The International Comparative Legal Guide to:

Pharmaceutical Advertising 2019

16th Edition

A practical cross-border insight into pharmaceutical advertising

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France

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1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products in France is mainly regulated by:

- Articles L. 5122-1 to L. 5122-16 and R. 5122-1 to R. 5122-17 of the French Public Health Code (the "**FPHC**") relating to advertising of medicinal products for human use;
- Articles L. 121-2 to L. 121-7 and L. 122-1 to L. 122-10 of the French Consumer Code, relating to prohibited and regulated commercial practices;
- Articles L. 1453-1 to L. 1454-10 of the FPHC, relating to transparency and anti-gifts principles;
- Article L. 162-17-4 of the French Social Security Code; and
- Law n° 94-665 as of August 4, 1994, requiring that all advertising be drafted in French.

The following various recommendations or codes also apply:

- the recommendations issued by the French National Agency for the Safety of Medicinal and Health Products (the "*Agence nationale de sécurité du medicament et des produits de santé*", the "**ANSM**");
- the "Charter for the information by doorstep selling or prospection aimed at promoting medicinal products" ("*Charte de l'information par démarchage ou prospection visant à la promotion des médicaments*"), signed by the Economic Committee of Medicinal Products ("*Comité économique des produits de santé*", the "**CEPS**", being the French competent authority for price fixing) and the French association of pharmaceutical companies ("*Les entreprises du medicament*", the "**LEEM**") dated October 15, 2014;
- the "Charter for the communication and the promotion of health products on the Internet and e-media" ("*Charte pour la communication et la promotion des produits de santé (medicaments et dispositifs médicaux) sur Internet et le e-media*") issued by the ANSM;
- the "Ethical professional provisions" ("*Disposition déontologiques professionnelles*") issued by the LEEM, which contain notably the provisions of the codes of good practices issued by the European Federation of Pharmaceutical Industries and Associations ("**EFPIA**") and the Federation of Pharmaceutical Manufacturers & Associations ("**FIIM**"); and
- the code named "Information on the medicinal product and editorial advertising" ("*Information sur le médicament et publicité rédactionnelle*") issued by the LEEM and by the SPEPS and UDA (media associations).

1.2 How is "advertising" defined?

Advertising is defined by Article L. 5122-1 of the FPHC, as any kind of information, including doorstep selling, prospection or inducement aimed at promoting the prescription, supply, sale or use of medicinal products, to the exception of information delivered by pharmacists managing hospital pharmacies.

According to Article L. 5122-1 of the FPHC, the following shall not be considered as "advertising":

- correspondence, together with, as the case may be, non-advertising documentation, necessary to answer a precise question relating to a specific medicinal product;
- concrete information and reference documents related, for example, to packaging modification, warnings concerning adverse effects identified in the context of pharmacovigilance, and sales catalogues and price lists, provided they do not contain any information on the medicinal product; and
- information relating to human health or human diseases, provided there is no 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?

Pursuant to Article R. 5122-1 of the FPHC, pharmaceutical companies must have a department in charge of advertising, under the supervision of the responsible pharmacist of the company, who must ensure companies' compliance with the provisions of the FPHC and, in particular, the scientific accuracy of the information released.

Furthermore, companies must keep a copy of each published advertising during three years from the last diffusion of such advertising and must make it available to the ANSM, which can have access to them upon request.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

In addition to the above (see question 1.3), Article L. 5122-11 of the FPHC provides that the personnel in charge of the promotional activities by doorstep selling or prospection (e.g., sales representatives)

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must have a scientific knowledge certified by a diploma, credentials or a certificate listed by a competent administrative authority.

Employers have the responsibility of checking that this knowledge is genuine and up to date.

In addition, the Charter for the information by doorstep selling or prospection aimed at promoting medicinal products also contains requirements for companies to provide to their employees (in particular, sales representatives) continuous educational training.

Furthermore, in the context of the price fixing process, pharmaceutical companies commercialising medicinal products reimbursed by French social security schemes have to sign a specific contract with the CEPS. In this respect, they have to comply with the requirements of the Charter for the information by doorstep selling or prospection aimed at promoting medicinal products. Moreover, pursuant to Article L. 162-17-4 of the French Social Security Code, compliance of such companies with those requirements is subject to an evaluation and certification process by accredited organisms, based on certification rules established by another authority, the French Public Health Authority (French "*Haute Autorité de Santé*", the "**HAS**").

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?

Pursuant to Articles L. 5122-8 and L. 5122-9 of the FPHC, the advertising to both the general public and healthcare professionals ("**HCPs**") shall be approved in advance by the ANSM, which is in charge of delivering the corresponding "visa" (i.e., name of the relevant authorisation). The request for authorisation must be submitted in accordance with a specific agenda determined by the ANSM and detailed on the ANSM website. The model forms and the list of required documents (in paper and electronic format) are also available on the ANSM website.

For the advertising to the general public and to HCPs, the visa is considered as delivered in the absence of any decision by the ANSM within a two-month delay further to the receipt, by the ANSM, of the application.

Visas are valid for a two-year period.

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 an advertisement for the general public or for HCPs is in breach of the law, the visa can be removed upon the reasoned decision of the ANSM, after the company has been invited to submit its comments in a delay that cannot be less than one month. In case of emergency, the ANSM can suspend the visa, with immediate effect, for a maximum period of three months (Articles L. 5122-8 and 9 and Articles R. 5122-7 and R. 5122-15 of the FPHC).

Decisions of the ANSM are in principle published on the ANSM's website.

The ANSM also has a general power to pronounce injunctions. It is not entitled to specifically request the issue of a corrective statement, however, if an unlawful advertising entails a risk for the general public, the ANSM may presumably request the issue of such a corrective statement.

The decisions of the ANSM can be appealed before the French 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? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

The ANSM can pronounce financial sanctions for failing to comply with the rules governing the advertising of medicines, with optional daily penalties (Articles L. 5312-4-1 and L. 5471-1 of the FPHC). As the case may be, the ANSM can order the concerned company to regularise its situation, and enable it to present its observations, with a possibility of being assisted by an advisor.

Pursuant to Article L. 5422-18 of the FPHC, the following unlawful promotional activities for medicinal products are subject to financial sanctions:

- advertisements for medicinal products which have not obtained the relevant product marketing authorisation for commercialisation;
- advertisements whether made for the general public or for HCPs, which have not obtained the "visa" (i.e., the authorisation – see question 1.5) delivered by the ANSM, or which are realised despite the suspension or withdrawal of such "visa";
- advertisements made for the general public for a prescription only medicinal product;
- advertisements made for the general public for a medicinal product reimbursed by the French social security schemes, except for certain vaccines;
- advertisements made for the general public for a medicinal product subject to limitations regarding advertisements for the general public, due to the potential risk on public health; and
- advertisements made for the general public or for HCPs for a medicinal product subject to an authorisation for temporary use ("*Autorisation temporaire d'utilisation*", ATU).

The financial sanction cannot exceed €150,000 for individuals and, for companies, 30% of the turnover made on the concerned product(s) during the last financial year, within the limit of €1 million (Article L. 5471-1 of the FPHC).

The ANSM can also pronounce, in addition to the above financial sanctions, daily fines.

Decisions relating to the above financial sanctions can be published on the ANSM's website.

To our knowledge, there is no recent important example where a financial sanction has been pronounced by the ANSM in relation to an advertisement for medicinal products. The number of such financial sanctions is rather low (for example, there were no more than five cases for 2017). Most of the time, the ANSM pronounces injunctions, suspensions or withdrawals of the "visa", and more rarely, financial sanctions.

Besides, the FPHC also contains criminal sanctions regarding advertising, which can be pronounced by French Courts.

Pursuant to Article L. 5421-2 of the FPHC, the promotion of medicinal products which have not obtained the relevant marketing authorisation, or whose authorisation has been refused, suspended, withdrawn, or is outdated, is punished by five years of imprisonment and a fine of €375,000 (€1,875,000 for legal entities). Some

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aggravating circumstances may even lead to seven years of imprisonment and a fine of €750,000 (€3,750,000 for legal entities).

Also, pursuant to Article L. 5422-8 of the FPHC, every advertisement which was not authorised by a "visa" or whose "visa" was suspended or withdrawn, is punished by one year of imprisonment and a fine of €150,000 (€450,000 for legal entities).

Regarding advertising to the general public, infringers are notably subject to one year of imprisonment and a fine of €150,000 (€450,000 for legal entities) every advertisement for:

- a medicinal product subject to an authorisation for temporary use (Article L. 5422-3 of the FPHC);
- a prescription only medicinal product (Article L. 5422-5 of the FPHC);
- a medicine which is reimbursed by the French social security schemes (Article L. 5422-5 of the FPHC); or
- a medicine with which the marketing authorisation contains restrictions relating to the potential risk to the public health (Article L. 5422-5 of the FPHC).

In addition to the above criminal sanctions, pharmaceutical companies declared criminally liable may also be subject to additional sanctions listed in the French Criminal Code, such as, among others, the exclusion from the public procurement tenders.

Also, pursuant to Article L. 162-17-4 of the French Social Security Code, if a "visa" relating to an advertisement for HCPs has been withdrawn by the ANSM, the CEPS can pronounce a financial fine against the concerned company, amounting to up to 10% of its turnover realised in France (excluding VAT) with the concerned medicinal product during the six months before and six months after the date of withdrawal of the "visa".

Competitors may also take direct action through the civil courts in relation to advertising infringements, on the grounds of unfair competition, and seek indemnification.

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?

In France, the self-regulatory body is the CODEEM ("*Comité de Déontovigilance des Entreprises du Médicament*"), which is the committee, created by the LEEM in 2011, responsible for ensuring that members of the LEEM comply with the self-regulatory ethical rules established by the LEEM. Among its prerogatives, the CODEEM has a mediation and sanctioning role: it organises mediations in the event of a dispute relating to ethical questions; and it has the power to pronounce sanctions (which can range from a formal warning to an exclusion from the LEEM) in case of non-compliance by a member with ethical rules.

As a general principle, there is no specific relationship between the self-regulatory process of the pharmaceutical industry and the supervisory and enforcement function of the competent authorities. As a consequence, the decisions or other measures of a self-regulatory body such as the CODEEM do not have any legal impact on the potential actions of the French competent authorities.

In practice, French competent authorities may investigate matters drawn to their attention that may constitute a breach of both the laws and any relevant self-regulatory code, even though such matters are already being assessed by the competent self-regulatory body. In every case where there is an infringement of applicable laws and regulations, French competent authorities are entitled to investigate the case. They are not supposed to, however, investigate matters that would only constitute a breach of a self-regulatory code of practice or ethical code.

Although there is not a specific provision in this respect, French competent authorities may also take up a matter based on an adverse finding of any self-regulatory body, if such matter relates to a breach of applicable laws or regulations. Conversely, the self-regulatory body may presumably take up a matter based on adverse findings of French competent authorities. In this respect, whenever a matter is brought before the CODEEM while being brought before a Court, the CODEEM can stay proceedings and await the decision of the Court.

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?

In the event that the infringement of the laws and regulations relating to pharmaceutical advertising also constitute an act of unfair competition, it is possible to take action directly before the French commercial Courts. As a general principle, non-compliance of a competitor with applicable laws and regulations can constitute an act of unfair competition.

Any person may bring such action. In practice, this person will have to demonstrate a fault (e.g., breach of applicable laws and regulations), a damage (e.g., loss of profits due to the unlawful promotional activities of a competitor) and a causal link. In such case, the competitor can be sentenced to pay damages, calculated based on the estimated loss of profits of the claimant due to the unfair practices, or based on the estimated gains of the competitor due to such unfair practices. Public releases can also be pronounced.

The claimant may also request from the Court a ban on the advertising under emergency proceedings.

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)?

In the context of promotional activities, HCPs can only be provided with information relating to authorised medicinal products. Therefore, information about a medicinal product before that product is authorised can be made available to HCPs only if such information is not promotional.

The exchange of information relating to an unauthorised medicinal product during the development phase is also possible, provided that such exchange of information is not considered as promotional. For example, such exchange of information can be made during independent scientific committees, meetings or congresses (i.e., committees, meetings or congresses which programmes/presentations are approved by an independent committee and are purely scientific, with

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no branding and only reference to the International Non-proprietary Name ("**INN**"), even sponsored by a pharmaceutical company).

The position is the same with regard to the provision of off-label information. In this respect, companies can also provide to a HCP scientific information (on-label and off-label), to respond to a specific unsolicited question from said HCP about a particular product. Indeed, such communication of information is deemed to be non-promotional. However, the information provided to the HCP must not go beyond the scope of the question (otherwise, such communication could be considered as promotional).

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

In relation to independent congresses or meetings, medical press publishers can issue special editions to report all or part of the work presented during such congresses or meetings. Whenever these special editions contain research data that have not been validated by French authorities, this shall be clearly specified by a warning on the first page of the edition.

The publication of these special editions, as well as their content, is made under the sole responsibility of the publishers and their reading committees. These publications can contain advertisements, excluding for medicinal products mentioned in the edition and for which off-label information is provided.

The distribution of these special editions is made under the sole responsibility of the publishers and shall not be repeated. If these special editions contain off-label information, their use in the context of promotional activities (notably, their use by sales representatives) is prohibited.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.

Press releases issued by pharmaceutical companies can be considered as promotional. Therefore, press releases must be made with extreme caution. A press release about unauthorised medicinal products and/or off-label information is permitted if such press release is not intended to promote the medicinal product itself, but to present a development achievement of the company from a scientific perspective. In this respect, the press release must be factual and not include allegations or any cheerful description.

In practice, press releases are supposed to be sent to journalists or chief editors, and not be accessible to the general public or to HCPs.

The code named "Information on the medicinal product and editorial advertising" ("*Information sur le médicament et publicité rédactionnelle*") issued by the LEEM and by the SPEPS and UDA (media associations) states that pharmaceutical companies have to reserve press conferences to important matters, that are, among others, original research started by a pharmaceutical company, clinical study results, economic and financial results or industrial restructuration, etc. It is the companies' responsibility to be selective regarding the matters to be developed, and the editors' responsibility to assist with press conferences, depending on the appropriateness of the information for their target audience. Attention has to be paid by the two parties to ensure that the press conference and related reports are not qualified as promotional. Invitations have to be addressed to media redaction.

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

No, such information (press releases) cannot be sent to HCPs, except in response to a specific unsolicited request from a HCP. In such case, the information provided to the HCP must not go beyond the scope of the his/her question (i.e., the information contained in the press release must correspond exactly to the information request – if this is not the case, the press release should not be sent (see also question 2.1 concerning unsolicited questions from HCPs)).

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 your jurisdiction?

Article L. 5122-1 of the FPHC provides that information contained in sales catalogues and price lists are not considered as promotion, provided they do not contain any information on the medicinal product. This principle was already included in the FPHC before the decision in the *Ludwigs* case.

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?

The FPHC does not provide for any specific exception in this respect. In practice, such information is likely to be considered as promotional if it is communicated (even indirectly) to HCPs, except where such information is communicated in response to a specific request from a HCP.

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

Yes, provided the contractual relationship complies with standards required for services agreements (notably, such contractual relationships must comply with principles applicable to services agreements with HCPs – see question 5.4) and that the real purpose of the market research is to obtain feedback from HCPs, and not to communicate information on unauthorised products or information to said HCPs. There are no official guidelines on that topic.

3 Advertisements to Healthcare Professionals

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

The following mandatory information, listed by Article R. 5122-8 of the FPHC, must appear in advertisements directed to HCPs:

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- the name of the medicinal product;
- the name and the address of the pharmaceutical company;
- the pharmaceutical form;
- the composition;
- the number of the related marketing authorisation;
- the pharmaceutical properties with respect to its indications;
- the therapeutic indications and contraindications;
- the method of administration;
- the posology;
- the side effects;
- the specific precautions for use;
- the drug interactions;
- the classification of the medicinal products in terms of prescription and delivery;
- the maximum sale price;
- the position regarding reimbursement; and
- any additional information if the medicinal product is a generic one.

Such mandatory information is the same regardless of the support (electronic, paper, audio-visual media).

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

As a general principle, an advertisement mainly based on the results of an opinion survey is prohibited. However, it may be allowed if such results are in line with the marketing authorisation, the option of the Transparency Commission (which is the competent commission for evaluation of the medical benefit of medicinal products), and the proper use of the medicinal product.

In any case, an individual endorsement by a HCP in promotional materials is not allowed. Notably, pursuant to Article R. 4127-20 of the FPHC, the HCP shall ensure the accurate use of his/her name, profession and statements. He/she must not accept that private or public entities he/she works for or he/she assists use his/her name or his/her professional skills for promotional activities.

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

Pursuant to Article L. 5122-2, the advertisement must not be misleading.

As a general principle, the elements contained in the advertisement must conform to the SmPC.

Also, information contained in an advertisement shall be accurate, updated, verifiable and exhaustive in order to allow the HCP to make his/her own opinion on the therapeutic value of the medicinal product. Quotations, citations, tables and other illustrations from medical journals or scientific medias used for promotion shall be quoted faithfully and shall specify the source (Article R. 5122-9 of the FPHC).

As concerns studies, according to the recommendations issued by the ANSM, studies that can be used for promotion are the ones published in peer-reviewed journals, conducted in accordance with the conditions of use of the medicinal product, as defined in its marketing authorisation.

Please note that the following non-published studies can be used in the context of promotional activities:

- studies referred to in the marketing authorisation dossier and which comply with the terms of the marketing authorisation; and
- as the case may be, studies selected and used by the Transparency Commission to issue its opinion, and which comply with the conclusions of the Transparency Commission.

These studies shall be communicated to any HCP requesting so.

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 may be made?

No, there is no explicit written requirement under French law.

However, comparison shall be as exhaustive as possible and, in order to be objective, shall be made on essential, significant, relevant and ascertainable characteristics, which implies that the comparison be based on relevant data.

For further detail concerning comparative advertisements, see question 3.5.

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 or indication which had not yet been authorised in your jurisdiction?

General comparative advertisements are regulated under the French Consumer Code (Articles L. 122-1 and L. 122-2), and they are considered to be lawful provided that:

- they are not misleading or likely to be misleading;
- they relate to products that respond to the same needs or have the same purposes;
- they objectively compare at least one or more essential, relevant, ascertainable and significant characteristics of the products (including the price as the case may be);
- they do not take undue advantage of the reputation attached to a manufacturer brand, commercial trademark or service brand, to other distinctive trademarks of a competitor or to the protected designation of origin or geographical indication of a competing product;
- they do not lead to the discredit or the denigration of the trademark, trade name, other distinctive signs, goods, services, activity or situation of a competitor;
- they do not lead to the confusion between the advertiser and a competitor or between the trademarks, commercial names, other distinctive marks, goods or services of the advertiser and the competitor; and
- they do not present goods or services as an imitation or a reproduction of a good or service having a protected mark or commercial name.

Besides the above general principles, the ANSM issued recommendations regarding pharmaceutical products as follows:

1) **Products subject to comparison**: comparative advertising may concern two or more products, under their brand name or under their INN. They may be products from the same therapeutic class, or from different chemical classes, but in any case, with the same therapeutic use.
2) **Comparison criteria**: comparison shall be as exhaustive as possible, without giving priority exclusively to positive elements. To this end, comparison shall concern essential characteristics, and significant, appropriate and verifiable information. Comparison shall at least contain efficiency and security criteria (risk/benefit ratio). Comparison may also indicate useful details for the HCP such as posology, treatment period, interaction, acceptance, etc. Comparison shall not detail pharmacological properties without any validated clinical result.

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3) **Comparison of costs**: the ANSM recommends comparing the costs of the treatment (instead of the strict prices of the products), which are more relevant, provided the prices are published.

4) **Types of studies that can be used for comparative advertisements**: the studies (whether published or not) referred to in the marketing authorisation dossier and studies selected and used by the Transparency Commission to issue its opinion, provided they comply with the therapeutic indications validated by the marketing authorisation and, if any, with the opinion of the Transparency Commission opinions. However, other clinical studies (i.e., studies that are not specifically referred to in the marketing authorisation dossier nor in the opinion of the Transparency Commission) may also be used for promotion provided they are in line with the indications validated by the marketing authorisation and the opinion of the Transparency Commission; in such case, they must have been published in a peer-reviewed journal.

5) **Presentation of the results of the comparison**: the information so provided shall be clear, accurate, balanced and processed in a homogeneous way.

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

If such scientific papers and/or proceedings of congresses contain only on-label information, they can be distributed to HCPs in the context of promotional activities. In such case, companies must obtain a "visa" from the ANSM and insert mandatory legal mentions on the promotional material.

As concerns scientific papers and/or proceeding of congresses which contain off-label information, see response to question 2.2.

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

There is no specific regulation relating to "teaser" advertisements under French law. Therefore, such advertisements should be permissible provided they comply with laws and regulations relating to the promotion of medicinal products. Indeed, the "teaser" and its content shall be reviewed carefully in order to determine whether it has to be considered as a medicinal product advertising – depending on the information contained in such "teaser": in such case, it must relate to a product which has been duly authorised, and contain all the mandatory information (see question 3.1) which may be contradictory in the nature of what is usually considered as a "teaser".

3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

In our opinion, the holder of product A should be able to rely upon the approved use of product B with product A to promote the combination use, provided it respects the marketing authorisation of product A and the recommendation issued by the French HAS, and provided it participates in the good use of the medicinal products.

However, the holder of the MA for product B shall first vary the SmPC before requesting the "visa" in order to be compliant with the MA.

4 Gifts and Financial Incentives

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

The provision of free samples of medicinal products to HCPs is subject to specific conditions, set forth by Articles L. 5122-10 and R. 5122-17 of the FPHC.

Free samples can be provided only to persons qualified to prescribe or supply them.

The provision of free samples is allowed only for two years following the first effective commercialisation, in France, of either (i) a medicinal product authorised for the first time, or (ii) a product already authorised, for a new dosage or a new pharmaceutical form, provided the authorisation is extended.

The provision of free samples of medicinal products must also comply with the following conditions.

Such samples may be provided only upon a written, dated and signed request from the recipient.

The number of free samples that can be provided is limited to four samples per year and per recipient. Each sample shall not be larger than the smallest presentation on the market and contain the following mention: "free sample". Each sample shall be accompanied by a copy of the summary of the product characteristics.

When the product is subject to restricted prescription, the samples can be distributed only to the HCPs qualified to prescribe it and to the head pharmacist of hospital pharmacies within hospitals.

No samples of medicinal products containing psychotropic or narcotic substances may be supplied.

Also, it should be mentioned that the direct supply of free samples to the general public for promotional purposes, as well as the supply of free samples in medicinal or pharmaceutical congresses which are accessible to the public, are prohibited.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Pursuant to Article L. 1453-3 of the FPHC, it is prohibited for (i) HCPs, (ii) students intending to practice a healthcare profession, (iii) associations grouping HCPs, and (iv) public agents who participate to the drawing up of the public-health policy or who have administrative police powers, to receive "advantages" (gifts or donations), whether in cash or in kind, directly or indirectly, from any person or entity commercialising health products (which of course includes pharmaceutical companies). It is also prohibited for such persons or entities to provide to HCPs (and to other people/entities mentioned above) any such advantages (Article L. 1453-5 of the FPHC).

These anti-gifts provisions, which have been modified recently by a Law dated January 26, 2016 and by an Ordonnance dated January 19, 2017 and which are now set out in Articles L. 1453-3 *et seq*. of the FPHC, have entered into effect on July 1, 2018, except for the

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provisions which need the publication of an implementation decree. The prohibition is now applicable to any person or entity commercialising health products (e.g., pharmaceutical companies), and not only to those companies which products are reimbursed by the social security schemes (as was the case under the former set of rules).

As concerns advantages in cash or in kind of a "negligible value", the FPHC expressly provides that, if they are related to the HCPs' practice and do not exceed an amount determined by an *Arrêté* (specific decision to be taken by the competent Ministry), they are not considered as prohibited advantages (Article L. 1453-6, 4° of the FPHC). The above-mentioned *Arrêté* has not yet been published. However, until then, the commonly accepted maximum amount taken into account is €30, which is the limit recommended by the French Medical Board.

For the sake of completeness, the FPHC (Article L. 1453-7) also provides for derogations to the general prohibition, namely:

- the remuneration and compensation of research activities, scientific evaluation activities, consultancy services, services, or commercial promotion, if the remuneration is proportional to the services and the compensation of costs does not exceed the costs actually incurred by the HCP;
- the donations, in cash or in kind, aimed at directly financing research activities, valorisation or scientific evaluation;
- the donations to HCP associations, provided their purpose is related to their professional activities; and
- the direct or indirect hospitality offered in the context of professional or scientific meetings, or in the context of events intended to promote healthcare products, provided that such hospitality is reasonable, limited to the purpose of the meeting or event, and limited to the HCP (to the exclusion of his/her relatives).

In such situations, a contract must be executed and either (i) declared, or (ii) submitted for prior authorisation (depending on the amount at stake) to the competent board of professionals.

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? If monetary limits apply, please specify.

French law does not contain a general prohibition for pharmaceutical companies to give gifts or donations of money to healthcare organisations such as hospitals. More specifically, such gifts or donations of money to healthcare organisations are allowed. The purpose of the gift or donation must be, in principle, to sustain research or education of HCPs.

In principle, donations of equipment or funding of medical or technical services for a collective use are also allowed. There are no monetary limits. As concerns public entities, such gifts or donations must not infringe public procurement and anti-corruption rules (gifts and donations must be made independently of sales operations and must not be intended to influence procurement decisions).

In any case, the gift or donation must be formalised by a contract.

Also, it must be noted that the above-mentioned rules relating to the provision of advantages to HCPs apply. Therefore, gifts or donations to healthcare organisations are allowed if they are intended for a collective use and do not result in an individual advantage for an HCP.

For example, in the case where a pharmaceutical company purely funds a nurse, this may be critical and may entail the risk of being considered as the provision of an individual advantage to an HCP.

Also, a gift or donation to a private healthcare organisation is usually not allowed. Indeed, as HCPs are presumably shareholders of the organisation, the provision of gifts or donations could potentially be considered as an indirect benefit to the HCPs, because the cost savings for the organisation would increase the benefit and dividends accruing to the HCPs (shareholders).

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?

As a general principle, Article 24 of the Professional Code for Physicians in France prohibits physicians from accepting any advantage in cash or in kind, in whatever form, directly or indirectly, as consideration for any prescription or medical act.

Therefore, such advantages can be allowed only if they do not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. They must also be of a "negligible value" (as required by Article L. 1453-6, 4° of the FPHC).

More specifically, such advantages could be:

- informational or educational materials, provided they are (i) related to the practice of the medicine or the pharmacy, and (ii) for the direct benefit of the patient care; or
- items for medical use, provided they are (i) intended for the education of HCPs and for the care of the patients, and (ii) they do not reduce costs usually born by the HCPs for their day-to-day practice.

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, volume-related discounts to public or private organisations purchasing medicinal products are permitted by applicable rules in France. Such discounts are not considered as prohibited advertising or inducements. In this respect, Article L. 1453-6 of the FPHC specifies that such type of business advantages offered in the context of contracts governed by the provisions of the French Commercial Code ("**FCC**") are not considered as prohibited advantages within the meaning of Article L. 1453-3 of the FPHC.

In practice, such discounts must comply with commercial principles set forth in the FCC, e.g., the volume-related discount must clearly appear on the invoice.

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? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?

There are no specific restrictions regarding such extra services or equipment, provided it complies with public law when a public

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institution is concerned (and in particular, public tenders procedure) or private law when a private institution is concerned (in particular, commercial, civil and competition law).

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?

French law does not contain any specific regulation in this respect. However, the offering of a refund scheme if the product does not work does not seem to be allowed. This could be considered as misleading information relating to the product (i.e., suggests that the product may not work).

In this respect, the fact that the product is a prescription-only medicine or an over-the-counter medicine does not make any difference.

However, from a social security point of view, it would be far more difficult to implement such a refund scheme if the product is reimbursed by the social security schemes (in such case, the refund would have to be offered to the social security).

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

Yes. Pursuant to Article L. 1453-7, 5° of the FPHC, the funding, or the participation to the funding, by a pharmaceutical company, of actions of continuing medical education is permitted, by derogation to the general prohibition of advantages to the HCPs.

In principle, the funds must be granted to legal entities which offer continuing medical education, for a collective use, and not to a HCP directly. In this respect, the provisions of the FPHC have been recently strengthened with the Law dated January 26, 2016 and the Ordonnance dated January 19, 2017. Pursuant to Article L. 1453-4 of the FPHC, the provision of an advantage to associations grouping HCPs, including those offering continuing medical education programmes, is subject to the general prohibition of advantages. However, in such case, a derogation exists (see question 4.2), which provides that donations to HCP associations is permitted, provided the purpose of the association is related to the professional activities of the HCPs concerned. In this case, the donation must be formalised by a contract to be declared or submitted for authorisation by the competent professional board.

In practice, a pharmaceutical company can provide funds to other types of legal entities, such as educational institutes or organisations. Although it is not specifically required by French law, it is recommended that the legal entities receiving the funds are entities duly registered with the French competent authority (the national agency for continuing professional education – the "**ANDPC**") as organisms providing medical education. In France, HCPs have to comply with compulsory and continuous educational training. To be considered compliant, they have to undergo said training sessions, which are proposed by organisations duly registered with the ANDPC. The purpose of this is to guarantee the quality of the training and the independence towards the pharmaceutical companies sponsoring or financing the organism.

4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

The anti-bribery provisions are set out in the French Criminal Code.

Bribery is defined as unduly proposing, directly or even indirectly, offers, promises, grants, presents or advantages to a public person, either 1° to execute, or to prevent the person from executing an action in the context of his/her function, mission or mandate, or 2° in order for this person to abuse his/her influence, in the view of obtaining from a public authority or administrative body distinctions, markets or other favourable decisions.

A person that proposes, directly or even indirectly, to a private person who, in the context of his/her professional or social activities, has a director position or works for a physical person, a legal entity or any organism, offers, promises, grants or presents any advantages, for himself/herself or for other people, in the view of obtaining from him/her that he/she acts, or prevents himself/herself from acting, in violation of his/her legal, contractual or professional obligations, is also punished by the French Criminal Code.

The French authorities competent for anti-bribery practices, i.e., the "General Directorate for Competition Policy, Consumer Affairs and Fraud Control" ("*Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes*", the "**DGCCRF**") and the "**AFA**" ("*Agence française anti-corruption*") can investigate breaches to the anti-bribery rules independently from the pharmaceutical authorities.

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 and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

The offering of hospitality to HCPs is governed by the anti-gift rules of the FPHC. As a derogation to the general prohibition, the offering of hospitality to HCPs is allowed. More specifically, Article L. 1453-7 of the FPHC provides that hospitality can be offered, directly or indirectly, in the context of exclusively professional or scientific meetings, or in the context of events intended to promote health products, provided the hospitality (i) is reasonable, (ii) is strictly limited to the main objective of the meeting or event, and (iii) is not extended to the HCPs' relatives.

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Also, a contract must be executed in this respect and either (i) declared, or (ii) submitted for prior authorisation (depending on the amount at stake) to the competent board of professionals.

It does not make any difference if the hospitality offered takes place in a foreign country. If the HCP is French, the rules applicable in France must be complied with. In principle, the contractual arrangements should be set up by the company offering the hospitality, and not the company affiliate where the hospitality takes place. In practice, however, if the HCP is French and if a company affiliate exists in France, it would make sense to involve such French affiliate in the setting up of the hospitality arrangements with the HCP, notably for the purpose of declaring or submitting for authorisation the contract to the competent board of professionals.

There are no explicit and official thresholds applicable to hospitality. However, the maximum amounts mentioned by the French medical board of professionals are commonly used as a reference:

- for accommodation: €250 in France; €325 in Paris and European capitals; and €350 in the US, Asia, Australia, Switzerland;
- for meals: €70;
- for breaks: €15 for Europe; and €25 in the US, Asia, Australia, Switzerland; and
- for transportation: 1st class train, flight in economy class up to six hours, above which business class is allowed.

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?

If the HCP actively participates in the scientific meeting, for example as a speaker, it is possible to pay him/her for this. In such case, a services contract must be executed between the pharmaceutical company and the HCP, and be either (i) declared, or (ii) submitted for prior authorisation (depending on the amount at stake) to the competent board of professionals.

On the other hand, it is not possible to pay a HCP if he/she is just attending the meeting, passively (e.g., to pay him/her for his/her time). In such case, however, the pharmaceutical company can offer him/her hospitality, under the conditions and within the limits above-mentioned.

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?

Pharmaceutical companies may be held responsible for the contents of scientific meetings organised by the company. It is also the case in the context of scientific meetings, except if it can be proven that the content of the presentations was exclusively non-promotional (which may be difficult in practice). As an example, if off-label information is provided during a meeting organised or sponsored by a company (and if it cannot be proven that the meeting was exclusively non-promotional), the company may be held responsible for the presentation of off-label information in the context of promotional presentations.

However, a pharmaceutical company will not be held responsible for the contents of a scientific meeting if it has only offered hospitality to HCPs attending the meeting, but has not organised nor sponsored such meeting.

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, it is possible to pay HCPs to provide expert services (e.g., participating in advisory boards), under certain conditions.

Pursuant to Articles L. 1453-7 *et seq*. of the FPHC, it is possible to pay HCPs for research activities, scientific evaluation activities, consultancy services, services, or commercial promotion services, if the remuneration is proportional to the services and the compensation or expenses do not exceed the costs actually incurred by the HCP.

Also, a contract must be executed and specify the services concerned. Such contract must be either (i) declared, or (ii) submitted for prior authorisation (depending on the amount at stake) to the competent board of professionals.

In addition to those principles, the Ethical professional provisions issued by the LEEM specify supplementary principles that must be complied with and provisions that must be inserted in the contract with the HCP. Among those principles, the LEEM indicates that:

- the services must correspond to a precise legitimate need, clearly identified by the company before the conclusion of the contract;
- selection criteria of the experts are related to the said identified need of the company and the employees in charge of their selection are competent to check whether these criteria are complied with or not;
- the number of experts shall not exceed the number of participants reasonably necessary to meet the identified need;
- the company keeps records of the documentation relating to the services and makes appropriate use of the services;
- the solicitation of the HCPs for the services does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products; and
- remuneration is reasonable and corresponds to the fair market value of the services provided.

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

Yes, it is possible to pay HCPs to take part in post-marketing surveillance studies. In such case, Articles L. 1453-7 *et seq*. of the FPHC shall apply (see question 5.4).

In addition to those principles, the ethical professional provisions issued by the LEEM also specify supplementary principles that must be complied with, and notably:

- the study shall pursue a scientific objective;
- there must be (i) a study plan/protocol, and (ii) written contracts between, on the one hand, HCPs and/or institutions where the study is conducted and, on the other hand, the company which is a sponsor of the study, specifying the services to be rendered;
- the remuneration, if any, shall be reasonable and correspond to the fair market value of the services;

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- the study shall comply with applicable laws and regulations relating to data protection;
- the study shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products;
- the study protocol shall be approved and managed by the scientific department of the company;
- the study results shall be analysed by or on behalf of the company and reports shall be provided to the scientific department of the company, which shall keep records of these documents for a reasonable period of time. The company shall send the documents to all HCPs participating in the study and, upon request, to competent authorities. If the results have a subsequent importance for the benefits/risks evaluation, the report summary shall be sent to the concerned competent authority; and
- the sales representatives shall not take part in the implementation of these studies.

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

Yes, it is possible to pay HCPs to take part in market research involving promotional materials. In such case, the same rules and principles as those mentioned in question 5.4 apply.

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?

Yes, it is possible to advertise non-prescription medicinal products to the general public, provided none of the different presentations of such medicinal products are reimbursed by the French social security schemes and provided that the marketing authorisation of the medicinal product does not contain any restriction nor prohibition regarding advertising to the general public due to a potential risk for public health, notably if the use of the medicinal product is dependent upon the HCP's intervention for diagnostic, initiation or surveillance of the treatment (Article L. 5122-6 of the FPHC).

The promotional character of the advertising must be obvious, and the medicinal product shall be clearly identified as a medicinal product.

Pursuant to Article R. 5122-3 of the FPHC, the advertisement shall contain, at least, the following information:

- the name of the medicinal product, as well as the INN;
- the necessary information for a proper use;
- the express invitation to read carefully the instructions mentioned on the notice or on the package, as the case may be;
- a word of caution, an invitation to talk to a pharmacist and, if the symptoms persist, an incentive to consult a doctor; and
- the mention of the generic character of the product, as the case may be, together with additional information.

Please note that, pursuant to Article R. 5122-4 of the FPHC, the advertisement cannot contain certain specific allegations, e.g., that the benefit of the medicinal product is guaranteed.

As indicated, any advertisement to the general public is subject to the prior obtaining of the "visa" from the ANSM (see question 1.5).

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

No, it is not possible to advertise prescription-only medicinal products to the general public, except in some limited cases: advertising for anti-tobacco medicinal products or vaccines, that are subject to prescription; and/or reimbursable by the French social security schemes, is possible under certain conditions (provided in Articles L. 5122-6 and L. 5122-8 of the FPHC).

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, such disease awareness campaigns are permitted, provided they do not contain any direct or indirect reference to a medicinal product (Article L. 5122-1 of the FPHC). Indeed, the FPHC excludes from the definition of "promotion" the release of information related to human health or human diseases, as soon as there is no reference, even indirectly, to any medicine.

Pursuant to the recommendations issued by the ANSM, such non-promotional information can mention, on a non-exclusive basis, the therapies available, whether of medicinal nature or not. The therapeutic classes (from the ATC classification system) can be mentioned provided they contain more than one medicinal product.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

There are no specific prohibitions in France which prohibit the issuance of press releases concerning prescription-only medicinal products to non-scientific journals. However, such press releases are allowed, provided they have informative purposes and they are not intended, in practice, to promote a specific medicinal product.

On this subject, the Court of Appeal of Versailles pointed out that the fact that the information is provided during a press release does not exclude a potential promotional character. However, the promotional intention of the company has to be evidenced. In this respect, attention has to be paid to the lyrical style employed and any allegations, as the case may be (Court of Appeal of Versailles, June 25, 2014, N. 14/03658).

If the press release does not constitute advertising, it is not specifically prohibited for it to refer to developments in relation to as yet unauthorised medicinal products or unauthorised indications. However, press releases must be made with extreme caution to ensure that they cannot be considered as promotional.

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

Restrictions that apply to advertising do not apply to information documents of a scientific, technical or financial character, issued by the company, provided they are not promotional (Article R. 5124-67 of the FPHC).

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ANSM refers to this information as "institutional information". In its recommendations, the ANSM indicates which information can be mentioned in this context:

- the name of the medicinal product;
- the INN; and
- the therapeutic class.

According to the ANSM, any other information related to the medicinal product would be deemed as promotional, in particular the therapeutic indication, posology, method of administration, contraindications, tolerability, adverse effects, pictures of dosage forms and packaging.

Similarly, every term with a reference to a hierarchy, such as "leader", "first", "best", "number 1", "the only one", qualifying a medicinal product, may be used only if these qualifiers refer to the turnover, market share, quantities sold, etc. Such qualifiers may not be used if they refer to a comparative evaluation of therapeutic benefits of a treatment or medicinal product.

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

There are no specific legal provisions in France which govern the meeting with, and the funding of patient organisations. As a general principle, the provisions of the FPHC governing the promotion of medicinal products, and notably the prohibition of advertising of prescription-only and/or reimbursed medicinal products to the general public, apply to the relationship between the pharmaceutical industry and patient organisations.

There are additional requirements set out in the "Ethical professional provisions" ("*Disposition déontologiques professionnelles*") issued by the LEEM. Cooperation between the pharmaceutical industry and patient organisations, as well as their funding by the pharmaceutical industry, is possible provided certain principles are complied with. If a pharmaceutical company provides financial support to a patient organisation, a written agreement is required, which shall mention notably the amount provided and the purposes of the support. It shall also detail the indirect and non-financial support. Also, the pharmaceutical companies have to stay neutral and respect the organisation's independence. The collaboration has to be conducted in a transparent and open manner. Also, such collaboration must not entail any promotion of prescription-only and/or reimbursed medicinal products.

According to the above "ethical professional provisions", pharmaceutical companies must also disclose publicly all financial and non-financial supports provided to patient organisations.

Regarding hospitality, similar principles as those governing hospitality to HCPs apply (e.g., the hospitality must be reasonable, strictly limited to the main objective of the event, and not extended to the relatives of the patient organisation).

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

Free samples of medicinal products cannot be provided for a promotional purpose to the general public (Article L. 5122-10 of the FPHC).

Also, pursuant to Article R. 5122-4 of the FPHC, the advertising of medicinal products to the general public shall not contain any direct or indirect offer of objects, products or material advantages.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

Pursuant to Article L. 1121-15 of the FPHC, information/details relating to clinical trials authorised by the ANSM have to be disclosed on a national database (register).

All clinical trials shall be registered before the study starts.

The "*Arrêté du 9 décembre 2008 fixant le contenu du répertoire des recherches biomédicales autorisées portant sur des médicaments à usage humain*" as of December 9, 2008, lists the information that the register must contain. Among others, the register must contain the title of the clinical trial, the EudraCT number, details on the sponsor, a description of the clinical trial as well as some details on the investigational medical product.

The sponsor of the clinical trial can refuse to make publicly available some of the information requested if it considers that such disclosure is likely to prejudice its legitimate interests, notably regarding confidentiality. According to the above-mentioned *Arrêté*, the information that a company may refuse to make publicly available are: the complete title of the trial; the main secondary objectives, if any; and the number of participants expected in France or the number of participants expected in the countries where the clinical trial is conducted.

According to the above *Arrêté*, the register must also disclose, within one year from the end of the clinical trial, the overall results of the research.

In practice, this register is available on the website of the ANSM, which contains a link to the EU clinical trials database.

7.2 Is there a requirement in the legislation 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 companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

Yes, Article L. 1453-1 of the FPHC provides for the obligation for companies to make publicly available, on a public website (transparency central platform), the following information relating to the agreements concluded with, among others, HCPs, associations of HCPs, patient organisations and healthcare institutions:

- the specific purpose of the agreement;
- the date of the agreement;
- the direct and final beneficiary; and
- the amount of the agreement.

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Also, companies shall make publicly available on the above-mentioned public website any transfer of value (remuneration or direct or indirect advantage) exceeding €10 granted to the above-mentioned persons/entities (e.g., HCPs, associations of HCPs, patient organisations, healthcare institutions) (Articles L. 1453-1 and D. 1453-1 of the FPHC).

All companies manufacturing or commercialising health products or executing related services are concerned by this requirement, regardless of whether they are settled in France or not and regardless of whether their products are commercialised in France or not, as long as they have a relationship with the above-mentioned French persons/entities (e.g., French HCPs, French associations of HCPs, French patient organisations, French healthcare institutions (*Circulaire* issued by the French Direction Générale de la Santé, see http://circulaires.legifrance.gouv.fr/pdf/2017/06/cir_42320.pdf).

The companies shall declare such information on the public website no later than (i) September 1 of each year, for agreements concluded or transfers or value granted during the first semester of the year, and (ii) no later than March 1 of each year, for agreements concluded or transfers of value granted during the second semester of the year.

7.3 Is there a requirement in your 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 companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

The EFPIA "Disclosure Code" (binding on the member companies of the LEEM) requires companies to disclose transfers of value made to HCPs or to healthcare organisations. Such disclosure shall be made every year by June 30 for payments made the year before (e.g., by June 30, 2019 for payments made in 2018), either on the company's websites or on a central platform (Section 2.04 of the EFPIA "Disclosure Code").

Since French legislation already provides for a specific central platform dedicated to the disclosure of transfers of value, the disclosure of such information on the companies' websites is not required.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

Since the above-mentioned publication of transfers of value is a legal requirement, HCPs cannot object to such publication. Moreover, French legislation does not provide for any obligation for the company to obtain the consent of HCPs for the publication of their information, not for any right of objection in favour of HCPs. In practice, companies must, however, inform HCPs of this publication, in accordance with applicable laws and regulations relating to data protection (i.e., notably the General Data Protection Regulation). This information is usually provided by a clause in the contract signed between the company and the HCP.

8 The Internet

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

The advertising of medicinal products on the Internet is subject to the rules governing the advertising of medicinal products in general (please see section 7 above). Internet advertising is also regulated by the "Charter for the communication and the promotion of health products on the Internet and e-media" ("*Charte pour la communication et la promotion des produits de santé (médicaments et dispositifs médicaux) sur Internet et le e-media*") issued by the ANSM.

This Charter aims notably to help companies design and process their websites in accordance with the principles relating to the advertising of health products.

As a general principle, the website must particularly identify the processor of the website, the intended recipients and the type of information provided. Also, the website must be regularly updated and mention clearly the last update, and the advertisements must be clearly identified (the promotional character can be either deducted from the specific promotional format of the website page, or specified with a written mention if the promotional character is not obvious).

More specifically, the structure of the website must comply with the rules governing the advertising of medicinal products, e.g., provisions relating to the prohibition of the promotion to the general public of certain medicinal products (prescription-only and/or reimbursed medicinal products). As a consequence, advertisements intended for HCPs must be displayed on web pages accessible to HCPs only.

The advertisement must contain the mandatory information required by the FPHC in relation to the medicinal product concerned (see question 3.1). They shall be immediately apparent and the size of the characters shall not be smaller than the smallest characters used for promotional statements.

The relevant authorisation ("visa") must be obtained from the ANSM before the advertisement is put online (see question 1.5).

The Charter for the communication and the promotion of health products on the Internet and e-media also requires websites to clearly separate the promotional section of the website from other sections, such as, for example, those relating to "institutional information" (see questions 6.5) or those containing information relating to human health or human disease (which is not deemed promotional, provided there is no reference, even indirectly, to a medicinal product).

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?

Pursuant to the "Charter for the communication and the promotion of health products on the Internet and e-media", genuine restrictions of access have to be implemented by companies to ensure that members of the general public do not have access to sections of websites intended for HCPs.

This Charter is not very specific in this respect, but it provides that, as an example, an access code can be granted to the HCP once the company has been able to duly confirm his/her statute of HCP, via the fulfillment of an electronic form or by the registration and/or identification of the HCP by means of his/her professional number.

In any case, the mere confirmation by the user that he/she is a HCP is not sufficient.

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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?

Pursuant to the "Charter for the communication and the promotion of health products on the Internet and e-media", a link from a company-sponsored website to an independent website shall not aim at circumventing the rules governing advertising of medicinal products. Companies will be responsible for any such link that would circumvent applicable rules. In that respect, a company may be held responsible due to the content of the independent website.

The Charter distinguishes the "simple link", which gives access to the homepage of a website, from the "deep link", which gives access to a subpage. As a general principle, a "deep link" may be used for every public official website page. In this respect, the Charter also provides for specific recommendations relating to peer-reviewed journals' or congresses' websites.

In any event, the transition from one website to the other shall be obvious for the user (either by a message of information, or by opening a new tab).

If the linked websites are restricted to HCPs, the access codes or other security system employed cannot, in any event, be provided by the initial website. Every website shall manage its own security system, with specific access codes, unless the linked websites benefit from a common authentication system.

Reverse linking is not specifically addressed by the above-mentioned Charter. However, the principles of the said Charter shall apply.

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

Medicinal products for which advertising to the general public is allowed can be advertised on a website which is accessible to the general public, provided such advertising complies with the applicable requirements (see question 6.1).

Also, a website accessible to the general public can contain information which is not considered as promotional, e.g., "institutional information" (see questions 6.5), or information relating to human health or human diseases, provided such information does not contain any reference, even indirectly, to a medicinal product (see question 1.2), or concrete information and reference documents related, for example, to packaging modifications, warnings concerning adverse effects identified in the context of pharmacovigilance, and sales catalogues and price lists, provided they do not contain any information on the medicinal product (see question 1.2).

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

According to the "Charter for the communication and the promotion of health products on the Internet and e-media", the use of the "like" button of social networks such as a Facebook page relating to a medicinal product may be interpreted as a claim of recovery by the general public or as a validation by a HCP. It shall therefore be considered as not compliant with the provisions of the FPHC.

Therefore, the promotion of the medicinal products via social media shall be considered as not allowed, unless these options (such as the "like" button) can be deactivated.

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?

The significant developments that have occurred in recent years concern the anti-gifts provisions, which have been modified recently by a Law dated January 26, 2016 and by an Ordonnance dated January 19, 2017 and which are now set out in Articles L. 1453-3 *et seq*. of the FPHC. Such new provisions have entered into effect on July 1, 2018, except for the provisions which need the publication of an implementation decree.

The purpose of these provisions is to strengthen and to broaden the scope of the anti-gifts regulations (see question 4.2).

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

To date (May 2019), an implementation decree is expected to specify notably the process applicable to the contracts and relationship between pharmaceutical companies and HCPs (and other stakeholders). For example, contracts must now be executed and either (i) declared, or (ii) submitted for prior authorisation (depending on the amount at stake) to the competent board of professionals.

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

No, there are no general practice or enforcement trends that have become apparent in France.

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Agathe Simon, "who is very talented and has solid experience in contract law, provides a solid experience in business law, notably in the field of complex operations in a multijurisdictional environment, and has strong skills in the regulatory area of the health sector" (*The Legal 500 EMEA*, Edition 2017).

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François-Maxime, "who takes heed of his clients' particular needs and adapts his advices to every single situation, provides a very high level of skills in both the life science and business law spheres" (*The Legal 500 EMEA*, Edition 2017).

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Mercure Avocats is a law firm specialised in business law with strong expertise in the field of pharmaceutical law/life sciences. The founders of Mercure Avocats were trained in one of the most reputed international law firms in the field of life sciences. Mercure Avocats has developed expertise in regulations in life sciences, in the pharma, cosmetics, food products and associated technology sectors. Mercure Avocats also specialises in preparing and negotiating all types of contracts specific to the healthcare sector (e.g., R&D contracts, licence agreements, contracts with HCPs, etc.). Thanks to the "human size" of the firm, the files are directly handled by the partners and the team is committed to working intimately with clients in order to find solutions fitting to their individual challenges, in a long-term relationship. Mercure Avocats strives to offer flexible working methods and to implement pragmatic solutions taking into account its clients' operational/business constraints.

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