will encourage its members to carry out a greenhouse gas emissions audit by making available CarbonEM®, a tool and methodology to account for greenhouse gas emissions specific to the sector.
 - o Performance indicator: number of carbon audits carried out in 2012, 2013, 2014
- LEEM will encourage its members that are not obliged to carry out a greenhouse gas audit
 under the terms of article 75 of the Grenelle 2 law (legal entities with less than 500 employees)
 to perform a greenhouse gas audit and send it in
 - Performance indicator: number of companies / sites carrying out a greenhouse gas audit without being obliged to do so, in 2012, 2013, 2014
- LEEM will encourage its members to take account of indirect emissions for all process components including transport (scope 3) in the greenhouse gas audit. LEEM will provide feedback on inclusion of scope 3 at the National Coordination Centre.
 - Performance indicator: number of companies / sites having carried out a greenhouse gas audit to take account of indirect emissions (scope 3)
- Companies will do their best to implement action plans to reduce greenhouse gas emissions and energy saving plans. They will do their best, further to the savings made, to replace conventional energy sources used by renewable sources.
 - Performance indicator: number of companies / sites implementing a greenhouse gas emissions reduction and energy saving plan in 2012, 2013, 2014

Objective: modification of peoples' transport behaviour

- When renewing their fleet, companies will do their best to opt for vehicles eligible for the 'ecological bonus', those emitting less than 105 grams of CO₂ per km or carbon neutral.
 - Objectives 2014: 50% of the vehicle fleet will comprise vehicles emitting less than 105 grams of CO₂ per km or carbon neutral.
 - Performance indicator: ratio of vehicles emitting less than 105 grams of CO₂ or carbon neutral (company fleet) in 2012, 2013, 2014
- Regarding the incentive for employees to car-share between their homes and workplace, companies will encourage and implement company travel plans. An approach to rationalising journeys will be undertaken using mechanisms favouring public transport, i.e. car-sharing, use of alternative transport (electric cars, hybrids, etc.) or when possible to use eco-friendly and active means of transport (bicycle, rollerblades, etc.)
 - Performance indicator: number of company travel plans implemented
- Regarding reducing individual business transport modes generating greenhouse gases, companies will focus on the following methods:
 - Increasing the use of 'conference call' systems or remote-working instead of journeys by air or car
 - > To offer training in eco-driving for employees, particularly for medical representatives;
 - Performance indicator: number of employees made aware and trained in economical, safe driving (eco-driving)
 - Performance indicator: percentage of employees including medical representatives receiving training in economical, safe driving (eco-driving)
 - To encourage the development of business travel policies: favour the train rather than flights for short distances, prefer public transport over taxis
 - Performance indicator: number of companies implementing a business travel policy

Objective: modification of goods transport behaviour

- Companies will favour systematically seeking to improve the entire logistic chain with the aim of being committed to a 'green supply chain' approach, particularly by improving palletisation and lorry loading levels
- Companies will implement best practices in their distribution processes and particularly by optimising rounds, by creating storage and distribution sites and by developing the use of alternatives to road transport (rail or waterway).
 - Performance indicator: number of companies having put actions in place related to the distribution process and implemented best practices

Objective: To optimise energy efficiency of buildings

- For new or renovated buildings:
 - > Include HQE (high quality environmental) criteria
 - Tend towards high energy efficiency objectives
 - Performance indicator: percentage of new or renovated buildings that meet the HQE standard out of the total number of new buildings and percentage of new m² constructed to exceed compliance with RT 2012 in 2012, 2013, 2014
- For existing buildings:
 - Conduct energy audits to find out energy consumption per m²
 - Performance indicator: number of audits carried out in 2012, 2013, 2014
 - Performance indicator: number of action plans and best practices implemented to reduce consumption

2.1.2. To contribute to waste reduction

Objective: Operational use of eco-organisations responsible for collecting and destroying potentially-

infectious healthcare waste from patients undergoing self-treatment and to measure its efficiency

- In accordance with article 187 of law 2011-788 creating a national commitment to the
 environment, companies marketing products that generate production of potentially-infectious
 healthcare waste so-called 'sharps' by patients undergoing self-treatment will set up an ecoorganisation to collect and dispose of this waste as well as informing all stakeholders that this
 sector exists.
 - Objective for 2017: to reach a national collection level of 60% for potentially-infectious healthcare waste
 - Performance indicator: tons of potentially-infectious healthcare waste recovered annually in 2012, 2013, 2014

Objective: to increase recycling of drug packaging and encourage the return of unused medicines to the pharmacy

- Companies will refer to 'Cyclamed' on patient information leaflets and will recommend unused medicines are returned to the pharmacy and refer to 'Adelphe' by recommending that packaging from medicines be discarded in recycling bins
- Companies will implement publicity campaigns (eg. link to Cyclamed and Adelphe web sites from their company sites) to encourage recycling of packaging materials and returning unused medicines to pharmacies.
 - Objective: increase the collection of unused medicines by 2% per year
 - Performance indicator: amount of unused medicines collected
 - Performance indicator: number of companies having implemented publicity campaigns to encourage recycling of packaging materials and returning unused medicines to pharmacies.

Objective: to establish an eco-design approach to packaging

- Companies will continue and increase their work in eco-design for secondary and tertiary packaging of pharmaceutical products. They are encouraged to use recycled paper and cardboard in their secondary and tertiary packaging and to measure the tonnage of cardboard avoided in order to recognise progress made in this area. The sector will also undertake a study of eco-design and safety of primary packaging materials through dialogue with EMA and ANSM [EMA: European Medicines Agency; ANSM: national safety agency for pharmaceutical and healthcare products].
 - Performance indicator: number of companies having eco-design actions in 2012, 2013, 2014

2.1.3. To contribute to preserving natural resources and protecting the environment

Objective: to be committed to biodiversity

- The sector will continue to make its contribution to discussions and initiatives that will help to implement the objectives of the Convention on Biological Diversity and particularly the 'Access and Benefit Sharing' protocol on access to genetic resources and fair and equitable sharing of the benefits resulting from their use, adopted in 2010 in Nagoya.
- Companies will make their employees aware of the challenges and impacts of biodiversity and will set up biodiversity protection programmes (positive actions to promote flora and fauna).
- LEEM will encourage companies to follow the national biodiversity strategy.
 - Performance indicator: number of companies following the national biodiversity strategy (companies having implemented positive actions to protect biodiversity (flora and fauna) in 2012, 2013, 2014
 - Performance indicator: number of companies consulting EBEvie I in 2012, 2013, 2014

Objective: to participate in implementing the national plan on drug residues in water, launched by the ministries on 30 May 2011.

- As a member of the monitoring committee for the national plan on drug residues, LEEM will
 relay requests from the monitoring committee and scientific support group for the plan to
 the sector.
- The sector will take part in discussions on implementing a national data bank and on supplying data to put into it, as well as on sharing procedures that will remain to be defined, to guarantee issues such as industrial confidentiality.
- LEEM will draw up preventive recommendations for companies to check emissions of drug residues into the environment.
 - Performance indicator: number of companies implementing an action plan on drug residues in water

2.2. To promote an ethical and transparent approach to match society's expectations

Objective: to create an ethics body for business practices and to ensure ethical business rules are applied

- In 2011 LEEM established an ethics body for business practices, called Codeem (ethical vigilance committee for drug companies). With a role monitoring ethics and real powers of sanction, its objectives are:
 - To issue recommendations for responsible practices appropriate to the healthcare environment,
 - To promote and ensure compliance with rules and ethical behaviour in the profession.
- In addition to their internal ethical code, companies comply with professional ethical requirements governing their activities, the conduct of those carrying them out and relationships between them and their stakeholders.
 - Performance indicator: number of employees trained in ethics and compliance

Objective: to be committed to responsible lobbying

- In relation to Codeem and its stakeholders, LEEM will develop a lobbying charter during 2012 with support from companies. This code of good conduct will encourage transparency and integrity of strategies and influencing practices. LEEM will encourage companies to adopt this charter and/or lobbyists to comply with the charters of organisations representing lobbyists.
 - Objective 2012: to draw up the LEEM lobbying charter and roll it out,
 - Performance indicator: number of companies having a lobbying charter or having ratified the LEEM lobbying charter or having lobbyists complying with the charter of organisations representing lobbyists in 2012, 2013, 2014.

Objective: to continue studies to reduce animal experimentation

- Companies will renew the commitment to complying with the 3R rule (Reduce, Replace, Refine) and will continue their studies into reducing the use of animals for research.
 - Performance indicator: number of companies complying with the national charter relating to the ethics of animal experimentation drawn up by the National Committee for ethical review on animal experimentation in 2012, 2013, 2014.

Objective: to encourage responsible purchasing actions

- Companies will progressively include sustainable development / CSR criteria (environmental, social and societal) in invitations to tender, the choice of suppliers and purchasing procedures, in complying with quality and safety requirements. In this way companies opt for initiatives such as:
 - Internal training for purchasers in responsible purchasing;
 - Supporting suppliers to improve their products progressively;
 - Monitoring and assessing suppliers using a CSR approach;
 - > Including the CSR commitment in responses to invitations to tender.
 - o Performance indicator: number of companies having a responsible purchasing policy in

2.3. To promote access to pharmaceutical products to the greatest number of people and to be involved locally in sustainable development

Objective: to promote access to the greatest number of medicines

- Through the French Pharmaceutical Companies Federation (LEEM), the sector will develop its support to organised projects for chronic illnesses and rare diseases, and for initiatives aimed at reducing vulnerabilities and inequalities in the national healthcare system. Furthermore, the companies will use their own foundations to develop drug access and health improvement programmes.
 - Performance indicator: number of projects supported and budget allocated by the French Pharmaceutical Companies Federation (LEEM) in 2021, 2013, 2014
- TULIPE Transfert d'Urgence de L'Industrie PharmaceutiquE [pharmaceutical industry emergency transfer] will develop its role consolidating donations from Drug Companies as emergency responses to the needs of populations in distress during acute health crises, natural catastrophes and conflicts.
 - Performance indicator: number of companies belonging to TULIPE in 2012, 2013, 2014.

Objective: be involved with regional and local communities and get involved in society

- Companies will continue to give their support to local organisations and associations through partnerships aimed at improving societal and environmental aspects of the company
 - Performance indicator: number of partnerships established by companies in 2012, 2013, 2014
- Furthermore, they will encourage their employees to take part in voluntary activities, skills sponsorship programmes, etc., to serve society.
 - o Performance indicator: number of employees taking part in voluntary activities (in equivalent man-days) in 2012, 2013, 2014

3. IMPLEMENTING THE COMMITMENT

This agreement does not create legal obligations between parties likely to serve in a legal or regulatory framework.

It defines the framework of a shared development approach.

LEEM is committed to promote, monitor and steer the implementation of this Agreement.

Companies belonging to LEEM, with help from their business organisation, will implement this agreement to the best of their capabilities. While remaining fully responsible for their own approach, member companies may rely on joint working groups set up within LEEM, that will be responsible for monitoring and facilitating these development objectives.

The two ministries will take account of the societal and environmental service rendered by Drug Companies that may be included in discussions relating to the prices of medicines.

The Ministry for Sustainable Development and Health will ensure that all regulations that could affect the pharmaceutical sector, particularly with regulatory and financial implications, will be agreed with the profession in advance.

Drug companies emphasise the need to take account of imported products when considering potential changes to taxation related to sustainable development.

Monitoring and annual review

The voluntary commitment agreement is for a period of three years.

Annual meetings between the Ministry for Sustainable Development / Ministry for Health / LEEM and the stakeholders involved will evaluate the progress made corporate social responsibility programmes affecting the sector.

A Monitoring Committee covering companies, ministries and stakeholders will be convened once per year.

These performance indicators will be monitored annually using a 'CSR questionnaire'. The scope of companies responding to the questionnaire, in terms of number and representation of the sector (sales and number of employees) will be stated. LEEM will implement an approach to increase the number of companies responding to the questionnaire annually.

Advances will be released publicly in the sector CSR report.

As appropriate, based on the results of the annual reviews, the agreement may be revised by joint agreement of all signatories or suspended at the initiative of one of the signatories.

Signed in Paris on 26 April 2012

Dominique Dron

General Commissioner for Sustainable Development Ministry for Ecology, Sustainable Development, Transport and Housing

Christian Lajoux

President of the French Pharmaceutical Companies Federation (LEEM

Dr Jean-Yves Grall

Director General for Health Ministry for Work, Employment and Health

Appendix: Summary table of commitments including measurable objectives

PROGRAMMES	MEASURABLE OBJECTIVES	SUMMARY TABLE OF INDICATORS FOR MONITORING THE AGREEMENT
Programme 1 To implement governance	To double the number of companies that put CSR on the agenda for their management bodies at least once per year by 2014	Number of companies that put CSR on the agenda for their management bodies at least once per year
of CSR in companies	All companies will have appointed the CSR coordinator in 2014	Number of companies having CSR coordinators
	To double the number of companies that have established formal dialogue with their stakeholders	Number of companies that have established formal dialogue with their stakeholders
	Once a year the sector will inform the OREs about the CSR policy in the sector	Number of companies that have informed OREs about their CSR policy
		Number and percentages of employees that have taken awareness / training programmes in sustainable development / CSR
Programme 2		Percentage of women in management positions
Promoting diversity and continuous	To double the number of placement contracts by 2016	Number of placement contracts signed with young people
improvement in working conditions	To reach 4.10% of seniors in recruitment at the end of 2012	Proportion of seniors in recruitment
	To recruit 400 disabled people by the end of 2014	Number of disabled people recruited
	100% of companies will have appointed a disabled persons' coordinator at the end of 2014	Number of disabled persons' coordinators
	To develop performance indicators on working risk prevention at the end of 2012	
Programme 3		Number of carbon audits carried out
To develop environmental action programmes		Number of companies / sites carrying out a carbon audit without being obliged to do so
throughout the drug life		Number of companies / sites having carried out a carbon audit to take account of scope 3
cycle:		Number of companies / sites implementing a greenhouse gas emissions reduction and energy saving plan
Climate change Waste reduction Natural resources	50% of the vehicle fleet will comprise vehicles emitting less than 105 grams of CO ₂ or carbon neutral	Ratio of vehicles emitting less than 105 grams of CO ₂ or carbon neutral (company fleet)
		Number of company travel plans implemented
		Number of employees taking a training course in eco-driving, including medical representatives

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		Number of companies implementing a 'business travel policy'
		Percentage of new or renovated buildings that meet the HQE standard out of the total number of new buildings and percentage of new m ² constructed to exceed compliance with RT 2012
		Number of audits carried out and number of action plans and best practices implemented to reduce consumption
	To reach a collection level for potentially- infectious healthcare waste of 60% in 2017	Tons of potentially-infectious healthcare waste recovered annually
	To increase the collection of unused medicines by 2% per year	Number of companies with publicity campaigns for Adelphe and Cyclamed
		Number of companies having eco-design actions
		Number of companies following the national biodiversity strategy and/or companies having implemented positive actions to protect biodiversity (flora and fauna)
		Number of companies implementing an action plan on drug residues in water
Programme 4		Number of employees trained in ethics and compliance
To promote an ethical and transparent strategy		Number of companies having a lobbying charter or having ratified the LEEM lobbying charter or having lobbyists complying with the charter of organisations representing lobbyists
transparent strategy		Number of companies complying with the national charter relating to the ethics of animal experimentation drawn up by the National Committee for ethical review on animal experimentation
		Number of companies having a responsible purchasing policy
Programme 5		Number of projects supported and budget allocated by LEEM
		Number of companies belonging to TULIPE
To promote access to pharmaceutical products to		Number of partnerships established by companies
the greatest number of people and to be involved locally in sustainable development		Number of employees taking part in voluntary activities