

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2005

A practical insight to cross-border Pharmaceutical Advertising work



Published by Global Legal Group with contributions from:

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1 General - Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your country?

Most of the important provisions relating to advertising of medicinal products in Luxembourg can be found in the Law dated April 11, 1983 concerning the marketing authorisation procedures and the advertising of medicinal products (*Loi du 11 avril 1983 portant réglementation de la mise sur le marché et de la publicité des médicaments*, as amended, hereinafter referred to as the “1983 Law”) and in the Grand-Ducal Regulation dated December 15, 1992 concerning the marketing authorisation procedure for medicinal products (*Règlement grand-ducal du 15 décembre 1992 relatif à la mise sur le marché des médicaments*, as amended, hereinafter referred to as the “1992 Regulation”) under its Chapter 3 (Articles 17 - 29). This 1992 Regulation implemented the Council Directive 92/28/EEC of March 31, 1992 (now incorporated in the Directive 2001/83/EC of November 6, 2001) on the advertising of medicinal products for human use into national law. The provisions of the Directive 92/28/EEC have been taken over by the Luxembourg lawmaker almost literally. The 1992 Regulation also contains rules pertaining to labelling and accompanying package leaflets.

A medicinal product (“médicament”) is defined as any substance or combination of substances presented for treating or preventing human or animal illness. Furthermore, any substance or combination of such which can be given to humans or animals in order to establish a medical diagnosis or to restore, correct or modify human or animal organic functions is also considered being a medicinal product (cf. Article 1, Nr. 1-3 of the 1983 Law).

Chapter III (Articles 19 and 19-1) of the 1983 Law provides for the general legal framework with regard to advertising of medicinal products.

Article 19 of the 1983 Law empowers the Government to regulate advertising to the public and health professionals. It stipulates that the Ministry of Health must approve any advertisement prior to its use (for details, see question 1.3 below). Moreover, Article 19-1 of the 1983 Law determines how and by whom actions can be brought to court in case advertising rules are violated.

1.2 How is “advertising” defined?

Article 17 paragraph 1 of the 1992 Regulation defines advertising of medicinal products (“*publicité pour des médicaments*”) as any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. It particularly includes:

- the advertising of medicinal products to the general public;
- advertising of medicinal products to persons qualified to prescribe or supply them;
- visits by medical sales representatives to persons qualified to prescribe medicinal products;
- the supply of samples;
- the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal;
- sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and
- sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

1.3 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Pursuant to Article 19 of the 1983 Law, any advertisement which by any means reaches the public is prohibited unless it has obtained prior approval by the Minister of Health or the person he has delegated to this effect. However, an advertisement which exclusively mentions the name and composition of the medicinal product, the name of its producer and his address, is not subject to this rule.

There is no regulation addressing a specific approval procedure. Art. 19 of the 1983 Law empowers the Government (i.e. the Ministry of Health) to regulate advertising by any means it might consider appropriate. The 1992 Regulation constitutes a major instrument as to this effect, but does not cover the Ministry’s possibilities

exhaustively. To our understanding, nothing would prevent the Ministry from imposing a prior approval in specific cases. However, such prior approval procedure would need to take into account the administrative practice as applied in similar cases. The justification for such prior approval procedures would need to be very well founded.

- 1.4 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

Although the applicable provisions do not explicitly mention such a right to stop such illegal advertisements, it does nevertheless ensue from the broad powers given to the *Division de la Pharmacie et des Médicaments* under the 1992 Regulation that the latter can take such measures. General administrative procedural law applies as to the possibility of appeal.

- 1.5 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?**

Article 19 of the 1983 Law sanctions any prohibited advertisement as well as the ordering of such. Any breach of the principle of prior approval (see question 1.3 above) constitutes a criminal offence.

The penalties for such offence are specified in Article 20 of said law: imprisonment (eight days to six months) or a fine between €251.00 and €10,000.00 or both of these penalties. Pursuant to Article 28 of the 1992 Regulation, the *Division de la Pharmacie et des Médicaments de la Direction de la Santé* (Department for Pharmacy and Medicinal Products in the Ministry of Health) controls the pharmaceutical advertising and enforces the rules related hereto.

Competitors may take direct action through the courts (order of cessation) pursuant to Article 19-1 of the 1983 Law. This provision allows anybody (provided there is a proper interest) to request pharmaceutical advertising to cease or to be prohibited if it violates the law. The failure to comply with a court judgment following such action can result in a fine between €251.00 and €10,000.00.

In practice, the Department for Pharmacy and Medicinal Products first sends out a warning to companies violating the advertisement provisions. It does not immediately revert to sanctions.

An important amendment to Article 19-1 of the 1983 Law was introduced by the Law dated December 19, 2003 setting out the authorisation requirements for the entities entitled to claim cessation in the field of consumer protection (*Loi du 19 décembre 2003 fixant les conditions d'agrément des organisations habilitées à intenter des actions en cessation en matière de protection des intérêts collectifs des consommateurs*, hereinafter referred to as the 2003 Law). It now entitles consumer protection organisations, set up according to its requirements, to introduce actions to cease and desist concerning pharmaceutical advertising.

In the recent years, there have been no significant examples of actions in Luxembourg taken by the Ministry of Health against pharmaceutical companies in the field of unlawful advertising.

- 1.6 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Article 23 of the law pertaining to commercial practice, unfair competition and comparative advertisement of July 2002 (*Loi du 30 juillet 2002 réglementant certaines pratiques commerciales, sanctionnant la concurrence déloyale et transposant la directive 97/55/CE du Parlement Européen et du Conseil modifiant la directive 84/450/CEE sur la publicité trompeuse afin d'y inclure la publicité comparative*, hereinafter referred to as the Law on Unfair Competition) foresees the possibility of an action leading to an order of cessation. In our view, such action could be envisaged under the Law on Unfair Competition, as a violation of the rules on advertising could be - depending on the circumstances - be considered as unfair competition. However, Article 19-1 of the 1983 Law seems to already cover such action and should thus apply as *lex specialis*. In the absence of specific case law as to such matter, there remains an uncertainty as to how courts would decide on which procedure would prevail and on the question whether parallel actions under different laws can be taken. The persons entitled to bring such action under the Law on Unfair Competition are competitors, associations of professionals or consumer organisations.

2 Providing Information Prior to Authorisation of Medicinal Product

- 2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product?**

Sponsorship of scientific meetings is considered being an advertisement for medicinal products. Furthermore, Article 18 Nr. 1 of the 1992 Regulation prohibits advertisements for unauthorised products. Thus, information - especially in the framework of scientific meetings - can only be made available in a way which excludes it being regarded as an advertisement (see question 1.2 above).

Furthermore, the Medical Disciplinary Code (*Code de Déontologie Médicale*, dated May 15, 1991) needs to be taken into account. Article 19 of the Medical Disciplinary Code stipulates a doctor is not allowed to conduct advertising activities for him or for specific institutions.

- 2.2 May information on unauthorised medicines be published? If so, in what circumstances?**

Since any advertisement for unauthorised medicine is prohibited pursuant to Article 18 of the 1992 Regulation, the publishing of such information must be done in a way it

cannot be considered or regarded as advertising.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

There are no provisions expressly prohibiting this. However, as stated above, everything that could be interpreted as being advertisement must be avoided.

2.4 May such information be sent to health professionals by the company? If so, must the health professional request the information?

The same guidelines as described under questions 2.1 and 2.2 apply. No provisions stipulate that the health professional must request such information.

2.5 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

There are no specific provisions prohibiting such kind of information.

3 Advertisements to Health Professionals

3.1 What information must appear in advertisements directed to health professionals?

Article 22 Nr. 1 of the 1992 Regulation, in accordance with Article 91 of the EC Directive 2001/83, requires that advertising to persons qualified to prescribe or supply medicinal products must include the following information: essential information compatible with the summary of product characteristics and the supply classification of the medicinal product. Furthermore, the Luxembourg legislator decided that such advertising may include only the name of the medicinal product, if it is intended solely as a reminder.

Where documentation relating to a medicinal product is transmitted as part of the promotion of that product, it must contain the information listed in Article 22 Nr. 1 of the 1992 Regulation and must indicate when it was last drawn up. This information must be accurate and allow the health professional to form his opinion of the therapeutic value of the product. Quotations, tables and other illustrative matters used for the documentation given to the health professional must be faithfully reproduced and the sources indicated.

3.2 What rules govern comparator advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in your country?

The rules governing comparative advertisement ensue from the implementation of Directive 97/55/EC of the European Parliament and of the Council of October 6, 1997 amending Directive 84/450/EEC concerning misleading advertising so as to include comparative advertising. This implementation was achieved by the passage of the law pertaining to commercial practice, unfair competition and comparative advertisement in July 2002 (*Loi du 30 juillet 2002*

réglementant certaines pratiques commerciales, sanctionnant la concurrence déloyale et transposant la directive 97/55/CE du Parlement Européen et du Conseil modifiant la directive 84/450/CEE sur la publicité trompeuse afin d'y inclure la publicité comparative, hereinafter referred to as the Law on Unfair Competition).

Article 15 of the Law on Unfair Competition defines "advertising", following the Directive 84/450/EEC, as "the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations."

As the special rules pertaining to advertising for medicinal products in the 1992 Regulation do not contain any provisions with regard to comparative advertisement, the Law on Unfair Competition applies as a general rule.

Comparative advertisement is defined as any advertising which explicitly or by implication identifies a competitor or goods or services offered by a competitor (Article 18, paragraph 1 of the Law on Unfair Competition). Thus, the use of another company's brand name is possible. To our understanding, it could - under specific circumstances - be possible to refer to a competitor's product which has not been yet authorised in Luxembourg, provided that such competitor can indeed be qualified as such under the Law on Unfair Competition, although not authorised to market the product yet. Comparative advertising is legal, provided several conditions are met, which have been taken over literally from the Directive 97/55/EC in Article 18, paragraph 2 of the Law on Unfair Competition:

- Comparative advertising shall not be misleading. Misleading advertisement, according to Article 17 paragraph 1 of the Law on Unfair Competition is defined as "advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for those reasons, injures or is likely to injure a competitor".
- Comparative advertising compares goods or services meeting the same needs or intended for the same purpose.
- It objectively compares one or more material, relevant, verifiable and representative features of those goods and services, which may include price.
- It does not create confusion in the market place between the advertiser and a competitor or between the advertiser's trade marks, trade names, other distinguishing marks, goods or services and those of a competitor.
- It does not discredit or denigrate the trade marks, trade names, other distinguishing marks, goods, services, activities, or circumstances of a competitor.
- For products with designation of origin, it relates in each case to products with the same designation.
- It does not take unfair advantage of the reputation of a trade mark, trade name or other distinguishing marks of a competitor or of the designation of origin of competing products.
- It does not present goods and services as imitations or replicas of goods or services bearing a protected trade mark or trade name.

- 3.3 Are “teaser” advertisements permitted, which alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

These are permitted as long as they are not misleading in terms of the law.

4 Gifts and Financial Incentives

- 4.1 Is it possible to provide health professionals with samples of products? If so, what restrictions apply?

The provision of samples is dealt with in Article 27 of the 1992 Regulation, allowing free samples to be distributed only on an exceptional basis and only to persons qualified to prescribe them. However, the following restrictions apply (summary of the most important conditions):

- the number of samples is limited (per year and per prescribing agent);
- any supply must ensue from a written request;
- the supplier must maintain an adequate system of control and accountability;
- each sample shall be identical with the smallest presentation on the market;
- the sample must bear a marking identifying it as such;
- a summary of product characteristics must be added; and
- no psychotropic or narcotic substances may be provided in samples.

- 4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

This question is regulated by Article 25 of the 1992 Regulation, implementing Article 94 of the EC Directive 2001/83. In summary, with regard to gifts or donations, this provision sets out:

- Only inexpensive gifts, pecuniary advantages or benefits in kind and only such relevant to the practice of the health professional can be supplied, offered or promised in a framework of promotion.
- Health professionals are not allowed to solicit any inducement prohibited according to the aforesaid.

- 4.3 Is it possible to give gifts or donations of money to institutions such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

The establishing and planning of hospital structures in Luxembourg is governed by the Law dated August 28, 1998 on hospitals (*Loi du 28 août 1998 sur les établissements hospitaliers*, as amended). The Ministry of Health coordinates the financing and investment policy in this sector. Many grand-ducal regulations further specify the aforementioned law, one of the most important being the National Hospital Plan Regulation dated April 18, 2001 (*Règlement grand-ducal du 18 avril 2001 établissant le plan*

hospitalier national). Pursuant to Articles 17 and 18 of the National Hospital Plan Regulation, the acquisition of certain expensive equipment for hospitals necessitates national planning. For some, the number of acquisitions even is restricted.

Although no provisions expressly prohibit any gifts, donations or equipment funding, the allocation of such advantages will need to comply with the infrastructure plans established by the different health authorities, notably the Ministry of Health. Furthermore, such donations shall clearly be distinguishable from those prohibited according to the aforementioned principles (see question 4.2 above).

- 4.4 Do the rules on advertising and inducements permit the offer of a volume related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

Article 25 Nr. 4 of the 1992 Regulation expressly states that the rules on advertising and inducements (relating to gifts and hospitality) do not affect existing measures or trade practices relating to prices, margins and discounts.

The pricing of medicinal products is regulated in detail by a Regulation dated December 13, 1998 (*Règlement grand-ducal du 13 décembre 1998 concernant les prix des spécialités pharmaceutiques et des médicaments préfabriqués*, as amended). The prices fixed in this Regulation need to be observed. However, exceptions are possible, subject to the Ministry of Economy’s approval in special cases due to exceptional production and distribution factors of the respective medicinal product.

- 4.5 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

The provision of such additional medical or technical services will need to observe the general rules pertaining to advertising, donations and gifts to health practitioners where the provision of additional medical or technical service and equipment is directly linked to the purchase of medicinal products.

- 4.6 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

No specific conditions need to be observed with regard to such a refund scheme.

5 Hospitality and Related Payments

- 5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

Hospitality at sales promotions shall always be reasonable in

level and secondary to the main purpose of the meeting and must not be extended to other than health professionals (Article 25 Nr. 2 of the 1992 Regulation).

Moreover, doctors are, on their side, bound by the rules of the Medical Disciplinary Code (see above, question 2.1). Article 17 of the Medical Disciplinary Code underlines the medical profession cannot be exercised like a commercial activity. Doctors, while acting in public (through the media or during a conference), always have to behave in a discrete, tactful way and with the prudence and dignity inherent to a medical profession.

The disciplinary sanctions under the Medical Disciplinary Code, being an instrument by which health professionals are bound regardless of where they act as such, could apply in case hospitality is offered abroad and if health professionals violate the provisions of the mentioned code.

5.2 Is it possible to pay for a doctor in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

Hospitality offered at events for purely scientific or professional purposes has to be reasonable in level and remain subordinate to the main scientific objective of the meeting. It cannot be extended to persons other than health professionals (Article 26 of the 1992 Regulation). No provisions prevent a company from paying the doctor for attending the meeting or for his time.

5.3 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

This is possible within the limits of Article 26 of the 1992 Regulation (see question 5.2 above).

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Certain restrictions apply to the advertisement of non-prescription medicine. The medicinal product must be, by virtue of its composition and purpose, intended and designed for use without the intervention of a medical practitioner, with the advice of a pharmacist, if necessary.

As a general principle, no medicinal product may be advertised if a marketing authorisation has not been granted by the Minister of Health (or otherwise via the centralised procedure or the mutual recognition procedure). Furthermore, the complete advertising must be in conformity with the information listed in the summary of product characteristics. Finally, the advertising must encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties and shall not be misleading (the exact same wording of the corresponding EC Directive was used by the Luxembourg legislator).

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

Advertising to the general public of prescription only medicines is prohibited pursuant to Article 19 paragraph 1 of the 1992 Regulation.

6.3 If it is not possible to advertise prescription only medicines to the general public, are disease awareness campaigns permitted, encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Pursuant to Article 14 paragraph 4 of the 1992 Regulation, vaccination campaigns carried out by the industry are permitted, but must be approved by the Minister of Health.

The Medical Committee, an entity representing the Luxembourg health professionals established under the Medical Committee Law (*Loi du 8 juin 1999 relative au Collège médical*), supervises all questions of professional discipline and practice. It is entitled, at its own discretion or on behalf of the Ministry of Health, to examine all health issues. The Ministry of Health and the Medical Committee both have to be consulted before engaging in any disease awareness campaign.

6.4 Is it possible to issue press releases concerning prescription only medicines to non-scientific journals? If so, what conditions apply?

Such press releases are possible to the extent they do not circumvent the prohibition under Article 14 paragraph 1 of the 1992 Regulation and the general rules pertaining to pharmaceutical advertising.

7 The Internet

7.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Internet advertising in Luxembourg is mainly governed by Articles 46 - 48 of the law dated August 14, 2000 on electronic commerce (*Loi du 14 août 2000 relative au commerce électronique*, hereinafter referred to as the Electronic Commerce Law). Article 46 of the Electronic Commerce Law defines “commercial communications” as “any kind of communication used to promote, directly or indirectly, goods, services, the image of a company, of an organisation or a person conducting commercial, industrial or handicraft activities or member of a liberal profession”.

Article 47 of the Electronic Commerce Law sets out general rules of transparency: commercial communication must be clearly identifiable as such. Moreover, the person or entity in the name of which the communication takes place must be identifiable as well. Where contests or promotion games are used, these have to be clearly identifiable as such. Their terms and conditions have to be easily accessible and shall not be confusing.

It goes without saying the rules pertaining to misleading and comparative advertisement apply (see question 3.2 above).

7.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for health professionals?

There is no level of security specially required for such websites.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of medical devices in your country?

The advertising of medical devices is scarcely regulated. The only reference as to this subject can be found in Article 1, paragraph 1 of the *loi du 16 janvier 1990 relative aux dispositifs médicaux* (law dated January 16, 1990 pertaining to medical devices, as amended, hereinafter referred to as the Medical Devices Law). The mentioned provision states that commercialisation, import, advertisement and use of medicinal devices is subject to the supervision of the Ministry of Health and the Ministry of Justice, according to their respective competences. Medical devices are defined as “any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process; or



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- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.” The definition used corresponds to the one used in the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Although Article 1 of the Medical Devices Law enables this supervision to be further specified by a grand-ducal regulation, the adopted Medical Devices Regulation dated August 11, 1996 (*Règlement grand-ducal du 11 août 1996 relatif aux dispositifs médicaux*), implementing the mentioned Directive and its following amendments, does not mention advertisements.

The department responsible for the supervision of advertisements for medical devices is the *Division de la Médecine Curative*. This department controls such advertisements subsequently. There is no prior approval procedure in place. The department notably controls whether the medical devices have the “CE”-marking required.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

Although the Luxembourg legislator did not specify rules as to advertisement for medical devices as it did for medicinal products, the Ministry of Health and the Ministry of Justice are empowered to monitor the medical devices sector on the grounds of Article 1 of the Medical Devices Law (see question 8.1 above). There are, however, no restrictions on payments or hospitality with regard to the promotion of medical devices where there is no link to any pharmaceutical advertising.



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