

Intuity Legal France

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In France, the advertising of medicinal products is governed by certain provisions of the French Public Health Code (PHC), which complies with Directive 2001/83/CE of the Community Code relating to medicinal products for human use.

The guidelines on advertising in the French Health Products Safety Agency (AFSSAPS) shall also be taken into account, together with the code of practice on representatives in pharmaceutical products, which is signed between the professional organisation of the pharmaceutical industry (LEEM) and the economic comity for medicinal products (CEPS).

Any advertising for medicinal products must be submitted to the AFSSAPS. Advertising intended for the public must be authorised before diffusion. On the contrary, advertising intended for health professionals only has to be submitted

within eight days from its first diffusion.

The advertising of medicinal products on the Internet is subject to the general rules. However, taking into consideration the specific character of this media, a code of communication has been signed between the LEEM and the AFSSAPS and applies to pharmaceutical companies advertising on the Internet. Under this code, there are a number of general rules that must be followed. For example, the date of the last update must be clearly specified and the information intended for recipients of foreign countries must be clearly indicated as such. In addition, the site must clearly indicate the pages with advertising intent and distinguish the promotional part from the informational part and the pages intended for the public from those intended for the professionals. For such pages, access must be strictly limited to healthcare professionals whose identity has to be checked.

Communication and advertising on the Internet is monitored by the AFSSAPS. Furthermore, competitors can also bring an action, on the basis of unfair competition, before a commercial court against the firm suspected to have infringed the relevant rules.

Infringement of the general provisions on advertising is a criminal offence in France. A maximum penalty of €37,500 shall be pronounced, most notably for any advertising not submitted or approved by the AFSSAPS.

Additional consequences of non compliance with the laws and provisions include the prohibition of sales and/or the confiscation of the concerned products, and/or the destruction of the related documents.

Moreover, a pharmaceutical firm may incur a financial penalty totaling a maximum of 10% of the turnover of the concerned products in France during the six-month period preceding and following the decision.

“Advertising intended for the public must be authorised before diffusion”

Intuity Legal was established in 2005 by Christophe HENIN to answer the pharmaceutical industry’s specific needs regarding legal advice. Currently comprising a team of 15 people, Intuity has since been recognised by both law professionals and the pharmaceutical industry as a leading French law firm with regard to health and pharmaceutical law.

The firm provides comprehensive legal advice relating to pharmaceutical products and advertising law and assists with the analysis and the implementation of advertising campaigns. Intuity also assists its clients in proceedings against competitors.

Cuatrecasas, Gonçalves Pereira Portugal

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CUATRECASAS. GONÇALVES PEREIRA

The advertising of medicinal products in Portugal is governed by Decree-Law 176/2006, of 30 August 2006 (Medicinal Products Act) which implemented into Portuguese Law Directive 2001/83/EC of November 6, 2001 as modified.

The Portuguese Advertising Code (approved by Decree-Law 330/90 of October 23) is also applicable in all the aspects which are not specifically foreseen in the Medicinal Products Act. We also must consider the resolutions of Infarmed, the Portuguese regulatory agency for medicinal products, regarding advertising issues, namely Resolution 044/CD/2008. The advertising of medicinal products, namely of

prescription medicinal products, is subject to strict conditions and effective monitoring. The main difference between pharmaceutical advertising directed at health professionals and advertising directed at the general public remains in the fact that it is forbidden to advertise to the general public medicinal products which are available on medicinal prescription only. Also, medicinal products containing substances defined as psychotropic or narcotic and medical products that are reimbursed by the state must not be advertised to the general public.

According to Portuguese law, the advertising of medicinal products is only permitted for medicinal products with a valid marketing authorisation. In order to make scientific information available to health care professionals before the product is commercialised it is necessary that such information is not considered as advertising, so no specific references to the products commercial aspects or to the company are permitted. This situation must always be analysed on a case to case basis.

There is no special regulation regarding the advertisement of medicinal products on the Internet. The same rules stated in the Medicinal Products Act are applicable to advertising in general and are also applicable to advertising on the Internet.

However, the code of ethics of the Portuguese pharmaceutical industry association states that advertising on the Internet must be based on technical, scientific and professional principles and that the companies involved must adopt measures

ensuring that only health professionals have access to the promotion of medical products on the Internet.

Cuatrecasas, Gonçalves Pereira is an Iberian law firm assisting clients in many areas of expertise, such as corporate and commercial law, mergers and acquisitions, administrative law, regulatory and public procurement, banking and financial law, capital markets, project finance, real estate, EU and competition law, tax law, litigation, arbitration, criminal law, labour law, energy, transport law, pharmaceutical law, intellectual property, media and information technology.

The firm has approximately 170 lawyers in Portugal and each of them is specialised in one or two areas of expertise, in order to provide not only advice on a wide variety of areas, but also specialised assistance to clients.

Regarding pharmaceutical law, and in particular the advertising of medicinal products, Cuatrecasas, Gonçalves Pereira has been assisting its clients in many aspects, namely the firm provides training sessions on compliance, as well as a draft and review of a company’s rules of procedures on compliance with advertising rules. The firm also assists with the preparation and organisation of advertising documentation that pharmaceutical companies must present to the competent authorities and represents clients on misdemeanour procedures regarding advertising issues.