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France

PHARMACEUTICAL ADVERTISING

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in France.

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FRANCE
PHARMACEUTICAL ADVERTISING

1. What laws are used to regulate advertising on medicines in your jurisdiction?

The rules governing advertising on medicines are laid down in articles L.5122-1 and seq. and R.5122-1 and seq. of the Public Health Code ("**PHC**"), (other legal provisions apply to medical devices which are not considered here).

In addition to the legal provisions that are specific to medicines, the general legal provisions governing unfair commercial practices, including false advertising, which are laid down in the Consumer Code, also apply.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

Various guidelines and self-regulatory rules frame the advertising of medicines. They are of different nature and include recommendations of authorities applicable to any company, as well as self-regulatory rules applicable to members of given industry bodies.

a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

i) Guidelines of the French Medicines Agency (ANSM):

The French Agency for the Safety of Health Products (herein after the "**ANSM**"), published recommendations on advertisement of medicinal products directed towards healthcare professionals [1] and to the general public [2], available on its website. Recommendations relating to advertisement towards the general public also includethe "*Charter concerning communication and promotion of health products (medicines and medical devices) on the Internet and in the electronic media"*[3].

These recommendations are applicable in principle to any company advertising medicines.

ii) Self-regulation by the industry:

The LEEM (*Les Entreprises du Médicament* – the French professional organisation of pharmaceutical companies) has its own ethical rules of conduct applicable to its members entitled "*Dispositions Déontologiques Professionnelles"* [4] (Professional Ethical Provisions).

The Professional Ethical Provisions include the rules governing the advertising of medicines, notably the "*EFPIA Code of Practice"* [5] as well as the "*Charter relating to information by canvassing or prospection for the promotion of medicinal products*"[6] signed between the LEEM and the Economic Committee for Health Products (herein the "**CEPS**").

iii) Agreements between the industry and the Economic Committee for Health Products (CEPS):

A "*Charter relating to information by canvassing or prospection for the promotion of medicinal products*"[7] has been signed between the LEEM and the CEPS.

b) What is the legal status of the self-regulatory codes?

i) Guidelines of the French Medicines Agency:

The ANSM is a public entity placed under the supervision of the Ministry of Health. Its recommendations do not have legal force but are very useful guidelines since authorities and courts take them into account in their decisions.

ii) Self-regulation by the industry:

The LEEM ethical rules are of self-regulatory nature and do not have a legal force. They are binding for the LEEM members. The CODEEM (*Comité de déontovigilance des*

entreprises du médicament),the ethical vigilance committee of the LEEM is in charge of monitoring the implementation of these ethical rules and can pronounce sanctions in case of non-compliance by LEEM members. These rules also serve as good practice standards for non-LEEM members companies.

iii) Agreements between the industry and the Economic Committee for Health Products:

The "*Charter relating to information by canvassing or prospection for the promotion of medicinal products*" signed between the LEEM and the CEPS aims to frame commercial and promotional practices.

On the basis of this Charter and in accordance with article L.162-17-8 of the French Social Security Code, the CEPS has the power to set annual quantified objectives concerning promotional practices.

Failure to comply with the objectives set by the CEPS may result in financial penalties.

[1] https://ansm.sante.fr/documents/reference/recommandations-pour-la-publicite-des-medicaments-aupres-des-professionnels-de-sante

[2] https://ansm.sante.fr/documents/reference/recommandations-pour-la-publicite-des-medicaments-aupres-du-grand-public

[3] Charter on the communication and promotion of health products (medicines and medical devices) on the Internet and e-media

[4] Professional Ethical Provisions of the LEEM, in force since 1 June 2021

[5] The EFPIA Code of Practice

[6] Charter relating to information by canvassing or prospection for the promotion of medicinal products

[7] bid.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

"*Advertising of medicinal products*" is legally defined under article L.5122-1 of the PHC – essentially the same definition as in article 86 of EU Directive 2001/83 – as "*any form of information, including door to door information, canvassing or inducement, designed to promote the prescription, supply, sale or consumption of medicinal products*".

a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

Anything falling within the broad definition of article L.5122-1 of the PHC may constitute advertising regardless of the medium used.

The following exclusions are listed in the same article(essentially the same exclusions as in article 86 of the EU Directive):

- information provided, in the framework of their functions, by pharmacists managing hospital pharmacies;
- correspondence, possibly accompanied by materials of non- promotional nature, needed to answer a specific question about a particular medicinal product;
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general medicine precautions, trade catalogues and price lists, provided they include no product claims;
- information relating to human health or diseases, provided that there is no reference, even indirectly, to medicinal products.

Article R.5124-67 of the PHC also excludes informative documents, of scientific, technical or financial nature, prepared by a pharmaceutical company that are not designed to promote a medicinal product.

Besides, advertising does not include patient information such as the labelling and the package leaflets accompanying medicinal products, which are subject to the provisions of Title V of the PHC.

The definition of advertising however includes all forms of promotion, including medical visits, sample delivery, advantages perceived by healthcare professionals whether in kind (i.e. gifts, equipment donations, invitations, catering costs, payment of travel expenses) or in cash (i.e. commissions, discounts, rebates or reimbursement of expenses).

b) Does the definition apply equally to all target audiences?

The definition is the same for all target audiences.

However, the legal regime governing advertisement differs depending on whether the advertisement targets the public [1] or healthcare professionals [2].

(i) Advertisement of medicinal products directed at the public:

Advertisement of medicinal products directed at the public is only possible for medicines that are not subject to prescription and are non-reimbursable by the compulsory health insurance schemes. Prescription medicines (compulsory or facultative) as well as reimbursable products are excluded.

There is an exception with respect to vaccines and tobacco-weaning medicines which can be advertised, even if they can be prescribed or reimbursed.

Furthermore, the marketing authorisation must not contain any prohibition or restriction on advertising to the public due to a possible risk to public health, in particular when the medicinal product is not suitable for use unless a physician is involved in the diagnosis, initiation or monitoring of the treatment.

The requirements as to the content of the advertisement are specific depending on whether it is directed at the public or at healthcare professionals (see explanations in the sections below).

The requirements regarding content of advertising directed to the public are set out in articles L.5122-6 to L.5122-8 and R.5122-3 to R.5122-7 of the PHC.

(ii) Advertisement of medicinal products directed at healthcare professionals:

Advertisement of medicinal products directed at healthcare professionals is be possible for all medicines.

Detailed rules for advertising to healthcare professionals are set out in articles L.5122-9 to L.5122-10 and R.5122-8 to R.5122-17 of the PHC. These include requirements as to the content of such advertising, for example the requirement to include the pharmaceutical form of the medicine and its adverse reactions.

[1] Article L.5122-6 and seq. PHC

[2] Article L.5122-9 and seq. PHC

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Press release regarding medicines are allowed in France and should be regarded as advertisement. However, if the press release brought informative documents, of scientific, technical, or financial nature, prepared by a pharmaceutical company and are not designed to promote a medicinal product, it will not be considered as advertisement [1].

(i) Advertising to the general public

Provided that the advertising includes the mandatory information provided for by the Public Health Code in a legible manner under normal reading conditions, it may be carried in printed media and press announcements. There are no further restrictions than those applying to advertisements made to the public [2].

(ii) Advertising to healthcare professionals

Similarly, when the advertisement includes the mandatory information, press, special issue, and in-house magazine advertisements are generally allowed as advertising supports [3].

[1] Article R.5124-67 of the PHC

[2] ANSM recommendations regarding media to be used for advertising to public

[3] ANSM recommendations regarding media to be used for advertising to healthcare professionals

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

Pharmaceutical companies must have a dedicated service in charge of advertisement under the responsibility of the "responsible pharmacist" known as the Chief pharmaceutical officer ("*pharmacien responsable*") who is in charge of ensuring compliance with the rules governing advertisement and in particular the scientific validity of the information [1].

The company must keep a copy of all advertisements made for three years as of the last date of dissemination thereof and make it available to the ANSM together with a record the addressees, the method of dissemination and the date of first dissemination [2].

With respect to advertisements directed at the public, the applicant must assign an internal reference number for all advertisement materials [3] according to rules defined by a decision of the Director General of the ANSM [4]. This number must be mentioned on the advertisement, except for advertisements made on radio broadcast.

[1] Articles L.5124-2 and R.5122-2 of the PHC

[2] Article R.5122-2 PHC / Art. 98 of the Directive

[3] Article R.5122-6 PHC

[4] Decision of April 25, 2013 setting the rules for the development of the internal reference number relating to advertisements for medicines and products mentioned in Articles L. 5122-14, R. 5134-11 and R. 5134-15 of the Public Health Code

6. Do companies have to have material approved by regulatory bodies prior to release?

Advertisement for medicinal products must be pre-approved by the ANSM [1]. The approval by the ANSM is called an advertisement "*visa*". Whilst previously advertising directed at healthcare professionals did not require pre-approval, since 2012 the ANSM pre-approves all advertising for medicinal products, whether directed at the general public or at healthcare professionals.

Each year, the ANSM publishes a calendar indicating the yearly sessions during which *visa* applications can be filed [2]. The visa is deemed granted in the absence of decision by the ANSM within two months as of the day on which the application was filed. A *visa* has a validity of period of two years but cannot exceed the validity period of the marketing authorisation.

The *visa* can be suspended or withdrawn in case of non-compliance with the applicable legal provisions [3].

[1] Articles L.5122-8 and L.5122-9 of the PHC, R.5122-5 to -7, R.5122-12 to -16 of the PHC

[2] Articles R.5122-5 and R.5122-13 of the PHC

[3] Articles L.5122-8 and -9 of the PHC

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

Pursuant to articles L122-1 and seq. of the Consumer Code, comparative advertising is allowed but (i) shall not be misleading, (ii) shall cover products or services addressing the same need, (iii) shall objectively compare one or several relevant main features of the products/services which can be verified, and which are essential to the concerned products/services.

When it comes to medicines, in addition to the requirements mentioned above, the advertisement [1] must not undermine the protection of public health[2] and must present the medicinal product objectively in order to promote its proper use.

(i) Advertisement to the general public

Advertisement of a medicinal product to the public may not contain any element that "*suggests that the effect of the medicine (...) is greater than or equal to that of any other treatment or medicine*" [3]. Therefore, comparative advertising to the public may not relate to the pharmaceutical qualities of the medicinal product, but only and possibly to the economic aspects.

(ii) Advertisement to healthcare professionals

Comparative advertising is possible when addressed to healthcare professionals, as long as it complies with the ANSM recommendations [4].

Comparative advertising may concern two or more products, under their brand name, under their the international non-proprietary name (INN) where the brand is identifiable, as long as they have the same therapeutic purpose (non-medicinal therapy is not excluded from the scope).

Any advertising comparing medicines should be based on relevant and comparable product characteristics. Indeed, comparative advertising must be objective and should lead to a distortion in the representation of results, so as to unduly value one product over another. Furthermore, such advertising should not focus exclusively on favourable elements. It shall at least include criteria of efficacy and safety of use (elements of the risk-benefit balance), but may also include criteria of interest to the practitioner such as dosage, duration of treatment, interactions, acceptability, etc.

Regarding generics, price alone can be a criterion for comparison, whether the comparison is with the princeps or with other generics from the same group. For non-generic medicines, it is more relevant to consider a comparison of treatment costs instead of the prices alone.

[1] As defined in article L.5122-1 of the PHC

[2] Article L.5122-2 of the PHC

[3] Article R.5122-4 of the PHC

[4] ANSM recommendations on comparative advertising

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

(i) Providing information on unauthorised medicines or unauthorised indications

Only authorised medicines can be advertised, more precisely medicines that have a marketing authorisation or benefit from a parallel import authorisation [1].

Article L.5122-2 of the PHC provides that advertising must comply with the provisions of the marketing authorisation as well as the therapeutic strategies recommended by the French High Authority for Health (*Haute Autorité de Santé*). Thus, it is forbidden to anticipate the results of studies that have not yet been filed concerning possible changes to the marketing authorisation, or even during the examination by the marketing authorisation commission (properties, indications, dosage, etc.). This is the case for studies for which the indications, dosage or duration of treatment have not been validated yet and therefore cannot be advertised [2].

With regard to medical congresses with an independent scientific committee, or meetings organised under the aegis of scholarly societies or groups of experts mandated by them, which report on the progress of research, the publishers of the medical press publish special editions covering all or part of the work presented, in order to inform healthcare professionals.

When these special editions present data from research not yet approved by the French authorities, they must include a warning on the first page stating so. The publication of these special editions, and their content, is the responsibility of the publishers and their reading committee [4].

These publications may contain advertising inserts (excluding advertisements for products mentioned in these documents and for which the information provided is not mentioned in the marketing authorisation).

The distribution of these special editions and the selection of the healthcare professionals concerned by the subject is ensured exclusively by the publishers and not repeated. Whenever articles in these special editions provide scientific information on pharmaceutical products outside the terms of their marketing authorisation, their promotional use is prohibited (in particular through medical visit) [5].

[1] Article L.5122-3 of the PHC

[2] ANSM recommendations relating to ongoing clinical studies

[3] Article L.5122-1 of the PHC

[4] Editorial Advertising Charter, 2015, article 8

[5] ANSM recommendations on professional meetings and congresses

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

Medicines subject to medical prescription and medicines reimbursable by compulsory health insurance schemes may not be advertised to the general public (with an exception for vaccines or tobacco-weaning products).

Medicine advertising directed to the public must be designed so that the promotional nature of the message is obvious and the product is clearly identified as a medicine. The advertising must at least include the following information [1]:

- The name of the medicinal product, as well as its common name;
- Essential information for the proper use of the medicine;
- An express invitation to read carefully the instructions on the leaflet or on the outer packaging, as the case may be;
- A cautionary warning, a recommendation to seek medical advice from a pharmacist and, if symptoms persist, an invitation to consult a physician;
- For a generic speciality, the indication of this status and, if the generic group to which the speciality belongs includes one or more reference specialities, the indication: "*This speciality is a generic of*", followed by the name of the reference speciality or

specialities, their dosage and their pharmaceutical form. In such case, the advertisement also includes the statement: "*Medicine listed in the generic groups list. At the time of substitution, consult the list of excipients of known effect on the packaging as well as the generic groups list to find out about any warnings that may exist*."

For an advertising on a radio broadcast, the mention of the international non-proprietary name is only required when the medicine contains two or less active ingredients. For generics it is not necessary to refer to the active ingredient, however the mention that the speciality is a generic is required.

Furthermore, an advertisement for a medicinal product to the public may not contain any element that [2]:

« 1° Would make medical consultation or surgery appear unnecessary, in particular by offering a diagnosis or recommending treatment by correspondence;

2° Would suggest that the effectiveness of the medicine is guaranteed, is free of adverse effects, or is greater than or equal to that of another treatment or medicine;

3° Would suggest that a normal state of health can be improved by the use of the medicine;

4° Suggests that a normal state of health may be affected in the event of non-use of the medicinal product; this prohibition does not apply to advertising campaigns for vaccines or medicinal products mentioned in the third paragraph of article L. 5122-6;

5° Would be targeted exclusively or primarily at children;

6° Would refer to a recommendation from scientists, healthcare professionals or persons who, although neither scientists nor healthcare professionals, may, by their reputation, encourage the consumption of the medicinal product concerned;

7° Would assimilate the medicinal product to food, cosmetics or another consumer product;

8° Would suggest that the safety or efficacy of the medicine is due to the fact that it contains a natural substance;

9° Could lead, through a detailed description of symptoms, to a false self-diagnosis;

10° Would abuse of the use of frightening or misleading visual representations of changes to the human body due to disease or injury;

11° Would excessively or deceptively depict the action of the medicinal product in the human body;

12° Would refer to certificates of recovery;

13° Would emphasise that the medicinal product has received a marketing authorisation or has been the subject of a registration;

14° Would contain offers of bonuses, objects or products of any kind or direct or indirect material benefits of any kind.»

[1] Article R.5122-3 of the PHC

[2] Article R.5122-4 of the PHC

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

The provisions of the "anti-gift law" [1] apply. Specifically, they require transparency of the ties between the health industries and other actors in the health field, including patient associations (but also healthcare professionals, medical students or associations regrouping healthcare professionals or students).

All agreements concluded with patient associations must be made public through their publication on the public database "Transparency – Health" (*Transparence santé*). The same is true for all benefits in kind or in cash that companies would provide, directly or indirectly, to associations (i.e. for any remuneration or benefit whose amount is equal to or greater than €10, including all taxes pursuant to article D.1453-1 of the PHC [2]).

Furthermore, the subject is addressed in the LEEM's Professional Ethical Provisions, which include a section on relations with patient associations [3]. It is especially forbidden for the pharmaceutical industry to request, and for patient associations to promote, any medicine subject to compulsory prescription.

The objectives and scope of any partnership between patient organisations and the pharmaceutical industry should be transparent. The financial and non-financial support provided by the pharmaceutical industry should always be disclosed and should have been the subject of a written agreement specifying the amount of funding and their purpose or, where appropriate, include a description of any significant indirect support or non-financial support. Each pharmaceutical company is

expected to have an approval process in place for such agreements.

A pharmaceutical company may not publicly use a patient organisation's logo and/or branded materials without its written permission. Moreover, a pharmaceutical company should not seek to influence the language of the materials of patient organisations it funds in a way that would be favourable to its own commercial interests.

Each company must publish a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support, together with a brief description of the nature of the support.

Concerning events and hospitality, all events subsidised or organised by or on behalf of a company must take place in an appropriate location (i.e. it must be in line with the objective and purpose of the event). All forms of hospitality provided by the pharmaceutical industry to patient organisations and their members must be reasonable. Extended hospitality, depending on the event, should be limited to transport, meals, accommodation, and registration fees.

In principle, the company should not organise or subsidise an event that takes place outside its own country.

[1] Article L.1453-1 and seq. of the PHC

[2] Transparency – Health database: https://www.transparence.sante.gouv.fr

[3] Professional Ethical Provisions of the LEEM, in force since 1 June 2021 (pages 18-24, 31)

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

Advertising of a medicine to healthcare professionals must always be in accordance with the terms of the marketing authorisation. It must contain information that is accurate, up-to-date, verifiable and sufficiently complete to allow the recipient to form a personal opinion regarding the therapeutic value of the medicine [1]. It must specify the date on which it was last established or revised and include at least the following information [2]:

- The name of the medicine;
- The name and address of the company exploiting the medicine;
- The pharmaceutical form of the medicine;
- The qualitative and quantitative composition of the active ingredients, with the common name, and the components of the excipient, whose knowledge is necessary for the proper administration of the medicinal product;
- The marketing authorisation or registration numbers;
- Essential pharmacological properties with regard to therapeutic indications;
- Therapeutic indications and contraindications;
- The method of administration and, if appropriate, the route of administration;
- The dosage;
- The adverse effects;
- Special warnings and special precautions of use;
- Medicine interactions and other;
- The classification of the medicinal product in terms of prescription and delivery mentioned in the marketing authorisation;
- The limit selling price to the public when such a price is determined in application of the laws and regulations in force, accompanied, in such case, by the cost of the daily treatment;
- The situation of the medicinal product with regard to reimbursement by health insurance organisations or approval for public authorities provided for in article L.5123-2 of the PHC;
- For a generic speciality, the indication of this status and, if the generic group to which the speciality belongs includes one or more reference specialities, the indication: "*This speciality is a generic of*", followed by the name of the reference speciality or specialities, their dosage and their pharmaceutical form. In such case, the advertisement also includes the statement: "*Medicine listed in the generic groups list. At the time of substitution, consult the list of excipients of known effect on the packaging*." However, for an advertisement on a radio broadcast medium, only the statement that the product is a generic is required.

The ANSM's recommendations only require the following information to be included in the advertising document [3]:

1. Name, common name(s);
2. Indication and, where appropriate, inclusion in the therapeutic strategy in accordance with the procedures described in the

recommendation in force;
3. Safety data as described in the recommendation in force;
4. Prescribing and dispensing conditions;
5. Status of the medicine with regard to reimbursement by health insurance organisations or approval for public authorities provided for in article L.5123-2 of the PHC.

The other information provided for in article R.5122-8 of the PHC may be made available via a cross-reference to the product information sheet of the public database of medicinal products [4].

Any written mention must be perfectly legible [5]. According to the recommendations of the ANSM, these entries must comply with six essential criteria to ensure good legibility: the background, characters adapted and contrasted in relation to the background, the highlighting of titles, headings and key words, the absence of breaks in titles, the arrangement of compulsory information in the reading direction, the size of the characters, which may not be less than 7 Didot points or 8 pica points (known as '8 point font') for printed documents.

Furthermore, quotations, tables and other illustrations borrowed from medical journals or scientific books, used in advertising, must be faithfully reproduced and the exact source must be indicated [6].

It is not appropriate [7] to include in an advertisement for a medicinal product information relating to physiological or pathological conditions which would contraindicate the use of the advertised medicinal product.

It is permissible to use clinical studies as long as they have been published in a peer-reviewed journal, carried out under the conditions of use of the medicinal product as defined in the product's marketing authorisation and other existing reference documents [8]. Communication must focus primarily on the results of the study's rather than secondary criteria. Unpublished studies that may be used are:

- those from the marketing authorisation documentation which are in accordance with the wording of the marketing authorisation;
- and, where appropriate, those selected for the elaboration of the opinion of the Transparency Commission and which are in accordance with the conclusions of the Transparency Commission.

It must be possible to make these studies available to any practitioner who so requests. However, the presentation in an advertisement of an ongoing or future clinical study is not acceptable [9].

Where a medicinal product is subject to restricted prescribing conditions, advertising may be carried out only to prescribers authorised to draw up prescriptions and pharmacists practising in structures likely to dispense the medicinal product [10].

[1] Article R.5122-9 PHC

[2] Article R.5122-8 PHC

[3] ANSM recommendations regarding mandatory mentions on advertisement for HCPs

[4] http://base-donnees-publique.medicaments.gouv.fr

[5] Article R.5122-9 of the PHC

[6] *Ibid.*

[7] ANSM recommendations on content of adversement for HCPs

[8] ANSM recommendations on data sources

[9] ANSM recommendations relating to ongoing clinical studies

[10] Article R.5122-10 of the PHC

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

The regulatory framework governing transfers of value to healthcare professionals is commonly named "anti-gift" regime. Pursuant to articles L.1453-3 and seq. of the PHC, no gift, pecuniary benefit or benefit in kind of any value may be granted, offered or promised to a healthcare professional by the pharmaceutical industry [1]. There are however some derogations.

1) Article L.1453-6 of the PHC provides that the following do not constitute prohibited transfers of value:

- Remuneration, compensation and payment of expenses for activities provided for in an employment contract or a contract of practice;
- Proceeds from the exploitation or transfer of intellectual property rights relating to a health product;
- Commercial benefits offered under the agreements governed by articles 441-3 and L. 441-9 of the French Commercial Code and

whose purpose is the purchase of goods or services.
- Benefits in cash or in kind relating to the exercise of the beneficiary's profession and of negligible value, which may not exceed the amounts provided for, by type of benefit and over a specified period, by order of the ministers responsible for the economy and health.»

2) Transfers of value of negligible value remain possible. An Order published on August 7th, 2020 [2], specifies the ceilings under which some categories of advantages in kind or in cash are considered to be of negligible value, and thus fall out of the scope of the "anti-gift" regime. It sets both the maximum amounts for such benefits and the maximum frequency per calendar year. Otherwise, such benefits are prohibited:

- unplanned meals and snacks related to the recipient's professional occupation: 30€ within the limit of two occurrences per calendar year;
- book, publication or magazine, including subscription, relating to the professional occupation of the beneficiary: 30 € per book, publication or magazine and within a total limit, including subscriptions, of 150 € per calendar year;
- Sample of health products for health purposes or demonstration sample: 20€ within the limit of three per calendar year.

As a derogation, the following samples of health products for health purposes and demonstration samples are authorised without a limitation of their amount:

- samples of medicinal products the supply of which is governed by articles L.5122-10 and R.5122-17 of the PHC;
- samples and demonstration samples supplied for educational or training purposes to the healthcare professional and that cannot be used for the patient's care;
- samples and demonstration samples used by the healthcare professional for educational purposes with the patient or given to the patient exclusively for the purpose of testing or adaptation to the product and for temporary use;
- office supplies: 20€ in total per calendar year;
- other product or service related to the professional occupation of the beneficiary: 20€ in total per calendar year.

In addition, products whose supply to professionals is requested by a public authority are authorised without a limitation of their amount.

Furthermore, certain transfers of value, limitatively enumerated, are subject to derogations and thus permitted under terms and conditions set out in articles L1453-7. and seq of the PHC. These include:

- remuneration, compensation and reimbursement of expenses for research, use of research findings, scientific evaluation, consultancy, services or commercial promotion, provided that the remuneration is proportionate to the service rendered and that the compensation or reimbursement does not exceed the costs actually incurred by the beneficiaries of the advantage;
- donations and gifts, whether in cash or in kind, intended exclusively to finance research, the promotion of research or scientific evaluation activities;
- donations and gifts intended for associations of professionals and students subject to the prohibition on receiving benefits, including those involved in the training of such persons, and in particular for scholarly societies and national professional councils, with the exception of associations whose purpose is unrelated to their professional activity ;
- hospitality offered, directly or indirectly, during events that are exclusively of a professional or scientific nature, or during events promoting health products or health services, provided that this hospitality is of a reasonable level, strictly limited to the main purpose of the event and is not extended to other persons;
- financing or participation in the financing of professional training or continuing professional development programs.

These transfers of value must be declared to or authorised by the competent authorities – the National Boards of the healthcare professionals concerned (*conseil national de l'Ordre*) or to the relevant Regional Health Authority – depending on the amounts at stake (see details below). They must be framed by a written agreement meeting the requirements set out in the PHC.

Non-compliance with these rules is subject to criminal sanctions for both healthcare professionals and the pharmaceutical companies.

All benefits in kind or in cash that companies would provide, directly or indirectly, to healthcare professionals, the amount of which is equal to or greater than €10, all taxes included, must be made public via

the public database "Transparency – Health" (article D.1453-1 of the PHC) [3].(see below for transparency obligations).

[1] Rules governing professional ethics (1.2.2.1. Prohibition of gifts – page 15) – LEEM December 2019):

[2] Order of August 7th, 2020 fixing the amounts below which benefits in kind or in cash are considered to be of negligible value pursuant to 4° of Article L.1453-6 of the Public Health Code

[3] Transparency – Health database: https://www.transparence.sante.gouv.fr

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

In accordance with article L.5122-10 of the PHC, complimentary samples of medication may only be given to healthcare professionals at their request. These samples may not contain substances classified as psychotropic or narcotic, they must be identical to the pharmaceutical specialities concerned and bear the wording: "*free sample*".

They may not be handed over in areas accessible to the public during medical or pharmaceutical congresses.

Furthermore, only new medicines may be subject to the submission of samples during the two years following the first marketing in France [1]. In addition, the submission of samples must comply with the following conditions:

- each supply of samples must be in response to a written, dated and signed request from the recipient;
- only a limited number of samples, up to a maximum of four per year and per recipient, may be submitted, depending on the nature of the medicinal product and the need for the prescriber to become familiar with it;
- each sample must be identical to the smallest package on the market;
- each pharmaceutical establishment supplying samples must arrange within its own organisation the control of this supply and the follow-up of the samples; and
- each sample must be accompanied by a copy of the summary of product characteristics.

In addition, the medical sales representative charter [2] specifies that the handing over of medical samples by medical sales representatives is prohibited. Failure to comply with these rules is punishable by criminal sanctions.

[1] Article R.5122-17 PHC

[2] Charter relating to information by canvassing or prospection for the promotion of medicinal products

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

(i) With regard to meetings or congresses organised/sponsored on behalf of a company.

Organising or sponsoring professional, scientific, and promotional events (such as congresses, seminars, trainings, case observations, promotional activities, staff meetings…) is possible providing that the anti-gift law requirements are complied with. This includes in particular the rules regarding hospitality offered to healthcare professionals and the obligation to submit all the conventions concluded with healthcare professionals to the relevant French authorities (see question 12 above).

(ii) With regard to the sponsorship of healthcare professionals' participation in such meetings or congresses

The "anti-gift" rules governing transfers of value apply (see question 12 above). The term "hospitality" covers transfers of value relating to invitation to events, including the payment of accommodation, travel, and catering costs, as well as congress registration fees, in the context of professional, scientific and promotional events.

Hospitality offered, directly or indirectly, during events of an exclusively professional or scientific nature, or during events dedicated to the promotion of products or services is authorised pursuant to article L.1453-7 of the PHC provided such hospitality remains reasonable, strictly limited to the main objective of the event and does not benefit to other persons than the professional directly concerned (such as family members). This hospitality, as any transfer of value under the anti-gift regime (see above) must be the subject-matter of an agreement between the company and the healthcare professional, and shall be the subject of a declaration or authorisation, depending on the amount at stake, to the relevant administrative authority or professional

order[1].

According to the regulatory provisions (Order published on August 7th, 2020 [2]), the amounts above which an authorisation is required are the following:

- 50 € for a meal,
- 15 € for a break,
- 150 € for a hotel night,
- 000 € as a total hospitality per invitation (including the meals, breaks, hotel nights and transportation),
- up to 1.000 € for the registration fees, in addition to the other above-mentioned disbursements.

Hospitality towards students training to become healthcare professionals is absolutely prohibited: nor derogation are provided.

Furthermore, under the transparency provisions of the PHC[3], all agreements concluded with healthcare professionals must be disclosed on the Transparency database Transaprence.santé.gouv website (see below).

The rules governing professional ethics provide that: "*The reasonableness of hospitality is appreciated according to:*

- *the medical relevance of the event,*
- *the suitability of the healthcare professionals invited,*
- *the type and extent of benefits provided and paid for in whole or in part (transport, hotels, restaurants), and*
- *the programme timetable during the event, the topics covered and the medical and scientific content*" [4].

Reasonableness is also appreciated in view of the positions taken by the competent regulatory bodies or administrative authorities pursuant to the provisions of articles L.1453-3 and seq. of the PHC, particularly with regard to the recommendations they may make, the authorisations or refusals of authorisation issued, or the report they publish every two years.

(iii) Concerning events taking place abroad

The LEEM rules governing professional ethics [5] provide that a company may not organise or sponsor an event that takes place outside its country of incorporation unless:

- most of the guests are coming from a country different from the country where the company is incorporated; or
- given the geographical location of the relevant resources or expertise that are the object or subject of the event, it appears more rational, from a logistical point of view, to organise the event in another country (an "international event").

[1] Articles L.1453-8 and L.1453-9 PHC

[2] Order of August 7th, 2020 fixing the amounts above which an agreement provided for in article L. 1453-8 of the PHC is subject to an authorisation

[3] Articles R.1453-2 and seq. of the PHC

[4] Professional Ethical Provisions of the LEEM, in force since 1 June 2021 (page 20)

[5] Professional Ethical Provisions of the LEEM, in force since 1 June 2021 (page 19)

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

The organisation of events of a cultural, sporting or other than scientific nature by the pharmaceutical industry is prohibited. The rules governing professional ethics of the Leem specify that pharmaceutical companies should avoid the use of venues that are renowned for their leisure facilities or that are sumptuous or eccentric. This means that "*the hosting venue must above all be conducive to the scientific or educational nature of the event the structure must not include any entertainment, sports or leisure activities (...) This excludes, for example, golf clubs, wellness centres, thalassotherapy wellness centres, thalassotherapy centres, gambling establishments (casinos or others), seaside facilities in season and ski facilities in season.*

Nor can it be a place of entertainment such as an amusement park or aquatic centre, or a place for tourists such as an abbey, a museum, a wine estate, a castle or a famous monument, or a place for festivals such as a concert hall or theatre. Furthermore, a suitable place is one that is not of a luxury nature, such as a place with a starred restaurant. Castles and manor houses are very likely to be considered sumptuous or ostentatious. If in doubt, it may be worth asking whether the structure hosts weddings, parties or tourists. If so, then the venue is likely to be inappropriate" [1].

[1] Professional Ethical Provisions of the LEEM, in force since 1 June 2021 (page 21):

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

Payment for services fall under the “anti-gift” provisions (see question 12 above).

Transfers of value corresponding to remuneration, compensation and expenses for research activities, research valorisation, scientific evaluation, consulting, provision of services or commercial promotion, are allowed provided that the remuneration is proportionate to the service rendered and that the compensation or expenses do not exceed the costs actually borne by the persons.

They must be declared to or authorised by the competent authorities – National Board (*Conseil national de l’Ordre*) or ARS (Regional Health Authority) – of the concerned professional.

They must be laid down in an agreement between the company and the professional concerned [1].

The amounts determining whether a declaration suffices or whether an authorisation is necessary are specified by an Order of August 7, 2020 [2]. Concerning the remuneration, compensation and disbursements for activities corresponding to research, research valorisation, scientific evaluation, consultancy, services or commercial promotion, the thresholds are different given the considered persons:

- For healthcare professionals, the hourly rate is 200€, 800€ for half a day, and a total amount of 2.000€ for the whole contract;
- For students wishing to become healthcare professionals, the hourly rate is 80€, 320€ for half a day, and 800€ for the whole contract;
- For associations bringing together healthcare professionals or students, the hourly rate is 200€, 800€ for half a day and 2,000€ for the whole contract.

Over these amounts an authorisation is required.

[1] Art. L.1453-8 of the PHC

[2] Order of August 7th, 2020 fixing the amounts above which an agreement provided for in article L. 1453-8 of the PHC is subject to authorisation

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

This falls under the “anti-gift” regime (see question 12 above), applicable to transfers of value either in cash or in kind.

The PHC [1] provides for the following derogations to the prohibition of transfers of value when it comes to grants or donations:

- Donations and gifts, in cash or in kind, intended exclusively to finance research activities, the valorisation of research or scientific evaluation;
- Donations and gifts, in cash or in kind, intended for associations regrouping healthcare professionals or students, with the exception of national professional councils and associations whose purpose is unrelated to their professional activity (for instance, an association of golfing physicians).

An agreement must be concluded between the beneficiary and the entity providing the benefit, then it must be submitted to or authorised by the competent authorities [2].

Under the regulatory provisions of August 7, 2020 [3], pharmaceutical companies can benefit from the declaration regime for:

- Grants and donations intended exclusively to finance research, research valorisation or scientific evaluation activities up to an amount of:
    - €5,000 for healthcare professionals,
    - €1,000 for students who intend to become healthcare professionals,
    - and €8,000 for associations of healthcare professionals or students
- Grants and donations intended for another health-related purpose (only for an association of healthcare professionals or students, it is forbidden to finance a healthcare professional or a student), the maximum amount is 1.000€.
- Grants and donations to associations recognised as having a public interest, including those intended exclusively to finance research, research valorisation or scientific evaluation activities: the maximum amount is 10.000€.

Over these amounts an authorisation is required.

[1] Article L.1453-7 of the PHC

[2] Article L.1453-8 of the PHC

[3] Order of August 7th, 2020 fixing the amounts above which an agreement provided for in article L. 1453-8 of the PHC is subject to an authorisation

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

Pharmaceutical companies are required to make public on a website called *Transparence-santé*, "*the precise purpose, date, direct beneficiary and final beneficiary, and the amount of the agreements concluded*" [1] with:

1° Healthcare professionals;

2° Associations of healthcare professionals;

3°Students training for the healthcare profession as well as associations and groups representing them;

4° Associations of users of the healthcare system (patient associations);

5° Healthcare institutions;

6° Academies, foundations, learned societies and consulting companies or organisations involved in the products or services sector mentioned in article L. 5311-1 of the PHC;

7° Legal entities publishing press, radio or television services and online communication services to the public;

7° bis Persons who, in the media or on social networks, present one or more health products in such a way as to influence the public;

8° Publishers of prescription and dispensing assistance softwares;

9° Legal persons providing or participating in the initial or continuing training or continuing professional development of healthcare professionals.

The public database "*Transparence – Santé*" requires [2] the following information:

- For agreements: the identity of the parties involved, the date of the agreement, its precise purpose, the amount at stake, the organiser, the name, date and place of the event;
- For benefits in kind and in cash, whether direct or indirect: the identity of the parties concerned, the amount, nature and date of each benefit where the amount of each benefit is greater than or equal to €10 including tax.
- For remunerations: the identity of the parties, the date of payment, the amount whenever it is greater than or equal to €10.

This obligation [3] therefore applies to foreign companies and companies that do not have a product on the market yet. Indeed, the information note explicitly states that *"any company producing or marketing health products (...) whether its registered office is located in France and whether its products are operated or marketed in France, is required to make public the agreements it enters into with healthcare professionals practicing in France (and students studying for these professions) or with any organisation or association located in France (...). The benefits or remuneration provided to these same persons must also be made public.* »

Non-compliance with these rules is subject to criminal sanctions [4].

[1] Article L.1453-1 of the PHC

[2] https://www.transparence.sante.gouv.fr/

[3] Ministry note No. DGS/PP2/2017/180 of May 29, 2017 on the transparency of benefits granted by companies producing or marketing products for human health and cosmetic purposes

[4] Articles L.1454-3 to -4 of the PHC

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access

restrictions on websites containing advertising or other information intended for healthcare professionals?

(i) Authorising advertising in France

Advertising for medicinal products must be pre-approved by the ANSM via a visa (see question 6). When the advertising is directed to the public, the adverting authorisation is called a *GP visa*, when directed to healthcare professionals, it is called a *PM visa*. In all cases, advertising must meet the following criteria (art. L.5122-2 of the PHC):

- comply with the provisions of the marketing authorisation and the therapeutic strategies recommended by the High Health Authority,
- present the medicinal product objectively, promote its proper use,
- not be misleading for the protection of public health.

If these criteria are not met, the ANSM will reject the application.

In addition, the ANSM must verify whether the medicine is subject to a risk/benefit reassessment procedure; there is a strict ban on advertising until the end of such procedure [1].

There are three exceptions to the control of advertising authorisation for public health reasons:

- vaccines may be the subject of promotional campaigns aimed at the general public if they appear on a list drawn up for public health reasons by order of the Minister of Health [2];
- tobacco-weaning products can also be the subject of promotional campaigns aimed at the general public,
- medicines that are not subject to compulsory medical prescription and not reimbursed under compulsory health insurance schemes [3].

The ANSM must control the mentions of the advertising document [4]. Advertising for a medicinal product must be adapted to its recipients (see question 9 for content requirements for advertising directed at the general public, and question 11 for advertising directed at healthcare professionals).

(ii) Advertising on the internet

The ANSM drew up a Charter [5] in March 2014 regulating advertising on the Internet. This document, which has no legal authority, reflects the provisions applicable to the pharmaceutical and medical device industries when they publish information on their websites [6].

A website must present the information provided for in article 6 of Law N° 2004-575 of 21 June 2004 on the confidence in the digital economy and must in particular show the identification of the operator as well as the intended recipients and the type of information disseminated. It must be structured and present, from the home page, the site map.

The information shall be updated regularly and the date of the last update shall be specified. The site must be designed in such a way that sections intended for the promotion of a health product are explicitly distinct from other non-promotional sections. Advertising must therefore be clearly identified. This may be achieved by any clearly perceptible means that makes the advertising nature of the message unequivocal to the public.

Each promotional page of a website must display the mandatory information provided for by the PHC for the product category presented and the public for which it is intended. This information must be seen immediately.

Concerning the access to the promotional pages, the advertising must be adapted to its recipients:

- for healthcare professionals, it must be presented on pages that are reserved for them.
- the PHC imposes restrictions on the distribution of certain advertisements, in which case real access restrictions must be put in place by the operators. Such security measures are essential and the simple commitment of the Internet user, certifying that he or she is a healthcare professional, is insufficient to access promotional pages for a medicine for which advertising to the public is prohibited.
- for the public, no restriction of access is necessary.

The promotional pages of a medicine's website must be subject to a request for authorisation from the ANSM before being displayed online. The terms and conditions for requesting an advertising authorisation are described on the ANSM website [7].

(iii)Advertising on social networks

The Charter [8] strictly regulates advertising on social networks. The functionalities inherent to open social networks (such as Facebook, twitter, youtube, etc.)

imply "*linking the content of pages to comments and messages whose content is free and not controllable*". Consequently, advertising for the general public, in the form of a product page, is not possible on social networks that do not allow moderation of users' comments. In addition, the [x] people like feature, which displays the number of people who pressed the like button on the promotional page, can be interpreted as testimonial of recovery by the public or a guarantee (if the like is made from the profile of a healthcare professional) and is therefore contrary to article R.5122-4 6° of the PHC (advertising directed at the general public cannot include any element that would refer to a recommendation from scientists, healthcare professionals or persons who may, by virtue of their reputation, encourage the consumption of the medicine).

General consumer regulation and guidelines issued by the French advertising self-regulatory body (ARPP) applicable to general online advertising also apply.

[1] Article L.5122-3 of the PHC

[2] Order of September 28, 2012 establishing the list of vaccines mentioned in Article L.5122-6 of the PHC

[3] Article L.5122-6 of the PHC

[4] Article R.5122-8 of the PHC

[5] Charter on the communication and promotion of health products (medicines and medical devices) on the Internet and e-media

[6] Article L.5122-1 of the PHC

[7] ANSM webpage on the modality to request an advertising visa

[8] Charter concerning communication and promotion of health products (medicines and medical devices) on the Internet and in the electronic media (2.4 Social networks)

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

The PHC frames the rules on bribery through two articles, the first one targets the person who offers, the second one targets the person who receives.

The bribery of a healthcare professional in order to promote medicines is prohibited [1], this is aimed at the person who offers the benefit. It is provided that the granting, offering or promising of a pecuniary advantage or in kind to healthcare professionals (unless of negligible value), for the purpose of promoting medicines, is punishable by two years imprisonment and a fine of €75,000.

The second one is aimed at the healthcare professional who accepts these benefits. Indeed, the fact, for healthcare professionals (including students and associations of healthcare professionals or students) to receive benefits in kind or in cash, in any form, directly or indirectly, provided by pharmaceutical companies are punishable with two years' imprisonment and a fine of €75,000 [2].

For healthcare organisations, the subject is addressed in the LEEM's rules governing professional ethics, which include a section on relations with patient associations [3] where it is especially forbidden for the pharmaceutical industry to request, and for patient associations to promote, any medicine subject to compulsory prescription.

When a company provides support, financial or otherwise, to an association, they must put in place a written agreement. In addition, each company must make public the list of patient associations to which it provides financial or non-financial support.

Article 17 of the Sapin II law [4] provides that the presidents and managers of a company which:

- employs at least 500 employees or belong to a group of companies whose parent company has its registered office in France and whose workforce includes at least 500 employees;
- and whose turnover or consolidated turnover is greater than €100 million;
- are required to take measures to prevent and detect the commission, in France or abroad, of acts of corruption or influence peddling.

Sanctions can be a fine (up to €200,000 for an individual, €1,000,000 for a legal entity) that is proportionate to the seriousness of the breaches observed and the financial situation of the individual or legal entity sanctioned.

[1] Article L.5422-9 of the PHC

[2] Article L.1454-7 of the PHC

[3] Professional Ethical Provisions of the LEEM, in force since 1 June 2021 (page 31)

[4] Law no. 2016-1691 of 9 December 2016 on transparency, fight against corruption and the modernisation of economic life

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

See question 12 above concerning the "anti-gift" rules that govern any transfers of value from the industry to healthcare professionals.

In addition to this legal framework, the LEEM (the French Pharmaceutical Companies organisation) issued the "*Charter relating to information by canvassing or prospection for the promotion of medicinal products*" signed between the LEEM and the CEPS (the Economic Committee for Health Products) which aims to frame commercial and promotional practices [1]. The Charter specifies the duties of the medical sales representatives, the quality standards to be met, in particular with respect to the presentation of information, the ethical standards of the representatives regarding patients, healthcare professionals, and monitoring of the representatives' activities.

[1] Charter relating to information by canvassing or prospection for the promotion of medicinal products

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

The ethical rules of the LEEM are of self-regulatory nature and do not have legal force. They are binding on the LEEM members. The CODEEM (*Comité de déontovigilance des entreprises du médicament*), the ethical vigilance committee of the LEEM, is in charge of monitoring the implementation of these ethical rules and can pronounce sanctions in case of non-compliance by LEEM members. These rules also serve as good practice standards for LEEM non-members companies.

The ANSM is the administrative authority responsible for authorising, monitoring and sanctioning non-compliance with standards relating to the advertising of health products in general.

The ANSM's decisions imposing financial penalties are administrative decisions that may be appealed before its Director General and before the administrative judge [1].

When the ANSM withdraws an advertising visa, the CEPS (Economic Committee for Health Products) may impose a financial penalty on the company [2].

The French Economic Regulation Authority (DGCCRF) can also initiate investigations and claims before French Courts in particular under French Consumer regulation.

Finally, there is the possibility of going before the civil and criminal courts since there may be a civil action for compensation for the damage suffered (unfair commercial practice) or criminal sanctions for violation of the general principles of medicine advertising.

See question 12 above concerning the "anti-gift" rules.

[1] ANSM 2016 Report– Financial sanctions

[2] Article L.162-17-4 of the Social Security code

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Pharmaceutical advertising is only legal if it is not misleading; therefore, the legal basis for companies is article L.5122-2 of the PHC [1].

Moreover, the provisions of the Consumer Code apply to advertising of medicinal products. The Consumer Code prohibits any advertising that is false or misleading [2]. The DGCCRF is authorised to establish breaches of article L.121-1 of the Consumer Code by means of statements, which are then sent to the Public Prosecutor. [3]

The use of comparative advertising [4] is only permitted for promotion to healthcare professionals. Besides, it is prohibited to suggest to the general public that the effect of a medicine "*is greater than or equal to that of another treatment or medicine*" [5].

The criterion put forward in the Charter on promotional information [6] is that the information provided must be "*exempt from any denigration*", thus insisting that the person exercising an information activity by canvassing or prospection refrains from denigrating the specialties of competing companies, including generic and biosimilar.

The Charter clarifies what could be considered disparagement of a competing pharmaceutical product or company: "*Even if it is possible (which in practice only concerns reimbursable medicines), such advertising may not, however, take undue advantage of the notoriety attached to a competitor's trademark, bring it into disrepute or denigration, cause confusion between the advertiser and a competitor or between the trademarks, or between the goods of the advertiser and those of a*

competitor, or present goods or services as an imitation or reproduction of a good or service benefiting from a protected trademark".

[1] Comments under Article L.5122-2 of the PHC, Dalloz.

[2] This is assessed with regard to the product's nature, composition, substantial quality, origin, properties, conditions of use, results expected from its use, etc. See article L.121-2 of the Consumer Code.

[3] Article L.511-3 of the Consumer Code.

[4] Article L. 122-1 of the Consumer Code

[5] Article R.5122-4, 2° of the PHC

[6] Charter relating to information by canvassing or prospection for the promotion of medicinal products

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

The ANSM may initially take administrative and financial sanction measures [1].

Can be subject to financial sanctions by the ANSM [2]:

- any advertising of a medicinal product that has not obtained a marketing authorisation, registration or parallel import authorisation;
- any advertising to the public that has not obtained the appropriate visa or that is carried out in spite of its suspension or withdrawal;
- any advertising carried out among healthcare professionals who have not obtained the visa necessary or which is carried out despite its suspension or withdrawal;
- any advertisement to the public for a prescription medicinal product (with the exception of campaigns to reduce tobacco addiction and for vaccines);
- any advertisement to the public for a medicine for which the marketing authorisation or registration includes restrictions on advertising to the public for public health reasons;
- any advertisement to the public or healthcare professionals for a medicinal product benefiting from a compassionate authorisation or compassionate prescription scheme;
- any advertising to the public for a medicinal product reimbursable by the compulsory health insurance schemes;
- any advertising for generators, kits or precursors;
- any non-institutional advertising campaign for vaccines.

The amount of the sanction cannot exceed €150,000 for a natural person. In addition, it may not exceed 30% of the turnover of the product(s) concerned during the last financial year, up to a limit of €1 million for a legal entity.

The sanction may be accompanied by a daily penalty payment which may not exceed €2,500 per day. In addition, for some of these infringements, the ANSM may issue a ban on the advertising concerned after the company has been given formal notice.

Financial penalties may be published on the ANSM's website [3].

When a financial sanction pronounced by the ANSM is likely to be combined with a criminal fine imposed on the author for the same acts, the total amount of the fines and financial sanctions does not exceed the highest legal maximum [4].

When a withdrawal of advertising visa has been pronounced by the ANSM, the CEPS can pronounce, after the company has been given the opportunity to present its observations, a financial penalty against it.

This penalty may not exceed 10% of the company's sales excluding tax in France of the specialties that were the subject of the prohibited advertising during the six months preceding and the six months following the date of withdrawal of the visa. Its amount is set according to the seriousness of the infringement sanctioned by the prohibition measure and the sales trend of the specialties concerned during the period [5].

Finally, there are criminal sanctions applicable in the event of violation of the general principles governing medicine advertising [6]. Such violations are punishable by five years' imprisonment and a fine of €375,000 if an advertisement for a pharmaceutical specialty which has not been the subject of a marketing authorisation or an import authorisation, or whose authorisation has been refused, suspended, withdrawn or lapsed, is produced or caused to be produced, broadcast or caused to be broadcast. These penalties are increased to seven years' imprisonment and a fine of €750,000 for offences that:

- are likely to cause a serious risk to human health;

- were committed in an organised gang;
- were committed on a telecommunication network intended for a public not determined;
- were committed by licensed pharmaceutical companies, brokers, pharmacies.

Additional penalties, such as the closure of the establishment, are also provided for [7]. It is punishable by one year's imprisonment and a fine of €150,000 for the dissemination of an advertisement for a medicinal product marketed under a temporary authorisation for use [8]. The court may even go so far as to prohibit the sale and order the seizure and confiscation of the medicines concerned, as well as the seizure and destruction of the documents and advertising material relating to them [9].

French Consumer Regulation provides for a criminal fine of up to €1,500,000 (or alternatively (i) an amount equal to the benefit generated by the advertising, (ii) 10% of the average annual turnover during the past three years, (iii) 50% of the expenses associated with advertising) and up to two years' imprisonment and business prohibition for up to five years or forced closure of the seller's business. The sanction may also be made public.

[1] https://www.ansm.sante.fr/Activites/Processus-d-inspection/Les-suites-de-l-inspection-mesures-administratives/(offset)/2

[2] Article L.5422-18 of the PHC

[3] Article L.5471-1 of the PHC

[4] Article L.5471-2 of the PHC

[5] Article L. 162-17-4 of the Social Security code

[6] Article L.5421-2 of the PHC

[7] Articles L. 5421-7, L. 5421-9, L. 5421-10 and L. 5421-11of the PHC

[8] Article L.5422-3 of the PHC

[9] Article L.5422-14 of the PHC

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

The ANSM's decisions [1] are subject first of all to an administrative review before its director, and then if this does not succeed, a judicial review can be carried out before administrative courts. Sanctions may therefore be reduced, cancelled or increased, knowing that it has been specified that the ANSM considers the company's ability to pay its contributions when imposing sanctions.

Should the ANSM identify a breach, it shall inform the company concerned, which may make observations. Binding measures may be imposed by the ANSM on a pharmaceutical company to induce it to comply with its obligations or to put an end to the failure to comply. If the difficulties persist, the ANSM may take the company in question to court [2].

For unfair commercial practice, the procedure operates independently from others and is not dependent on the outcome of other reviews by other authorities or courts. It is necessary to go directly before the judicial judge, as for criminal sanctions.

[1] ANSM 2016 Report: financial sanction imposed by ANSM

[2] Article Geneste & Devulder, §11.4, p.25

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

The ANSM has, in recent years, issued few decisions, and when it does, the grounds are usually not given. As an example [1], in 2020 the ANSM did not render any decision relating to the advertising of medicines. Both in 2018 and 2019, one sanction procedure took place, but no motives were specified or published.

In 2017 [2], the ANSM wrote in their yearly report that "*Proceedings initiated against breaches of advertising rules, medical devices and medicinal products combined, represent the majority of proceedings initiated in 2017. These proceedings mainly concern the broadcasting of advertising on the Internet without prior authorisation from the ANSM. (...) 8 proceedings for breaches of advertising rules for health products were initiated this year, mainly in the sector of advertising for medicinal products, which saw a significant increase in the number of proceedings initiated".*

In 2016, there were no sanction proceedings relating to advertising. Before 2015, no information is available.

There is no publication of the CEPS' decisions, but courts' decision against CEPS' decisions may be published.

Concerning case-law, whether administrative or judicial, no proceedings relating to infringements of advertising have been pronounced recently.

The last important case dates back to 2016, that has been opposing Leclerc to the pharmacists' monopoly on the sale of medicines for about ten years [3].

[1] Actualités – Injonction ANSM (sante.fr)

[2] Sanctions financières : bilan 2017 des sanctions financières prononcées par l'ANSM

[3] https://www.legifrance.gouv.fr/affichJuriJudi.do?idTexte=JURITEXT000032781366

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