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Pharmaceutical Advertising 2022

France: Law & Practice
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FRANCE

Law and Practice

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CONTENTS

1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

In France, the legal framework applicable to advertising relating to medicinal products for human use is mainly to be found in the Public Health Code. The relevant provisions are partly legislative (Articles L.5122-1 to L.5122-16) and partly regulatory (Articles R.5122-1 to R.5122-17). The regulatory provisions must conform with the legislative provisions and, in the event of conflict between these two standards, the legislative provisions take precedence over the regulatory provisions.

The criminal provisions applicable to the advertising of medicinal products can be found in Articles L.5422-3 of the same Code and were amended by the Order of 19 December 2013 on the harmonisation of criminal and financial penalties relating to health products.

In addition to these "hard law" provisions, recommendations issued by the French National Agency for the Safety of Medicines and Health Products (ANSM) clarify this legal framework. These recommendations, which are regularly updated, can be consulted on the ANSM website.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The legislative and regulatory provisions contained in the Public Health Code governing the advertising of medicinal products have general scope and binding legal force.

The ANSM, a public establishment under the supervision of the Ministry of Health, is responsible for ensuring that pharmaceutical companies' laboratories comply with the rules on the advertising of medicines. To this end, the ANSM regularly issues recommendations. While these recommendations have only an interpretative role and are not legally binding, pharmaceutical companies' laboratories are, in practice, required to comply with them, in particular to facilitate the examination of their files by the ANSM when an authorisation to advertise is required.

2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

2.1 Definition of Advertising

Advertising for medicinal products is defined in Article L.5122-1 of the Public Health Code as "any form of information, including solicitation, canvassing or incitement aimed at promoting the prescription, supply, sale or consumption of these medicinal products".

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

The provision of information, which does not constitute advertising within the meaning of the Public Health Code, is free. The boundary between the notions of advertising and giving information is blurred, however, because the notion of advertising is interpreted very broadly.

The purpose of the message is the decisive factor in distinguishing advertising from mere information.

The following constitute information and not advertising:

- information provided by pharmacists managing a hospital pharmacy as part of their duties;

- correspondence required to answer a specific question about a particular medicinal product;
- factual information and reference documents relating to packaging changes, pharmacovigilance adverse reaction warnings, and sales catalogues and price lists if there is no information on the medicinal product;
- information relating to human health or human diseases, provided that there is no reference, even indirectly, to a medicinal product; and
- documents relating to legal information concerning the product (eg, a summary of product characteristics).

For example, disease awareness aimed at patients is not subject to the rules governing advertising if it is sufficiently general and not targeted at a specific medicinal product.

2.3 Restrictions on Press Releases regarding Medicines

Press releases are permitted, provided they comply with the rules applicable to advertising. Regardless of the target audience, press releases must – if they constitute advertising – be authorised in advance by the ANSM.

Press kits and press releases to promote medicinal products may be sent to journalists by email but may not be presented on pharmaceutical companies' websites if they mention one or more medicinal products.

Real access restrictions must, therefore, be put in place by companies that want to make press releases accessible to journalists. For example, the allocation of a personal access code, given after checking the applicant's status as a media professional, can prevent access by unauthorised persons.

However, institutional press kits or press releases do not constitute advertising. Consequently, they are not subject to authorisation by the ANSM and are authorised to appear on pharmaceutical companies' websites.

2.4 Comparative Advertising for Medicines

Comparative advertising may concern two or more medicinal products, under their trade name or under their international non-proprietary name where the trade mark is identifiable, whether they are products of the same pharmaco-therapeutic class or medicinal products with the same therapeutic purpose.

The comparison may be as exhaustive as possible without emphasising favourable elements. It must cover essential, significant, relevant and verifiable characteristics. The advertiser must be able to justify the accuracy, relevance and interpretation of the results of the comparative study.

Comparative advertising must not:

- take undue advantage of the reputation of a competitor's trade mark, trade name, or other distinctive signs;
- lead to the discrediting or disparagement of a competitor's trade marks, trade names, other distinctive signs, or position;
- cause confusion between the advertiser and a competitor or between the advertiser's and a competitor's trade marks, trade names, or other distinctive signs; or
- subject to the provisions on proprietary medicinal products, present medicinal products as an imitation or reproduction of another medicinal product with a protected trade mark or trade name.

Furthermore, comparative advertising to the general public may not imply that the effect of a medicinal product is greater than or equal to that of any other medicinal product on the market.

Failure to comply with these rules exposes the advertiser to civil and criminal penalties.

3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Information on unauthorised medicinal products or indications may be freely provided if it does not constitute advertising. The information must therefore not be intended to promote the prescription, supply, sale or consumption of medicinal products.

Furthermore, the provision of information constituting advertising is not permitted:

- for medicinal products or indications which have not been granted marketing authorisation;
- where the medicine is the subject of an ongoing or future clinical trial; or
- where the medicinal product is the subject of a reassessment of its risk-benefit ratio following a pharmaco-vigilance report, until the end of that procedure (the operating company is obliged to inform health professionals of this reassessment in accordance with the information issued by the ANSM – Article L.5122-3 of the Public Health Code).

In addition, for medicinal products and indications benefiting from marketing authorisation, it will be necessary to ensure that the marketing authorisation does not contain any prohibition or restriction on advertising.

3.2 Provision of Information during a Scientific Conference

It is permissible to freely provide information on unauthorised medicinal products or indications at a scientific conference aimed at health professionals if it does not fall within the scope of the definition of advertising.

In this case, publishers of the medical press are required to include a warning on the first page of the information documents sent to professionals that the data resulting from the research has not yet been validated by the French authorities. This publication is made under the responsibility of the publishers and their reading committee.

This being said, it is prohibited to provide information constituting advertising for medicinal products which have not obtained marketing authorisation.

3.3 Provision of Information to Healthcare Professionals

It is possible to send information on unauthorised medicinal products or indications as long as this does not fall within the scope of the definition of advertising.

In this case, publishers of the medical press are required to include a warning on the first page of the information documents sent to professionals that the data resulting from the research has not yet been validated by the French authorities. This publication is the responsibility of the publishers and their reading committee.

3.4 Provision of Information to Healthcare Institutions

It is permissible to provide information on unauthorised medicinal products or indications to healthcare institutions so that they can prepare budgets, provided that this information does not fall within the scope of the definition of advertising.

3.5 Publication of Compassionate Use Programmes

The "compassionate use" programmes referred to in Article 83 of Regulation (EC) No 726/2004 of 31 March 2004, laying down European Community procedures for the authorisation and supervision of medicinal products for human and veterinary use, correspond in France to the early access procedure, which replaces the temporary authorisation procedure for use (ATU) since 1 July 2021.

The early access procedure allows the reimbursement in France of medicinal products that do not yet have marketing authorisation (AMM) or that have one indication that is not covered by the AMM. This derogatory method of reimbursement affects presumed innovative medicines. The granting of this authorisation is decided by the French National Authority for Health ("HAS").

The promotion of medicinal products benefiting from early-access authorisation to prescribers is allowed, in the same way as for medicinal products with an AMM.

4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Medicinal products may be advertised to the general public provided that they are not subject to medical prescription, that none of their various presentations are reimbursable by compulsory health insurance schemes, and that their marketing authorisation or registration does not contain a prohibition or restriction on advertising to the general public on the grounds of a possible risk to public health.

The advertising of vaccines to the general public is subject to special rules. It is permitted if the following conditions are met:

- firstly, the vaccine appears on a list of vaccines drawn up for public health reasons by decree following the opinion of HAS;
- secondly, the content of the advertising campaigns is in accordance with the opinions of HAS and clearly identifies the mandatory information required by this body; and
- thirdly, the ANSM has authorised the advertising by means of a visa.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertising of a medicinal product intended for the general public must contain mandatory information to highlight the advertising nature of the message and clearly identify the product (Article R.5122-3 of the Public Health Code). These particulars must include the name of the medicinal product and the common name of all the active ingredients, the information essential for proper use, an express invitation to read the instructions on the package leaflet or on the outer packaging carefully, a message of caution and, in the case of a generic speciality, a reference to this quality.

There are also prohibited terms listed in Articles L.5122-7 and R.5122-4 of the Public Health Code, such as:

- information that would make a medical consultation superfluous;
- information which suggests that the effect of the medicinal product is guaranteed, that it is free of adverse effects, or that it is superior or equal to another treatment or medicinal product;
- information that suggests that a normal state of health can be improved by the use of the medicine;

- information suggesting that a normal state of health may be affected if the medicinal product is not used;
- information intended exclusively or mainly for children; and
- information referring to a recommendation from scientists, health professionals or persons who, although neither scientists nor health professionals, may by reputation encourage the consumption of the medicinal product concerned, etc.

By way of illustration, it is therefore possible to mention a price on the advertising of medicinal products, when it is not a medicinal product reimbursed by social security.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There are no binding provisions (ie, legislative or regulatory) restricting interactions between patients or patient organisations and industry.

However, industrial unions have issued "Ethical Charters", which member companies undertake to respect.

In addition, in application of the "transparency" mechanism (Article L.1453-1 of the Public Health Code), companies producing or marketing medicines must make public the agreements concluded with associations of users of the health system as well as the benefits provided (see **10. Pharmaceutical Companies: Transparency**). This provision applies to agreements concluded with "influencers" (ie, people who, in the media or on social networks, present one or more health products in such a way as to influence the public).

5. ADVERTISING TO HEALTHCARE PROFESSIONALS

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Advertising of medicinal products is in principle permitted to all health professionals who are authorised to prescribe or dispense medicinal products or use them in the exercise of their art.

By way of exception, where a medicinal product is subject to restricted prescribing conditions, advertising may be carried out only among health professionals authorised to prescribe it and among pharmacists working in structures capable of dispensing that medicinal product.

Advertising of a medicinal product to health professionals must be tailored to its intended audience and specify the date on which it was last established and revised. In addition, it must contain certain mandatory information (Article R.5122-8 of the Public Health Code) such as:

- the name of the medicinal product;
- the name and address of the company operating the medicinal product;
- the pharmaceutical form of the medicinal product;
- the qualitative and quantitative composition in terms of active ingredients, with the common name, and the constituents of the excipient, knowledge of which is necessary for the proper administration of the medicinal product;
- the marketing authorisation or registration numbers;
- the essential pharmacological properties with regard to the therapeutic indications;
- the therapeutic indications and contraindications;

- the method of administration and, if necessary, the route of administration, the dosage, adverse reactions, special warnings and precautions for use;
- interactions with other medicinal products;
- the classification of the medicinal product in terms of prescription and dispensing mentioned in the marketing authorisation;
- the limit price for sale to the public when such a price is fixed in accordance with the laws and regulations in force, together with the daily treatment costs; and
- the situation of the medicinal product with regard to reimbursement by social security.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertising directed at health professionals may contain claims that are not in the summary of product characteristics if such claims are consistent with the summary of product characteristics.

Thus, claims supplementing the information in the summary of product characteristics may be advertised to health professionals if they confirm or clarify the information in the summary of product characteristics and do not distort it.

It is therefore, in principle, prohibited to refer in advertising to new scientific developments and results which go beyond the information included in the summary of product characteristics. As an exception, it is possible to refer to information or research that is not required in the summary of product characteristics but which is nevertheless useful to health professionals when seeking the most appropriate treatment for their patients.

The ANSM has published recommendations on studies that can be referenced in advertising. Only the following may be used in advertising:

- studies published in a peer-reviewed journal, carried out under the conditions of use of the medicinal product as defined in the product's AMM and other existing standards; and
- unpublished studies which are derived from the marketing authorisation dossier and which are consistent with the wording of the marketing authorisation and, where appropriate, those which are consistent with the conclusions of the Transparency Commission, which gives an opinion on the treatment of medicinal products in France.

5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Advertising for combination products or complementary diagnostics that are not included in the summary of product characteristics is possible, if the conditions listed in **5.2 Reference to Data Not Included in the Summary of Product Characteristics** are met.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Companies may provide reprints of journal articles to healthcare professionals under certain conditions:

- the reprint must be a faithful reproduction of the articles concerned; and
- the source must be cited and referenced in an international database and submitted to a reading committee.

5.5 Medical Science Liaisons

Medical Liaison Officers are authorised to discuss scientific information on medicinal products with health professionals. However, advertising regulations may apply, particularly if the exchanges with health professionals are the result of a proactive approach by the Medical Liaison Officer.

Pursuant to the Act of 13 August 2004 on health insurance, a quality charter for medical examinations has been drawn up and provides a framework for medical examinations.

Any person carrying out an information activity must perform their missions exclusively by means of dated documents made available to them by the company, validated by the pharmacist in charge, and for which an advertising visa has been granted by the ANSM. Promotional material must be in accordance with the legislation, dated and up to date, and clear about the use of the product.

Verbal Presentation and Accompanying Documents

The charter requires that the verbal presentation of a medicinal product made by a medical sales representative must be accompanied by the hand-delivery to the healthcare professional of a certain amount of information, in each of the indications of the marketing authorisation, such as:

- a summary of product characteristics;
- a classification of the medicinal product in terms of prescription and dispensing mentioned in the marketing authorisation;
- the maximum price limit for sale to the public;
- the situation of the medicinal product with regard to reimbursement by health insurance bodies or approval by public authorities; and
- the most recent opinion delivered by the Transparency Commission with regard to the medical service provided by the medicinal product.

Other documents may also be submitted, eg, recommendations for good practice or consensus conferences.

6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

6.1 Requirements for Prior Notification/ Authorisation

Both to the general public and to healthcare professionals, advertising of medicinal products is subject to prior authorisation by the ANSM, irrespective of the advertising medium used.

This prior authorisation is granted by way of an advertising visa called a “GP visa” for the general public and a “PM visa” for health professionals. Visa applications are deemed to be accepted in the absence of a reply from the director general of the Agency within two months.

The visa is granted for a period of two years and may not exceed the period of validity of the marketing authorisation for the medicinal product concerned.

6.2 Compliance with Rules on Medicinal Advertising

In order to ensure compliance with the rules on the advertising of medicinal products, any company operating a medicinal product must set up an advertising department, under the supervision of the pharmacist in charge, which must ensure compliance with the rules on advertising and, in particular, check the scientific validity of the information provided.

The company must keep a copy of each advertisement it publishes for three years from the date of its last publication and must make this copy available to ANSM, together with a sheet indicating the addressees, the method of publication, and the date of first publication.

7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

7.1 Regulation of Advertising of Medicinal Products on the Internet

Advertising on the internet for medicinal products is governed by the common provisions applicable to the advertising of medicinal products contained in the Public Health Code, in particular Articles L.5422-1 et seq.

Advertising is therefore subject to an advertising endorsement and must in principle contain all the mandatory particulars (see **4.2 Information Contained in Pharmaceutical Advertising to the General Public** and **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**).

The ANSM does, however, provide for derogations of the compulsory information required on certain media.

Authorised Advertising Media

Any media distributed in service (displays, supports for the pharmacy counter, umbrella stands, wall thermometers, etc), internet banners, internet pop-ups or various objects (material used by a health team at a sports event, a vehicle engaged in a sports race, etc) constitute authorised advertising media with the compulsory reduced particulars. These particulars are as follows: the name of the medicinal product, the common name, the indication, the medicinal product, the age limit and specific warnings.

Internet promotion

The ANSM has drawn up a charter concerning the communication and promotion of health products on the internet and on e-media. The purpose of this charter is to clarify the advertising provisions of the Public Health Code in order to adapt them to this medium.

In practice, the charter requires that the internet user be able to critically analyse the information received in so far as the sites of pharmaceutical companies will henceforth have to display a clear distinction between the information, services and advertising sections. The text also specifies the conditions under which pharmaceutical companies may offer certain services such as access to bibliographic databases, the dissemination of information relating to human health and diseases, and access to other sites via hyperlinks.

The charter allows an operator to set up discussion forums on their website under certain conditions. In particular, the operator is expected to moderate the discussions a posteriori in order to ensure the proper use of the health products referred to therein.

In addition, the operator must put in place means to ensure that remarks that do not comply with the regulations in force do not remain on the website for more than 24 working hours.

7.2 Advertising of Medicines on Social Media

The advertising of medicines on social networks is governed by the charter of the ANSM on the communication and promotion of health products on the internet and on e-media.

This charter specifies that the inherent functionalities of social networks lead to linking page content to comments and messages, the content of which is free and not controllable.

Consequently, advertising of a medicinal product to the general public in the form of a “products” page is not possible on social networks, unlike the discussion forums available directly on the operator’s website, as it is impossible to moderate the comments of internet users.

In addition, the "like" option available on some social networks may be perceived as an attestation of healing by the public if it is the profile of a health professional, which is contrary to the Public Health Code.

However, a closed forum between health professionals on social networks is allowed if the operator intervenes through moderation of discussions.

7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Companies are required to implement access restrictions on websites containing advertising or other information intended for healthcare professionals.

For example, the attribution of a personal access code, given after checking the qualification of the health professional, makes it possible to prevent unauthorised persons from accessing these sites.

7.4 Provision of Disease Awareness Information to Patients Online

Disease awareness aimed at patients is not within the scope of the definition of advertising if it is sufficiently general and is not targeted at a specific medicinal product.

As regards communication on the internet, the company's website must comply with specific regulations. The site must be designed to distinguish the promotional section from the information and services section.

7.5 Online Scientific Meetings

Online scientific meetings do not fall within the scope of a specific national regulation. Despite this, a broader approach to the matter occurs in French legislation in the form of the new "anti-gift" system (see **9.1 Gifts to Healthcare Professionals**). This regulates two components considered as benefits under French law and this can be extended to virtual symposiums when:

- pharmaceutical companies sponsor scientific meetings or congresses attended by healthcare professionals; or
- pharmaceutical companies finance healthcare professionals when virtually attending scientific meetings.

Conversely, pharmaceutical companies may be allowed to make a donation to associations of healthcare professionals or of students organising scientific meetings, pursuing the Order dated 7 August 2020. This Order sets two thresholds:

- EUR8,000 ATI (all taxes included) to finance research activities, funded research or scientific evaluation; or
- EUR1,000 ATI intended for other purposes related to health issues.

Under these limits, the pharmaceutical company must report the gifts and donations made to the association, to the council of the competent professional body, eight days before the congress. Above these limits, an authorisation procedure must take place before the council of the competent professional body within two months before the meeting.

Easing Participation

Pharmaceutical companies may ease healthcare professional's participation and online experience by supporting them before, during and after the meeting. This support could qualify as gifts under the "anti-gift" scheme.

This easing incarnates, first, in the hospitality derogation. This provision implies that hospitality is offered directly or indirectly during strictly scientific or professional events or promotional

events by pharmaceutical industries. In addition, the hospitality offered must be reasonable and strictly limited to the principal objective of the event.

In order not to fall under the authorisation procedure, hospitality fees should not exceed EUR1,000 ATI for the registration fees, EUR50 ATI for meals and EUR15 ATI for snacks (knowing that the total amount of these fees must not exceed EUR2,000 ATI).

Applicability of derogation

It is worth pointing out that this derogation only applies to healthcare professionals. Therefore, it does not cover healthcare students or healthcare associations that are subjects of the anti-gift system for other matters. Likewise, the principle of hospitality does not apply to healthcare professionals' relatives.

Attendee bags

Healthcare professionals' virtual attendance could be furthered by sharing handouts, materials or attendee bags during and after conferences, which may be perceived as gifts.

What may constitute an attendee bag could fall under the negligible value threshold imposed by the Order dated 7 August 2020. Under it, the items' value would not be subject to any specific restrictions whereas above it, these gifts will be prohibited.

Thus, items or materials, like office supplies (under EUR20 ATI/calendar year), books, reviews or review subscriptions (under EUR30 ATI/calendar year) or services linked to the beneficiary's profession (under EUR20 ATI/calendar year) are considered to be negligible value. The total amount of these expenses must not exceed EUR150 ATI/calendar year. If these limits are respected, these gifts may be granted. The negligible value appreciation also depends on the context and the nature of the product offered by pharmaceutical companies during online meetings.

8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

General anti-corruption rules are subject to stricter regulations regarding health products due to the existence of the "anti-gift" system.

As indicated in **9. Gifts, Hospitality, Congresses and Related Payments**, the "anti-gift" system was substantially modified by Order No 2017-49 of 19 January 2017, ratified by Law No 2019-774 of 24 July 2019 relating to the organisation and transformation of the healthcare system, and the implementing legislation. The provisions of this Order have applied since 1 October 2020.

The new "anti-gift" scheme prohibits companies from providing benefits, producing or marketing products covered by compulsory social security schemes, or producing or marketing health products listed by Article L.5311-1 of the Public Health Code (whether or not the products are covered) from offering benefits in kind or in cash, in any form whatsoever, directly or indirectly, to all health professionals (dentists, dental surgeons, etc, occupational and psychomotor therapists, nurses, masseur-physiotherapists, doctors, speech and language therapists, and orthoptists, chiropodists, pharmacists, midwives, etc), to students in the health professions, to associations representing these health professionals and students, and to civil servants and employees of the administration. This prohi-

bition applies to both private and public sector health professionals.

8.2 Legislative or Self-Regulatory Provisions

The new "anti-gift" scheme prohibits companies that provide benefits, or that produce or market products covered by compulsory social security schemes, from offering benefits to health professionals, students, and associations of health professionals and students – including those involved in the field of their training, learned societies and national professional councils – as well as civil servants and officials of public administrations (see **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals**).

In addition, companies producing or marketing health products are also subject to the new "anti-gift" scheme, whether or not the products in question are covered.

Conversely, the new "anti-gift" scheme does not prohibit companies from offering benefits to healthcare institutions or patients.

9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

9.1 Gifts to Healthcare Professionals

The "anti-gift" scheme was amended by Order No 2017-49 of 19 January 2017 relating to benefits offered by persons manufacturing or marketing health products or services, which repealed Article L.4113-6 of the Public Health Code.

The new "anti-gift" scheme specifically prohibits companies that provide benefits, or that produce or market products covered by compulsory social security schemes, or that produce or market health products listed by Article L.5311-1 of the Public Health Code (whether or not these products are covered) from providing benefits in kind or in cash, in any form whatsoever, directly or indirectly, to a health professional, a student, an association of health professionals or students, or civil servants and employees of the administration.

The "anti-gift" scheme does not expressly define the notion of "benefit".

Items Not Considered Benefits

However, benefits in cash or in kind which relate to the exercise of the beneficiary's profession and which are of negligible value (defined by an Order dated 7 August 2020 and depending on the benefit's type) are not considered as advantages within the meaning of the "anti-gift" system in force. The new "anti-gift" scheme also stipulates the following as being items not considered as benefits:

- the remuneration, compensation, or expenses for activities provided for in an employment contract or a contract of practice;
- the proceeds from the exploitation or assignment of intellectual property rights relating to a health product;
- commercial benefits offered in connection with the procurement of goods or services; and
- benefits in cash or in kind that relate to the practice of the beneficiary's profession, and of negligible value that does not exceed the amounts provided for, by nature of the benefit, and over a specified period, by the Order dated 7 August 2020.

With the exception of the cases listed above, the "anti-gift" scheme prohibits manufacturers in principle from offering benefits to health professionals, students and associations representing them.

Benefits Authorised by Way of Derogation

The following benefits in kind or in cash may be authorised by way of derogation and subject to conditions:

- the remuneration, compensation and defrayal of expenses for research activities, research exploitation, scientific evaluation, consultancy, provision of services or commercial promotion;
- donations and gifts in cash or in kind, intended exclusively to finance research activities, the exploitation of research or scientific evaluation activities;
- donations and gifts intended for associations bringing together health professionals and students, with the exception of the national professional councils mentioned in Article L.4021-3 and associations with a purpose unrelated to their professional activity;
- hospitality offered, directly or indirectly, at events of an exclusively professional or scientific nature, or at events promoting health products or services, provided that such hospitality is of a reasonable level, strictly limited to the main purpose of the event and is not extended to other persons, with the exception of students in initial training and student associations; and
- the financing or participation in the financing of vocational training and continuing professional development actions.

9.2 Limitations on Providing Samples to Healthcare Professionals

Pharmaceutical companies may provide samples of a product to healthcare professionals for a period of two years following its first actual marketing in France. Only health professionals authorised to prescribe medicines may receive samples (ie, physicians, dentists, midwives, paediatricians, nurses, physiotherapists and hospital pharmacists).

In addition, this discount 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 organise 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.

For medicinal products subject to the conditions of restricted prescription, samples may be given only to pharmacists managing pharmacies for use inside healthcare institutions and to prescribers authorised to draw up the prescription.

The Promotional Information Charter of 15 October 2014, which succeeds the 2004 medical examination charter, prohibits “the handing over of samples of cosmetic products, food supplements and medical devices by persons exercising a promotional information activity by solicitation or canvassing, as long as they present a pharmaceutical speciality”.

9.3 Sponsorship of Scientific Meetings

The “anti-gift” system not only applies to associations representing health professionals or students (ie, associations responsible for defending the categorical interests of a profession) but also to associations which bring together – but do not represent – those people, particularly learned societies. Therefore, pharmaceutical compa-

nies have to comply with the terms and conditions laid down in the regulations (in particular, in financial terms) for sponsoring scientific meetings and congresses.

Under the new "anti-gift" scheme, funding for the participation of health professionals in a scientific meeting or congress is considered a benefit. However, this benefit may, by way of exception, be permitted if it is of a reasonable level, strictly limited to the main purpose of the event and if it is not extended to other persons.

The benefit of this derogation will be subject to a declaration or to a request for authorisation from the council of the competent professional body (depending on the amount). In the case of a request for authorisation, the application must be submitted no later than two months before the date of the meeting or congress.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies are not allowed to organise or sponsor cultural, sporting or other non-scientific events in connection with scientific conferences where this confers a benefit to healthcare professionals.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Under the new "anti-gift" scheme, it is possible to award grant ordinations to health professionals if they are exclusively intended to finance research activities, the promotion of research or scientific evaluation. The benefit of this derogation will be subject to a declaration or, when the amount exceeds EUR5,000, to a request for authorisation from the council of the competent professional body. In the case of a request for authorisation, the application must be submitted no later than two months before the date of the meeting or congress.

It is also possible to award grants or donations to associations of health professionals, even if they are not intended to finance research activities, or the promotion of research or scientific evaluation. The benefit of this derogation will again be subject to a declaration or to a request for authorisation from the council of the competent professional body, when the amount exceeds EUR8,000 for research, promotion of research or scientific evaluation, or when the amount exceeds EUR1,000 for other purposes related to health. Special rules apply for grants and donations to associations classified in France as "public charities".

The "anti-gift" act does not apply to healthcare facilities. Therefore, pharmaceutical companies may provide grants, donations or gifts to healthcare institutions, subject to compliance with other provisions in force. Law No 2016-1691 of 9 December 2016 on transparency, the fight against corruption and the modernisation of economic life, known as "Sapin II", requires the implementation of an anti-corruption compliance programme for companies based in France employing at least 500 employees and with a turnover of more than EUR100 million.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

The new "anti-gift" scheme specifies that the commercial advantage offered by a pharmaceutical company to a healthcare professional in the context of the commercial relations between them for the purchase of goods or services does not constitute a benefit. Discounts and rebates may, therefore, be granted to healthcare professionals.

However, it should be noted that discounts and rebates granted to pharmacists are capped at 2.5% of the manufacturer's price, excluding tax, for non-generic medicines and 40% of the

manufacturer's price, excluding tax, for generic medicines.

Pharmaceutical companies may also grant such commercial advantages, in the form of rebates or discounts, to healthcare institutions, since the latter are not affected by the "anti-gift" scheme.

9.7 Payment for Services Provided by Healthcare Professionals

By way of derogation from the general principle of the prohibition of providing benefits to health professionals, health professionals may be remunerated, compensated or defrayed for services provided if the remuneration granted to them is proportionate to the service provided and if the payment does not disproportionately exceed the costs actually incurred by the health professional. This derogation is subject to a declaration or a request for authorisation from the competent professional body when the amount exceeds EUR200 per hour or EUR800 per half-day or EUR2,000 for the entire contract.

9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

The new "anti-gift" scheme provides that:

- if the value of the benefits provided for in the agreement is less than a certain amount, the agreement must be declared to the competent professional body; and
- if the value of the benefits provided for in the agreement exceeds a certain amount, the agreement is subject to authorisation by the competent professional body.

The amounts in question are defined by the Order of 7 August 2020 published in Official Journal No 0199 of 14 August 2020 (text No 5).

The required information has to be provided by electronic means only (using IDAHE 2 teleprocedure portal when the beneficiary is a doctor and EPS otherwise).

10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

In particular, pharmaceutical companies are required to make public, on a single public website, the amount contained in any agreements they conclude with healthcare professionals and healthcare institutions.

The remuneration granted to healthcare professionals under these agreements and the benefits otherwise offered to them must also be made public on the same site if they are greater than or equal to EUR10.

As those declarations are made ex-post, companies only declare what has been concluded or granted. Therefore, remuneration and benefits that were promised but ultimately not paid out (eg, due to COVID-19) do not have to be declared on the basis of transparency.

The voluntary omission to declare agreements or benefits is punishable under criminal law (Article L.1454-3 of the Public Health Code).

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Transparency requirements apply to any company producing or marketing health products, regardless of the location of its registered office or the existence of an operation or the marketing of health products in France.

11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

11.1 Pharmaceutical Advertising: Enforcement Bodies

The ANSM, under the supervision of the Ministry of Health, is the competent authority for enforcing the rules on advertising of medicinal products.

In addition, pharmaceutical companies that market pharmaceutical specialities and wish to promote medicines reimbursed by the Health Insurance must follow a certification procedure set up by the HAS.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Pharmaceutical companies may take legal action against competitors for advertising infringements on several levels. On the one hand, a competitor of the company may be sued before the competent commercial court if the practices in question constitute defamation, disparagement or misleading advertising. On the other hand, criminal proceedings may be brought against a competitor before the criminal court for infringements of the regulations on pharmaceutical advertising.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

Penalties for Advertising Offences

Infringements of advertising regulations are subject to administrative sanctions imposed by the ANSM, and financial penalties imposed by the ANSM and the French Economic Committee for Health Products ("CEPS"), which is responsible for setting the price of medicines covered in France, as well as criminal sanctions.

Regarding administrative sanctions, the Director General of ANSM may give formal notice to the person concerned to withdraw the advertisement and regularise the situation and, in a second stage, ban the advertisement.

Criminal and financial penalties are provided for in Articles L.5422-3 et seq of the Public Health Code. For example, fines of EUR150,000 can be imposed for advertising of unauthorised medicines or advertising without a visa.

Penalties Applicable to Breaches of the "Anti-gift" Scheme

Pursuant to Article L.1454-8 of the Public Health Code, read in conjunction with Article L.131-38 of the Criminal Code, it is punishable by a fine of EUR750,000 for companies that provide services, or that produce or market products covered by compulsory social security schemes, or that produce or market health products listed by Article L.5311-1 of the Public Health Code, to offer or provide benefits to health professionals or students, or associations of health professionals or students or civil servants. The amount of the fine may be fixed to 50% of the expenses incurred for the practice constituting the offence.

Pursuant to Article L.1454-8 of the Public Health Code, read in conjunction with Article L.131-39 of the Criminal Code, the following additional penalties may also be imposed:

- a permanent ban, for a maximum of five years, on the direct or indirect pursuit of one or more professional or social activities;
- placement, for a period of up to five years, under judicial supervision;
- the permanent closure, or closure for a maximum of five years, of the establishments or one or more of the establishments of the company which were used to commit the acts in question;

- the exclusion of public contracts on a permanent basis or for a maximum of five years; and/or
- the posting of the decision pronounced or its dissemination to the public, either through the written press or by any electronic means of communication.

In addition, legal representatives are also liable to a fine of up to EUR150,000 and two years' imprisonment.

11.4 Relationship between Regulatory Authorities and Courts

Should the ANSM identify a breach, it must inform the company concerned, which may make comments. Binding measures may be imposed on a pharmaceutical company by the ANSM to induce it to comply with its obligations or to put an end to its failure to comply.

If the difficulties persist, the ANSM may take the company in question to court.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Courts interpret the scope of the "anti-gift" scheme very broadly. By way of example, while the "anti-gift" scheme which was in force until 1 October 2020 applied to companies providing benefits, and producing or marketing products covered by compulsory social security schemes, the Court of Cassation has ruled that this scheme is also applicable to companies that produce and/or market products that are not reimbursed directly by social security but are used for the provision of benefits covered by social security (Paris Court of Appeal, 29 March 2017, No 15/8757).

In any event, the scope of the "anti-gift" scheme has been significantly extended with the entry into force of Order No 2017-49 on 1 October 2020.

GD Avocats is a Parisian law firm specialising in matters concerning health products and healthcare professionals. The firm was created in 2019 by Bernard Geneste and Marine Devulder, who welcomed a new associate, Maud Vanlierde, in September 2021. Bernard Geneste retired from the firm in January 2022. GD Avocats advises pharmaceutical and medical technology industries on regulatory issues – covering market access, pricing and reimbursement, clinical trials, advertising and compliance – as well as dealing with competition issues. The team also assists clients before French and European courts, in particular, in matters of reimbursement and free movement of health products.

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Marine Devulder trained in European law and competition law before joining one of the leading French business law firms in 2016, where she worked, alongside Bernard Geneste, on health product regulatory issues for four years. Drawing on their experience, Marine and Bernard Geneste set up Geneste & Devulder Avocats in 2019 (which became GD Avocats in January 2022). In this new structure, Marine is involved in regulatory issues concerning health products and health professionals, both in advice and in litigation (in particular, Council of State and CJEU). She has developed strong expertise in market access to health products, their advertising and relations between manufacturers and health professionals.

Maud Vanlierde did a general course in European business law and specialised in health products law. Following her training, Maud joined several international business law firms as well as two leading pharmaceutical companies as a trainee for a period of three years. This work experience enabled her to develop solid expertise in contractual matters and in issues relating to the interactions between healthcare players. Within GD Avocats law firm, Maud assists healthcare manufacturers and professionals – both as an adviser and in litigation – with their regulatory issues as well as with the implementation of their business projects.

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