PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

Under French law, the advertising of health products (which we could also call 'promotion') is strictly regulated, including online. Some activities are prohibited per se, especially when they directly target consumers. Other activities must satisfy a variety of criteria (with imposed content and prohibited content) and may involve a prior visa procedure.

In France, the promotion of pharmaceuticals and medical devices is mainly regulated by the French Public Health Code (PHC) and Social Security Code (SSC).

Two regulatory authorities are entitled to enforce those rules and control health product-related promotional activities: the high authority for health (Haute Autorité de Santé or HAS) and the National Agency for the Safety of Medicinal Products and Health Products (Agence Nationale de Sécurité du Médicament et des Produits de Santé or 'ANSM').

In addition to the PHC and SSC, both HAS and ANSM have issued policies on the subject of the promotion of health products.

As far as it is concerned and among other activities, HAS controls information activities by canvassing aimed at promoting health products covered by the compulsory health insurance scheme. As soon as a pharmaceutical company or medical device manufacturer that has signed an agreement with the CEPS carries out (or sponsors) any such activity for the promotion of at least one reimbursable product, it must comply with the requirements of HAS charters dedicated to these activities.

Article L161-37 et seq of the SSC also entrusts HAS with the task of establishing a certification procedure for the presentation, information and promotion of healthcare products and related services. The main aim of this certification procedure is to ensure compliance with the charters governing pharmaceutical companies, and manufacturers and distributors of other reimbursed healthcare products and associated services.

The certification procedure drawn up by HAS enables private bodies accredited by the French Accreditation Committee (Comité Français d'Accréditation or COFRAC) to audit companies in the sector conducting the above presentation, information and promotion activities. Such a procedure aims at the certification of a company's quality management system. The standard covers the means implemented by laboratories to comply with quality criteria (and not the quality of messages) in the following areas: (1) quality policy for promotional information; (2) training and assessment of staff involved in canvassing or prospecting; (3) rules of professional conduct applicable to these people and those accompanying them; and (4) organising contacts with healthcare professionals.

ANSM has the authority to approve any advertising related to healthcare products. Hence, pharmaceutical companies willing to carry out advertising activities regarding their pharmaceutical products must obtain ANSM's visa beforehand, regardless of the targeted audience (professionals or consumers) and whether subject to medical prescription ('on prescription') or not. Advertising for certain medical devices that present the greatest risk to public health also requires ANSM's prior authorisation.

Actors in the sector also rely on professional codes of conduct, such as the Code of Ethical Business Practice released by MedTech Europe.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

Under French law, advertising activities for healthcare products are widely defined.

Indeed, under Article L 5122-1 of the PHC, drug advertising for human use means 'any form of information, including canvassing, prospection or inducement, designed to promote the prescription, dispensing, sale or consumption of such medicinal products, with the exception of information provided, as part of their duties, by pharmacists managing a pharmacy for internal use'. A similar definition is provided

in Article L 5213-1 of the PHC for medical devices.

Three general exceptions are provided for and are not considered advertising under French law:

1. correspondence, accompanied by any non-promotional documents, required to answer a specific question about a particular drug;
2. specific information and reference documents relating, for example, to changes in packaging, warnings about adverse reactions in the context of pharmacovigilance, and sales catalogues and price lists, if they do not contain any information about the drug; and
3. information relating to human health or human diseases, provided there is not even indirect reference to a drug.

Substantially similar exceptions apply to medical devices, which also are not deemed advertised when the wording consists of the label and instructions for use of the device.

French law does not make any distinction between the promotion and advertisement of healthcare products: the definition of advertising is wide enough and encompasses any activity dedicated to the promotion of healthcare products.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

As exposed in the response to Question 1, two regulatory authorities are mainly involved in the regulation and enforcement of rules regarding the advertisement of health products in France, that is, HAS and ANSM, which have their respective scopes of involvement. As detailed above, while ANSM has a broad scope of intervention on the subject and prior authorisation power on a number of types of advertising content, HAS is rather involved in the monitoring of information activities by canvassing aimed at promoting reimbursed health products and certification procedures for presentation, information or promotion activities for health products and any associated services.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

French law also regulates the promotion of several other products, including by imposing the sharing of some sanitary messages with consumers or restricting the volume, format or timing of the said messages: beverages with added sugar, salt or artificial sweeteners or food products manufactured for a young audience, alcoholic beverages, pharmacy advertising and tobacco.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisement) in your country and if so, which ones?

As a general principle, the advertising of health products must not be misleading and must present the product objectively and favour its good use.

For medicinal products, it must also comply with the marketing authorisation and the therapeutic strategies recommended by HAS.

A medicinal product may only be advertised to the general public if: (1) it is not subject to medical prescription; (2) none of its various presentations is reimbursable by public health insurance schemes; and (3) the marketing authorisation or registration does not contain any prohibitions or restrictions on advertising to the general public due to a possible risk to public health, in particular where the medicinal product is not suitable for use without the intervention of a healthcare professional for the diagnosis, initiation or monitoring of any treatment. The therapeutic indications that may not be advertised to the public are determined by a decree of the Minister of Health, taking ANSM's recommendations into account.

Advertising may only relate to medicinal products that have obtained marketing authorisations or parallel import authorisations. In addition, the advertising of medicinal products undergoing a benefit/risk

reassessment is prohibited.
The advertising of medical devices subject to reimbursement to the general public is also prohibited, except for those presenting a low health risk and listed by ministerial decree. Where authorised, the advertising of medical devices shall comply with the 'CE marking' (by which the device manufacturer declares that the product complies with European safety and performance requirements), and with the essential requirements concerning the safety and health of patients. When permitted, advertising a medicinal product or medical device to the general public should be designed in such a way that the advertising nature of the message is obvious and the product is clearly identified as a medicinal product or medical device.

While some mentions are prohibited, the advertising of a medicinal product or medical device must also contain several mandatory pieces of information, such as the name of the product, information essential to its proper use, a message of caution and reference to the CE mark (for medical devices etc). Rules also vary depending on the nature of the product between a medicinal product and medical device.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

Under the PHC, 'classic' rules regarding the advertising of healthcare products also apply to the internet and social networks.

In addition, in 2014, ANSM released a policy for the communication and promotion of healthcare products (medicinal products and medical devices) on the internet and e-media. It provides for general principles on promotion, such as the obligation to comply with the provisions of the PHC on healthcare products promotion or the obligation to adapt the advertising for a product to its target audience. The 2014 policy rules vary according to the promotion type of site or medium envisaged, with special rules applying to the promotion of health products on social networks.

The 2014 policy also positions itself on non-promotional sections (eg, institutional information or safety information) and non-professional services (correspondence, bibliography, discussion forum, congress and press releases).

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

In this respect, the French legal framework varies between medicinal products and medical devices.

Advertising a medicinal product to the general public, as well as advertising campaigns for vaccinations, are subject to ANSM's prior authorisation, known as the 'advertising visa'. This approval is issued for two years. ANSM may suspend and/or withdraw the advertising visa if advertising is not compliant.

Each year, ANSM's General Director sets the calendar for the submission of applications for advertising approvals for medicinal products. No application may be submitted outside these time periods. The only exception concerns drugs whose benefit/risk ratio has been reassessed.

ANSM has two months from the day following the end of the application period to notify the company of its decision. The application is deemed to have been accepted in the absence of a decision by ANSM's General Director at the end of this two-month period.

Regardless of the targeted population, advertising for medical devices and accessories that present a significant risk to human health, and whose list is established by order of the Minister for Health, is subject to prior authorisation issued by ANSM for a duration of five years. The application for the said authorisation is submitted to ANSM's General Director and is deemed to have been accepted in the absence of a decision by ANSM's General Director at the end of a two-month period.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

Unauthorised pharmaceuticals and/or off-label information cannot be advertised under French law.

Indeed, only medicinal products for which marketing authorisation has been obtained or authorisation mentioned in Article L. 5121-9-1 (ie, medicinal product benefiting from authorisation issued in another European Union or European Economic Area member country and for which the ANSM authorises

marketing in France) or one of the registrations mentioned in Articles L 5121-13 (ie, homeopathic medicinal products registered with the ANSM) or L 5121-14-1 (herbal medicines registered with the ANSM), or which benefit from a parallel import authorisation may be advertised.

Furthermore, advertising a medicinal product is prohibited when the product is the subject of the reassessment of the risk-benefit ratio.

For medical devices, advertising can only benefit authorised medical devices bearing the CE mark (which guarantees compliance with essential European health and safety requirements).

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

Without prejudice to specific rules governing the advertisement of health products, French law regulates comparative advertising in itself, regardless of the sector. Comparative advertising implies a competitive situation between the protagonists. Any advertising that compares goods or services by implicitly or explicitly identifying a competitor, or goods or services offered by a competitor, is lawful only if: (1) it is not misleading or likely to mislead; (2) it relates to goods or services that meet the same needs or have the same objective; and (3) it objectively compares one or more essential, relevant, verifiable and representative characteristics of these goods or services, which may include price.

As a result, this shall relate only to a factual and objective (technical) comparison of products or services belonging to the same market segment and truly competing with each other in view of their intrinsic characteristics.

As another result, comparative advertising cannot:

- take undue advantage of the notoriety attached to a trademark or service mark, a trade name, other distinctive signs of a competitor or the appellation of origin and protected geographical indication of a competing product;
- discredit or denigrate a competitor's trademarks, trade names, other distinctive signs, goods, services, business or position;
- cause confusion between the advertiser and a competitor, or between the advertiser's trademarks, trade names, other distinctive signs, goods or services and those of a competitor;
- present goods or services as an imitation or reproduction of a good or service benefiting from a protected trademark or trade name.

The advertiser shall be responsible for proving, without delay, the material accuracy of the statements, indications and presentations contained in the advertisement.

However, applied to health products, comparative advertisement to the public cannot be carried out as the PHC prohibits any advertising that would suggest that the effect of one health product is superior or equal to another one.

Applied to healthcare professionals, the comparison must be as exhaustive as possible, without focusing exclusively on favourable elements. To be objective, the comparison must focus on essential, significant, relevant and verifiable characteristics. At a minimum, this should include criteria of efficacy and safety (elements of the benefit/risk ratio), but may also include criteria of interest to the practitioner: dosage, duration of treatment, interactions, acceptability and so on. Cost-of-treatment comparisons can be considered relevant for prescribers when the prices of the specialties being compared are officially published in the French Official Journal. On the other hand, when cost is zero (in the case of specialties not reimbursed by social security) or negotiated (in the case of specialties for hospital use only), the treatment cost comparison is irrelevant.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

The concept of healthcare professionals is broadly defined by the PHC and covers two main categories of professionals: medical and paramedical.

The PHC only covers three types of medical professionals: doctors, dental surgeons and midwives. These professionals enjoy a medical monopoly. Other professionals are paramedical professionals. Although they are not medical professionals, they are healthcare professionals.
In the same way as advertising to the public, promotional communications directed to healthcare professionals are regulated.

Subject to the case of prohibited advertising, promotional communications on medicinal products are subject to ANSM's advertising visa. Promotional communications on medical devices may be subject to prior authorisation if they present a serious risk to public health.

Promotional communications directed to healthcare professionals are adapted to their recipient but must nonetheless include several mandatory pieces of information (name of the medicine product or the medical device, name and address of the company exploiting the medicinal product, name of the manufacturer (or its agent) of the medical device, information essential to the proper use of the product/medical device etc).

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

The above rules also apply to virtual advertising (cf our observations above on online or more general advertising).

For instance, under Article R 5122-12 of the PHC, an application for an advertising visa for medicinal products must be made for any form of information communicated to healthcare professionals authorised to prescribe, dispense or use this medicinal product in the practice of their art. Such a regulatory framework also applies to information activities by canvassing, studies or surveys of these professionals; scientific meetings or congresses attended by these professionals, in particular when these meetings or congresses are sponsored by a contribution to their financing; and television broadcasts aimed at these professionals, in particular when these broadcasts are sponsored under the conditions and within the limits set by regulations governing audio-visual communication.

In March 2014, ANSM drew up a 'Charter for the communication and promotion of health products (medicines and medical devices) on the Internet and e-media', with guidelines in this regard.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?

Any healthcare professional may be called on to make public statements about health products and contribute to their promotion. When doing so, healthcare professionals are required to disclose their links of interest during public events, university teaching, continuing education or therapeutic education activities in written or audio-visual press, or via any written or online publication. As a result, they must make their links with the companies and establishments producing or exploiting the health products at stake known to the public.

The scope of this declaration is particularly broad because it extends to links with all companies producing or operating health products falling within ANSM's competence, whatever their status with regard to social protection bodies. In addition, relations with consulting organisations (consultants, communications agencies etc) are also covered.

Learning societies also generally ask healthcare professionals contributing to their publications or other activities to declare their links of interests.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

The PHC does not contain any provisions for free samples of medical devices.

Regarding free samples of medicinal products, the PHC provides that these samples may only be given to persons authorised to prescribe or dispense medicinal products within the framework of in-house pharmacies at their request. These samples may not contain substances classified as psychotropic or narcotic, or to which narcotic regulations apply in whole or in part. They must be identical to the pharmaceutical specialties concerned and marked as a 'free sample'. Such samples may not be directly handed out to the public for promotional purposes, nor may they be handed out in public areas on the occasion of medical or pharmaceutical congresses.

In other cases, the 'anti-gifts' regulation (see below), which forbids the granting of benefits by healthcare companies to certain healthcare professionals, should apply.

The PHC defines the term 'sample' only for medicinal products. Samples of other products (including medical devices) have no specific status in the PHC and may therefore be considered as advantages within the meaning of the anti-gift law if they are given without consideration. In this respect, the National Union for the Healthcare Technology Industry (Syndicat national de l'industrie des technologies médicales or SNITEM) has published general recommendations on relations between companies and healthcare professionals regarding anti-gifts.

In addition, the MedTech Europe Code (which applies to companies that are members of MedTech Europe) provides that companies may provide their medical technology as samples at no charge in order to enable healthcare professionals to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the medical technology.

14. What rules govern the offering of hospitality to healthcare professionals?

Offering hospitality to healthcare professionals is subject to the French anti-gift system, which prohibits healthcare professionals from receiving benefits in cash or in kind offered or provided by industry players producing health products or organisations providing healthcare services.

Several exemptions are allowed, subject to the drafting of an agreement with specific provisions, on the one hand, and a declaration to or prior authorisation from the professional body of the healthcare professional at stake, on the other hand, depending on the purpose of the agreement and the amount of the benefit granted. Within that scope, a reasonable level of hospitality is allowed, considering that the amounts beneath which no declaration is required are extremely low.

The MedTech Europe Code also provides that member companies may provide 'reasonable hospitality' to healthcare professionals in the context of company events and third-party organised educational events when they are attending the event in person, but any hospitality offered must be subordinate in time and focus to the event purpose (no home delivery is permitted).

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

Donations are defined as the payment of a sum of money without any counterpart for the donor and without any requirement as to the use of the money.

All benefits in kind or in cash, in any form whatsoever, offered or provided, directly or indirectly, by pharmaceutical companies, medical device manufacturers and healthcare institutions, are, in principle, covered by the anti-gift regulation.

Also, under French Transparency Law, companies producing or marketing healthcare products for human use are required to declare any agreements (which could include donations), remuneration and benefits above a certain threshold they enter into with, or grant to, beneficiaries from the healthcare professions, as well as a number of other actors linked to the health sector (eg, foundations, learned societies, healthcare system users, healthcare professional or students associations and consulting companies) when they are established in France.

Under the transparency regime, companies that conclude eligible agreements or grant eligible remuneration or benefits must declare the same a posteriori in a centralised national database called 'Base Transparence Santé', available at **https://transparence.sante.gouv.fr**. Declarations must be filed every six months according to a schedule that depends on the date of signing the agreement, or the granting of the remuneration or benefit during the year.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

The financing of meetings possibly falls within the scope of the anti-gift and transparency regimes mentioned above.

Benefits to any HCPs or associations of HCPs, HCP students and their associations, as well as a number of civil agents that have a link to the health sector, fall within the scope of the anti-gift regime, including if the projected donation or remuneration to the beneficiary relates to their contribution to a scientific or educational meeting.

Transparency rules apply to a wide range of beneficiaries, as already mentioned above. This includes remuneration for a contribution to any scientific or educational meeting.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

In France, patients and their associations are not part of the beneficiaries covered under the anti-gift regime, but they are covered by transparency law in their capacity as users of the healthcare system.

Rules on the promotion of health products to patients are detailed above.

Under certain conditions, the industry may also take part in therapeutic education programmes or learning programmes for the benefit of patients, but may not be in direct contact with the latter.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

While there is no particular prohibition to delegate promotion activities to a third party, it is important to note that this cannot lead to a full delegation because the promoter will stay in charge of the promotion activities and must, in any event, have an internal service dedicated to such promotional activities.

Furthermore, and in line with what is described in the response to Question 1, as soon as an operating pharmaceutical company that has signed an agreement with the CEPS (ie, products covered by compulsory health insurance schemes) carries out (or sponsors) an information activity by canvassing or prospecting for the promotion of at least one covered product, all the requirements of the charter and the guidelines apply to promotional information for all of its covered products. As a result, should such an activity be outsourced, a pharmaceutical company will have to ensure such compliance from its subcontractor.

Under certain conditions, the subcontractor may also need to be certified for the conduct of the outsourced promotional activity.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

Under the anti-gift regime, it is mandatory to do so if the granting exceeds a given list of thresholds that depend on the nature of the grant (housing, goodies, remuneration etc), those thresholds being extremely low.

Under the transparency regulation, it is mandatory to report remuneration to eligible beneficiaries beyond a value of €10.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

The PHC financially and criminally sanctions infringements on the rules governing health product advertisements.

For instance, any advertisement made to the public for a medicinal product (1) subject to medical prescription; (2) reimbursable by public health insurance schemes; or (3) whose marketing authorisation or registration includes the restriction on advertising to the public, is punishable by a one-year imprisonment and €150,000 fine. A similar penalty applies to any advertisement for a medicinal product or medical device that has not obtained ANSM's visa/authorisation, whereas it should have, or which is carried out despite the suspension or withdrawal of said visa/authorisation.

French law provides for a series of sanctions for a series of non-compliance categories with the rules governing health products advertisement, including of a financial nature: those sanctions may amount to €150,000 for an individual and 30 per cent of sales in the last financial year for the product or group of products concerned, up to a maximum of €1m, for a legal entity.

Authorities are active on the subject and sanctions may be pronounced publicly under certain conditions, but industry actors are generally compliant.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

In France, ANSM is the authority that has the power to enforce the above regulatory framework related to the advertisement of health products.

Competitors may also take direct action in relation to advertising infringements. Indeed, French case law traditionally considers that failure to comply with the regulations in force places its author in an abnormally favourable situation compared with its competitors, and therefore constitutes an act of unfair competition. This undue competitive advantage over competitors complying with the same regulations entitles the latter to compensation for the damage suffered. This principle is regularly reiterated by the French Supreme Court, which has established a presumption by virtue of which the existence of prejudice can necessarily be inferred from an act of unfair competition.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

No major change to the above rules is expected in the coming months in France. Hence, rules on the advertising of health products are now well-known and generally followed by the industry.

The last reform of the French anti-gift regime dates back to 2020, so this is a rather recent reform, which brought a substantial move towards further transparency in and monitoring of the health industry's relationships with healthcare professionals and the fight against corruption. Several years were necessary to revamp this system, therefore a big change in the same area on a short-term basis is unlikely.

The transparency regime has been stable since 2017.