

# France

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### 1 General - Medicinal Products

#### 1.1 What laws and codes of practice govern the advertising of medicinal products in France?

The advertising of medicinal products is subject to the strict provisions of the French Public Health Code (CSP). These provisions are based on the implementation into the CSP of the provisions of Directive 2001/83, as modified on the Community Code for medicinal products, and Law No. 2011-2012, dated 29 December 2011, on sanitary safety of medicinal and health products.

Additionally, the National Agency for safety of medicinal products and health products (ANSM – “*Agence nationale de sécurité du médicament et des produits de santé*”) (formerly named AFSSAPS – Agency for Sanitary Safety of Health Products) has published a list of guidelines on the advertising of medicinal products that have to be observed.

Pharmaceutical companies shall also comply with the "Medical sales representatives' Code of Practice", signed between the Economic Committee of Health Products (CEPS) and the syndicate of the pharmaceutical industry (LEEM), and with Charter of the AFSSAPS, relating to the communication of pharmaceutical companies on the internet.

The LEEM established a Code of deontological rules (LEEM Code) which covers advertising activities and implements the EFPIA Code, which was updated on 1 January 2014.

#### 1.2 How is “advertising” defined?

Article L.5122-1 CSP defines advertising as any form of information including canvassing, prospecting or enticement aimed at promoting the prescription, the delivery, the sale or the consumption of medicinal products, except the information given by pharmacists within the framework of their activities in their pharmacies.

It is not considered as advertising to:

- answer a precise question on a specific medicinal product;
- provide information on packaging changes, on warnings within the framework of pharmacovigilance activities and on sales catalogues or lists of prices; and
- provide information on human health or diseases if they do not include reference even indirectly to a medicinal product.

#### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as “sign off” of promotional copy requirements?

There are no legal requirements in this respect.

#### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

No. Nevertheless, pharmaceutical companies usually have internal procedures in place to ensure the compliance with the applicable regulations on advertising.

#### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

The ANSM checks both the content and the presentation of the advertising. According to Law No. 2011-2012, both advertising to the general public and advertising to health professionals must be authorised by the ANSM prior to its launch. A calendar of the periods of application for approval is fixed every year by the General Manager of the ANSM. The 2014 calendar fixes four periods per year for advertising to professionals, and nine periods for advertising to the general public during which the applications can be filed. The applications are deemed approved after two months of silence from the ANSM from the end of the period of filing. The approval is valid for two years.

#### 1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

If the ANSM considers that an advertisement is in breach with the provisions of the CSP, it can request the company to modify the document or to stop the publication of the advertisement within a determined period of time and impose a financial sanction that cannot exceed 10,000 EUR if not executed. The decision of the ANSM can be challenged before the Administrative Courts.

- 1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?**

The CSP provides for criminal sanctions in case of non-compliance with the regulations relating to advertising of medicinal products. A maximum fine of 30,000 EUR or 37,500 EUR can be pronounced depending on the breach.

In all these cases, the Criminal Court may furthermore prohibit the sale and order the seizure of the products, as well as the seizure and destruction of the promotion documentation.

In case of a decision of prohibition of an advertisement by the ANSM, the CEPS can pronounce a financial penalty. This penalty can amount to a maximum of 10% of the turn-over realised by the company regarding the concerned medicinal product, for six months before and after the breach.

- 1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The LEEM has created on 8 June 2011 the CODEEM (Deontology Committee of the pharmaceutical industry). The mission of the CODEEM is, among others, to have a mediation role between LEEM members in case of litigation on deontological questions and to sanction in case of violation of deontological rules. If the mediation is successful, the decision binds the parties. However, recourse against this decision can be brought in front of the competent jurisdiction. Without recourse, the mediation sentence is confidential. A member of the LEEM can also ask the CODEEM to pronounce a sanction against another member of the LEEM in case of violation of a deontological rule. If the CODEEM is hearing a case which is already before Court, it can decide to postpone its decision.

There is no relationship between the ANSM and the CODEEM. The ANSM is not bound in any manner to the decisions of the CODEEM.

- 1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

The breach of law on advertising constitutes as such a fault that may cause a prejudice to a competitor. Any competitor can bring an action for unfair competition if it considers that it has suffered a prejudice due to the unlawful advertisement of its competitor.

## 2 Providing Information Prior to Authorisation of Medicinal Product

- 2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

According to Article L.5122-3 CSP, advertising is only allowed for medicinal products having already obtained a Marketing Authorization (MA) in France.

Only general scientific information and general information on the disease can be given during meetings. According to the Guidelines of the ANSM for advertising of medicinal products, the presentation in an advertisement of a clinical trial that is not finalised is prohibited, as it does not provide complete information to the physicians and may be an anticipation of uncompleted and non-validated results.

Mere scientific or technical information can be given to the healthcare professionals. Institutional information must have a scientific, technical or financial character and must not aim at promoting a medicinal product of the company. It can only mention the products of the company (name of the proprietary medicinal product, INN, therapeutic class) or the company's fields of research and development if it is for an informative purpose. Any other information regarding a medicinal product (for example, the therapeutic indication, the posology or the mode of administration) is considered as promotional.

When the companies financially sponsor scientific meetings, precautions regarding the programme and the content of the meeting should be taken to avoid any requalification as a promotional event.

The same rules apply to off-label promotion.

- 2.2 May information on unauthorised medicines be published? If so, in what circumstances?**

Only mere scientific or technical information on an unauthorised product can be published.

- 2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?**

See question 2.2.

- 2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Information sent to healthcare professionals on an unauthorised product must comply with the rules on institutional information.

A specific question asked of a healthcare professional on a product does not fall within the definition of advertising.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in France?**

The outcome of the ECJ judgment in the *Ludwigs* case has not been reflected for the time being in the legislation or practical guidance in France. Price lists, which do not contain any information on the products, are not considered as advertising under French law.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

No. Only institutional information can be sent.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Yes. The name of the product should not be mentioned. There is no guideline issued in this respect.

### 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

The Summary Product Characteristics (SPC) must be mentioned in the advertisements. Article R.5122-8 CSP specifically lists the necessary information that must appear in the advertisement.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not in the SmPC?**

Information that may appear in the advertisement must be in compliance with the MA, the opinion of the Transparency Commission and good use of the product.

An advertisement may refer to studies that (i) have been published in a peer-reviewed journal, and (ii) have been realised in the conditions of use of the medicinal product as defined in the MA and the opinion of the Transparency Commission. Non-published studies can be used if they are contained in the MA file or used for the drafting of the opinion of the Transparency Commission.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

The use of the results of opinion queries must have a scientific aim. The endorsement of the healthcare professional included in the advertisement must be in compliance with the MA, the opinion of the Transparency Commission and the good use of the product. Endorsements by healthcare professionals are prohibited for advertising to the general public.

**3.4 Is it a requirement that there be data from any or a particular number of "head to head" clinical trials before comparative claims are made?**

There is no such requirement. Nevertheless, the references of the clinical trials mentioned must be specified.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in France?**

The comparison shall be as complete as possible and shall not only mention the facts in favour of the medicinal product. To be objective, the comparison shall take into account the essential, significant, relevant and verifiable characteristics.

Any advertising which compares (explicitly or implicitly) a medicinal product with another medicinal product can only be made if:

- the advertising is not deceptive or misleading;
- it relates to medicinal products responding to the same needs and having the same therapeutic indication; and
- it compares objectively on the essential, accurate and true characteristics of the medicinal products (including the price).

The comparative advertising cannot:

- benefit from the notoriety of a trademark, trade name or other signs;
- denigrate a trademark, trade name or other signs; or
- create confusion between the trademarks, trade names or other signs of the two companies.

In addition, these guidelines stress that the results of the clinical studies which had been conducted for the products at stake can be used for comparative advertising only when made in line with the therapeutic indications validated by the MA and with the conclusions of the Transparency Commission, if any.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

The rules on advertising govern the distribution of scientific papers and/or proceedings of congresses.

**3.7 Are "teaser" advertisements permitted that alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?**

Teaser advertisements are not permitted. Advertising must be objective and permit the good use of the product.

### 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of products? If so, what restrictions apply?**

Free samples can be supplied to healthcare professionals only on their written request. These samples cannot concern psychotropic or narcotic products.

Samples must be marked “free sample”. The supply of samples is only permitted during the two first years of commercialisation in France for a new product or for a product with a new dosage or pharmaceutical form in case of an extension of indication. A maximum of four samples per recipient can be given per year. Each sample is identical to the smallest packaging sold. The company must organise a monitoring and control of the supply. The SPC is supplied with each sample.

Their supply to the general public for promotional purposes or within the framework of congresses accessible to general public is prohibited.

The ANSM can limit the supply of samples in case of public health risks.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply?**

Healthcare professionals, medical students and medical associations cannot receive directly or indirectly a financial advantage or a physical gift of any kind from a pharmaceutical company that produces or markets products or provides services reimbursed by French social security schemes, and such companies cannot propose or procure such advantages. As an exception, they may receive gifts of negligible value and that are relating to the exercise of their activity. According to Law No. 2011-2012 and Decree No. 2013-414 dated 21 May 2013, all financial advantages of and above 10 EUR procured directly or indirectly to those persons must be made public. Please refer to question 7.3.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?**

Yes, so long as a health professional does not benefit directly or indirectly from it. Donations are admitted if their aim is to support research or the training of health professionals. They must be declared by the company to the Manager of the Regional Agency of Health of the institution’s location. According to Law No. 2011-2012 and Decree No. 2013-414 dated 21 May 2013, all financial advantages of and above 10 EUR procured directly or indirectly to hospitals must be made public. Please refer to question 7.3.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

It is prohibited to offer goods and services that could lead to changes in prescription.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Yes, if it does not constitute a breach of any competition law provisions (abuse of dominant position or loss leading).

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?**

It is possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent to the purchase of a medicinal product if it does not breach any competition law provisions.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Yes, it is possible to offer a refund scheme if the product does not work in compliance with the rules on defective products/latent defect.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Yes, pharmaceutical companies may sponsor continuing medical education. The institutions providing continuing medical education must have obtained the appropriate accreditation for this activity.

**5 Hospitality and Related Payments**

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

A hospitality granted during a professional or promotional event is exempt if the advantages granted in this context are of a reasonable value and remain incidental as compared with the main purpose of the event and it is offered only to the professionals who are directly concerned with the event. The hospitality granted must be laid down in a written agreement notified to the Medical Doctor Society one month before the event for prior opinion. This rule applies to French healthcare professionals independently of the location of the event.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

It is not possible to pay for a doctor in connection with attending a scientific meeting.

It is possible to pay for his expenses if the expenses are of a reasonable value (see question 5.1).

It is not possible to pay for his time if no professional services are provided by him.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Failure to comply with the prohibition to grant financial advantages to a medical doctor may lead to criminal prosecution. The medicinal doctor may be convicted and given a fine of 75,000 EUR and two years' imprisonment. The company may be convicted and given a fine of 375,000 EUR and a suspension or prohibition to exercise its activity.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Yes, regarding the compensation paid, the company must be able to demonstrate, if requested by French authorities, that the compensation is appropriate and proportional and corresponds to the payment of the performance of real services.

Pharmaceutical companies have to make public the agreements signed with healthcare professionals, medical students and medical associations.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

See question 5.4.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

See question 5.4.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Only the advertisement of non-prescription medicines is possible to the general public. Moreover, the product must not be reimbursable through the social security scheme and the MA must not contain any prohibition of advertising to the general public for public health reasons. Medicinal products that are subject to a benefice/risk assessment or pharmacovigilance alert cannot be advertised.

The promotional character of the advertising must be obvious and it must be clear that the product is a medicinal product. The advertisement must contain:

- the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance;
- the information necessary for the correct use of the product;
- an express, legible invitation to read carefully the instructions on the leaflet or on the packaging; and
- a message of caution, a reference to the advice of a pharmacist and an invitation to consult a doctor.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

No. However, there are two exceptions: vaccination campaigns; and advertising for products for the reduction of tobacco addiction.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Yes, disease awareness campaigns are permitted if they comply with the rules applying to information relating to human health or to human diseases. They are not considered advertising if there is no direct or indirect reference to any medicinal product. The information can cover the possible available therapeutics. The therapeutic class (i.e. ATC classification) can be indicated.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply?**

No. Only institutional information or information on diseases could be provided in press releases available to the general public.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Only technical, scientific and financial information can be given. (See question 2.1 on institutional information.)

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

Rules on advertising to the general public apply to patient support groups. Donations can be made to these groups to support research or medical education. The donation must be declared to the Manager of the Regional Agency of Health of the location of the patient group.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, what information should be disclosed, and when and how?**

The ANSM holds a national clinical trial database for clinical trials authorised and conducted in France, which is accessible on the ANSM website. The information made available concerns the title of the clinical trial and its EudraCT number, the name and address of the sponsor, the countries where patients are included, a short description of the clinical trial, the objective of the trial, the inclusion criteria, the number of patients included, the status of the trial (ongoing or completed), and the experimental product. At the end of the clinical trial, a summary of the results is required to be drafted by the sponsor and disclosed on the database. The summary of the clinical trial must be transmitted by the sponsor to the ANSM within one year of the completion of the clinical trial.

**7.2 Has your national code been amended in order to implement the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations and, if so, does the change go beyond the requirements of the EFPIA Disclosure Code or simply implement them without variation?**

The LEEM Code was amended on 1 January 2014 to implement the EFPIA Disclosure Code. The LEEM decided to implement the EFPIA Disclosure Code in two phases:

- End of 2013, the LEEM included in the LEEM Code the principles of publication of interactions as laid down by Decree No.2013-414.
- During 2014, the LEEM will implement the complementary provisions of the EFPIA Disclosure Code.

**7.3 If the EFPIA Disclosure Code has not been implemented in France, is there a requirement in law and/or self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what information should be disclosed, from what date and how?**

Law No. 2011-2012 inserted a new Article L.1453-1 in the CSP on the disclosure of any financial advantage offered to health professionals, patient groups or hospitals. Companies have to disclose the agreements signed with those persons and any direct or indirect financial advantage of and above 10 EUR offered. For the advantages granted, each company must disclose the identity of the recipient of the advantage and of the company, the amount of the advantages (all taxes included), the date and the nature of the advantages received by the recipient during the civil semester concerned. The said information must be disclosed in French on a unique public website created by an Order dated 3 December 2013. Before the creation of the unique website a transitional period was in place for the agreements signed and the advantages granted in 2012 and the first semester of 2013. Since 19 December 2013 (the date of the publication of the Order creating the unique website), the above rules are applicable. The unique website will be accessible to the general public on 1 April 2014. The companies will have to transmit the above-mentioned information to this authority within 15 days from the execution of the agreement and at least by 1 August of each year for the advantages granted during the first semester of the year and at least by 1 February of each year for the advantages granted during the second semester. The unique website must then disclose the information for the first semester of the year on 1 October and for the second semester on 1 April.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Internet advertising is regulated by the same rules governing the advertising of medicinal products. A Charter for communication on the Internet has been adopted by the ANSM. An updated version has been published on 7 April 2014. It takes into account new technologies such as social media and mobile apps.

The website must indicate the identification of the company, its address and to who the website is directed and the type of information supplied. The information on the website must be

regularly updated and the last update must be clearly specified. Information directed to foreign recipients must also be clearly specified. The website must expressly indicate which pages are promotional by mentioning “advertising” on the page and separate the promotional pages from the other pages.

The ANSM controls the application of the rules on advertising on the Internet. A prior authorisation from the ANSM is required before the pages are put online.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

A security system must be in place to ensure that the general public does not have access to sites intended for professionals. A personal access code shall be given after verification of the quality of the person (matriculation number with the Medical Doctor Society).

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Such links are lawful if they give access to the homepage of the websites. However, for official administrative websites, a link to all pages is authorised. For links to peer-review websites, a link to the tables of content is authorised. For links to congresses websites, a link to the programme of the events is authorised.

A message must indicate that the visitor is changing websites. Links to a company of the group, a congress website, a learned society website, a medical or scientific newspaper, an authority website or a patient association are authorised.

Each website must have its own security system in place.

The company is responsible for the link on the first level. The links shall not be a tool to violate the rules on advertising.

Links must be regularly verified and updated.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

The rules governing advertising to the general public apply to Internet advertising to the general public. General information on the product can be given. SPC, leaflet, transparency advice, and the European Public Assessment Report can be reproduced and the price and reimbursement indicated.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

The updated version of the Charter for communication on the Internet provides a section on social media. Advertising to the general public in the form of a product page is forbidden as it is not possible to moderate the comments. The tool “x persons like” violates the CSP as it could be interpreted as an endorsement of a physician or a statement of healing by the public.

**9 Developments in Pharmaceutical Advertising**

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

Decree No.2013-414 on transparency of the relationships with healthcare professionals was published on 22 May 2013. It implements the provisions of Law No. 2011-2012 on disclosure of interactions with healthcare professionals. The unique website for publication of these interactions has been created by an Order dated 3 December 2013.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

The updated version of the Charter on communication on the Internet was expected for the beginning of 2014 and is still expected at the date of preparation of this article in early March 2014. On 1 April 2014, the unique website for publication of the interactions with healthcare professionals will be accessible to the general public.

**9.3 Are there any general practice or enforcement trends that have become apparent in France over the last year or so?**

There has been an increase of litigation or pre-litigation on advertising matters.

**9.4 Has your national code been amended in order to implement the 2013 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (the EFPIA HCP Code) and, if so, does the change go beyond the new requirements of the EFPIA HCP Code or simply implement it without variation?**

The LEEM is member of the EFPIA. The LEEM Code implements the EFPIA Code without variations.



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Paule was dually trained as a pharmacist and a lawyer. She also has a post-graduate degree in Industrial Property. After 13 years as in-house counsel in the pharmaceutical industry, she joined the Paris Bar in 1994. She set up PDG Avocats in 2009 after having been a partner in UK and US law firms. PDG Avocats is a boutique law firm fully dedicated to the Life Sciences industries, which is ranked in the major French and international rankings such as Legal 500 and Best Lawyers in France. She has 33 years' experience in contentious and non-contentious matters in industrial property, French and European regulatory including pricing and reimbursement, compliance and product liability. She is a regular speaker in conferences and an author of articles in her fields of expertise.



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Juliette holds a post-graduate degree (DEA) in intellectual property law and an LL.M. in industrial property law from the Ludwig-Maximilian University of Munich. Juliette was admitted to the Paris Bar in 2000. She advises on both contentious and non-contentious matters for companies dealing in Life Sciences. Her practice covers, in particular, IP, regulatory, compliance and commercial work. After having worked with Paule in UK and US law firms, Juliette joined PDG Avocats.

**PDG Avocats**

PDG Avocats is a boutique law firm dedicated to life sciences issues. Our team has extensive experience gained from many years' experience spent advising companies in the Life Sciences sector. We have acquired the industry knowledge required to assist Life Sciences companies mainly in contentious and non-contentious matters related to regulatory, compliance, product liability and intellectual property rights.

Our belief is that in-depth knowledge of these industries, a good level of reactivity and exceptional client care create an on-going relationship with clients.