
Rules of Professional Conduct (Dispositions Deontologiques Professionnelles (DDP))

Applicable to pharmaceutical companies

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1. Definitions

For the purposes of these Rules of Professional Conduct (hereinafter referred to as the *DDPs*), the following terms and their definitions will apply:

Patient Organisation

A non-profit legal entity in which the majority of members are patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers, and which business address, place of incorporation or primary place of operation is in France. Additional criteria, such as statutory purpose, legal representatives, etc., may be applied by Pharmaceutical Companies in their definition of Patient Organisation.

Recipient:

Any Healthcare Professional, Healthcare Organisation or Patient Organisation located in France or whose primary practice is in France.

Medical Sales Charter:

This refers to the Charter on information provided for the promotion of medicinal products through canvassing and prospecting, signed by Leem-CEPS in accordance with Article L.162-17-8¹ of the French Social Security Code.

EFPIA Code:

The EFPIA Code of Practice, including those annexes which are expressly mentioned as binding and which form part of this Code.

National Code:

The code of practice applied by a Member Association. In France, this means these **DDPs**.

Codeem:

The Ethics Committee of the French Association of Pharmaceutical Companies (Leem). Its central mission is to promote and enforce the rules of conduct and ethics governing the profession.

Informational or educational document:

Documentation or information of negligible value relative to the practice of medicinal product or pharmacy and of direct benefit in terms of patient care.

Donations and grants:

Funding, material support or services provided freely given for the purpose of supporting healthcare, scientific research or education.

Medical Sample:

Within the meaning of Directive 2001/83/EC² and Articles L.5122-10³ and R.5122-17⁴ of the French Public Health Code.

Company:

Companies manufacturing and/or marketing Medicinal Products for human use in France, and subject to these DDPs.

Non-Interventional Study:

Within the meaning of Article L.1121-1⁵ of the French Public Health Code, these are studies that do not involve any risk or constraint and in which all procedures are performed, and products used, in the usual manner.

Events:

All professional, promotional, scientific, educational meetings, congresses, conferences, symposium and other similar events (including meetings of experts, advisory boards, site visits, etc.) organised or supported by, or on behalf of, a Pharmaceutical Company.

¹ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006741374/2005-11-03

² <https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:32001L0083&from=en>

³ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI0000033897307/2018-07-01

⁴ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006915000/2004-08-08

⁵ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006685825/2000-06-22

European Federation of Pharmaceutical Industries and Associations (EFPIA):

EFPIA is the organisation that represents the European pharmaceutical industry.

Medical Education:

Medical Education is intended to increase the scientific knowledge and skills of Healthcare Professionals in order to improve medical practice and patient care.

Hospitality:

Care of cost of meals, travel, accommodation and/or registration fees to facilitate the attendance of a Healthcare Professional or Patient Association representative at an Event organised by a Company and/or Third Party.

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) ⁶ :

IFPMA represents research-based biopharmaceutical companies, and regional and national associations across the world.

Event location:

The geographical location where an Event is hosted (e.g. city, town, district, etc.) and the venue in which the Event takes place (e.g. hotel, conference centre, etc.).

Medicinal Product:

Within the meaning of Article L.5111-1⁷ of the French Public Health Code. Within the meaning of these DDPs, the definition of a Medicinal Product also applies to proprietary medicinal products as defined in Article L.5111-2⁸ of the French Public Health Code.

MSL:

Medical Sales Liaison personnel provide and distribute medical and scientific information at regional level. These employees have the medical and/or scientific expertise required to respond to the needs of healthcare professionals by providing medical and scientific information and developing scientific partnerships for the purposes of improving patient care and developing clinical research.

Items of medical utility:

Inexpensive item aimed directly at the education of HCPs enhancing the provision of medical services and patient care and that do not offset routine business practices of the HCPs.

Healthcare Organisation:

Any entity (with the exception of PATIENT ORGANISATIONS) based in France that is either (i) an association of Healthcare Professionals or a healthcare facility, any medical or scientific organisation (particularly a hospital, clinic, foundation, university, learned society, etc.) or (ii) a structure via which one or more Healthcare Professionals provide services (distributors, healthcare service providers, etc.).

Support:

Support provided by, or on behalf of, a Company in any form whatsoever - but particularly in the form of sponsorships and/or partnerships - for an activity or Event organised or conducted by a Healthcare Organisation, Patient Association or Third Party from which the Pharmaceutical Company benefits.

Company Personnel:

Personnel employed by a Company or hired under a contract with Third Parties whose business activities are fully or partially subject to these DDPs.

Host Country Principle:

This term refers to the primacy of the monetary threshold for a meal (food and beverages) set by the relevant Member Association in its National Code. The monetary threshold set in the country where the Event is held would prevail, subject to mandatory national regulations.

Healthcare Professional:

An individual who is a member of a healthcare profession regulated by the French Public Health Code, regardless of whether he or she is a civil servant or public official, or any other person practising in France who, in the course of his/her professional activities, may prescribe, purchase, dispense, recommend or administer a Medicinal Product. This definition does not apply to Healthcare

⁶ www.ifpma.org

⁷ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006689867

⁸ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006689868

Professionals employed by Companies, wholesalers or distributors, excluding those whose primary occupation is that of a practising Healthcare Professional.

Promotion:

Within the meaning of Article L.5122-1⁹ of the French Public Health Code, any form of information, including canvassing, prospecting or incentivisation intended to promote the prescription, dispensing, sale or consumption of such medicinal products, with the exception of information provided as part of their duties by pharmacists managing a hospital pharmacy.

Patient Organisation Representative:

A person who is mandated to represent the interests and express the collective views of a Patient Organisation.

Third Party:

A legal entity or individual representing a Company or interacting with other Third Parties on behalf of a Company or those engaged in related business activities, such as distributors, wholesalers, consultants, contract research organisations, professional congress organisers, contracted sales forces, market research companies, advertising agencies, providers of services related to events, public relations services, and non-clinical/non-interventional study management services.

Transfers of Value:

Direct and indirect transfers of value, whether in cash, in kind or in any form whatsoever made in connection with the development and sale of Medicinal Products. Direct transfers of value are those made directly by a Company to a Recipient. Indirect transfers of value are those made on behalf of a Company to a Recipient, and those made via a Third Party where the Company knows or can identify the Recipient of the Transfer of Value.

Medical Sales Representative:

Personnel employed by a Company or retained by way of contracts with Third Parties, who interact with healthcare professionals and organisations for the purpose of Medicinal Product Promotion as defined in Article 5122-11¹⁰ of the French Public Health Code, and whose activity is regulated by the Medical Sales Charter and its implementing texts.

2. Foreword

Medicinal products help to protect and restore humanity's most precious assets: health and quality of life.

The mission of our companies is to develop and provide Medicinal Products that prevent and treat disease for present and future generations.

As key actors in the healthcare system, Companies play an essential role in scientific research, participate in the proper use of treatments, proactively contribute to the healthcare system efficiency and maintain partnerships with all other healthcare stakeholders.

Fully aware of their responsibilities to society, Companies have been working together for several years to integrate professional conduct and societal responsibility issues into all their business practices.

This experience has led Leem to draw up these Rules of Professional Conduct, which incorporate the EFPIA Code of Practice, with the aim of setting out the fundamental principles that should guide every Company in delivering its mission as a healthcare stakeholder:

- Compliance with the principles of ethics and professional conduct in operational activities
- Quality, reliability and clarity of information provided by companies
- Transparency of relations with healthcare stakeholders
- Respect for the independence of health partners.

⁹ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006689929/2000-06-22

¹⁰ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006689947/2000-06-22

2.1. Core principles of professional conduct

2.1.1. Mission-related principles of professional conduct

The following key principles of professional conduct guide the interpretation and application of DDPs.

Principle 1

The fundamental mission of Companies is to work to protect and improve the health of people and prevent illness as part of their wider general interest mission to promote personal and public health.

Companies contribute to the general interest. Their core missions of medicinal product research and development, production and supply target the ultimate goals of improving the health of individuals and population groups. The commercial aspects inextricably linked to the supply of medicinal products are essential to ensure the long-term sustainability of their business activities and investments.

Principle 2

The health and wellbeing of individuals are central to the concerns of these Companies. More specifically, patients are treated as individuals and responsible users, rather than simply as anonymous consumers.

Companies ensure proper use of their products for the benefit of patients, take responsibility for their health and are involved in the care they receive.

Principle 3

The business activities of Companies contribute to identifying innovative and/or efficient healthcare solutions.

Company core missions contribute to achieving progress that delivers universal benefits on which their reputation is built.

2.1.2. Stakeholder-specific principles of professional conduct

Principle 4

Companies build trust-based transparent relationships and engage in constructive dialogue with all their stakeholders.

More specifically, Companies treat patient representative associations with respect, care and transparency. They see them as active and legitimate partners. And they maintain responsible relationships with public authorities within a framework of constructive dialogue to ensure mutual trust, respect and transparency.

Principle 5

Companies interact with Healthcare Professionals and their representative associations on the basis of integrity, respecting their independence and preventing conflicts of interest.

The expertise of Healthcare Professionals is essential to therapeutic progress that relies on productive interaction with Companies. This expertise makes a fundamental contribution to the development of new Medicinal products and improvements in patient care quality. These interactions comply with the DDPs and the French legal and regulatory framework that governs such interactions.

Principle 6

Companies implement measures that effectively prevent risks and the potentially harmful consequences of their activities on humans, animals, and the environment.

In conducting their activities, Companies accept their responsibilities to society ethically and with integrity.

Principle 7

Companies are responsible for the accuracy of communication around their products and activities.

As part of their obligation to ensure transparent communication around their products and activities, Companies undertake to comply fully with all relevant laws and regulations in providing patient organisations, patients, healthcare professionals, public authorities and other stakeholders with complete, objective, intelligible and verifiable information, particularly in respect of any potentially adverse effects.

2.1.3. Principles governing inter-Company relationships

Principle 8

Companies interact on the basis of working relationships.

When Companies find themselves in dispute with each other regarding issues that have no potential effect on other stakeholders, they must attempt to use mediation wherever possible.

Principle 9

Companies put in place all the conditions required to ensure that every one of their employees adheres to all these principles of professional conduct.

Encouraging and guaranteeing the adherence of every employee to the key professional conduct principles for Pharmaceutical Companies is a Company mission, especially by developing educational initiatives. Companies lead by example through their behaviour.

2.2. Scope

2.2.1. Companies subject to these rules

These DDPs apply:

- to all Leem member companies;
- to EFPIA member companies based outside France, but which operate in France alongside French Healthcare Professionals, Health Organisations and Patient organisations;
- under the terms of Annex D, point C, of the EFPIA Code of Practice to EFPIA member companies that are not members of Leem, as well as to their subsidiary companies in France, provided that they have made a formal commitment to adhere to this code. The EFPIA Code of Practice requires these categories of companies to enter formally into such a commitment. It is however noted that adherence to the Code does not imply adherence to Leem;
- To companies that are neither members of EFPIA nor of Leem on a voluntary basis, subject to a commitment being provided in writing.

When a company subject to these DDPs uses a service provider, it puts in place all the measures - and especially contractual measures - required to ensure that the service provider complies fully with these provisions.

2.2.2. Operations subject to these rules

These DDPs apply to operations carried out in France and implemented, supported, or organised by, or on behalf of, a Company based in France and carried out in conjunction with Beneficiaries based in France.

These DDPs also apply to:

- The remuneration received by French Healthcare Professionals / Healthcare Organisations from Companies based outside France
- The paid-for attendance of French Healthcare Professionals at an Event hosted outside France, regardless of whether the host Company is based in France

The paid-for attendance of French Healthcare Professionals at an Event hosted outside France is governed by the Host Country principle, i.e. the monetary threshold for food and beverages is that in force in the Host Country.

2.3. Domains and operations covered by the DDPs

The domains and operations covered by the DDPs are as follows. The DDPs effectively transpose the EFPIA Code of Practice, and include provisions that are more specific to France, adopted by Leem and Codeem (the Ethics Committee of the French Association of French Pharmaceutical Companies), or resulting from binding French regulatory commitments.

And since French national legal and regulatory provisions may impact the conditions governing application of some Articles of DDPs derived from the EFPIA Code of Practice, these are indicated within the relevant DDP Articles.



The specific Rules of Professional Conduct adopted by Leem and Codeem and referred to as “*specific rules*” are shown in blue boxes in the DDPs.



Mandatory French legal and/or regulatory provisions, as well as recommendations from public authorities and collectively referred to as “*National regulation*”, are shown in pink boxes in the DDPs.

Leem has adopted these DDPs, whose content is as follows:

- The EFPIA Code of Practice adopted by the EFPIA General Assembly on 27 June 2019, which covers the promotion of prescription-only medicinal products, interactions with Healthcare Professionals, Healthcare Organisations, Patient organisations and the disclosure of links and interests, as well as the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) Code of Practice¹¹ on promotional information published on 1 January 2019.



Specific rule: Leem member companies have extended the scope of DDPs to cover all medicinal products, whether prescription or non-prescription. Leem member companies felt that professional conduct issues should not be limited to prescription medicinal products, and should therefore apply to all medicinal products available in the market

¹¹ https://www.ifpma.org/wp-content/uploads/2018/09/IFPMA_Code_of_Practice_2019.pdf / https://www.ifpma.org/wp-content/uploads/2019/02/IFPMA_Code_of_Practice_2019_FR.pdf / <https://www.ifpma.org/resource-centre/ifpma-code-of-practice-2019/> / <https://www.ifpma.org/subtopics/new-ifpma-code-of-practice-2019/>



National regulation: A number of EFPIA Code¹² Articles are impacted directly by mandatory legal and regulatory obligations binding on companies based in France. These obligations are indicated in the corresponding Articles.

- The joint Leem/CEPS charter on information provided for the promotion of medicinal products through canvassing and prospecting published on 15 October 2014



National regulation: since the joint Leem/CEPS¹³ charter has its basis in law, the provisions of this Charter are shown unchanged in these DDPs and may not be modified in any way. Nevertheless, both Leem and Codeem may add further specific rules as long as they remain compliant with the Charter

- Rules adopted by Codeem relative to the persons responsible for providing medical and scientific information at regional level (MSL)



Specific rule: Leem has incorporated the MSL-related rules adopted by Codeem into these DDPs¹⁴

- The ANSM Charter on communication and promotion of health products and e-media of March 2014



National regulation: the Charter on communication and promotion of health products and e-media was enacted and published by the ANSM (French National Agency for medicinal products Safety)¹⁵, and therefore constitutes recommendations for public authority good practice. This Charter may not be modified in any way. Nevertheless, both Leem and Codeem may add further specific rules as long as they remain compliant with the Charter.

- The tripartite Leem/UDA (French Union of Advertisers)/SPEPS (Press & Publishing Federation for the Healthcare Professions) Charter on medicinal product information & editorial publicity of July 2015.



Specific rule: Leem has incorporated the Charter on editorial publicity prepared jointly with the UDA and SPEPS¹⁶ into these DDPs.

Leem also supports and encourages the transparent disclosure of clinical trial results and their publication in external registries, such as the ClinicalTrials.gov. registry.

¹² <https://www.efpia.eu/media/554677/efpia-code-2020.pdf> / <https://www.efpia.eu/relationships-code/the-efpia-code/#/>

¹³ See Chapter “[8. Information provided through canvassing and prospecting](#)”

¹⁴ See Chapter “[9. Persons responsible for providing medical and scientific information at regional level](#)”

¹⁵ See Chapter 10 “[10. Communication and promotion on the Internet and e-media](#)”

¹⁶ See Chapter “[11. Trade press relations](#)”

2.4. Application of legislative and regulatory provisions

The legal and regulatory obligations applicable to Companies also apply regardless of circumstances to the various domains and activities covered by the DDPs.

As a result, these DDPs have been aligned to ensure full compliance with the laws and regulations applicable to the various domains and activities they cover.

The following provisions in particular apply:

- Those provisions of the French Public Health Code that apply to the advertising of proprietary medicinal products, which is supervised by the ANSM (French National Agency for medicinal products Safety);
- Those provisions of the French Public Health Code that apply to relationships with healthcare professionals, students in training for the healthcare professions and the associations representing them;
- Those provisions of the French Public Health Code that apply to persons providing information through canvassing and prospecting, as well as the texts adopted for their application (Medical Sales Charter, certification standard, etc.)

It is the responsibility of each Company to ensure full compliance with the obligations arising from the legal and regulatory provisions applicable to the various domains and activities covered by these DDPs.

The orange-shaded inserts included in some Articles indicate the existence of applicable legal/regulatory texts on the basis that companies have individual responsibility to refer to these provisions as they appear within the legal and regulatory measures concerned, since the full content of these provisions may not be included into the DDPs.

2.5. Amendments and changes to the DDPs

The DDPs may be amended or changed in the following circumstances:

- Amendments to the legal and regulatory provisions affecting the content of these DDPs;
- Amendments to the EFPIA Code of Practice;
- The addition of new specific rules initiated by Codeem and approved by the Leem Board of Directors under the conditions provided for in its articles of association;
- Amendment of Leem and/or Codeem operating rules;
- The signature by Leem of charters involving external partners, where Leem wishes to incorporate the provisions of those charters into the DDPs.

These amendments and changes will be the subject of dated updates to the DDPs, and will be notified to Companies by Leem and Codeem.

New specific rules added by Codeem or arising as a result of charters signed by Leem are shown in the blue-shaded inserts in the DDP text.

2.6. The Codeem website

The DDPs are available on the Codeem website at <https://www.leem.org/codeem>.

The website also provides two sets of FAQs for companies: one covering the arrangements for events, conferences and exhibitions stands, and the other relating specifically to Medical Science Liaison (MSL) staff as well as about the operation and activities of Codeem.

Further sets of FAQs may be added to the Codeem website in the future.

3. Promotion of proprietary medicinal products



National regulation: The Articles contained in Chapter 3 must be read in the context of the legal and regulatory framework applicable to medicinal product advertising and comparative advertising.

- The advertising of medicinal products is governed by Articles L.5122-1 and subsequent¹⁷ of the French Public Health Code and its implementing texts. Reference should also be made to the recommendations published on the ANSM website regarding advertising that targets healthcare professionals, and advertising that targets the general public, both of which are also covered by these DDPs.
- Comparative advertising is governed by Articles L.122-1 and subsequent¹⁸ of the French Consumer Code. Reference should also be made to the specific recommendations published by the ANSM regarding the comparative advertising of medicinal products.

3.1. Scope



Specific rule: this chapter applies to the promotion of all Medicinal Products, regardless of whether they are prescribed by a healthcare professional or otherwise.

3.2. Marketing authorisation

3.2.1. A Medicinal Product must not be promoted prior to the grant of the marketing authorization allowing its sale or supply or outside its approved indications.

3.2.2. Promotion must be consistent with the particulars listed in the summary of product characteristics of the relevant Medicinal Product.



National regulation:

The French Public Health Code also requires that promotion must comply with the recommendations made by the Transparency Commission, Good Practice Guidelines, accredited consensus meetings and HAS therapeutic strategies¹⁹.

¹⁷ <https://www.legifrance.gouv.fr/codes/id/LEGIARTI000034079745/2017-05-23/>

¹⁸ <https://www.legifrance.gouv.fr/codes/id/LEGIARTI000032227222/2016-07-01/>

¹⁹ <https://www.has-sante.fr/>

3.3. Information to made available

All promotional material must include the following information clearly and legibly:

- Essential information consistent with the summary of product characteristics, specifying the date on which such essential information was generated or last revised;
- The supply classification of the Medicinal Product;
- When appropriate, the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.



National regulation:

The mandatory information that must appear in Medicinal Product advertising is set out in Articles R.5122-4²⁰ of the French Public Health Code, which relates to advertising targeting the general public and R.5122-8²¹ of the French Public Health Code, which relates to advertising targeting healthcare professionals.



National regulation:

Reminder advertising within the meaning of Article 89 of Directive 2001/83²² is not permitted in France.

3.4. Promotion and its substantiation

- 3.4.1. *Promotion must be balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the Medicinal Product concerned. It must comply with the marketing authorisation and be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.***
- 3.4.2. *Promotion must be capable of substantiation which must be promptly provided in response to requests from a Healthcare Professional; in particular, the safety and tolerance information must reflect available pharmacovigilance evidence and be supported by validated scientific data.***
- 3.4.3. *Promotion must encourage the rational use of Medicinal Products for the indications covered by their marketing authorisation and do so by presenting them objectively and without exaggerating their properties. Claims must not imply that a Medicinal Product or an active ingredient has some special merits, quality or property unless this can be substantiated.***
- 3.4.4. *Where Promotion refers to published studies, clear references must be given.***

²⁰ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000025853155/2012-05-11

²¹ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000025853172/2012-05-11

²² <https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:32001L0083&from=en>

- 3.4.5.** *Any comparison made between different Medicinal Products must be based on relevant and comparable aspects of the Medicinal Products. Comparative advertising must not be misleading or disparaging.*
- 3.4.6.** *All artwork, including graphs, illustrations, photographs and tables taken from published studies included in the promotional material must: (a) clearly indicate the precise source(s) of the artwork, (b) be faithfully reproduced, except where adaptation or modification is required in order to comply with these DDPs, in which case it must be clearly stated that the artwork has been adapted and/or modified.*
- 3.4.7.** *Particular care must be taken to ensure that the artwork included in Promotion 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).*
- 3.4.8.** *The word “safe” must never be used to describe a Medicinal Product.*



National regulation:

The ANSM “*efficacy - safety in use of a treatment*” recommendation is that advertising may not contain any suggestion that the effect of a medicinal product is certain, that it is without adverse effects, or that its effect is equivalent or superior to that of any other treatment or medicinal product.

- 3.4.9.** *The word “new” must not be used to describe any Medicinal Product or presentation which has been generally available or any therapeutic indication which has been generally promoted, for more than one year.*



National regulation:

The ANSM “*Terminology*” recommendation is that the use of the term “*new*” must not be applied more than one year from the date on which it was first marketed.

- 3.4.10.** *It must not be stated that a Medicinal Product has no side effects, toxic hazards or risks of addiction or dependency.*

3.5. Use of quotations

- 3.5.1.** *Quotations from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required to comply with the DDPs, in which case it must be clearly stated that the quotation has been adapted and/or modified), and the precise sources identified.*

3.6. Acceptability criteria

- 3.6.1.** *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 recognizes the special nature of Medicinal Products and the professional or general public standing of the intended audience; (c) not be likely to cause offence.*

3.7. Distribution

- 3.7.1. *Promotion must only be directed at those individuals whose need for, or interest in, the particular information can reasonably be assumed.*
- 3.7.2. *Mailing lists must be kept up to date in accordance with the General Data Protection Regulation, and the rights of all data subjects must be fully respected.*
- 3.7.3. *The use of faxes, postal mail, e-mail, telephone calls, automated calling systems, text messages and other digital communications for the purposes of the Promotion must comply with the General Data Protection Regulation and all applicable national regulations.*



National regulation:

More specifically, digital promotional techniques must be used in compliance with certain provisions of the French Data Protection Act, the recommendations of the CNIL (the French Data Protection Agency) and Article L.34-5²³ of the French Postal and Electronic Telecommunications Code. Furthermore, online medical sales visits must be made in compliance with the [ANSM recommendations set out in point 10 below](#).

3.8. Transparency of promotion

- 3.8.1. *Promotion must not be disguised.*
- 3.8.2. *Clinical assessments, post-marketing surveillance and post-authorization studies (including those that are retrospective in nature) must be conducted for scientific or educational purposes, and not be disguised Promotion.*
- 3.8.3. *Where a Company directly or indirectly funds the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.*
- 3.8.4. *Material relating to Medicinal Products and their uses, whether promotional nature or not, which is sponsored by a Company must clearly indicate that it has been sponsored by that Company.*

²³ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000042155961/

3.9. Promotional information provided during international events

- 3.9.1.** *Promotional information which appears on exhibition stands or is communicated to participants at International Events may, 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, as long as: (i) any such promotional material is accompanied by a suitable statement indicating the countries in which the Medicinal Product is registered, and makes clear the Medicinal Product or indication is not registered locally, and (ii) any such promotional material which refers to the prescribing information (indications, warnings, etc.) authorised in a country or countries where the Medicinal Product is registered must be accompanied by an explanatory statement indicating that the registration conditions differ internationally.*



Specific rule:

The exhibition area of the stand must not be such as to accommodate any activities unrelated to the scientific objective of the conference. Stands must be simple, plain, tastefully designed and appropriately fitted out in a professional manner. If a company markets medicinal and other products simultaneously, the stand must be structured into separate sections such that the two forms of presentation are visually distinct. It is forbidden for pharmaceutical companies to distribute gifts on exhibition stands.

3.10. Personal medical matters

- 3.10.1.** *In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer must be advised to consult a Healthcare Professional.*

4. General rules governing relationships with healthcare professionals, healthcare organisations and patient organisations



National regulation:

Relationships with Healthcare Professionals and associations of healthcare professionals are regulated by Articles L.1453-3 and subsequent²⁴ of the French Public Health Code and are subject to prior oversight by the professional boards or the ARS.

4.1. Events and hospitality



National regulation:

The conditions governing hospitality for Healthcare Professionals and associations of healthcare professionals are governed by Article L.1453-7, 4°²⁵ of the French Public Health Code, subject to oversight by the professional boards and the ARS.

The same article makes clear that **hospitality granted directly or indirectly to students in training for the healthcare professions or the associations representing them is strictly forbidden.**

4.1.1. *All Events must be held in appropriate locations that are conducive to the main purpose of the Event, avoiding those that are renowned for their entertainment facilities or are extravagant*



Specific rule:

Codeem specifically identifies the following concepts:

An “appropriate” location is one that adequately fulfils the purpose and primary objective of the Event. The geographical location of the Event should be in - or near - a town or city with a recognised scientific or business centre. It must also be easily accessible and chosen with the aim of minimising travel times for potential attendees. The location should not be best known for its tourist facilities or leisure attractions.

The fact is that some towns and cities are known primarily for their status as tourist destinations. Conversely, capital and major cities are predominantly urban centres recognised more as business hubs than as

²⁴ <https://www.legifrance.gouv.fr/codes/id/LEGIARTI000033897284/2018-07-01/>

²⁵ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000038888276/

tourist destinations. The Event location and venue should not be the main attraction of the Event or be perceived as such.

A renowned location for its range of entertainment services or its ostentatious nature:

The host venue must primarily be appropriate for the **scientific** and/or **educational** purpose of the event. The venue must also have all the facilities required to accommodate the event and its attendees. The venue must not include entertainment, sports or leisure facilities. This excludes, for example, golf clubs, wellness centres, health spas, gaming establishments (casinos or gambling venues), seaside resorts and ski resorts.

Recreational locations, such as theme parks or water parks, **tourist destinations**, such as abbeys, museums, vineyards, castles, famous monuments, and **entertainment locations**, such as concert halls and theatres are equally unsuitable. An “appropriate” location also means one that is not extravagantly luxurious, such as a hotel with a Michelin-starred restaurant. Châteaux and mansions are highly likely to be considered as extravagantly luxurious and/or ostentatious. If in doubt, it may be helpful to ask if the venue hosts weddings and parties or is open to tourists. If the answer is “yes”, then it is likely to be inappropriate.

Please refer to the FAQs published on the Codeem website for more details about these concepts and the practicalities they are intended to cover.

4.1.2. No Companies may organize or sponsor an Event outside France unless:

- most of the invitees are from outside its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Event outside France, or
- Given the geographical 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 (an “international event”).

4.1.3. Companies may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of these DDPs.

4.1.4. Hospitality extended in connection with Events must be limited to travel, meals/snacks, accommodation, and registration fees.

4.1.5. Companies must not provide or offer any meal (food and beverages) to Healthcare Professionals, members of Healthcare Organisations or representatives of Patient organisations unless, in each case, the value of such meal does not exceed the monetary threshold set out below in these DDPs.



Specific rule:

The value of meals (including beverages) provided in this context must not exceed €60 (sixty) including taxes. Where meals are offered to Healthcare Professionals in countries other than France, the **benchmark value for meals is the monetary threshold that applies in the Host Country**, subject to assessment by the professional boards or the ARS where such issues fall within the scope of their oversight (see “National regulation” insert below)



National regulation:

In accordance with Article L.1453-10²⁶ of the CSP (French Public Health Code), the conditions governing the provision of hospitality for Healthcare Professionals and their representative associations must be the subject of an agreement and report or a request for authorisation by the relevant professional boards or the ARS, depending on the value of hospitality provided, as set by the ministerial order of 7 August 2020.²⁷

- 4.1.6. Hospitality may only be extended to persons who qualify as participants in their own right. In exceptional cases of established health needs (e.g. disability or injury), the travel, meals, accommodation and registration fee costs of an accompanying person can be reimbursed within the same parameters.**



National regulation:

Due to legal reasons, this exception does not apply to healthcare professionals in France.

Payment of the costs incurred by accompanying persons for any reason whatsoever is prohibited by Article L.1453-7 4²⁸ of the CSP.

- 4.1.7. All forms of hospitality offered to Healthcare Professionals, members of Healthcare Organisations or representatives of Patient organisations must be “reasonable” in level and strictly limited to the main purpose of the Event. As a general rule, the hospitality provided must not exceed what those recipients would normally be prepared to pay for themselves.**



Specific rule:

“Reasonableness” is based on the medical interest and relevance of the Event, the qualifications of the healthcare professionals invited, the type and level of services provided (transport, hotels and restaurants), the Event programme and its medical and scientific content.

- 4.1.8. Hospitality must not include sponsoring or organising entertainment events (e.g. sporting or leisure).**

²⁶ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000033897268/

²⁷ Ministerial order of 7 August 2020 setting the value above which an agreement of the type provided for in Article L. 1453-8 of the French Public Health Code confirming a benefit in kind is subject to authorisation (published in the OJ of 14/08/2020: <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000042234024/>)

²⁸ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI00003888276/

4.2. Prohibition of gifts

- 4.2.1.** *Direct or indirect gifts for the personal benefit of Healthcare Professionals, members of Healthcare Organisations or representatives of Patient organisations - such as sporting or entertainment tickets, social courtesy gifts - are prohibited. Providing or offering cash or personal services is also prohibited. For these purposes, “personal services” are any type of service unrelated to the profession and that confer a personal benefit to the recipient.*



Specific rule:

Books, other publications, magazines, subscriptions and office supplies are all considered as gifts when they benefit healthcare professionals. They are therefore prohibited.

- 4.2.2.** *A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in section Erreur ! Source du renvoi introuvable.). Providing or offering them to Healthcare Professionals, members of Healthcare Organisations or representatives of Patient organisations in relation to the Promotion of proprietary pharmaceuticals is prohibited.*

4.3. Donations and grants to Healthcare Organisations and Patient Organisations



National regulation:

Donations and gifts to associations of Healthcare Professionals and students (provided that they are not intended to pay for hospitality) are subject to the provisions of Articles L.1453-3 and subsequent²⁹ of the French Public Health Code and to oversight by the relevant professional boards/ARS. Article R5124-66³⁰ also includes an obligation to disclose to the ARS donations made to legal entities for the purpose of encouraging research and training of healthcare professionals.

- 4.3.1.** *Donations and grants (in cash or in kind or otherwise) to Healthcare Organisations and/or Patient Organisations are only allowed if: (i) they are made for the purpose of supporting healthcare, research or education; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer Medicinal Products.*

²⁹ <https://www.legifrance.gouv.fr/codes/id/LEGIARTI000033897284/2018-07-01/>

³⁰ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006915155/2004-08-08

- 4.3.2. Donations and grants to individuals are not permitted. The payment of Event-related expenses to enable Healthcare Professionals to attend Events is covered in Article 4.1.**



National regulation:

This ban does not however apply to transactions that are permitted by national legislation or regulation, which is the case in France.

The “*anti-gift*” scheme (Article L.1453-3 and subsequent³¹ of the French Public Health Code, derived from Ordinance 2017-49 of January 19, 2017³² relating to the benefits offered by entities manufacturing or marketing healthcare products or services, clarified by Decree 2020-730 of 15 June 2020³³ relating to the benefits offered by entities manufacturing or marketing health products or services and two decrees of 7 August 2020³⁴) does not exclude the possibility of making a donation to a natural person (healthcare professional or student in training for the healthcare professions who falls within the scope of the scheme), provided however, that the benefit concerned is granted for the purpose of research, the promotion of research or scientific assessment.

4.4. Contributions to costs related to Events and Support

- 4.4.1. Under the terms of these DDPs, Companies must implement and comply with criteria governing the selection and support of Healthcare Professionals, members of Healthcare Organisations or representatives of Patient Organisations to attend training or Events. No payment must be offered to compensate merely for the time spent by Healthcare Professionals, members of Healthcare Organisations or representatives of Patient Organisations in attending Events.**
- 4.4.2. The use of a Healthcare Organisation or Patient Organisation’s logo and/or proprietary material by a Company requires written permission from that organisation. In seeking such permission, the specific purpose, and the way the logo and/or proprietary material will be used must be clearly stated.**
- 4.4.3. Companies must ensure that their Support to Healthcare Organisations and Patient Organisations is always clearly acknowledged and apparent from the outset.**

4.5. Companies funding

- 4.5.1. No Company may require that it be the sole funder or sponsor of a Healthcare Organisation or Patient Organisation or any of its programmes.**
- 4.5.2. Companies welcome broad funding and sponsoring of Patient organisations and Healthcare Organisations from multiple sources.**

³¹ <https://www.legifrance.gouv.fr/codes/id/LEGIARTI000033897284/2018-07-01/>

³² <https://www.legifrance.gouv.fr/loda/id/JORFTEXT000033893406/2020-10-15/>

³³ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000041999448?r=vOvXEBOq4f>

³⁴ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000042234007/>
<https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000042234024/>

4.6. Contracted services



National regulation:

Article L.1453-7³⁵ of the French Public Health Code requires service provision contracts with healthcare professionals, students and associations of healthcare professionals to be disclosed and authorised

4.6.1. *Contracts between Companies and Healthcare Professionals, members of Healthcare Organisations or representatives of Patient Organisations’ representatives under which those provide any type of services to Companies are only allowed if such services: (i) are provided for the purpose of supporting healthcare, research or education; and (ii) do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer Medicinal Products.*

4.6.2. *It is permitted to contract Healthcare Professionals or representatives of Patient Organisations as consultants, whether in groups or individually, for services such as speaking at meetings, taking part in medico-scientific studies, clinical trials or training services, sitting as members of advisory boards and contributing to market research, where such services involve receiving remuneration and/or hospitality. These services must meet the following criteria:*

- a) A written contract is entered into before commencement of service provision specifying the nature of the services concerned and, subject to paragraph (g) below, the conditions governing remuneration for such services;
- b) A legitimate need for the services concerned has been clearly identified and documented before requesting the services and drawing up the contract;
- c) The consultant selection criteria relate directly to the identified need, and those responsible for selecting the consultants have the necessary expertise to assess whether or not a particular consultant meets these criteria;
- d) The number of consultants selected and the nature of the services provided are proportionate to the need identified;
- e) The Company documents and retains evidence of the services actually provided by the consultants and makes appropriate use of those services;
- f) The use of the consultant does not constitute an inducement to recommend and/or prescribe, purchase, provide, sell or administer Medicinal Products ;
- g) The remuneration paid for these services is reasonable and reflects their fair market value. In this context, service provision agreements entered into as a token gesture cannot be used to justify the payment of remuneration to healthcare professionals or representatives of Patient organisations.

³⁵ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000038888276/

- 4.6.3. Companies are strongly recommended to ensure that the contracts they enter into with consultants include provisions requiring the consultant to specify that he/she is acting as a consultant to the Company whenever writing or speaking in public on a subject matter covered by the terms of the contract, or on any other subject matter relating to the Company concerned. Similarly, Companies that employ Healthcare Professionals on a part-time basis are strongly encouraged to ensure that these individuals are required to disclose their links with the Company whenever they write or speak in public on a subject matter relating to the nature of their employment, or on any other subject matter relating to the Company. These provisions apply even if these DDPs do not otherwise cover general non-promotional Company information.**



National regulation:

Article L.4113-13³⁶ of the French Public Health Code requires members of the medical professions who have links with companies and facilities producing or using healthcare products, or with advisory bodies working on these products, to make such links known to the public when referring to the products concerned at a public event, university lecture, continuing professional development training session or therapeutic education initiative, and to do so via the printed or digital press or via any printed or online publication.

- 4.6.4. Limited market research, such as occasional telephone interviews, responding to questionnaires made available by post, e-mail or online, are excluded from the scope of this Article, provided that the Healthcare Professional, Healthcare Organisation or Patient Association member concerned is not consulted on a regular basis (whether in terms of the frequency of calls on general issues or the frequency of calls on a particular research topic), and that the remuneration paid is minimal.**



Specific rule:

The term “*minimal*” means a reasonable payment for the time spent, given the special expertise and knowledge of those concerned.

- 4.6.5. If a Healthcare Professional or a Representative of a Patient Association attends an Event (national or international) in a consultative capacity, the relevant provisions of Article 4.1 must be applied.**

³⁶ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006912562/

5. Specific rules governing relationships with healthcare professionals and patient organisations

5.1. Medical education:

- 5.1.1. *Medical Education is aimed at increasing the scientific knowledge and competence of Healthcare Professionals to enhance medical practice and improve patient care. In the context of these DDPs, the term refers specifically to the provision of scientific and medical information initiated by Companies or funded by them.*
- 5.1.2. *Companies can be engaged in different types of Medical Education, but such activities must not constitute Promotion.*
- 5.1.3. *When funding independent Medical Education or organising Medical Education activities directly or in collaboration with Third Parties, Companies must ensure that their participation and role is clearly acknowledged and apparent from the outset.*
- 5.1.4. *When organising Medical Education activities in which Companies have input in the content, they are responsible for what is communicated during the activities. Such content must be fair, balanced, objective, and designed to allow the expression of diverse theories and recognized opinions.*



National regulation:

In the context of Continuing Professional Development (CPD), the funding by Companies of qualification- or validation-based training **must comply with the CPD legal and regulatory framework**, and particularly Articles L.4021-1 and subsequent³⁷ of the CSP and its implementing texts.

³⁷ <https://www.legifrance.gouv.fr/codes/id/LEGIARTI000031919976/2016-01-28/>

5.2. Informational or educational materials and items of medical utility



National regulation:

The supply of these informational or educational materials and items of medical utility must be made under conditions compatible with the **Order of 7 August 2020**³⁸ *setting the amounts below which benefits in kind or in cash are considered to be of negligible value* (implementing text of *Ordinance no. 2017-49 of 19 January 2017*³⁹ relating to the benefits offered by persons manufacturing or marketing health products or services, specified by the decree of 15 June 2020⁴⁰).



Specific rule:

As a reminder, **books, other publications, magazines and subscriptions** do not qualify as “*information or educational materials and items of medical utility*”, and are considered as **gifts** when provided for the benefit of healthcare professionals, and as such are prohibited (cf. 4.2.1 of the DDPs).

- 5.2.1.** *The provision of Informational and Educational information is permitted provided that they: (i) are of “negligible value”, (ii) are directly related to the practice of medicine or pharmacy, and (iii) directly beneficial to the care of patients.*
- 5.2.2.** *Items of Medical Utility aimed directly at the education of Healthcare Professionals and patient care can be provided, if they are of “negligible value”, and do not offset routine business practices of the Healthcare professionals who receive them.*
- 5.2.3.** *The nature of such Informational and Educational Materials and Items of Medical Utility may not constitute a circumvention of the prohibition on gifts covered by [Article 4.2. of this Code](#). The transmission of such materials or items must not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer a Medicinal Product.*
- 5.2.4.** *Informational and Educational Materials and Items of Medical Utility can include the Company name, but must not be product branded, unless the Medicinal Product’s name is essential for the correct use of the material or item by the patient.*



National regulation:

Items of medical utility that qualify as medical devices must comply with **Articles L.5211-1 and subsequent**⁴¹ of the French Public Health Code and, more specifically, their obligations regarding traceability.

³⁸ <https://www.legifrance.gouv.fr/loda/id/LEGITEXT000042234974/2020-08-24/>

³⁹ <https://www.legifrance.gouv.fr/loda/id/JORFTEXT000033893406/2020-10-15/>

⁴⁰ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000041999448?r=v0vXEBOq4f>

⁴¹ <https://www.legifrance.gouv.fr/codes/id/LEGIARTI000006690282/2010-03-20/>

5.3. Non-interventional studies

5.3.1. Non-interventional studies must be conducted with a scientific purpose and must not be disguised Promotion.

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

- a) There is a written study plan (observational plan/protocol)
- b) The study plan must be submitted to the *Comités de Protection des Personnes* (CPP) – for the purpose of this translation only: *i.e equivalent to Institutional Review Boards in the US and Ethics Committees in the UK*
- c) The study plan must be approved by the Company's scientific service and the conduct of the study must be supervised by the Company's scientific service as described in Section "[5.5. Company Personnel](#)" below
- d) The study results must be analysed by, or on behalf of, the Company, and summaries thereof must be made available within a reasonable period of time to the Company's scientific service (as described in Article 5.5), which service must maintain records of such reports for a reasonable period of time. The Company must send the summary report to all the Healthcare Professionals who participated in the study and must make the summary report available to Codeem upon its request. If the study shows results that are important for the assessment of risk/benefit, the summary report must be immediately forwarded to the relevant competent authority.
- e) Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the Company scientific service that will also ensure that the Medical Sales Representatives are adequately trained. Such involvement must not be linked to the Promotion of any Medicinal Products.



National regulation:

The involvement of Medical Sales Representatives in non-interventional studies must comply with the Charter on information provided for the promotion of medicinal products through canvassing and prospecting referred to in [Chapter 8 below](#).

5.3.3. To the extent applicable, Companies are encouraged to comply with the provisions set out in the previous paragraph for all other types of NIS, including epidemiological studies, registries and other studies that are retrospective in nature. In any case, such studies are subject to the provisions set out in Article 4.6.1.

5.4. Medical samples



National regulation:

The regulations applying to medical samples are set out in Articles L.5122-10⁴² et R.5122-17⁴³ of the French Public Health Code.

Free samples of the following product types may be distributed only during the **two years following the effective marketing launch of the medicinal product concerned in France**:

- proprietary medicinal products with an initial registration or initial marketing authorisation
- Proprietary medicinal products that are already registered or authorised, and for which a further registration or marketing authorisation has been granted for a new dosage or pharmaceutical form, where the registration or authorisation is accompanied by an extension of indication.

It is also permitted during the two years following a change in the classification of the medicinal product, as referred to in 1° of Article R.5121-36

The provision of free samples must also comply with the following conditions:

- Free samples must be provided only in response to a written, dated and signed request from the recipient;
- Subject to a maximum level of four samples per year, per recipient, only a limited number of samples of each medicinal product may be provided, the actual number being dependent on the nature of the medicinal product and the need for the prescriber to familiarise himself/herself with it; each sample is identical in size to the smallest pack marketed;
- Where a medicinal product is subject to prescription restrictions, samples may be provided only to pharmacists managing hospital pharmacies and to prescribers authorised to prescribe such products;
- Pharmaceutical companies providing samples are responsible for controlling supplies of samples and monitoring them;
- Each sample must be accompanied by a copy of the summary of product characteristics;

The Director General of the French National Agency for Medicines and Health Products Safety (ANSM) may restrict the distribution of samples of certain medicinal products that pose a potential risk to public health.

5.4.1. Free samples of medicinal products are provided in accordance with the conditions set out in the French Public Health Code

5.4.2. The provision of Medical Samples must not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

⁴² https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000033897307/2018-07-01

⁴³ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006915000/2004-08-08

5.4.3. Medical Samples are provided to Healthcare Professionals so that they may familiarize themselves with the Medicinal Product and its use.

5.5. Company staff

5.5.1. Company staff must be fully conversant with the relevant requirements of the DDPs and laws and regulations.

5.5.2. Each Company must establish a scientific service in charge of the approval and supervision of Non-Interventional Studies. Companies are free to decide how best to establish such service(s) in accordance with this Article. The scientific service must include a medical doctor or, where appropriate, a pharmacist who will be responsible for the oversight of any non-interventional studies (including the review of any responsibilities related to such studies). Such person must certify that he or she has examined the protocol relating to the nis and that, in his or her belief, it is in accordance with the requirements of the DDPs and any relevant laws and regulations.

5.5.3. Every Company marketing Medicinal Products must establish a service responsible for advertising which reports to the Head Pharmacist, whose specific responsibilities include ensuring that Promotions and promotional material comply with regulatory requirements and obtaining the necessary authorisations from the ANSM. The Head Pharmacist organises and supervises the provision of scientific and medical information to ensure that the data provided are accurate and non-promotional in nature.



National regulation:

Article R.5122-2⁴⁴ of the French Public Health Code provides that “Companies marketing a medicinal product shall institute a department responsible for advertising within the meaning of Article L. 5122-1⁴⁵, which reports to the Head Pharmacist, who will ensure compliance with the provisions of sections 1 to 3 of this chapter, and particularly the scientific validity of the information disseminated”.

5.5.4. Every Company must appoint at least one senior employee who must be responsible for supervising the Company and its subsidiaries to ensure that the standards of the DDPs are met.

5.5.5. Every Company must ensure that its Medical Sales Representatives are familiar with the relevant requirements of the DDPs, 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.

- a) Medical Sales Representatives must comply with all relevant requirements of the DDPs, and all applicable laws and regulations, and Companies are responsible for ensuring their compliance.
- b) Medical Sales Representatives must approach their duties responsibly and ethically.
- c) During each visit, and subject to applicable laws and regulations, Medical Sales Representatives must give the persons visited, or have available for them, a summary of the product characteristics for each Medicinal Product they present.

⁴⁴ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000025853203/2012-05-11

⁴⁵ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000025853142/2012-05-11

- d) Medical Sales Representatives must transmit to the scientific service of their companies forthwith any information they receive in relation to the use of their company's Medicinal Products, particularly reports of the side effects.
- e) Medical Sales Representatives must ensure that the frequency, timing 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) Medical Sales Representatives must not use any inducement or subterfuge to gain an interview. Medical 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.

**National regulation:**

Article L.5122-11⁴⁶ of the French Public Health Code provides that: *“Those persons who supply information on medicinal products (i.e Medical Sales Representatives for the purpose of the DDPs) through canvassing or prospecting must have sufficient scientific knowledge as certified by diplomas, certificates or other evidence of formal qualifications appearing on a list drawn up by the administrative authority. Employers of those employees referred to in the first sub-paragraph shall also ensure that their knowledge is updated. They must instruct them to report to the company any information relating to the use of the medicinal products which they are advertising, with particular reference to adverse events brought to their attention by the persons they visit”.*

The organisational structure governing medical visits is regulated by the Medical Sales Charter drawn up by Leem and the CEPS contained in [Chapter 8 below](#), and the Company concerned must be covered by certification

⁴⁶ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006689947/2000-06-22

6. Specific requirements for interactions with patient organisations

6.1. Principles

6.1.1. *Companies must comply with the following principles:*

- The independence of Patient Organisations, in terms of their political judgement, policies and activities, must be assured.
- All interactions between Patient Organisations and Companies must be based on mutual respect, with the views and decisions of each partner having equal value.
- All interactions between Patient Organisations and Companies must not request, nor shall Patient Organisations undertake, the promotion of a particular medicinal product.
- The objectives and scope of any collaboration must be transparent. Financial and non-financial support provided by Companies must always be clearly identified.
- Companies welcome broad founding of Patient Organisations from multiple sources.

6.2. Financial support

6.2.1. *When Companies provide financial support, significant indirect support and/or significant non-financial support to Patient Organisations, they must have in place a written agreement. That agreement must indicate the amount of funding provided, as well as its purpose (e.g. general financial support, support for a specific meeting or publication, etc.). It must also include a description of any indirect support (e.g. PR agency time provided free of charge and the nature of its involvement) and non-financial support (support in kind).*

6.3. Independence

6.3.1. *Companies must respect the editorial independence of Patient organisations.*

6.3.2. *If requested to do so by Patient organisations, Companies may contribute to authoring information with respect for scientific integrity, but without ever influencing its content, and without prejudice to the correction of factual inaccuracies.*



National regulation:

Subject to compliance with the regulations governing patient therapeutic education: therapeutic education, support initiatives and learning programmes are implemented subject to the conditions set out in Articles L.1161-1 and subsequent⁴⁷ of the French Public Health Code.

⁴⁷ https://www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006072665/LEGISCTA000020891754/#LEGISCTA000020892073

7. Publication of links and interests

**National regulation:**

Companies must publish their links and interests in accordance with Article L.1453-1⁴⁸ of the French Public Health Code and its implementing texts.

- 7.1.1. Companies are required to publish their links and interests under the conditions set out in Article L.1453-1 of the French Public Health Code.**
- 7.1.2. This publication fulfils the EFPIA Code disclosure requirements**

⁴⁸ https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000038888435/

8. Information provided through canvassing and prospecting



National regulation: information provided through canvassing and prospecting is governed by the provisions set out in the [Charter on information provided for the promotion of medicinal products through canvassing and prospecting signed by Leem and CEPS on 15 October 2014](#), and by the HAS certification standard. The provisions of this Charter are reproduced below in their original form, and may not be subject to change or modification.

Charter on information provided for the promotion of medicinal products through canvassing and prospecting

MODIFIED ON 15 OCTOBER 2014

The purpose of this charter is to set forth the conditions under which information is provided, anywhere, on proprietary medicinal products through canvassing or prospecting for promotional purposes.

Included within the scope of the charter is information in all its forms, regardless of medium, provided through canvassing, prospecting or incentives designed to encourage the prescribing, supply or use of proprietary medicinal products by any professionals licensed to prescribe, dispense and use such products.

In accordance with the law, the aim of this charter is to improve the quality of information provided in the promotion of medicinal products to ensure their proper use among healthcare providers.

The aim of delivering information based on regulated and validated scientific information is to promote medicinal products among healthcare professionals. Information provided in this setting must promote the quality of medical treatment in an effort to prevent misuse of the medicinal product, avert unnecessary costs and raise healthcare professionals' awareness.

I- Duties of persons engaged in information activities through canvassing or prospecting for promotional purposes

1- Persons engaged in information activities through canvassing or prospecting shall present the proprietary medicinal products to healthcare professionals in compliance with the legal provisions, this charter and the guidelines set out by the company which they represent. This promotional activity involves imparting high-quality medical information on the presented medicinal product in strict compliance with the marketing authorisation and ensuring its proper use among healthcare professionals.

Such information shall comprise the role of the medicinal product in the recommended therapeutic strategy, its treatment of the disease in question, approved by the French Transparency Commission and in accordance with the recommendations issued by the National Authority for Health, the ANSM and the National Cancer Institute, and with the consensus meetings approved by the National Authority for Health. This role must take account of campaigns to promote proper use and public health programmes. The information shall also include data on safety and monitoring of the medicinal product. Persons engaged in information activities through canvassing or prospecting shall provide and offer to submit all risk minimisation documents provided for by the risk management plans or the risk minimisation plans.

Information may not be provided through canvassing or prospecting for the promotion of a medicinal product which is subject to a benefit/risk reassessment following a pharmacovigilance alert until this procedure is completed.

- 2- The activity of providing information through canvassing or prospecting shall involve informing healthcare professionals of all the regulatory, pharmacotherapeutic and health economic aspects of the presented medicinal product:
- therapeutic indications specified in the marketing authorisation;
 - dosage (especially paediatric dosages if any);
 - treatment duration;
 - adverse reactions;
 - contraindications;
 - drug interactions and monitoring;
 - prescribing conditions;
 - price and funding arrangements (indications reimbursed to patients covered by national health insurance and reimbursement rates);
 - inclusion on the list of expensive medicinal products apart from diagnosis-related groups for internal-use medication and medicinal products sold by the health facility's pharmacy to outpatients.

Under the regulations, information may not be provided through canvassing or prospecting for promotional purposes on medicinal products granted temporary authorisation for use (ATU) status.

In addition, information may be presented on the existence of a temporary recommendation for use (RTU) and its updates provided that it is separated from all promotional activities, is approved by ANSM, and involves the delivery of documents intended to systematically gather information on such RTU.

- 3- In accordance with the laws in force (including art. L162-17-4-1 Social Security Code), if prescriptions are found not to comply with the marketing authorisation, the administrative authority may ask the company concerned to contact healthcare professionals to draw attention to the prescribing context set out in the marketing authorisation and, where appropriate, to disseminate such corrective statements as it deems necessary. These information actions specifically targeted at prescribers by the company or group of companies may be devolved to persons engaged in information activities through canvassing or prospecting. CEPS may request notification thereof.

These persons thus contribute to limiting the observed off-label use of medicinal products where such use is inconsistent with the recommendations of the competent health authorities.

When a company finds that a prescription does not comply with the proper use of a proprietary medicinal product, it may ask the persons engaged in information activities through canvassing or prospecting for promotional purposes to convey the appropriate information measures to the healthcare professionals and shall notify ANSM immediately thereof.

These persons shall inform the company fully on the use of medicinal products which they advertise, with particular regard to any adverse reactions and off-label uses which are brought to their attention.

- 4- The implementation (recruitment of and financial relations with professionals licensed to prescribe, dispense and use the medicinal products) of health economic analyses and clinical studies, including Phase IV and observational studies, does not fall within the remit of persons engaged in promotional information activities through canvassing or prospecting. They may however monitor such analyses and studies.

- 5- Information on apprenticeship schemes provided by persons engaged in information activities through canvassing or prospecting should be separated from any promotional activities relating to the medicinal product involved in the scheme.

II- the quality of the information provided

1- Preparation of the information by the company

a) *Preparation of documentation and training materials*

Promotional materials made available to persons engaged in information activities through canvassing or prospecting must be drawn up in accordance with the provisions of the CSP (Public Health Code) and with the recommendations of ANSM. These documents shall bear the date on which the information was produced or updated. They must include a valid visa issued by the ANSM.

Information related to the use of the medicinal product, especially adverse reactions, precautions and contraindications shall be clearly stated in such a way as to highlight their relationship with the indication and the proposed benefit.

b) *Updating of promotional materials*

The company shall take steps to ensure that the scientific, medical and regulatory content of the promotional documents is kept up to date.

c) *Post-marketing studies*

Studies which may be used are peer-reviewed published studies conducted under the conditions of use of the medicinal product as set out in its marketing authorisation and other existing reference standards (opinion of the Transparency Committee, good practice guidelines). Moreover, in an effort to fully inform audiences and to comply with the recommendations of ANSM on the advertising of medicinal products, advertising must specify whether the publication relates to a study included in the transparency dossier and/or in the marketing authorisation dossier.

When a company uses such studies, it shall present them in a comprehensive and impartial manner.

d) *Comparative advertising*

Information provided on a proprietary medicinal product and on competing products having the same therapeutic aim falling within the therapeutic strategy defined by the Transparency Commission, must meet the following criteria defined for comparative advertising:

Any advertising that compares medicinal products by identifying, implicitly or explicitly, medicinal products marketed by a competitor may only be used if:

- 1° It is not misleading or likely to mislead
- 2° It relates to medicinal products which meet the same needs or have the same therapeutic indication
- 3° It objectively compares one or more essential, relevant, verifiable and representative characteristics of these medicinal products, of which price may be one

Comparative advertising may not:

- 1° Take unfair advantage of the reputation of a trademark, trade name, or other distinguishing signs of a competitor.
- 2° Discredit or denigrate the trademarks, trade names, other distinguishing signs, or circumstances of a competitor.
- 3° Generate confusion between the advertiser and a competitor or between the advertiser's trademarks, trade names or other distinguishing signs and those of a competitor.

4^o Subject to the provisions governing generic medicinal products, present medicinal products as an imitation or reproduction of another medicinal product possessing a brand or protected trade name.

2- Training for persons engaged in information activities through canvassing or prospecting for promotional purposes

a) Initial training

In accordance with legal, regulatory, and contractual requirements, persons engaged in information activities through canvassing or prospecting for promotional purposes shall receive adequate initial training, as evidenced by a certificate, diploma or other formal qualification, including prior experience accreditation or an equivalence awarded to the prior experience accreditation pursuant to Article L.335-5 of the Code of Education.

b) Continuing training

In addition to the induction training given to each new recruit, the company shall provide as a matter of course the necessary training to update its recruit on regulatory and scientific developments and to maintain and further their professional skills, including preparation for oral presentations.

Training in knowledge of regulatory requirements shall cover the following topics:

- a. The medicinal product: classes of medicinal products, prescribing and dispensing rules, proper use of the medicinal product.
- b. The funding arrangements for the medicinal product.
- c. Pharmacovigilance and “product” complaints.
- d. Code of conduct: DMOS anti-gift act and transparency of company links.
- e. Advertising
- f. The Charter and certification.
- g. Organisation of the healthcare system.

The training should allow persons engaged in information activities through canvassing or prospecting to know and comply with the regulations governing the medicinal product so they may be a source of information and answers to healthcare professionals. Each training topic shall relate to the training objectives that determine the content of the training.

Training on scientific knowledge shall cover:

- a. The proprietary medicinal product and/or one or more conditions for which the presented medicinal product may be used;
- b. The treatment strategy for the proprietary medicinal product and/or condition concerned, or the state of the art.

For each training programme attended by a person engaged in information activities through canvassing or prospecting, the company shall conduct an annual assessment to certify that the employee has the knowledge to deliver high-quality information. The company shall establish the procedures and period for the assessment. This assessment shall be conducted as a matter of course prior to meeting with healthcare professionals whenever a new indication or new product is introduced. It shall also establish training validation thresholds so that the required level can be set, and corrective actions taken in the event of non-validation. The assessment procedures must comply with the following principles:

- o Knowledge is assessed based on the content of the training given.
- o The company must demonstrate the randomness of the assessment performed and its traceability.
- o The company must have a sufficient database of assessment items to ensure compliance with the random assessment principle.

c) Certificate of initial and continuing training via the professional card

Persons engaged in information activities through canvassing or prospecting for promotional purposes shall be in possession of a professional card awarded by Leem through the AGVM (Association for the management of medical sales activity). The award of this card ensures that the employee's level of regulatory and scientific knowledge meets the requirements of Article L.5122-11 CSP and the continued training requirement described above.

To this end, the company shall provide the AGVM each year with an individual report on the training given and the overall assessment outcomes. The AGVM may ask the company for additional information related to the assessment.

This information shall be available for inspection by the certification authorities.

See Chapter III Code of Conduct

3- Documents used by persons engaged in information activities through canvassing or prospecting for promotional purposes

These documents are all subject to prior oversight by ANSM and must therefore include a valid visa.

Persons engaged in information activities through canvassing or prospecting shall perform their duties exclusively by means of dated documents made available to them by the company, approved by the responsible pharmacist (name and signature) and for which an advertising permit has been issued by ANSM. When a document has been updated by the company, only the most recent may be used.

No exemption from delivery of the documents listed below may be sought as a result of using of audio, video or interactive materials.

Pursuant to Article R.5122-11 CSP, healthcare professionals must receive without fail:

- The summary of product characteristics referred to in Article R.5121-21 CSP;
- The product's prescribing and dispensing classification as stated in the marketing authorisation;
- The retail price ceiling, the reference rate or the transfer price where such price or rate is set by the laws and regulations in force, together, in this case, with the cost of daily treatment;
- The medicinal product's status in terms of its reimbursement by health insurance providers or its approval for public authorities pursuant to Article L. 5123-2;
- The opinion delivered pursuant to Article R. 163-4 of the Social Security Code by the Transparency Committee referred to in Article R. 163-15 of the same Code and most recently published in the conditions laid down in the last paragraph of section III of Article R. 163-16 of this Code (where the medicinal product has received several opinions due to an extension of the treatment indications, the concept of opinion refers to all opinions involving an assessment of the medical benefit provided for each of the treatment indications of the medicinal product in question);
- Ministerial order(s) to include it on the supplementary list and/or on the list of medicinal products sold on through hospital pharmacies, if applicable.

Healthcare professionals must also receive without fail any documents deemed necessary by the French National Authority for Health, ANSM, the National Cancer Institute, or CEPS.

These documents must be fully legible and include the date on which they were created or last revised.

The following documents must be presented and may be delivered by persons engaged in information activities through canvassing or prospecting:

- proper use of medicinal products leaflets;
- prescribing information;
- good practice guidelines;

- consensus meetings;
- The opinions of the High Council for Public Health (Technical Committee on Vaccinations)
- or other reference standards issued or validated by the National Authority for Health, ANSM, or the National Cancer Institute;
- as well as risk minimisation documents provided for by the risk management plans or the risk minimisation plans.

III- Code of Conduct

1- In respect of patients

Persons engaged in information activities through canvassing or prospecting for promotional purposes are bound by professional secrecy and may disclose nothing which they may have heard or seen in the places where they operate.

They should behave discreetly in the waiting areas and not hinder the delivery of care (limited conversations with professionals and mobile phone use, proper dress attire).

2- In respect of healthcare professionals met

Persons engaged in information activities through canvassing or prospecting shall be supervised to ensure that organisation, planning and frequency of visits are optimised.

In terms of professional ethics, persons engaged in information activities through canvassing or prospecting may not use incentives to secure a visit nor offer any remuneration or compensation to this end.

a) *Organising visits*

α- In any place where healthcare professionals practise

Persons engaged in information activities through canvassing or prospecting for promotional purposes shall endeavour not to disturb the smooth operation of the medical practice or health facility visited. Accordingly, they are required to comply with the following organisational procedures:

- They must ensure that their interlocutors are fully aware of their identity, their function, the name of the company and/or network being represented and, where applicable, the marketing authorisation holder of the proprietary medicinal product being presented.
- They must adhere to the timetables, the conditions of access and circulation within the various practice settings where the meeting takes place, as well as the duration and the venue decided by the healthcare professional or facility.

Accompanied visits (for example, with the regional director of the company or network) must be approved by the healthcare professionals visited. Accompanying persons must state their identity and position.

β- Within healthcare facilities

In healthcare facilities, persons engaged in information activities through canvassing or prospecting for promotional purposes are required to comply not only with the general rules set out in this charter but also the facilities' own internal rules of organisation and practice, including:

- Wearing a professional badge (e.g. business card worn as a badge, etc.);
- The conditions of access to the facility, to internal structures and to healthcare professionals regardless of their mode of practice within the facility;

- The rules governing identification and circulation within the facility as defined by its rules of procedure;
- The collective character or otherwise of the visit.

In all events, in healthcare facilities:

- Access to restricted facilities (operating theatres, sterile areas, intensive care, etc.) is prohibited without the prior approval, at each visit, of the heads of the facilities in question.
- Meetings shall be arranged in advance.
- Persons engaged in information activities through canvassing or prospecting may only meet staff undergoing training if given the prior approval of the facility's responsible officer or supervisory staff.
- Persons engaged in information activities through canvassing or prospecting may only meet interns in the presence, or with the prior approval, of their supervising practitioner.
- Persons engaged in information activities through canvassing or prospecting may not seek data (consumption, costs, etc.) specific to the internal facilities or prescribers.

b) Information gathering and compliance with the French Data Protection Act

Persons engaged in information activities through canvassing or prospecting shall gather information in relation to professionals licensed to prescribe, dispense and use medicinal products in accordance with the French Data Protection Act (Law No. 78-17 of 6 January 1978).

This information is gathered in order to reach a better understanding of the professionals' expectations with regard to the medicinal product and its use, or with regard to the therapeutic class concerned, to provide them with information tailored to their needs, and to streamline the work of persons engaged in promotional information activities through canvassing or prospecting.

Accordingly, information stored in databases must incorporate only professional and factual elements, to the exclusion of value judgements or information of a subjective nature.

The database in which this information is stored shall be notified to the CNIL (National Data Protection Agency). In accordance with the law, professionals licensed to prescribe, dispense and use medicinal products shall be notified that information concerning them is held in a computerised data base. Persons engaged in promotional information activities through canvassing or prospecting must notify professionals licensed to prescribe, dispense and use medicinal products of the data gained about them during individual or departmental prescribing or dispensing surveys, and that this information is available to them.

Upon written request of healthcare professionals, persons engaged in information activities through canvassing or prospecting may send them the personal data concerning them.

c) Professional relations - Congresses

Invitations to scientific congresses and/or to promotional events, as well as participation in research or scientific evaluation activities, must be subject to an agreement sent in advance to the relevant professional association. Such agreements may allow for the receipt by healthcare professionals of the benefits referred to in Article L. 4113-6 of the French Public Health Code. These benefits must be made public by the companies awarding them, pursuant to Article L. 1453-1 of the French Public Health Code, in accordance with the procedures set out in Articles D. 1453-1 and R. 1453-2 et seq. of the French Public Health Code.

d) Samples

Persons engaged in information activities through canvassing or prospecting are not allowed to hand out samples of proprietary medicinal products.

This prohibition also applies to the giving of samples of cosmetics, dietary supplements and medical devices by persons engaged in promotional information activities through canvassing or prospecting when they are presenting a proprietary medicinal product, without prejudice to the application of the 4th paragraph of Article L5122-10 CSP.

Samples of medical devices may, however, be used for demonstration purposes, subject to the provisions of Chapter III, Title 1, Book II, Part 5 of the French Public Health Code.

e) Gifts

Persons engaged in promotional information activities through canvassing or prospecting may not offer healthcare professionals gifts in kind or in cash, whether or not covered by an agreement, nor respond to any requests in this respect.

This prohibition also applies to offering or facilitating the provision of a benefit covered by the exceptions made in the second paragraph of Article L. 4113-6 of the French Public Health Code.

f) Meals

Meals offered to healthcare professionals by persons engaged in information activities through canvassing or prospecting may constitute benefits within the meaning of Article L. 4113-6 of the French Public Health Code.

In order to be exempted from an agreement, meals must in all instances be of an impromptu character and be linked to the visit made to the healthcare professional. They shall be made public, where applicable, pursuant to the provisions of Section II of Article L. 1453-1 and Articles D. 1453-1 and R. 1453-2 et seq. of the same Code.

3- In respect of competitors

The information provided by persons engaged in information activities through canvassing or prospecting in respect of the proprietary medicinal product being promoted and in respect of competing proprietary medicinal products having the same therapeutic aim and featured in the therapeutic strategy defined by the Transparency Committee, must not be disparaging and must be based principally on the opinions of the Transparency Committee. The ASMR (improvement in actual benefit) level set by the HAS (French National Authority for Health) must be faithfully presented.

Persons engaged in information activities through canvassing or prospecting shall refrain from disparaging the proprietary medicinal products of competitors, including generic and biosimilar medicinal products.

4- In respect of their own company

In accordance with the law, persons engaged in information activities through canvassing or prospecting shall immediately advise the responsible pharmacist or their pharmacovigilance department of any information received from healthcare professionals concerning pharmacovigilance and/or the improper use of their medicinal products.

5- In respect of Health Insurance

Persons engaged in information activities through canvassing or prospecting shall set out the reimbursable and non-reimbursable indications of the proprietary medicinal products being presented.

They shall present the different packaging options in terms of their health insurance cost and, with particular regard to chronic treatments, those that are most economical and best suited to the patient, especially where practitioners prescribing in a non-hospital setting are concerned.

They shall specify whether the proprietary medicinal product being presented is covered by a reference pricing.

IV - Oversight of the activity of persons engaged in information activities through canvassing or prospecting for promotional purposes

1- Responsibility of the Responsible Pharmacist

a) On content

The responsible pharmacist shall set up a quality control system that guarantees the scientific and economic content of the promotional materials used in the information activities through canvassing or prospecting and more generally shall ensure compliance with section II-1 of this charter. He/she shall approve these materials.

The responsible pharmacist shall ensure that the lists of materials that can and should be delivered by the persons engaged in information activities through canvassing or prospecting are kept up to date.

He/she is responsible for the content of the messages delivered by the persons engaged in information activities through canvassing or prospecting.

b) On training

The responsible pharmacist shall ensure that the persons engaged in information activities through canvassing or prospecting possess the necessary knowledge for the exercise of their profession and that they receive regular continuing training designed to update their knowledge and prepare for promotional campaigns.

c) On procedures

The responsible pharmacist shall ensure the proper development and implementation of information-related procedures within the company.

2- Procedures

a) Document traceability

The responsible pharmacist shall ensure that only those documents whose scientific, medical and economic quality is guaranteed by his/her signature and date are used at all times for medical sales visits.

b) Feedback

The healthcare professionals visited are regularly given the opportunity to provide the company, without cost to themselves, with their assessment of the scientific quality of the information, its objectivity and its compliance with laws, regulations and this charter.

The assessments sent to the company by the healthcare professionals are recorded and reviewed by the responsible pharmacist.

The company shall also provide itself with the resources to measure its contribution to proper medicinal use, to the detection of prescriptions that deviate from such use, and to steps aimed at correcting them (L5121-14-3 CSP).

c) Follow-up of contacts

The company shall provide itself with the resources to regularly measure its information activity through canvassing or prospecting.

These data shall be made available to the Joint Monitoring Committee referred to section V of this charter, which may request that they be submitted in the event that the quality of the promotional information is identified by the national observatory as having deteriorated and/or in case of an alert by ANSM or the HAS.

3- Certification and audits

Pursuant to Article L. 162-17-4 of the Social Security Code, a certification standard shall be established, subject to conditions to be determined by the National Authority for Health, guaranteeing compliance by the certified companies with the provisions of this charter.

This standard also sets out the procedures according to which company executives, supervisory staff and persons engaged in information activities through canvassing or prospecting adhere personally to the charter.

When, for the purposes of promoting its medicinal products through canvassing or prospecting, a company enlists a service provider or another pharmaceutical company, it shall be responsible for ensuring that the practices adopted by such service provider or such pharmaceutical company are in compliance with the Charter.

4- Implementation of Articles L162-17-4 and L162-17-8 CSS

The company shall prioritise the content of medical sales visits by persons engaged in information activities through canvassing or prospecting over their frequency in order to ensure that the information provided is as comprehensive and objective as possible and, in particular, that the time needed to instruct healthcare professionals on the proper use of the medication is sufficient.

To this end, CEPS and Leem have decided to establish a national observatory for promotional information. The aim of this observatory is to measure the quality of promotional practices based on objective, verifiable and transparent criteria.

The observatory will be used as a non-exclusive reference tool for the signatories to this charter and as a source of shared information between the parties to this charter. Pharmaceutical companies that fall within the scope of this charter shall conduct a survey once a year among healthcare professionals to measure the quality of their promotional practices on their most promoted medicinal product and on any other medicinal products, at the reasoned request of CEPS, totalling up to 3 products. The investigation method and criteria applicable to all companies shall be defined jointly by CEPS and Leem. They are contained in the Annex to this charter.

Once collected, the data shall be forwarded to a trusted third party able to aggregate and analyse them. This work will give rise to an annual report to be sent each year to the signatories to this charter. In addition, the trusted third party must be able to alert the charter's signatories to any quality practices that fall short of the requirements set out herein. The trusted third party shall be selected jointly by CEPS and Leem.

A CEPS-Leem Joint Monitoring Committee shall be established. It shall meet at the request of either party. It shall analyse primarily the evidence forwarded by the national observatory showing a deterioration in the quality of the promotional information and any other relevant findings (alert sent by the health authorities, evidence available to CEPS, etc.). The Committee shall meet at least once a year to review the national observatory's annual report drawn up by the trusted third party. At the meeting, it shall prepare its own annual report which it will make public. It shall serve as a forum for discussion, allowing manufacturers to explain their promotional practices and, where applicable, to provide answers to CEPS and/or the health authorities.

CEPS may set quantified annual targets for the development of promotional practices, if necessary for certain pharmacotherapeutic classes or products pursuant to Article L.162-17-8 of the Social Security Code. To do so, CEPS shall base itself on a body of evidence pointing to commercial and promotional practices which may affect the quality of care.

In light of the evidence gathered, if CEPS wishes to set quantified targets, it shall meet with the companies concerned. Following this exchange and such additional evidence as may be submitted by the companies, CEPS may, by agreement or by its own decision in the absence of an agreement within two months, set these quantified annual targets for the development of promotional practices.

If these targets are not met, CEPS may impose a financial penalty on the company, pursuant to Article L162-17-8 CSS, once the company has been given the opportunity to submit its observations.

V - Joint monitoring of the charter

The parties agree to establish a joint committee to monitor the implementation of this charter and the achievement of the objectives pursued. This monitoring committee shall consult, as necessary, the relevant professional associations on the rules of professional conduct, as well as ANSM and HAS. It shall meet at the request of either party and in particular each year on receipt of the national observatory's annual report. It shall review the issues raised by each party.

VI- Duration and termination

This agreement shall enter into force upon signature.

It shall be renewed annually by tacit agreement and may be amended by an additional agreement.

It may be terminated by either party.

In case of termination, the effective date of termination is 12 months following notice by one party to the other, such period allowing for the adoption of appropriate regulatory measures.

...

Annex to the charter on information provided for the promotion of medicinal products through canvassing and prospecting

Establishment and operation of the national observatory for the monitoring of promotional information

1) General framework

As part of the charter on information provided for the promotion of medicinal products through canvassing and prospecting, CEPS and Leem have decided to set up a national observatory to measure the quality of promotional practices based on objective, verifiable and transparent criteria.

This observatory is provided each year with data collected from healthcare professionals by the pharmaceutical companies falling within the scope of the charter. These companies shall conduct a survey each year to measure the quality of their promotional practices on their most promoted medicinal product and on any other medicinal products, at the reasoned request of CEPS, totalling up to of 3 products.

Once collected, the data shall be forwarded to a trusted third party responsible for aggregating and analysing them. If significant deviations in practice are found, the trusted third party shall inform Leem and CEPS thereof.

The trusted third party shall be selected jointly by CEPS and Leem following a competitive bidding process. The cost of the trusted third party's services shall be borne equally by CEPS and Leem.

The signatories to this charter shall draw up the specifications for selecting the service provider in the month following the signing of the charter and shall establish a scoring chart for selection purposes. Responses should be sent separately to CEPS and Leem within two months from the date on which the specifications were sent out.

The signatories to this charter shall meet in the ensuing 15 days to review the candidates' responses. At this meeting, the signatories to the charter may decide to interview the candidates.

2) Survey methodology

Companies shall conduct surveys among healthcare professionals by electronic questionnaire, the panel recruitment criteria for which shall be identical for all companies and established by the trusted third party.

Each questionnaire shall include questions set by the trusted third party on the following 4 topics:

Identification of the healthcare professional

- Specialism
- Place of practice
- Acceptance of the medical sales visit
- Frequency of visits

Description of the visit

- Identification of the medical sales representative and/or accompanying person
- Compliance with the visiting rules laid down by the healthcare professionals
- Place of the visit
- Sample distribution (MD)
- Number of products presented

Content of information provided for the products presented

Therapeutic indications

- Clinical data on the benefit of the medicinal product
- Role of the medicinal product in the therapeutic management of the patient
- Proper use: adverse reactions - contraindications
- Pharmacovigilance alert or Risk Minimisation Plan/Risk Management Plan
- Official recommendation (HAS, etc.)
- Handing over of the SPC
- Handing over of the opinion of the Transparency Commission
- Economic aspects (reimbursable and non-reimbursable indications, reference pricing, packaging, etc.).

Satisfaction of healthcare professionals

- Objectivity of the presentation
- Usefulness of the visit
- Appropriate frequency of visits

The questions proposed by the trusted third party will be validated in advance by the signatories to the charter during the course of a dedicated working group session.

The answers to the questions on the 4 listed topics shall be sent to the trusted third party in the month following completion of the survey and in all events before the end of each year.

This survey is implemented for the first time in 2014.

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9. Persons responsible for providing medical and scientific information at regional level



Specific rule: the 30 October 2018 meeting of the Leem Board of Directors and Codeem adopted the following specific rules for MSLs, which became effective on 1 January 2019.

9.1. Scope

This section applies to the regulation by Pharmaceutical Companies of the regional medical and scientific information officers commonly referred to as MSL (Medical Science Liaison).

The purpose of this section is to regulate the assignments and tasks of MSLs.

The job of the MSL is distinct from that of other members of staff involved specifically in promotion, whose work is governed by the Charter on information provided for the promotion of medicinal products through canvassing and prospecting of 15 October 2014. This section therefore complements the section entitled “*Promotion and relationships with healthcare professionals*”.

9.2. Definition, expertise and mission

The persons responsible for medical and scientific information at regional level are employees with the medical and/or scientific expertise required to respond to the needs of healthcare professionals by providing medical and scientific information and developing scientific partnerships for the purposes of improving patient care and developing clinical research. MSLs can also communicate proactively with healthcare professionals on issues related to additional product safety and medical study projects

The relationship between MSLs and healthcare professionals is based on the following principles:

- (1) The exchange of high-quality information that is solely scientific and non-promotional in nature
- (2) The sharing of skills needed to improve the use or future development of the medicinal product concerned

9.3. General principles

The actions of MSLs must comply with the principles of the process and scientific integrity. MSLs must engage and interact with healthcare professionals, academics and scientific partners.

Pharmaceutical Companies agree that their MSLs will not carry out any intervention whose content or supporting materials are promotional in nature within the meaning of the French Public Health Code and the regulations applicable to the promotion of medicinal products.

They also agree to ensure that interventions by MSLs occur only within a time frame notified and implemented separately from any intervention included in the scope of the Charter on information provided for the promotion of medicinal products through canvassing and prospecting of 15 October 2014. So where MSLs intervene in parallel, or jointly, with an activity or action covered by this Charter, pharmaceutical companies are committed to ensuring that the intervention by the MSL falls within a single dedicated time frame.

9.4. Information provided by the MSL

Pharmaceutical Companies agree to ensure that the information provided by MSLs is:

- (a) consistent with the latest and validated scientific data
- (b) solely scientific and non-promotional within the definition of promotional information given in the Charter on information provided for the promotion of medicinal products through canvassing and prospecting of 15 October 2014
- (c) compliant with the principles of scientific integrity set out in 1.5.5.

9.5. Scientific integrity

Pharmaceutical Companies must ensure that MSLs comply with the following information and communication rules:

- (a) Ensure that the best interests of the patient always take precedence in all interactions with healthcare professionals
- (b) Ensure compliance with the principles of data comprehensiveness and transparency, which means communicating all known and relevant data, whether positive or negative
- (c) Promote the principle of critical analysis of data, study structures, methodologies and the analysis and/or presentation of results
- (d) Provide only scientifically validated data
- (e) Combat and challenge all forms of scientific fraud, falsification of data and dissemination of incorrect information

9.6. Relationships with healthcare professionals

Pharmaceutical Companies must ensure that any interaction between MSLs and healthcare professionals has the aim of improving scientific and medical knowledge about a particular medicinal product.

Pharmaceutical Companies must ensure that MSLs, when introducing themselves, indicate their identity, the company they work for, their job title and their role. They must also ensure that there is no confusion between MSLs and staff whose missions are focused on promotion.

9.7. Skills and training

Pharmaceutical Companies agree to stress the scientific or medical expertise of MSLS prominently in job descriptions and job definitions.

Pharmaceutical Companies agree to ensure that all MSLS recruited after 1 January 2019 have a certificated qualification or have completed an appropriate course that demonstrates a high level of medical and/or scientific competence:

- (a) 2-year Masters or engineering degree (or higher) in a scientific or medical area
- (b) Gained exclusively as a result of further education or continuing education

Pharmaceutical Companies agree to ensure that MSLS in post on 1 January 2019 who have not yet achieved the minimum level of education/qualification required will, within three years of the date on which these provisions were incorporated into DDPs, be required to complete a training programme in order to continue in this role. This training programme and its structure will be designed by Leem to provide the levels of knowledge and skill required by all MSLS, based on the Codeem job description and criteria.

Pharmaceutical Companies agree to a programme of continuing training for MSLS in the professional and ethical rules by which they must be guided.

9.8. Within the company

The MSLS employed by all Pharmaceutical Companies will report exclusively to the Medical Department or, alternatively, to whichever department is responsible for medical affairs.

All Pharmaceutical Companies put in place control procedures and ensure that the actions and missions of its MSLS are - in common with all other careers within the company - supervised by the department responsible for business ethics, professional conduct, quality and/or compliance or, alternatively, whichever department is responsible for these aspects.

Where MSLS receive variable remuneration, it must not be based on criteria related to prescription volumes per practitioner or healthcare facility.

10. Communication and promotion on the Internet and via e-media



National regulation: Companies must comply with the provisions contained in the 2014 ANSM Charter reproduced below.

Charter for the Communication and Promotion of Health Products (medicines and medical devices) on the Internet and e-media

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Foreword

This document updates and replaces the “Charter governing Online Communication by Pharmaceutical Companies”, the final version of which was updated in 2010. It also incorporates the new CSP provisions governing the advertising of medical devices (MD), active implantable medical devices (AIMD) and in-vitro diagnostic medical devices (IVD). These 3 categories of product will be referred to collectively using the generic term of “medical devices”.

The Internet and its associated services and applications are media and channels that can be used to communicate and promote healthcare products (medicinal products and medical devices) in compliance with the French Public Health Code (CSP).

Given the technicalities of the online world, the purpose of this charter is to help operators design their web pages and digital offers in compliance with the relevant regulations, i.e. to distinguish between advertising (governed by the provisions of the French Public Health Code), information and online sales.

For this purpose, “operator” means the *exploitant* of a medicinal product or the manufacturer, agent, distributor or importer of a medical device.

This charter deals with websites and the media they contain (banners, etc.), social media and media developed specifically for smartphones and tablets, where the operator is the publisher.

It applies to any website or service that an operator would voluntarily bring to the attention of the French public or professional users practising in France.

1 Websites

1.1 General recommendations

A website must present the information required under the terms of Article 6 of Law 2004-575 of 21 June 2004 on trust in the digital economy and, more particularly, must identify the operator, the intended audiences and the type of information disseminated. It must be structured and offer users a site map on the homepage.

The information is updated regularly and the date of the last update must be specified.

Information targeted at audiences in foreign countries must be identified as such.

Websites must be designed in such a way that those sections specifically intended to promote a health product are explicitly distinct from other non-promotional sections.

Advertising must therefore be identified as such by using any clearly understandable method that enables users to unambiguously identify the message concerned as advertising. A distinction is made between two scenarios:

- a) In scenarios where the advertising status of the message is not clear, the recommendation is to add an explicit explanation that unambiguously identifies it as advertising. Where this is the case, the website must expressly flag up the promotional nature of particular pages by clearly using the words “Advertising” or “Promotional Message”, for example
- b) In scenarios where the message is obviously advertising, either due to its use of a commonly used advertising format or in terms of message content. Where this is the case, no additional identification is required. A graphic style specific to a particular health product and/or the use of its logo may suffice to identify the message or web page as promotional, especially where the graphic style is accompanied by an advertising banner, in which case the entire page is treated as advertising.

2 Online advertising

1.2 General principles

Like other advertising media, promotional websites must comply with the CSP provisions as they apply to the advertising of healthcare products and must also comply with the provisions that effectively ban the advertising of certain products to certain audiences (see section 1.2.3).

Websites that present products with different statuses (medicinal products, medical devices, cosmetics or other products) must clearly identify this status to avoid misleading users about the true nature of the product.

1.2.2 Mandatory information

Every website promotional page must display the mandatory information required by the CSP for the product category concerned and the intended audience. This information must be immediately visible and legible. The font size used to display this information must not be smaller than the smallest size used in the body of the promotional text shown on the web page.

However, those elements required to browse the website (thumbnails and product names on the cover pages, plans, responses from internal search engines, etc.) do not need to display the mandatory information as long as the landing pages of these links - the pages presenting the promotional material for healthcare products - do include the mandatory information.

Comments:

Given the length of medicinal product advertisements that target healthcare professionals, the mandatory information may be accessed via a clearly identified hyperlink whose purpose is obvious to the user.

For MD and IVD advertisements targeting healthcare professionals, the health insurance reimbursement status and, where applicable, the conditions governing their inclusion in the list referred to in Article L165-1 of the Social Security Code may, given the target group for this advertising, be provided by a link to www.ameli.fr

1.2.3 Access to promotional web pages

Advertising must be tailored to its audience(s). Advertisements targeting healthcare professionals should therefore be restricted to those pages accessible only to them.

The CSP also imposes restrictions on the dissemination of certain types of advertisement, and specifically prohibits all public advertising of reimbursable Class IIb and III MDs, AIMDs, breast implants and all reimbursable medicinal products, those for compulsory medical prescription, and those whose MA includes a ban/restriction on public advertising.

In all these cases, operators must implement effective restrictions on access. For example, the allocation of a login ID, having previously confirmed the status of the applicant as a healthcare professional (by completing an application form for submission by e-mail, by entering his/her professional body registration number or using a code provided by the operator) will prevent access for those who do not meet the required criteria. This level of security is essential, so a simple system of user self-accreditation of professional status is not sufficient to access pages that may promote a medical device or medicinal product for which public advertising is prohibited.

No access restriction is necessary for advertising that intentionally targets the general public.

1.2.4 Methods for requesting prior approval

Depending on the type of product concerned, prior authorisation for promotional pages must be sought from the ANSM (for those medicinal products and MDs/IVDs listed by ministerial decree) before they are published online. Promotional pages for MDs/IVDs not listed in this way will not require prior application but will be subject to subsequent inspection.

The terms and conditions governing applications for advertising authorisation are described in the “*Activités > Contrôler la publicité*” section of the ANSM website at www.ansm.sante.fr.

More specifically, the proposed domain name must be entered in the “dissemination methods” section of the application form. The access code or any other secure procedure to be used for restricting access to these pages must also be specified.

Where an application refers to a website with multiple promotional pages, the ANSM authorisation covers all these pages as a single advertisement. These pages are then treated as an indivisible whole, and cannot be used separately without a new application being made and granted.

Every change made to a promotional page (except for minor modifications accepted by ANSM as part of its other recommendations) requires a new application, which must highlight the changes made, and may include only new or amended promotional pages.

Online publication of a digital version of a promotional document that is absolutely identical to a document previously authorised in printed form (e.g. advertorial or brochure) or a video originally produced for a TV broadcast does not require a new application to be made, as long as the initial authorisation remains valid. However, the ANSM must then be informed of the website on which it appears, together with any access codes required to view the page(s) concerned.

Comment: Operators agree to provide the ANSM on request with access codes or details of any other secure procedures required to access their websites.

1.2.5 Online medical visits/canvassing

Online sales canvassing in general, and medical visits in particular, are conducted on screens, which means that at any time during the meeting, the medical sales representative and the healthcare professional are viewing the same screen simultaneously.

For medicinal products, this method may be used subject to compliance with the following conditions:

- the status checking and validation of healthcare professionals is completed prior to allocating a 'single use' personal access code,
- an ANSM visa is in place to cover the content presented,
- the website concerned is structured in accordance with this charter,

- the mandatory information and transparency notices for the proprietary medicinal product concerned are accessible at all times via a hypertext link throughout the online presentation
- a document containing the information specified in Article R.5122-11 of the French Public Health Code must be sent by e-mail or post after every such visit
- the visit must be conducted by persons qualified in accordance with the provisions of Article L.5122-11 of the French Public Health Code
- in accordance with Article R.5122-10 of the French Public Health Code, where the advertising relates to medicinal products subject to prescription directions, canvassing is limited solely to those prescribers permitted to issue prescriptions and pharmacists working in facilities where the medicinal product concerned is likely to be dispensed

For MDs, this method may be used subject to compliance with the following conditions:

- the status validation of healthcare professionals is completed prior to allocating a 'single use' personal access code
- ANSM authorisation of content relating to those MDs that require such authorisation
- the website concerned is structured in accordance with this charter
- the mandatory information is visible during the online presentation

1.3 Non-promotional sections of websites

1.3.1 Corporate information

In accordance with the relevant legal and regulatory provisions and ANSM recommendations, the corporate information provided must be scientific, technical or financial in nature (e.g. the company's annual report) and must not have the purpose of promoting a medicinal product or medical device.

Corporate information must be distinct from promotional information and be clearly identified as such, at least on the website homepage/introductory page.

The corporate information concerned may then be made accessible to the public at large.

1.3.2 Human health information

In accordance with the relevant legal and regulatory provisions and ANSM recommendations, information on human health or on human diseases falls outside the definition of advertisement provided that there is no reference – even indirect – to any medicinal product or medical device.

The relevant information on human health may then be made available to the public at large.

Comment:

Where a website is dedicated to a specific disease or illness, the presence of a 'products' section (as described in 1.3.3) featuring medicinal products and/or medical devices marketed by the operator for use in treating the disease or illness concerned, the fact of associating these products with information relating to treatment makes the website inherently promotional. It then falls within the scope of advertising supervision and must therefore comply with all the relevant regulations.

1.3.3 Product information

For medicinal products:

Operators may use an exclusively dedicated section of a corporate website to list all or some of their proprietary medicinal products, in which case they must distribute the following reference documents for non-promotional purposes: the summary of product characteristics (SPC), the pack leaflet, all transparency information and, where applicable, the Prescribing Information (FIT) for exceptional

medicinal products. The European Public Assessment Report (EPAR) in its original EMA version and the Public Assessment Report (RAPPE) may also be reproduced in full in this section of the website.

Where the risk-benefit ratio of the medicinal product concerned is in the process of reassessment as a result of a pharmacovigilance notification, this fact must be made clear by providing, where available, the most up-to-date information available from the ANSM or EMA.

The status of the medicinal product regarding reimbursement by health insurance bodies or approval by public authorities, as well as any retail price ceiling imposed by applicable laws and regulations (accompanied, where possible, by the cost of daily treatment) may also be displayed together with the official information, e.g. be inserted at the end of the online summary of product characteristics.

The status of proprietary medicinal products registered in the directory of generic groups and of the reference proprietary medicinal product may be displayed.

This information may also be made available by means of a link to the [public database of medicinal products](#).

Photographs of the packaging and pharmaceutical forms of a proprietary medicinal product may be displayed in association with the corresponding reference documents in a non-promotional way.

Documents developed as part of the Risk Minimisation Plan (e.g. videos or documents explaining the procedures for product reconstitution or administration) may also be included in this section as an extension of the communication plan validated by the ANSM. Where appropriate, a statement should be included to encourage patients to consult their healthcare professionals if they have not been provided with these resources or documents, since they are designed to work in parallel with the process of dialogue with healthcare professionals, rather than replace them.

This section of the website must be dedicated exclusively to the dissemination of this non-promotional content, and the viewing, ordering or downloading of these documents must not be accompanied by any encouragement to order documents of any other type (medical or promotional information).

For MDs/AIMDs/IVDs:

Operators can use an exclusively dedicated section of a corporate website to list all or part of their products and provide their key technical features, as shown in their directions for use or on their labels. This information must be factual, balanced and free of any promotional or other claims designed to highlight a particular characteristic. The directions for use, photographs of the device and/or its packaging, a diagram of the device, the tax-inclusive price and the HAS CEPP (Committee for the evaluation of products and services)/CNEDiMTS (Medical Device and Health Technology Evaluation Committee) recommendations may also be published online in a non-promotional way.

Documents of a non-promotional nature as described by the ANSM in its recommendations may be made available online as long they do not refer to the fact that the medical device concerned is covered, in whole or in part, by the compulsory health insurance schemes or by a private health insurance.

This section of the website may offer online sales, subject to compliance with the specifications and content of the kind of sales catalogue described in the relevant ANSM recommendation, and compliance with the regulations governing pharmaceutical monopolies or monopolies involving certain other professions.

The products shown on online sales sites may or may not be reimbursable. Information regarding their reimbursement status must then be displayed no later than the point at which the sale is transacted.

1.3.4 Safety information

The information used to convey warnings about any adverse reactions observed as a result of pharmacovigilance, medical device vigilance and/or in-vitro medical device vigilance may be presented and made available to all users in a dedicated section of the website, subject to compliance with the regulations governing the communication and submission of such information to the ANSM.

A link to this safety information may be inserted in the "products" section of the website or the promotional pages. On the other hand, this section may link only to the product section and under no circumstances to promotional pages.

Where an operator gives users the opportunity to report adverse reactions via its website, a link to the ANSM website reporting portal must also be included.

1.4 Non-promotional services

On the basis that the regulatory constraints provided for in Article L.4113-6 of the CSP are fully complied with, website visitors may also be offered a number of other services. These services must not be promotional in nature and must comply with the following conditions.

1.4.1 Correspondence

Correspondence groups together any request for an answer to a specific question. As such, correspondence is excluded from the CSP definition of advertising.

The provision of a mailing space containing one or more points of contact may therefore be provided, as long as:

- it occupies the "services" section of the website and is appropriately named for inclusion in this section,
- there is no incentive to request specific information about a healthcare product,
- users are not offered a pre-prepared list of documents available to order.

1.4.2 References

Only reference bibliographic databases (PubMed or similar) can be made accessible to the general public using hyperlinks.

In addition to the reference bibliographic databases, healthcare professionals may be offered other bibliographic databases.

These databases may cover only one field, one condition or one indication. Under no circumstances may a database be linked exclusively to a single medicinal product, medical device or product range.

Bibliographic requests from healthcare professionals must originate proactively from the latter and are therefore treated as correspondence. To avoid this service becoming analogous with promotion, it may under no circumstances suggest a request by, for example, distributing a list of available abstracts. However, it may provide a mailing space (without pre-selection form) that healthcare professionals can use to enter a precise request.

1.4.3 Discussion forum

Operators offering this type of service are expected to effectively moderate discussions to avoid any possibility of raising doubts about the proper use of the healthcare products mentioned.

Deferred moderation is the minimum level required, and is the responsibility of the operator, which must ensure that sufficient resources are available to guarantee that comments which contravene current regulations are removed within 24 working hours.

Simply implementing a charter or giving users the opportunity to report abusive forum use is not acceptable given the level of risk posed by allowing comments that contravene current regulations to remain.

Where discussion forums and personal contribution spaces are hosted on a third-party website, the operator may occasionally intervene in a discussion regarding one of its products to correct inaccurate information by providing links to the summary of product characteristics or pack leaflet. However, this response must not have the effect of promoting the medicinal product or medical device concerned.

1.4.4 Conferences

With the exception of advertorials, which are the responsibility of the publishers and their peer review committee, conference abstracts and/or minutes can be obtained via a link to the website of the publisher or conference concerned. However, such conference abstracts or minutes produced by an operator may not be disseminated outside the promotional sections of their websites if they mention one or more of their products.

1.4.5 Press reviews

Press reviews, summaries or overviews produced at the request of an operator and mentioning one or more of its products (including where only the active substance (INN) of a medicinal product is cited) may not be published in the “services” section of its website.

However, where they do not refer to a specific medicinal product or medical device, they may be published online and made accessible to the general public subject to compliance with current legislation governing press reviews and overviews.

1.4.6 Press packs and press releases

Press packs and press releases showcasing medicinal products or medical devices may be published online only if access restrictions are implemented to ensure that they are accessible only to journalists or editorial staff (e.g. by allocating an access code reserved specifically for the use of these press professionals).

Corporate press packs and press releases may be made freely accessible.

1.5 Website features

1.5.1 Domain name

The domain name is an integral part of a website and, as a communication channel for the website, it must comply with the advertising-related provisions of the CSP.

Where a domain name includes the name of a medicinal product or medical device that is not permitted to be advertised to the public, the website homepage must ensure secure access. In terms of medicinal products, this provision does not apply to websites created as part of a risk management plan (which may then present only the information provided for in this context). In terms of medical devices, it does not apply to websites offering MD-specific documents of a non-promotional nature, as described by the ANSM in its recommendations (technical data sheets, training in the use of a medical device and patient documents explaining its proper use).

A website whose domain name reflects the name of a healthcare product may not present other products that share the same name, and especially not those with a different status (e.g. a publicly accessible website bearing the name of a medicinal product may not present a cosmetic product under the same domain name). This provision does not apply to product-related accessories and consumables.

Nevertheless, a website may present a range of products of different statuses (in the form of an umbrella brand), in which case the domain name must include the word “range” in conjunction with the root shared by the name of all these products, where applicable (e.g. www.XXXRange.fr). Such websites must meet the requirements set out in paragraph 1.2.1 regarding the need to prevent misleading users about the nature of the product.

1.5.2 Hyperlinks

Hyperlinks must not be deliberately or effectively used for the purpose of undermining advertising regulations.

Simple links target the website homepage. Generally speaking, a simple link should be used when linking to a third-party website to prevent interfering with the active input of the user when browsing the Internet.

Deep links take users to a secondary page other than the homepage. They make it possible to link to any page of a publicly accessible official website. When used as links to peer-reviewed journal websites, they may provide direct access to the summary pages. When used as links to conference websites, they may provide direct access to the conference programme pages. When used as links to other websites operated by the same company, they may provide direct access to non-promotional pages or information on issues such as sustainable development, corporate foundations, financial data, etc.

It must be made clear to users that they are linking to a different website, either by displaying a message to indicate a change of website, or by opening a new web browser tab.

Operators are responsible for the first level of links created to external websites.

The websites linked to may be - for example - another website operated by the same group, the website of a learned society, a conference website, a corporate website, a medical/scientific press website or a patient association website.

Where hyperlinks redirect users to websites specifically intended for healthcare professionals, the referring website may under no circumstances provide the access codes or other secure procedures allowing access to the destination website. It remains the responsibility of each website to ensure that its own access methods are secure, except when linked websites show the same authentication service.

1.5.3 QR codes

A QR code (short for “Quick Response” code) is a two-dimensional barcode that provides direct access to website multimedia content (video, audio, photographic and/or information) on a website when scanned with a smartphone.

Its inclusion in an advertisement for a healthcare product is permitted when the target website complies with this charter and has a valid authorisation from the ANSM where one is required.

1.5.4 Profiling

Profiling, particularly that which uses “cookies” to recognise website visitor browsing habits and preferences to personalise the information presented on the basis of their browsing pathway, is not recommended. Operators are referred to the deliberations of the CNIL (the French data protection agency) on this subject matter and the various Codes of Good Practice (BPRs) and recommendations implemented by the industry.

1.5.5 Archiving

The website publisher has a number of archiving responsibilities, particularly:

- the archiving of promotional data uploaded to the website
- the archiving of user identification data (access codes and ID) in accordance with Law 78-17 of 6 January 1978 (the French data protection act).

2 Other online media

2.1 Website banners and pop-ups

These media may present summary information on the sole condition that all the mandatory information required by the CSP is clearly displayed in the hyperlinked pages: as a minimum, these media must display the name of the healthcare product, its purpose or indication, its status (medical device or medicinal product) and, where appropriate, an age limit.

2.2 Sponsored commercial links

Commercial links enable brands and/or products to feature prominently on search engines by purchasing keywords that associate a search engine query with the display of this commercial link (title and short description) at the top or on the right-hand side of the results page.

Where a commercial link directs users to an advertisement for a medicinal product or medical device, it must be constructed in accordance with the content of the promotional pages targeted. For this purpose, operators agreed to use only advertising claims taken from the promotional pages targeted and use only terms from these pages as keywords.

These media may present reduced information on the sole condition that all the mandatory information required by the CSP is clearly displayed on the hyperlinked pages, which must also comply with this charter and have a valid authorisation from the ANSM where one is required. Since the number of characters that can be used in these links is limited, these media must contain at least the name of the health product and its status (medical device or medicinal product).

2.3 e-mailings

Promotional e-mailings must comply with the provisions of Chapter II, Title II of Law 2004-575 of 21 June 2004 on trust in the digital economy (Articles 20 to 24).

Promotional e-mailing of members of the public is permitted only where users has previously given their consent to receive healthcare product advertising.

Wherever users are offered the option to receive iterative newsletters by e-mail, they must also be offered the opportunity to unsubscribe at any time.

2.4 Public social media

The functionalities offered by public social media channels (Facebook, Twitter, YouTube, etc.) enable page content to be linked to comments and messages whose content is unrestricted and uncontrollable (especially in terms of the sharing function).

Furthermore, where the “[x] people like” feature, which displays the number of people who pressed the “like” button on the page is used for a healthcare product, the impression can be created that there is a general consensus that the product provides a cure. When used in connection with a healthcare professional, it can imply a guarantee, which is therefore contrary to the French Public Health Code.

So given the features of today’s social media and the way they are currently used, they cannot be used to promote healthcare products (medicinal products and medical devices) to the general public by means of a “product” page unless such functions can be disabled by the operator.

Similarly, it is not permitted to share a website promotional page on a public social media channel using the sharing function.

“Environmental” communications and/or discussions relating to services, advice, or conditions, when intentionally dissociated from one or more health products, do not fall within the scope of this charter.

For more details on the use of social media in the form of closed discussion groups exclusive to healthcare professionals, see section 1.4.3 Discussion forum.

3 Smartphones/tablets/other mobile devices

3.1 Mobile apps

Application download platforms such as the Appstore® or GooglePlay® give users the opportunity to comment on, and rate, these apps, recommend them to others by e-mail or share comments on social media. The functionalities inherent to this type of application downloading technology, which enable advertising to be linked to comments and messages whose content is unrestricted and uncontrollable, is not compatible with the granting of advertising authorisation as required by the CSP.

So given the current terms of use applied by these download platforms, it is not possible to promote healthcare products (medicinal products and medical devices) to the general public in the form of smartphone and/or tablet apps that can be downloaded from these platforms, unless the functions referred to above can be disabled by the operator. The possibility to download directly from the operator's own website is available, subject to compatibility with the operating system of the smartphone or tablet used.

Nevertheless, non-promotional apps specific to a particular healthcare product and intended solely to ensure the proper use of that product and/or required to accompany treatment may be considered, provided that the operator can ensure that their use is restricted, either via the download access procedure, or, where the app is activated by the patient using the treatment or by family members, by using a code printed on the label (the batch number or other code) or provided by the prescriber.

Promotional apps intended for use by healthcare professionals may be offered where the operator is able to ensure that only they can access them, either via the download access procedure, or, where the app is activated by the healthcare professional, by using the same security procedures as for promotional web pages or using an access code provided by the operator.

Apps offering services, advice or information on conditions, where intentionally dissociated from one or more health products, do not fall within the scope of this charter.

The presence of certain functionalities is likely to bring an app within the scope of the definition of medical devices (article L.5211-1 of the CSP).

Operators are referred to the recommendations of the CNIL regarding the user personal data protection (contacts, geolocation, etc.).

3.2 Mobile interstitials

Smartphone and tablet advertising may take the form of mobile interstitials (intermittent display of advertising at start-up or between app screens) or mobile banners (permanently displayed at the top or bottom of an app screen). It is important to ensure that the mandatory information remains clearly legible when using this medium.

Nevertheless, using an interstitial to promote a health product within a "health" app published by the same operator - a product specifically designed to treat a particular condition, for example - is likely to give the app concerned a distinctly promotional character, especially where it uses clearly takes its inspiration from the app graphic style, thereby raising doubts about its overall suitability for distribution in light of the considerations referred to in 3.1.

3.3 Mobile websites

The alternative to using apps is to create a mobile website that optimises browsing on these devices.

ANSM authorisation must be sought for any new promotional website presenting products for which authorisation is required.

Mobile websites developed using responsive design technology (providing automatic adaptation of display to suit the device used) must offer the 2 or 3 browsing options simultaneously in response to the initial request. Each version of the homepage must be offered, while the rest of the website content remains strictly identical regardless of the browsing option selected.

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11. Trade press relations



Specific rule: Leem wanted to confirm its determination to ensure that only high-quality, accurate information is published in the press, and particularly the medical and health trade press.



Medicinal product information and advertorials

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Foreword

The medical and healthcare trade press - hereinafter referred to as the “medical press” - is a preferred space for communication between the broad diversity of partners across the medical world.

The French Advertising Union (*Union des Annonceurs* - UDA) and the French Press and Publishing Union of Healthcare Professionals (*Syndicat de la Presse et de l'Édition des Professions de Santé* - SPEPS) wanted

to define and promote a set of rules for adoption by their members to ensure good conduct in the best interest of readers.

More specifically, their intention was to define good conduct rules to guide the preparation and publication of editorial content reporting on the activities of healthcare companies - hereinafter referred to as “advertisers” - and/or their products, where this content is included in French medical press publications.

For this purpose, they extended the provisions first drawn up in 1967 as an “Ethics charter for pharmaceutical advertising in the medical press” (see Appendix I) by drafting a new ethics text in November 1989 entitled “Medicinal product information and advertorials”, which was subsequently revised in May 1993, November 1996, March 2001, June 2008, June 2011 and 2015.

Having fully supported this document since 2007, Leem (*Les Entreprises du Médicament*) wanted to be fully associated with its content by becoming a signatory to this eighth edition.

The recommendations that follow are inspired by compliance with these fundamental principles:

- Freedom of the press
- Readers’ entitlement to receive accurate information
- Advertiser control of their own communication

•••

Introduction

The signatories have adopted the following provisions:

Chapter I Editorial information independent of any contractual relationship between publisher and healthcare company advertiser

Chapter II Authored publications produced by a publisher with support from a healthcare company, and publications intended to support the training of healthcare professionals, with support from a healthcare company

Chapter III Information produced under a contractual relationship between a publisher and an advertiser formed for promotional purposes (advertorial content)

Chapter IV Oversight of agreements

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Chapter I

**Editorial information independent of any contractual relationship
between publisher and healthcare company advertiser.**

Section A - General provisions

Article 1

Definition

This chapter covers content published in medical publications for healthcare professionals and reports on the activities of healthcare companies, their scientific work, therapeutic studies, product launches and/or product life through conferences and press releases, books, video productions, etc. independent of any contractual relationship between the publishing journal and the healthcare company - or companies - concerned.

Article 2

Obligations of healthcare company advertisers

- a) Advertisers must not be involved in the editorial process of a media title; responding to requests from editors does not constitute involvement for the purposes of this text.

Similarly, advertisers must not make any connection between the existence or size of the editorial content referred to in this chapter and any financial or commercial advantage whatsoever

- b) When providing technical information to journalists, advertisers should not require the publisher of the journal to provide a final proof copy of the article
- c) Where a healthcare company wants to point out an error in an article reporting on one of its events, it may, depending on the circumstances, request a simple correction or exercise its legal right of reply (Article 13 of The Law on the Freedom of the Press of 29 July 1881).

Obligations of publishers

- a) Publishers must not accept, for publication, any editorial content provided by healthcare companies, with the exception of that produced by authors and researchers in the normal course of scientific publications
- b) To ensure that readers receive full information, every type of article referred to in this chapter must make clear reference to the source of the information by stating event dates and locations, for example
- (c) Publishers must not make any connection between the existence or size of the editorial content referred to in this chapter and any financial or commercial advantage
- (d) All articles must be signed or initialled in such a way as to enable identification of their authors. Where content is authored by healthcare professionals, they must make reference to their links and interests⁴⁹
- (e) Whether written by journalists or external authors⁵⁰, all articles published in a press title within the meaning of Chapter I of this Agreement will remain the responsibility of the publication manager
- f) Any presentation of a **clinical or pharmacological study**⁵¹ requires the publisher (Chapter I and Chapter II) to accept full responsibility for ensuring that the rules of transparency set out in the French Public Health Code⁵² are fully applied.

Section B - Press conferences

⁵⁰ See definition in Appendix 1

⁵¹ As defined by the French Public Health Code (especially Articles L1121-1 and subsequent, and those provisions applying to biomedical research and supplemented by regulatory provisions).

⁵² Article L.4113-13 of the French Public Health Code implemented under the terms of Article 26 of Law 2002-303 of 4 March 2002 on patients' rights and health system quality. "Members of the medical professions who have links with companies and other businesses involved in the manufacture or selling of healthcare products, or with consultancy firms working with such products, are required to disclose these relationships publicly when speaking about such products at a public event or communicating in the printed press audiovisual media. The implementing conditions for this Article are set by Council of State decree.

Failure to comply with the rules referred to above will be punished by the imposition of sanctions by the appropriate professional body.

Article 3

Healthcare companies should use press conferences only for the most important announcements

It is important to remember the need to choose press conference topics with extreme care.

Examples of important topics for which a press conference would be appropriate include, but are not limited to, the following:

- original research undertaken by a healthcare company
- the development of a new molecule
- the results of clinical trials
- epidemiological, morbidity/mortality, health economic studies, provided they comply with good professional practice
- changes in pharmaceutical form or administration pathway delivering a justified improvement in the medical service provided; e.g. improved bioavailability, greater tolerance, faster efficacy and/or better patient compliance
- economic and financial results or the announcement of production restructuring
- the official opening of a new research centre or production unit
- etc.

It is therefore incumbent on healthcare companies to be selective in their choice of topics for press conferences hosted to update the therapeutic and socio-economic knowledge of the medical profession, and on publishers to attend press conferences on the basis of how useful the information provided will be for their readers.

It is in the best interests of **both parties** that no press conference and/or its proceedings be construed as, or confused with, an advertising approach.

Article 4

Press conference invitations should be addressed to the editorial staff of newspapers and journals

Publishers agree that when invited to attend press conferences, they send editors whose expertise enables them to participate actively in the event and report on the information presented, even if they are not necessarily accredited press cardholders.

Article 5

The function of the press pack.

The information provided during the conference is supported by data, scientific publications and/or study results, the references of which are included in the press pack.

Editors attending a press conference should treat the press pack as a working document.

The press conference summary provided by the host healthcare company must not be simply reproduced in its original form.

Press conference reports are signed by the journalists who have drafted them. Sources of information must be specified.

Editors covering press conferences should make their own independent analyses of the proceedings.

Article 6

It may be sufficient simply to issue press releases

A healthcare company may simply issue press releases to the managing editors of medical journals for topics that do not warrant their own dedicated press conference.

Publishers remain responsible for publication of text abstracted from press releases, which must be signed by the editor, together with an acknowledgement of its source.

Chapter II

Authored publications produced by a publisher with the corporate support of a healthcare company, and publications intended to support the training of healthcare professionals, with support from a healthcare company

Article 7

Definition

This chapter covers special editions (special issues or supplements) for healthcare professionals drawn up at the initiative of the publisher and its peer review panel, which remain solely responsible for their content. Where such editions are sponsored, the contractual relationship must guarantee the independence of the publisher. The purpose of such editions is to update knowledge on general health issues, such as a condition or therapeutic field, and not to promote a medicinal product

Article 8

Scientific information provided at meetings and conferences⁵³

During medical or pharmaceutical conferences with an independent scientific committee, or meetings organised under the aegis of learned societies or groups of experts appointed by them, which outline the progress made in research, medical press publishers may publish special editions combining all or part of the work presented, in an effort to inform healthcare professionals.

Where these special editions present data from research not validated by the French authorities, they must contain a warning to that effect on the first page⁵⁴.

The publication of these special editions and their content is the responsibility of the publishers and their peer review board. These publications may contain advertising inserts to the exclusion of advertising of the products mentioned in these documents and for which off-label information would be provided. The distribution of these special editions and the selection of the healthcare professionals involved on the basis of their expertise in the topic(s) covered are the exclusive responsibility of publishers.

Since articles in these special editions would provide scientific information off-label about pharmaceutical products with no MA, their promotional use in medical sales visits would be prohibited.

⁵³ This text was developed in conjunction with the French National Agency for Medicines and Health Products Safety (ANSM) and approved by its Commission de Contrôle de la Publicité et de la Diffusion de Recommandations sur le Bon Usage des Médicaments (the committee responsible for advertising oversight and issuing recommendations on the proper use of medicinal products) on 9 November 2000.

⁵⁴ "First page" means either the outside cover, inside cover or the page facing the contents. This warning must be displayed in such a way as to ensure its legibility.

Article 9

Publications intended to support the training of healthcare professionals, with support from a healthcare company.

When a publisher produces a publication intended to support the continuing education of healthcare professionals, and the publication concerned is drawn up under the supervision of a peer review panel and/or a learned society, it may be sponsored by a healthcare company, subject to compliance with the relevant terms of the Leem Rules of Professional Conduct⁵⁵.

Where these editions present data from research not validated by the French authorities, they must contain a warning to that effect on the front page.

Article 10

These special editions must make clear the fact that they are sponsored. The name of the sponsoring healthcare company must be shown legibly on the first page⁵⁶.

Chapter III

Information produced under a contractual relationship between a publisher and an advertiser formed for promotional purposes (advertorial content)

Article 11

Definition

This chapter covers texts validated by an advertiser and published in publications intended for healthcare professionals, where the articles concerned report on the activities of healthcare companies, their scientific work, product launches and/or product life, where publication of these texts is covered under the terms of a contractual relationship between the publisher and the advertiser formed for promotional purposes.

Any promotion of a medicinal product contained in these texts must comply with the advertising obligations arising as a result of the provisions of the French Public Health Code and other applicable laws and regulations.

Article 12

Origination of advertorial texts

Advertorials may be written by:

1/ the editorial team of the publication

Where this is the case, the content must be accompanied by the signature(s) of its author(s). The initial insert of the article for publication is reviewed jointly with the sponsoring healthcare company, and a final proof copy submitted for validation.

2/ the healthcare companies

⁵⁵ See the CME code of good practice signed in November 2006 by Leem and the Minister for Health and Solidarity contained in the Rules of professional conduct applicable to Leem member companies (DDP - January 2014) (p.29). Please note: this code of good practice is not included in the new DDPs applicable to Leem member companies from January 2015 onwards. The Charter Oversight Committee has set up a working group on this subject matter.

⁵⁶ The first page means either the outside cover, inside cover or the page facing the contents. This warning must be displayed in such a way as to ensure its legibility

When texts covered by this chapter are drawn up directly by a healthcare company and submitted to the journal for publication, whether signed or otherwise, the healthcare company and the accepting publisher are equally responsible for its content.

3/ external writers⁵⁷

Where the texts covered by this chapter are written by medical teams that are not employed by healthcare companies or publishers, they must be signed by their authors. Such articles may, with the author's agreement, be covered by a commercial contract between a publisher and an advertiser.

The concept of the text to be published is considered in conjunction with the sponsoring healthcare company, which must receive a final proof for review and validation.

When texts submitted for publication have been published previously outside the terms of any commercial contract and to ensure copyright compliance, reference must be explicitly made to the original publication details at the beginning or end of the article⁵⁸. In no way do such references relieve the advertiser of responsibility, particularly with regard to the fact that no advertising text is permitted to highlight off-label indications.

Article 13

Marking of advertorial texts

The texts referred to in Article 11 must be preceded by the wording:

Information provided by healthcare company X

or

Information provided in conjunction with healthcare company X

The advertising nature of these texts imposes the requirement to comply with the advertising-related obligations imposed by the French Public Health Code and all current legislation and regulation, especially the inclusion of the regulatory information when the communication concerned relates to one or more medicinal products.

Article 14

Advertorials containing comparisons

All comparisons made between identified or clearly identifiable products as part of an advertorial article must comply fully with the provisions of Articles L121-8 and subsequent of the French Consumer Code and its implementation of Directive 2006/114/EC concerning misleading and comparative advertising.

Chapter IV

Oversight of the charter

Article 15

The members of all three signatory organisations are individually required to comply fully with this text.

Signed by the *Union des Annonceurs* (UDA), the *Syndicat de la Presse et de l'Édition des Professions de Santé* (SPEPS) and Leem, this charter instigates the formation of a committee responsible for overseeing its application.

⁵⁷ See definition in Appendix 1

⁵⁸ This reference, which is included for the purpose of informing readers, does not exempt the secondary publisher from the obligation to seek and secure the permission of the author and/or original publisher.

This oversight committee will include two bodies: one representing healthcare company advertisers with four representatives of UDA members and four representatives of Leem members; the other representing publishers, with eight members representing SPEPS publishers. Members are appointed for a 1-year term. Publishers' representatives may be reappointed by the SPEPS Board of Directors, and healthcare company advertiser representatives by the UDA Pharmaceutical & Healthcare Industry Committee and the Board of Leem. Each representative will appoint a deputy from within their own organisation to represent them if and when necessary.

The committee is also assisted by an expert advisory committee whose five external members have in-depth experience of the pharmaceutical and publishing industries but are no longer employed by them. This advisory committee has responsibility for reviewing articles published in the medical press - regardless of form and medium - and assessing their compliance with the provisions set out in this charter.

The tasks, organisational structure and procedures of the Oversight and Advisory Committees are set out in Rules of Procedure adopted by the Boards of Directors of all three signatory organisations to this charter, are appended to it, and may be revised subject to the same conditions.

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Appendix I

Definitions

Author:

For the purposes of this charter, an author is understood to be any person, whether a professional writer or otherwise, who is independent of the editorial staff of a publication and publishes under their own name a text commissioned by a press publisher or advertiser in return for payment. Once published, responsibility for the article lies with the publication manager.

Healthcare company: A company whose business involves healthcare products.

Publication

A press title subject to the provisions of the French Press Law of 1 August 1986. Its publication frequency can range from daily to quarterly.

This title includes a main publication with a peer review panel, which may be accompanied by supplements, special issues, or special editions.

Supplement

In accordance with Article D27 of the French Postal and Electronic Communications Code, a supplement to a periodical is defined as any separate publication appearing periodically or constituting an extension of the main publication due to the abundance of subject matters addressed, or which is intended to supplement or illustrate the text of the main publication.

The supplement may travel through the postal system separately from the periodical to which it relates. Where this is the case, the supplement must meet the same substantive and formal requirements as the main publication. More specifically, a supplement must be clearly marked "supplement" on its cover page. It must also show the title, date, and issue number of each publication to which it relates.

The number of copies distributed may not exceed that of the publication(s) it complements: it may not be sold separately, be the subject of a separate subscription or distributed free of charge unaccompanied by the main publication.

Special Edition or Special Issue

In accordance with Article D27-1 of the French Postal and Electronic Communications Code, any publication offered to the public outside its normal publication date to mark a major event or occurrence is considered to be a special issue or special edition of a periodical.

The special edition or issue must comply with the same requirements of substance and form as the main publication. It must be clearly marked “special issue” or “special edition”.

Nevertheless, one issue per year for quarterly publications and two issues per year for those published more frequently may be devoted to a single theme, provided that the subject matter has a clear link with the usual content of the main publication.

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Appendix II

The legislative, regulatory and industry texts on which the “Medicinal product information and advertorials” charter is based, and which are referenced by it

- Ethics charter for pharmaceutical advertising in the medical press (UDA/SNPM - 1967)
- FNPS Professional Rules (1985)
- French General Tax Code (Article 72, Appendix III)
- French Postal and Electronic Communications Code - Art. D.18 to D.20; art. D.27 and D.27-1
- French Law of 1 August 1986 reforming the legal status of the press
- SPEPS articles of association and rules of procedure
- Code of Ethics for Pharmaceutical Communication 1985 (National Chamber of Pharmacists, UDA and SNIP)
- Recommendation sheets - Advertising and proper use of medicinal products (the French National Agency for Medicines and Health Products Safety (ANSM) committee responsible for advertising oversight and issuing recommendations on the proper use of medicinal products). All these recommendations are available online at the ANSM website (<http://ansm.sante.fr/>)
- Legislative and regulatory provisions of the French Public Health Code in relation to the advertising of medicinal products, particularly Art. L.5122-1 and subsequent, L5422-3 and subsequent and R.5122-1 and subsequent
- Good practice commitments governing relationships between pharmaceutical companies and the medical press - Leem - SNPM - July 2007.
- Rules of Professional Conduct applicable to Leem member companies

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Appendix III

RULES OF PROCEDURE

SPEPS-UDA-Leem Charter Oversight Committee

Medicinal product information and advertorials

1. Oversight committee

a. Composition

The **oversight committee** is composed of two bodies. The first has eight members (and their deputies) representing publishers. The second represents healthcare companies as corporate entities and as advertisers. Four of its members (and their deputies) represent legal entity members of the UDA, while the remaining four members (and their deputies) represent legal entity members of Leem.

The members of the **oversight committee** are appointed for terms of one year, and may be reappointed. Each deputy member is employed by, and represents, the same legal entity as the member for whom he/she deputises.

UDA member representatives are appointed by the UDA Pharmaceutical & Healthcare Industry Committee, and publishers' representatives by the SPEPS Board of Directors. The four titular representatives of Leem and their deputies are appointed by the Board of Leem. One of these representatives also represents manufacturer members of Codeem. They are employed by legal entities other than those that employ the representatives appointed by the UDA Pharmaceutical & Healthcare Industry Committee.

The Chairman and Vice-Chairman of the **oversight committee** are elected by the members for a period of one year. The Chairmanship and the Vice-Chairmanship alternate annually between the two bodies.

The members of the **oversight committee** are bound by the strictest obligation of confidentiality. The same applies to the staff of the signatory organisations who attend meetings and take the minutes.

b. Mission

In accordance with Article 15 of the Charter - "Oversight of the Charter", the purpose of the **oversight committee** is to oversee application of the Charter by the members of its signatory organisations.

The purpose of this **oversight committee** is both informative and preventative. It achieves this purpose by preparing regular reports on the progress made in ensuring compliance with the provisions of the Charter by the medical and healthcare trade press (hereinafter referred to as medical publications), regardless of format and medium. These findings will underpin information campaigns designed and run to ensure effective application of the Charter.

The **oversight committee** also has a role to play in developing the good practices set out in the SPEPS-UDA-Leem Charter in accordance with the rules set out below.

For this purpose, it relies on the analytical work done by an independent **expert advisory committee**.

2. Expert advisory committee

a. Composition

The **oversight committee** is supported by an **expert advisory committee** of five external members who have in-depth experience of the pharmaceutical and publishing industries but are no longer employed by them. Each of these expert advisers must disclose their links and interests in terms of their relationship with publishers and/or pharmaceutical companies over the previous three years.

For this purpose, the term "interests" covers any and all financial, professional or family connections between the expert adviser, medical publications and/or healthcare companies. The links and interests that expert advisers are asked to disclose are the same as those detailed in the standard document for the public disclosure of interests provided for in Article R. 1451-2 of the French Public Health Code.

Membership of this committee is proposed by the **oversight committee** and ratified by the SPEPS Board of Directors, the UDA Pharmaceutical & Healthcare Industry Committee and the Board of Leem. Members are appointed for two years and may be reappointed. The members of the committee elect their chairman by majority vote. The members of the expert advisory committee are bound by the strictest obligation of confidentiality.

Staff members of signatory organisations attend, organise and provide secretarial services for **expert advisory committee** meetings. These staff members are bound by the same obligation of confidentiality as expert advisory committee members.

b. Mission

The **expert advisory committee** has responsibility for reviewing articles published in the medical press and assessing their compliance with the rules set out below.

3. Operation

- The **expert advisory committee** meets three times a year in plenary session. The schedule of meetings for the following year is prepared at the end of each year. Extraordinary meetings may be convened by the **expert advisory committee**.

The **expert advisory committee** meeting agenda includes reviewing articles published in the medical press solely to assess their compliance with the provisions of the “Medicinal product information and advertorials” charter.

The **expert advisory committee** may assess the degree to which any main publication, supplement and/or special editions of medical publications involving a member of the UDA, Leem or SPEPS comply with the provisions of the “Medicinal product information and advertorials” charter. This assessment will be made on the basis of a reading guide. This **reading guide** may be modified only subject to the agreement of the members of the Pharmaceutical & Healthcare Industry Committee, the Board of Leem and the SPEPS Board of Directors.

In the event of a conflict of interest regarding a publication or article for review, the expert adviser concerned will withdraw from reviewing that publication or article. A conflict of interest is a situation in which the nature or intensity of the links and interests of the expert adviser concerned have the potential to raise doubts regarding his or her impartiality or independence when reviewing the publication or article submitted for assessment.

The oversight committee implements a matrix for identifying and managing such links and conflicts of interest.

The assessment of compliance with the provisions of the said charter must cover a wide variety of medical publications in terms of intended audiences (those publications that target specialists, general practitioners and/or other healthcare professions) and frequency of publication (daily, weekly, etc.). The expectation is that each of the expert advisers on the committee should assess 7 publications per year.

The **expert advisory committee** is assisted in its work by the **oversight committee** providing it with an indicative list of publications for review and assessment.

Following assessment by the **expert advisory committee**, articles appearing in medical publications are classified into the following three categories:

- publications and articles that comply fully with the recommendations of the charter,
- those that contain minor deviations,
- Those that do not comply with the charter.

The classification decision is taken by a majority vote of expert advisory committee members. In the event of a tied vote, the Chairman has the casting vote. The classifications of individual publications or published articles remain strictly confidential.

The publisher and/or healthcare company responsible for, or associated with, a publication or article considered as containing minor deviations or failing to comply with the charter following this initial review by the expert advisory committee will receive a notification of the rules set out in the charter for educational purposes. This notification will be sent by the expert advisory committee through a staff member of the signatory organisation of which the publisher and/or healthcare company concerned is a member. Recipients of such notifications may respond verbally or in writing to the expert advisory committee, which may then, in light of observations made, modify its classification of the publication and the related reading guide. The publisher or healthcare company concerned is then informed of the classification adopted

Furthermore, where there are corroborative indications of serious breach of the charter by a publisher or a healthcare company, the expert advisory committee informs the SPEPS Board of Directors and Codeem via its Permanent Secretariat:

- Where there are corroborative indications of serious breaches by a publisher, the committee forwards the anonymised information to the SPEPS Board of Directors, which may then refer the matter to the SPEPS Ethics Committee to determine the severity of the misconduct concerned and, where necessary, recommend a sanction to be imposed by the SPEPS Board of Directors in accordance with SPEPS rules of procedure. Where this is the case, the Ethics Committee will receive all the relevant documents.
- Where there are corroborative indications of serious breaches by a pharmaceutical company, the expert advisory committee passes all the relevant documents to Codeem via its Permanent Secretariat so that a full investigation can take place and, where necessary, the company concerned can be sanctioned in accordance with Leem rules of procedure.

The UDA Management Committee is informed of the anonymised case details, together with confirmation that the pharmaceutical company concerned is one of its members.

- The “Medicinal product information and advertorials” charter **oversight committee** meets three times per year.

The schedule of meetings for the following year is prepared at the end of each year to reflect that drawn up for the expert advisory committee.

The **oversight committee** meeting agenda includes a presentation by one or more members of the conclusions of completed publication reviews. Only the reading guides specific to the publications reviewed by the **expert advisory committee** are forwarded to the **oversight committee**. These reading guides and the classifications they contain are anonymous. For those publications classified as containing minor deviations or which simply do not comply with the charter, only the final reading guides - those prepared after the publisher and/or healthcare company concerned have submitted their observations to the expert advisory committee - are forwarded to the **oversight committee**.

The oversight committee analyses the reading guides forwarded by the **expert advisory committee**, and summarises the classifications arrived at by the expert advisory committee relative to the provisions contained in the charter.

On that basis, it prepares its findings, as described below.

4. Disclosure of the work done by the oversight committee

- After each session, the **oversight committee** sends the members representing the signatory organisations an **information notice**. This notice is also published on the websites of the signatory organisations.

This notice includes:

- a **quantified assessment** of the degree of charter provision compliance shown by articles appearing in medical publications. This assessment summarises the number of publications reviewed by the **expert advisory committee**, the number of articles that contain minor deviations and the number that do not comply with the charter, using the following table format:

Period						
Total number of publications reviewed						
Classification of articles	Publisher's articles (Art. 1 and 2)	Press conferences (Art. 3, 4, 5 and 6)	Conference publications (Art. 7, 8 and 10)	Continuing training (Art. 7, 9 and 10)	Advertorials (Art. 11, 12, 13 and 14)	Total
	AV*	AV*	AV*	AV*	AV*	AV*
Containing minor deviations (orange)						
Non-compliant (red)						

* AV = in terms of Absolute Value

- a reminder of those charter provisions for which instances of deviations were particularly noticeable in the publications reviewed by the expert advisory committee
- optionally, those charter provisions for which the oversight committee would like to convene a meeting of the charter drafting committee for those healthcare companies, advertisers and publishers wishing to attend for the purpose of considering changes to facilitate the application and effectiveness of the charter⁵⁹. Where such a meeting is held, the decisions of the oversight committee are taken on the basis of a simple majority of votes cast. In the event of a tied vote, the Chairman has a double vote.
- where appropriate, the number of cases submitted to the SPEPS Board of Directors and/or Codeem, together with any sanctions applied under the provisions of the Charter by the SPEPS Board of Directors and the Leem Board of Directors or by the Litigation and Sanctions Section of Codeem.
- Additionally, the oversight committee makes an annual presentation of the results of its oversight of charter application to the members of SPEPS, the members of the UDA Pharmaceutical & Healthcare Industry Committee and Leem Board members. In accordance with the purpose of the charter, the purpose of this presentation is both informative and preventative. It assesses trends in the number of publications complying with the various provisions of the “Medicinal product information and advertorials” charter.
It also presents the findings of the research committee regarding compliance with the provisions of the charter, in light of any breaches that may have been reported by the expert advisory committee, together with any sanctions applied by the SPEPS Board of Directors, the Litigation and Sanctions Section of Codeem or the Leem Board of Directors.

⁵⁹ The charter is amended only following adoption of the amendments by the UDA Pharmaceutical & Healthcare Industry Committee and Board of Directors, the SPEPS Board of Directors and the Leem Board of Directors.