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Pharmaceutical Advertising

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Contents

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1. Regulatory Framework

1.1 Laws and Self-regulatory Codes

Pharmaceutical advertising is regulated by Article L. 5422-1 and seq and R. 5122-1 and seq of the French Public Health Code, which transpose, among others, the European Directive 92/28/CEE.

Furthermore, the National Agency for the Safety of Medicinal and Health Products (*Agence Nationale de Sécurité du Médicament et des Produits de Santé* (ANSM)) issues guidelines on the advertising of medicines.

1.2 Application and Legal Value of Regulatory Codes

Guidelines issued by the ANSM are not legally binding, but should undoubtedly be taken into account by all pharmaceutical companies, as it is the competent authority to deliver the relevant authorisations.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

Pharmaceutical advertising, under French law, is any form of information, including canvassing, prospecting or induce-

ment, intended to promote the prescription, supply, sale or consumption of such medicines.

2.2 Difference Between Information and Advertising

Information on medicine that does not fall under the definition of advertising is not considered to be advertising and is considered to be free.

Other information not considered to be advertising includes:

- information provided for by a pharmacist operating a pharmacy in the course of its functions;
- correspondence accompanied, where appropriate, by any non-promotional documents, necessary to answer a specific question about a particular medicinal product;
- concrete information and reference documents relating, for example, to changes in packaging, warnings concerning adverse reactions in the context of pharmacovigilance, as well as sales catalogues and price lists (if there is no information on the medicinal) product; and
- information relating to human health or human diseases, provided that there is no reference, even indirect, to a medicinal product.

Please note that disease awareness campaigns do not fall under the regulation of pharmaceutical advertising as long as they do not refer, even indirectly, to any medicine.

2.3 Restrictions on Press Releases

Press releases regarding medicines are allowed, but fall under the definition of advertising and shall follow its regulations ie prior approval by the ANSM.

2.4 Comparative Advertising

Comparative advertising for medicines is allowed, but under restrictions, which depend heavily on the target audience.

In both comparative advertising for medicines to the general public and to the healthcare professionals, the advertiser must be able to prove, to a short deadline, the material accuracy of the information contained in the advertisement. Moreover, the products compared must answer to the same needs or purpose. Finally, the comparative advertising must be based on real and verifiable evidence, based on its marketing authorisation file.

For comparative advertising for medicines to the general public, the comparative advertising cannot suggest that the effect of a medicine is greater or equal to that of any other medicine.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

It is possible to provide information on unauthorised medicines or unauthorised indications as long as the information does not fall under the definition of advertising.

Indeed, pharmaceutical advertising can only be done for medicines that obtained EU or ANSM marketing authorisation or which were registered by the ANSM.

Moreover, it is not possible to present in an advertising an ongoing or future clinical study on one or more medicines. This is not acceptable because it does not provide complete information to healthcare professionals and because it could, in certain cases, constitute an anticipation of results that are by nature incomplete and not fully validated.

3.2 Provision of Information During a Scientific Conference

It is possible to provide information on unauthorised medicines or indications as long as the information does not fall under the definition of advertising.

3.3 Provision of Information to Healthcare Professionals

It is possible to send information on unauthorised medicines or unauthorised indications as long as the information does not fall under the definition of advertising.

If there is a publication from a scientific journal directed at healthcare professional that provides information on unauthorised medicines or unauthorised indications, its first page must mention that the French authorities have not validated the date and/or the research.

3.4 Provision of Information to Healthcare Institutions

It is possible to provide information on unauthorised medicines or unauthorised indications as long as the information does not fall under the definition of advertising.

4. Advertising to the General Public

4.1 Main Restrictions on Advertising to the General Public

Advertising to the general public is possible under the following conditions:

- if it concerns an over-the-counter medicine;
- if it concerns a medicine that is not reimbursed by social security; and

- if the medicine's marketing authorisation or registration does not provide for an advertising prohibition or restriction.

By way of exception from what is mentioned above, advertising on vaccines, which are prescription-only medicines and can in some instances be reimbursed by social security, is authorised under two conditions:

- if the vaccine is on the list of the ones established for public health reasons; and
- if the advert's content is compliant with the High Council of Public Health's recommendations and with the mandatory information.

Moreover, advertising for medicines presented as suppressing or reducing the urge to smoke and or tobacco, which can be prescription-only medicines and reimbursed by social security, is authorised. For both exceptions, the advertising visa is still necessary.

Moreover, advertising to the general public is only possible through advertising media authorised by the ANSM. The list of authorised media is available on the authority's website and is fairly broad and changes from time to time.

4.2 Information Contained in Advertising to the General Public

First, the advertising character of the message must be obvious and the product must be clearly identified as a medicine.

Second, the following information is mandatory and must appear on all advertising:

- the name of the medicinal product, as well as the common name;
- information essential for the proper use of the medicinal product;
- an express invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be;
- a message of caution, a reference to the advice of a pharmacist and, in the event of persistent symptoms, an invitation to consult a doctor; and
- for a generic speciality, the indication of that status.

Finally, the following information is considered to be prohibited from all advertising:

- information that would make medical consultation appear superfluous, in particular by offering a diagnosis or recommending treatment by correspondence;
- information that would suggest that the effect of the drug is guaranteed, that it is free of adverse effects or that it is greater than or equal to that of another treatment or drug;
- information that would suggest that a normal state of health can be improved by the use of the drug;
- information that would suggest that a normal state of health may be affected in the event of non-use of the medicinal product;
- information that would be addressed exclusively or mainly to children;
- information that would refer to a recommendation from scientists, health professionals or persons who, although they are neither scientists nor health professionals, may, by their reputation, encourage the consumption of the medicinal product concerned;
- information that would assimilate the drug to a foodstuff, a cosmetic product or another consumer product;
- information that would suggest that the safety or efficacy of the drug is due to the fact that it is a natural substance;
- information that could lead, by a detailed description of symptoms, to a false self-diagnosis;
- information that would use in an abusive, frightening or misleading way visual representations of the human body affected by illness or injury;
- information that excessively or misleadingly presents the action of the drug in the human body;
- information that would refer to certificates of healing;
- information that would insist on the fact that the drug has received a marketing authorisation or has been registered; and
- information that would include offers of bonuses, objects or products of any kind or direct or indirect material benefits of any kind whatsoever.

It is thus possible to mention a price on the medicine's advertising, when it is not a medicine reimbursed by social security.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Companies whose main activity is the manufacturing or sale of medicines may only sponsor programmes to promote their name or image, and should not be intended to promote a medicine. Any other sponsorship is considered as advertising and should respect the relevant regulations.

4.4 Restrictions on Endorsements by Healthcare Professionals

Advertising for medicines to the general public cannot include any element that would refer to a recommendation from scientists, health professionals or persons who may, by virtue of their reputation, encourage the consumption of the medicine. Thus, the advertising cannot refer to any healthcare professional or a personality, or include any element that would suggest endorsement from a healthcare professional.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

First, information contained in advertising directed at healthcare professionals must be accurate, up-to-date, verifiable and sufficiently complete to enable the healthcare professional to have a personal idea of the therapeutic value of the medicinal product.

Moreover, the advertising must specify:

- the date on which the advertising was last established or revised;
- the name of the medicine;
- the name and address of the company operating the medicine;
- the pharmaceutical form of the medicine;
- 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 therapeutic indications;
- therapeutic indications and contraindications;
- the mode of administration and, if necessary, the route of administration;
- the dosage;
- undesirable effects;
- special warnings and precautions for use;
- interactions with other medicines;
- the classification of the medicine in terms of prescription and dispensing mentioned in the marketing authorisation;
- the limit price for sales to the public when such a price is fixed in accordance with the laws and regulations in force, with the cost of daily processing; and
- the situation of the medicine with regard to reimbursement by social security.

Lastly, where a medicine is subject to restricted prescribing conditions, advertising may be carried out only among prescribers authorised to prescribe it and pharmacists practising in structures likely to supply the said medicine.

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

It is possible to refer to scientific publications, but it shall be an accurate reproduction of the article and the source must be quoted. The ANSM also recommends that the source is referenced in an international database and is subjected to a reading committee.

It is also possible to refer to information resulting from the marketing authorisation file and which is in accordance with the wording of the marketing authorisation or that have been selected for the preparation of the opinion of the Transparency Commission (a body that evaluates medicines that have obtained marketing authorisation). Any other information from a different source from the one exposed should not be referred to in the advertising.

5.3 Restrictions on Reprints of Journal Articles

It is possible to refer to scientific publications, but it shall be an accurate reproduction of the article and the source must be quoted at all times. The ANSM also recommends that the source is referenced in an international database and is subjected to a reading committee.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

Advertising for medicines is subject to a prior authorisation from the ANSM – whatever the advertising medium used and whatever the target audience, ie, general public or healthcare professionals. It is necessary to obtain an advertising visa called 'visa GP' for general public and 'visa PM' for healthcare professionals. In order to obtain it, the advertising must comply with all the information restrictions explained above. The visa GP or PM can be requested during a certain period, whose schedule is set by the ANSM, and a fee must be paid. If the ASNM does not respond to the visa request within a period of two months after the date of the request, it is deemed granted. The visa GP or PM is granted for a period of two years (maximum), but cannot exceed the validity period of the marketing authorisation. The visa can be suspended or withdrawn if the conditions are not respected throughout the validity period.

6.2 Compliance with Rules on Medicinal Advertising

Any company operating a medicinal product shall set up an advertising department, under the control of the responsible pharmacist, who shall ensure compliance with advertising regulations, and in particular control the scientific validity of the information communicated.

The company shall keep a copy of each advertisement it issues for three years from the date of its last distribution and shall keep that copy at the disposal of the ANSM, together with a sheet indicating the recipients, the method of distribution and the date of first distribution.

7. Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Advertising on the internet for medicinal products is regulated as any advertising for medicinal products. It must obtain an advertising visa from the ANSM and thus respect all the mandatory information to provide.

7.2 Advertising of Medicines on Social Media

Advertising for medicines through a product page on social media is forbidden, unless the option of sharing the page in free comments and messages or the option of liking the page is deactivated.

It is possible to have a closed forum between healthcare professionals on social media if the operator achieves a real moderation of the discussions, to make sure that nothing is contrary to regulations.

7.3 Restrictions on Access to Websites

Companies are required to include access restrictions on websites containing advertising or other information intended for healthcare professionals. The pages directed at the healthcare professionals must only be accessible by them. It is thus necessary to grant personal access codes to healthcare professionals that allow them to exclusively access the advertising directed to them.

8. Inducement/Anti-bribery

8.1 General Anti-bribery Rules

It is forbidden for companies providing services, products or marketing medicines to offer benefits in kind, or in cash, in any form whatsoever, directly or indirectly, to any healthcare professional or to any association gathering healthcare professionals or to any administrative authority participating to a public health or a social security policy.

There are some exceptions, as described below, but then an agreement must be signed and communicated to the professional association for its authorisation. It shall also be made public on a website by the company.

8.2 Legislative or Self-regulatory Provisions

It is forbidden for companies providing services, products or marketing medicines to offer benefits in kind, or in cash, in any form whatsoever, directly or indirectly, to any healthcare professional or to any association gathering healthcare professionals or to any administrative authority participating to a public health or a social security policy.

There are some exceptions, as described below, but then an agreement must be signed and communicated to the professional association for its authorisation. It shall also be made public on a website by the company.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

It is forbidden for companies providing services, producing or marketing medicines to offer benefits in kind, or in cash, in any form whatsoever, directly or indirectly, to any healthcare professional or to any association gathering healthcare professionals or to any administrative authority participating to a public health or a social security policy.

The fiollowing are not considered as benefits:

- remuneration, compensation and expenses for activities provided for in an employment contract, if the purpose of the contract is the direct and exclusive exercise of a healthcare profession;
- the proceeds from the exploitation or transfer of intellectual property rights relating to a health product;
- the commercial advantages offered within an agreement for the purchase of goods or services by healthcare professionals; and
- benefits in cash or in kind relating to the exercise of the healthcare professional's profession and of negligible value.

9.2 Limitations on Providing Samples to Healthcare Professionals

Samples can be provided by pharmaceutical companies to people who have the authority to prescribe medicines (doctors, dentists, midwifes, podiatrists, nurses, physiotherapists) and to hospital pharmacists.

It is only possible to provide a sample for medicine within the first two years of its marketing in France. The sample provision must answer to a written, dated and signed request from the healthcare professional. Only four units of the medicine can be provided per year to one healthcare professional.

9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies can offer hospitality, directly or indirectly, during events of an exclusively professional or scientific nature, or during events promoting medicines, provided that such hospitality is of a reasonable level and strictly limited to the main objective of the event.

Sponsorship of scientific meetings and congresses is otherwise considered as advertising and is subject to the applicable regulations.

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

Companies whose main activity is the manufacturing or sale of medicines may only sponsor programmes to promote their name or image, and not intended to promote a medicine.

Any other sponsorship is considered as advertising. It should be noted that medicines containing a product on the Ministry of Health's list of doping substances may not sponsor at sporting events.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

It is possible for a pharmaceutical company to provide grants and donations, in cash or in kind, if it is intended exclusively to finance research activities, the promotion of research or scientific evaluation.

It is also possible for a pharmaceutical company to provide donations to healthcare associations, except to associations that have nothing to do with the donor's activity.

It is also possible for a pharmaceutical company to finance or participate in the financing of professional training or professional development activities.

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

Rebates or discounts to healthcare professionals or healthcare institutions would qualify as benefits in kind and are forbidden.

However, when supplying a pharmacist with its medicines, pharmaceutical companies can give rebates or discounts. Rebates or discounts on reimbursable medicines cannot exceed, per calendar year and per product line, for each pharmacy, 2.5% of the manufacturer price excluding tax for the medicine.

9.7 Payment for Services Provided by Healthcare Professionals

It is possible to give a remuneration, compensation or payment for research activities, enhancement of research, scientific evaluation, advice, provision of services or trade promotion, if the remuneration is proportionate to the service provided and if the compensation or payment does not exceed the costs actually incurred by the healthcare professional.

9.8 Prior Authorisations or Notifications

Any benefits allowed and granted must be done within the framework of an agreement between the pharmaceutical company and the healthcare professional. This agreement must be communicated to the competent professional association or the competent administrative authority. Some agreements, when the amount is lower than an amount that should be defined in an upcoming decree, only need to be declared. Other agreements, when the amount is greater than an amount that should be defined in an upcoming decree, need to be authorised.

Moreover, any healthcare professional that participates in a public manifestation or university conference or therapeutic action, in a media, must declare its link with a pharmaceutical company if he talks about its products.

10. Transparency

10.1 Requirement to Disclose Details of Transfers of Value

Agreements between healthcare professionals and pharmaceuticals companies along with the benefits concerned must be made public, according to Article L. 1453-1 of the French Public Health Code. Any remuneration or benefit of more than EUR10 must be published. That information must be published on a unique website, in French. The website is then transferred to the Ministry of Health. Information on the website must be held available to the public for five years.

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

The transparency requirements apply to companies producing or marketing health products or providing services associated with these products.

11. Enforcement

11.1 Enforcement Bodies

The ANSM is the body in charge of enforcing the rules on pharmaceutical advertising. The High Authority for Health (HAS) delivers certification for the pharmaceutical companies that market and wish to advertise medicines reimbursed by social security. Each healthcare professional is a member of a professional association, which is in charge of reviewing the benefits' agreements with pharmaceutical companies.

11.2 Initiating Proceedings for Advertising Infringements

A company could initiate proceedings against a competitor for defamation, disparagement, trade-mark infringement or deceptive advertising. Those proceedings should be initiated before the competent trade court, ie the trade court of the competitor's registered office.

A company could also initiate a criminal proceeding for pharmaceutical advertising infringements.

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

Violations of advertising rules can incur criminal penalties of up to one year of imprisonment and fines of up to EUR150,000 for individuals and up to EUR750,000 for legal entities.

Violations of rules ofn the granting of benefits can incur criminal penalties of up to one year of imprisonment and fines of up to EUR75,000 for individuals and up to EUR375,000 for legal entities.

Criminal courts can forbid the sale and order the seizure of the medicine along with the advertising.

The ANSM can also deliver an administrative fine of up to 30% of the company's turnover, with a limit of EUR1 million. The ANSM can also decide on the suspension or interdiction of the company's activity or marketing of its medicine.

11.4 Relationship Between Regulatory Authorities and Courts

The ANSM has inspection powers. If an infringement is identified, the company is notified and can present to the ANSM its observations. At the end of this process, the ANSM can give warnings or issue binding measures. The ANSM can also transfer the file to the court for criminal consequences.

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