

Codeem opinion on the dividing line between links based on shared interests and conflicts of interest - July 2021

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In this opinion, Codeem will summarise the current regulatory framework governing links based on shared interests and conflicts of interest in the health sector (1), before defining the scope and aims of its opinion (2) and reiterating the terms of its general position on the dividing line between links based on shared interests and conflicts of interest (3).

Codeem will then attempt to clarify the significance of this dividing line between links based on shared interests and conflicts of interest (4) and how it can be identified and responsibly managed to maintain a level of high-quality expertise for public and private decision-making in France (5).

Codeem would like to stress from the outset that this subject matter is currently poorly understood, with a significant level of confusion between the concepts of links based on shared interests and conflicts of interest, which could ultimately result in a downgrading of high-quality expertise in our country.

Opening remarks

Firstly, it is important to remember that there is an imperative difference between links based on shared interests and conflicts of interest. Links based on shared interests are referring to a situation where the partners concerned share a common interest, in pharmaceutical product development, for example. Within

a contractual relationship, such links based on shared interests may involve payment for work carried out. Indeed, no partnership would be possible without shared interests and their associated linkage. The links mean that there exists a mutual interest in working together on a scientific and intellectual project in the best interest of patients. This work requires time and investment. Links based on shared interests are therefore not only legitimate, but desirable, in a country that wishes to promote high-level research between public- and private-sector actors.

It is essential to make a clear distinction between this concept and that of conflict of interest. Reference should be made here to the definition of conflict of interest given by the Council of Europe and used by Transparency International (www.transparency-france.org). A conflict of interest arises out of a situation in which a public official has a personal interest which may influence, or appear to influence, the impartial exercise and purpose of his or her official duties. A conflict of interest arises when an organisation or individual is involved in multiple interests, one of which may corrupt the motivation to act for the benefit of the others. A conflict of interest may therefore arise when a person has to perform a public-interest task or function that competes with other interests and causes him or her to deviate from the public interest.

This raises questions around two essential values: on the one hand, the duty of probity, which must translate into total honesty in the exercise of a person's missions and, on the other hand, a duty of impartiality, which imposes the need for a person to exercise their mission with neutrality and intellectual rigour, without interference, in the knowledge that any failure in this respect may harm the validity and the quality of the overall process.

1. Summary of the regulatory context and framework

1.1 History of how the regulatory framework has come about

The regulatory framework governing links based on shared interests in the health sector has developed over many years, beginning with the health sector controversies of the 1990s and 2000s.

These cases highlighted the malfunctioning of the healthcare system in those decades. They have led the authorities to reform the conditions governing interaction between health care professionals and companies, as well as the decision-making procedures of health sector agencies, to ensure transparency and guard against conflicts of interest. At the same time, these legal and regulatory texts recognise the legitimacy of links based on shared interests, and have therefore attempted to draw a dividing line between links based on shared interests and conflicts of interest.

The system we have today has been gradually constructed by the following succession of laws and recommendations:

- Law 93-121 of 27 January 1993, known as the 'DMOS' or 'Anti-Gift Law', prohibits the granting of benefits to health care professionals by any natural or legal person involved in the manufacture or marketing of health products, regardless of whether such products are funded by social security or are involved in providing health services covered by French national health insurance scheme
- Law 2011-2012 of 29 December 2011, known as the 'Bertrand Law', strengthened the legal framework around the prevention and management of conflicts of interest, and is based on the implementation of 3 main principles:
 - The introduction of obligations binding different health sector actors to report links based on shared interests through the DPI (Déclaration Publique des Liens d'Intérêt / Public Disclosure of Links based on shared interests) system:

The DPI system serves two main purposes:

- To increase transparency around public-sector actions by publishing the links based on shared interests between decision-makers and health experts

- To give central government certainty about the impartiality and objectivity of those individuals involved in healthcare-related decision-making and health expertise through early-stage analysis of the links based on shared interests reported in relation to cases considered or responsibilities exercised
 - Compliance with strict rules where health sector actors are involved in a conflict of interest: these rules apply on the basis of verifiable management procedures and control facilitated by the traceability and public disclosure of discussions
 - Public disclosure of benefits granted to health care professionals by companies manufacturing or marketing health products for human use, by publishing these benefits on the 'Transparence-Santé' website
- Law 2013-907 of 11 October 2013 on transparency in public life created an independent administrative authority - the High Authority for Transparency in Public Life (Haute autorité pour la transparence de la vie publique or HATVP), whose mission is to verify the truthfulness of disclosures of assets and interests made by a number of elected officials and representatives of the authority

This law defines conflict of interest as follows: *"A conflict of interest is any situation where public and private interests conflict with the public interest, where conflict has the potential to influence, or appear to influence, the independent, impartial and objective exercise of a function."*

- The health expertise charter approved by decree 2013-413 of 21 May 2013 which purpose is to enable the sponsors and organisations responsible for providing expert opinion to respect the principles of impartiality, transparency, plurality and adversarial process set out in Article L. 1452-1 of the French Public Health Code. It is designed to provide assurance around such expert opinion in terms of the competence and independence of those providing the expertise concerned, the traceability of the sources used, the transparency of the methods used and the clarity of the conclusions submitted.

As provided for in Article L.1452-2 of the French Public Health Code, the charter sets out the procedures for selecting experts (I), the expertise process and its relationship with the decision-making body (II), the concept of links based on shared interests, conflict of interest scenarios and procedures for managing such conflicts (III), and exceptional cases where account may be taken of work carried out by experts where a conflict of interest exists (IV).

The Charter defines the concepts of 'links based on shared interests' and 'conflict of interest':

- *"The concept of links based on shared interests covers the asset-related, professional or family interests or activities of the expert concerned where these relate to the purpose of the expertise he or she is requested to contribute."*
 - *"A conflict of interest arises out of a situation in which the nature or intensity of the links based on shared interests of an expert have the potential to raise doubts regarding his or her impartiality or independence when exercising their mission in respect of the issues on which their expert opinion is sought."*
- The 23 March 2016 report of the Court of Auditors on the prevention of conflicts of interest relating to health expertise provides an initial assessment of the law of 29 December 2011 on this issue. It reiterates that the issue of conflicts of interest in the health sector is a central public concern, and one which demands guarantees that the decisions made by politicians and health agencies are impartial. It notes that the system in place to ensure transparency is flawed, and makes 10 recommendations for improving the organisational structure of central government and the health agencies, supporting the independence and quality of health expertise, improving the effectiveness of the system for declaring interests, and introducing effective checking of their truthfulness by an independent body

- Law 2016-41 of 26 January 2016, known as the ‘health system modernisation law’, strengthens the transparency system and provides for the disclosure and publication on the ‘Transparence-Santé’ website of payments made in the context of collaboration between pharmaceutical companies and health care professionals. The law also requires health agencies to appoint ethics officers
- Law 2019-774 of 24 July 2019, known as the ‘Ma santé 2022’ law, ratifies Order 2017-49 of 19 January 2017 reforming the ‘Anti-Gift’ system, and extends the ban on benefits to include students studying for careers as health care professionals, associations of health care professionals, learned societies and National Professional Councils
- Moreover, in recent years, the Council of State (Conseil d’Etat) has regularly been required to rule on conflicts of interest, the effect of which has been to clarify their contours. The Council of State conducts factual analyses of direct and indirect links based on shared interests to determine whether or not they are so close as to compromise the impartiality of the expert. The Council of State adopts a very narrow interpretation of the concept of conflict of interest.
- In March 2019, the Minister for Higher Education, Research and Innovation appointed Professor Truchet to clarify the conditions governing participation in public expertise processes, with particular emphasis on health issues. The resulting report - The Truchet report - on public health expertise, environment and food issues has yet to be published.

1.2 The Codeem perspective of the existing framework and its limitations

- It is clear that despite the progress resulting from these texts and recommendations, the subject remains topical today, due largely to the absence of universally accepted clear criteria on the basis of which an action is considered to be legitimate links based on shared interests or a conflict to be resisted. Opposing positions are emerging in society, with a major risk that eminent and respected experts may be deterred from contributing, thereby weakening the level of expert opinion provided. As a result, a climate of mistrust has developed in France, which is affecting the recruitment of experts in the health sector.
- The system is currently underpinned by three major pillars that Codeem believes to be essential:
 - the general introduction of obligations to disclose and publish interests
 - transparency around the decision-making processes of expert committees, which involves recording their discussions and publishing the minutes
 - lastly, transparency around benefits granted to health care professionals by pharmaceutical companies and their publication on a single website

The links of experts should be analysed to determine the actual level of their involvement in the work, depending on the nature, intensity and length of the relationship.

- However, Codeem is aware that these three cornerstones of the process to define the dividing line between links based on shared interests and conflicts of interest have yet to result in a clear and consensual definition around their implementation, which inevitably leaves room for disparities in interpretation, and ultimately results in significant risk regarding the quality of expert opinion provided: the risk here is that all experts become disqualified as soon as they have links based on shared interests on a given topic, thereby depriving the health sector of high-quality experts.
- Nevertheless, it is important to remember that any professional well respected within a given area of expertise may have links based on shared interests in his or her field of action (this is precisely what makes them an expert in their field), and that the fact of having such links is a guarantee of competence.

Conversely, the fact of not having any links may raise questions about the legitimacy of the ‘expert’, who may then be supposed to be unfamiliar with ‘the practical realities of the world of pharmaceuticals’. This would be particularly true if - as has already been seen - experts were required

to give an opinion in a medical field that was not their own: for example, a dermatologist being required to assess the medical benefits of a pharmaceutical product indicated for the treatment of diabetes.

- So in the context of the current public and political debate, the major risk would be to treat any links based on shared interests as a conflict, thereby excluding any competent person on the basis of their collaborations or professional status.

It is therefore important to emphasise that links based on shared interests do not necessary lead to a conflict of interest, and that the evaluation criteria are yet to be clearly stated, set out and agreed upon.

2. The scope and purposes of this opinion

2.1 The scope of this opinion

This opinion is not intended to:

- Be limited to consideration of the links based on shared interests and conflicts of interest specific to experts working on behalf of the pharmaceutical industry: it forms part of a wider reflection that includes all those involved in the process of pharmaceutical research, development and assessment
- Redefine the concepts of links based on shared interests and conflicts of interest
- Analyse the existing legislative and regulatory framework

This opinion is intended to:

- Summarise the existing legislative and regulatory framework
- Analyse current practices in the specific field of health. Other sectors are not addressed
- Propose a solution for clarifying these concepts and identifying criteria for deciding when the dividing line between links based on shared interests and conflict of interest is crossed.

2.2. The purposes of this opinion

- **To open** a genuinely collective and inclusive process of consultation and define evaluation criteria that will ensure that choices made in appointing experts are sound and transparent:
 - The criteria must be universally understood to ensure that there is one clear rule for everyone.
 - The relevance of the criteria should be questioned on the basis of the desired objective: high-quality expertise, with particular emphasis on interactions between health care professionals and manufacturers as part of pharmaceutical product research and therapeutic innovation, and as part of health authority assessment of pharmaceutical products.
- **To clarify** the dividing line between links based on shared interests and conflicts of interest on the basis of this objective, with the aim of sustaining the quality of health expertise essential for maintaining the high level of innovation and therapeutic progress in France.

3. The general position of Codeem on the dividing line between links based on shared interests and conflicts of interest

Codeem continues to assert the principles set out in its 2016 opinion (summarised below), and is taking this opportunity to clarify its position.

Extract from the 2016 Codeem opinion: *“it is worth restating the reality that every professional has links based on shared interests within his or her own field of expertise, but that **not every link based on shared interests is necessarily a conflict of interest**. It should also be highlighted at this point that if every specialist*

*were to be disqualified purely because he or she had an interest in a given topic, there would no longer be any high-quality experts eligible to provide expert opinion in France. In this context, Codeem would like to reiterate that all professionals are obliged to disclose and publicise their links based on shared interests so that they can be considered and checked in a spirit of total transparency. **The dividing line between links based on shared interests and conflicts of interest is part of the wider debate on transparency**".*

This issue is part of the wider debate on transparency.

Codeem believes that the principle of transparency and its application must be reasserted and supported, but the question nevertheless arises of determining the type of transparency our country wants to have, and how it will ensure high-quality expertise on technical and ethical issues.

In practical terms, applying the principle of transparency is an important aspect of integrity in professional relationships and trust, particularly in the world of pharmaceuticals. But looking beyond the principle, it is also about examining and assessing the way in which interests are disclosed and the way they are interpreted and acted upon.

In this context, two questions arise: should all links based on shared interests be treated as suspect? And how will that work in practice?

As a preliminary step, Codeem has identified two risks in analysing these issues:

- **The first risk is addressing the issue of expert independence by interpreting any links based on shared interests as a conflict of interest.** Supported by certain movements in society, this drift towards an extreme interpretation of all links based on shared interests as conflicts of interest runs the risk of making the provision of expert opinion a very perilous one, thereby depriving us of excellence in expertise - essential for therapeutic innovation - and excluding competent experts who are equally essential for informing the process of collective decision-making.

To address this risk and engage in a constructive national debate, it is essential that we resolve the ambiguity between the existence of links based on shared interests and the definition of conflicts of interest. Transparency should be seen as an asset, and not as a means of systematically justifying exclusion.

No links based on shared interests should be considered as suspect by default, but rather as a guarantee of competence.

- **The second risk is procedural: it appears that the methods used to analyse, assess and qualify links - and therefore the dividing line between a links based on shared interests and a conflict of interest - differ depending on the actors and settings involved (institutions, agencies, academia, etc.),** which inevitably means that interpretations can sometimes differ very widely. There is therefore a very real need for interpretative guidance on distinction between links based on shared interests and conflicts of interest.

It appears essential to adopt a common approach at national level to harmonise the way in which links based on shared interests are viewed, and crucially to define which constitute a valid reason for excluding an expert or otherwise.

4. Codeem proposals for clarifying the dividing line between links based on shared interests and conflicts of interest

Codeem begins with the belief that the concept of interest goes far beyond the purely financial: both links based on shared interests and conflicts of interest may involve financial considerations, but can also be intellectual, cultural, affective and cognitive; all these elements must therefore be taken into account by any analysis. Similarly, legitimate compensation for work done in the field of research, innovation and expertise should not be considered as systematically suspect and therefore a reason for exclusion.

It is on the basis of this premise that Codeem will use this opinion to propose a methodology for making this assessment:

- **Analysing situations on the basis of factual evidence:** the first recommendation is to avoid any default principle, but to analyse the situation concerned, i.e. the situation of the expert and the subject matter of the expert input he or she is providing on a collaborative working basis.

As previously stated, the existence of a link should not in itself be a criterion for excluding an expert.

This recommendation seems obvious at first glance, but the way the process is currently applied nevertheless argues for this common sense reminder.

- For the purpose of conducting this analysis, Codeem proposes **the introduction of a verification procedure** based on the following mechanisms:

➤ **Ensuring application of the criteria** specified in the current process so that reliable, transparent and reproducible decisions can be made which clarify who cannot be retained as expert, taking full account of:

- ✓ The concept of transparency in decision-making and publication of all links and benefits
- ✓ The concept and level of impartiality on the understanding that everyone speaks about and explains the background of their involvement and what interests they represent
- ✓ The concept of plurality and adversarial practice as it applies to expert opinion and counterbalances individual importance
- ✓ The concept of competence, which must always be the prime objective, since it is essential for the provision of expert opinion

➤ **Practical application of these criteria** could be achieved through an **assessment process** that includes the mandatory consideration of these 4 points.

The analytical matrix would be guided by the following considerations:

- ✓ Full and comprehensive transparency, with the recording of discussions, publication of minutes and systematic publication or provision of information about links based on shared interests, not only annually, but also before any provision of an expert opinion. This ultimate level of transparency makes it possible to identify situations that pose a real risk
- ✓ The principle of plurality through the use of multiple experts: the number and diversity of experts is an effective way of neutralising dependencies. This form of plurality in using expert opinions is essential, and should make it possible to dispense with any individual source of expert opinion when no longer required
- ✓ The principle of adversarial interaction, which reflects a plurality not only of viewpoints, but also of sectors (public/private, academic/industrial, professionals/users, etc.) and allows a balance to be struck between experts and their viewpoints. The principle of adversarial interaction should be actively promoted, since it facilitates contrasting competencies, ideas and opinions
- ✓ The principles of integrity and impartiality, including the concept of links based on shared interests: it is important to bear in mind that highly experienced experts lose neither their integrity, impartiality nor professional ethical principles simply because links based on shared interests exist. This is inherent to the ethics of experts, who must be aware of the need to resist any attempt at influencing their freedom of thought
- ✓ The principle of independence, which is to be relativised and balanced: in reality, it is possible not to be independent of a current of thought, institutional culture, competency or professional corpus. In such cases, the concept of independence may be poorly thought

through and assessed, and therefore be inconsistent with the subject concerned. Independence should not be instituted as a blind principle, but as an ultimate goal of expertise.

- ✓ The strict disconnection of the expert opinion process from the decision-making process. The expert must not be the decision-maker. On the other hand, decision-makers inevitably need to draw on a variety of adversarial expertise.

With such a structure, and particularly regarding plurality and collegiality when providing expert opinions, it could be possible even to envisage a situation where certain conflicts of interest that meet all the criteria set out above might not necessarily lead to the exclusion of certain experts, especially where the opinion of the expert concerned would be essential to shedding light on a subject, and his or her opinion would be purely consultative, and counterbalanced by the collective expertise of the others.

5. Going beyond the issue of identifying the dividing line between links based on shared interests and conflicts of interest | acknowledging the role of the expert

In addition to analysis, the diversity of experts available leads Codeem to the belief that all have the opportunity to make their personal contributions to the wider scientific debate.

Codeem is aware of the very broad diversity of experts with the potential to contribute to the wider health debate. All are potentially legitimate contributors of expertise. However, it appears that in practice, they are not all given the same level of consideration, due largely to the lack of clarity over what separates the concepts of links based on shared interests and of conflicts of interest.

Any clarification of the dividing line between the two must result in high-quality expertise achieved by involving a plurality of experts, but before that can happen, all these different types of expert must be recognised as legitimate contributors.

Codeem would like to draw particular attention to the following types of expert:

5.1. The role of health care professionals and academic experts in health expertise: a role to be reasserted and consolidated

The ethical expertise provided by health care professionals and academics is central to the corruption prevention system, and is therefore subject to the preventive rules referred to above. Nevertheless, it is now coming under increasing suspicion.

However, as a result of their knowledge not only of pathologies, treatments and care pathways, but also of pharmaceuticals, the majority of which they have acquired through research and scientific partnerships with pharmaceutical companies (i.e. links based on shared interests), these professionals are high-quality experts whose input is indispensable to the nation's health system. If these links are permitted to raise suspicion about the nature of their interest, then we risk impoverishing academic excellence in France.

Codeem is at pains to stress the need to retain the services of these experts, because unlike so-called 'institutional' experts who have no links based on shared interests, these health care professionals, researchers and academics have in-depth knowledge of the realities of professional practices and scopes of expertise.

Codeem also reiterates that advanced research needs close collaboration between these experts from the worlds of health and business to enable the development of new pharmaceutical products that improve quality of life for patients. In turn, these professionals need the expertise of industry to give substance to their projects and experiments, and to optimise scientific and medical knowledge.

5.2 The role of health industry experts in public health

The question over the role of health industry experts in public decision-making is probably the most complex and sensitive of all to answer.

This is the issue which underlies that of the integrity of expertise, and which has been undermined for some time. The challenge of rehabilitating the status of expertise is therefore a substantial one.

To succeed in that challenge means that we cannot afford to overlook the role that the competencies of these experts can play in public decision-making in terms of pharmaceutical products.

As is the case with other types of expert, public decision-making should not be deprived of private-sector expertise, where the skills concerned would benefit public decision-making. In this respect, Codeem is at pains to stress that the skills of ‘industry’ experts must be called upon to ensure that certain areas of public decision-making are relevant to the real world. We must therefore combat the ambient climate of suspicion, which is particularly strong in France, and which holds that all pharmaceutical companies are suspect and do not act in favour of the general interest and of patients. The recent health crisis has underlined the importance of such collaboration and the sharing of expertise with pharmaceutical industry actors.

Naturally, they must be fully and strictly bound by the rules of integrity that apply to the provision of expert opinion just as they do to other actors, and those rules must express the spirit of the criteria we set out earlier for identifying the dividing line between links based on shared interests and conflicts of interest.

5.3 The role of patients and patient organisations

The voice of patients and patient organisations is being increasingly and more attentively heard and acted upon by health sector actors.

Patient organisations and patients themselves have for many years been involved in a working relationship with the pharmaceutical industry, particularly in the context of the contribution to Scientific Councils.

The role of patients and patient organisations in the public decision-making of some health agencies is a more recent development: the HAS Transparency Commission, which has responsibility for pharmaceutical product assessment, has two representatives of patient and health system user organisations among its members.

This growing role being played by these actors is also developing the concept of the ‘expert patient’ and the implications of that status for increased transparency.

The HAS defines expert patients as *‘patients who have acquired substantial and detailed knowledge of their illnesses or diseases over time’*. The HAS also notes that there is currently no recognition by health institutions of the status of expert patients. At a symposium held in 2016, the HAS made the point that *‘The experience of patients contributes a viewpoint complementary to that of health care professionals. Taking this fact into account is a necessity if our health system is to evolve towards a greater level of democracy’*. (the words of HAS President Professor Agnès Buzyn in her opening address to the ‘Patient dynamics, innovation and measurement’ symposium) (https://www.has-sante.fr/jcms/pprd_2974297/en/patients-et-soignants-vers-un-necessaire-partenariat).

While stressing the need to apply the principle of transparency, Codeem welcomes the growing level of recognition around the expertise offered by patients and patient organisations, and encourages the use of that expertise.

Codeem calls for further collective reflection on these issues:

Codeem wishes to use this opinion to initiate a national debate on the dividing line between the concepts of links based on shared interests and conflicts of interest.

Codeem notes that there is an intrinsic link between this issue and that of the quality and competence of experts.

Codeem therefore wishes to continue the process of consultation around positive criteria, such as participation in international conferences and clinical research and number of years of expertise, as the basis for continuing to draw on the competencies and excellence of experts.