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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2009

A practical insight to cross-border Pharmaceutical Advertising work

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1 General - Medicinal Products

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

The rules on advertising for medicinal products in Belgium are set out in the Belgian Act on Medicines of 25 March 1964 (the "Belgian Medicines Act" or "BMA"), in particular in articles 9 and 10 BMA. Articles 9 and 10 BMA have been amended by the Act of 16 December 2004 and the Act of 27 April 2005 to *inter alia* address the "excesses" in pharmaceutical marketing and advertising. The BMA as a whole has been drastically amended by the Act of 1 May 2006 to implement the Directives 2001/83/EC and 2001/82/EC, as amended by Directives 2004/27/EC and 2004/28/EC respectively.

Several royal decrees have been adopted in execution of articles 9 and 10 BMA. The Royal Decree of 7 April 1995 (the "Advertising Decree") provides for detailed guidance and procedures on advertising to the general public and to healthcare professionals for medicinal products for human use, while the Royal Decree of 9 July 1984 applies specifically for medicinal products for veterinary use. Furthermore, the Royal Decree of 11 January 1993 (the "Sample Decree") determines the conditions under which samples of medicinal products for human use can be distributed.

Furthermore, there are two professional bodies which have issued codes of practice on the promotion of medicinal products in Belgium which are binding on their members. On the one hand Pharma.be, the trade association of (brand) pharmaceutical companies, adopted its own code of practice. On the other hand a self-regulatory body officially recognised by the Belgian health authorities, Mdeon, also adopted ethical rules in its own code of practice. Mdeon (www.mdeon.be) was established on 23 May 2006, and was officially recognised as of 1 January 2007 by Royal Decree of 25 February 2007. It is composed of the national associations of doctors and pharmacists, the brand and generic pharmaceutical industry and the medical devices industry.

1.2 How is "advertising" defined?

Article 9, § 1, 5th paragraph BMA defines "advertising for medicinal products" as any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. This definition is a literal implementation of article 86, § 1 of Directive 2001/83/EC. Explicitly excluded from the scope of article 9, § 1, 5th paragraph BMA are (i) the labelling and the accompanying package leaflets, (ii) correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product, (iii) factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims, and (iv) information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.

Article 2, § 2 of the Advertising Decree lists a number of specific examples of acts considered as "advertising for medicinal products".

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and Codes of Practice on advertising, such as "sign off" of promotional copy requirements?

Every marketing authorisation holder ("MA Holder") is required by virtue of article 13 of the Advertising Decree to designate a qualified person responsible for the compliance with the advertising provisions (the "person responsible for the information"). Article 15 of the Advertising Decree obliges the MA Holder to keep a register of all advertisements and of all benefits and/or advantages which have been promised, offered or awarded to health care professionals by virtue of article 10 BMA (see question 4.2).

With regard to the distribution of samples, MA Holders are required by virtue of article 8 of the Sample Decree to implement an internal control mechanism to track the number of samples distributed to a health care professional, as well as the name and address of each such health care professional. This data must be kept for a period of ten years.

Except for these particular circumstances, and except for the particular procedure mentioned under question 1.4, no other arrangements are foreseen to ensure compliance with the advertising requirements.

1.4 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 16, § 1 of the Advertising Decree, every radio and/or television information campaign on diseases or health issues which directly or indirectly refers to a medicinal product, and every radio and/or television advertisement on OTC ("Over the Counter") medicinal products is subject to the prior approval by the Minister of Public Health ("the Minister"). Without this prior approval such information campaign or advertisement cannot take place. Radio

and/or television advertisements for prescription-only medicinal products ("POM") are in any event prohibited given the general ban on direct-to-consumer advertising for prescription-only medicinal products (article 9, § 1, 2nd paragraph BMA).

Furthermore, article 16, § 2 of the Advertising Decree requires that all advertising to the general public for OTC medicinal products be notified to the Minister at least 30 days prior to its distribution. Unless the Minister objects within this timeframe to the proposed advertisement, the MA Holder can distribute it, without prejudice to the right of the Minister to forbid or to order the cessation of any advertising deemed to be infringing, and to order a rectification thereof.

For the purpose of the approval and notification mentioned above, the Minister has explicitly charged the Federal Agency for Medicinal and Health Products (the "Agency") with these tasks.

The Minister has charged the self-regulated body Mdeon (see question 1.1) with the task of granting prior visa to pharmaceutical manufacturers, importers or wholesale distributors wishing to contribute to the attendance of health care professionals at scientific events or meetings, including hospitality, including at least one overnight stay. Pursuant to article 10 § 3 BMA, the planned scientific event cannot take place in the absence of such visa. Said companies can also voluntarily notify Mdeon, or even ask its opinion, of the scientific events for health care professionals that do not include an overnight stay, and of any remuneration for legitimate services of a scientific nature.

1.5 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?

Pursuant to article 9, § 2, 4th paragraph BMA, any person with a legitimate interest can file a complaint with the Agency against an advertisement deemed in violation of the relevant provisions on advertising for medicinal products.

The Minister can also, on his own initiative, order in the public interest the cessation of any advertisement in violation of the relevant provisions, or, if the advertisement has not been published yet, prohibit such advertisement. Thereto the Minister does not have to prove any actual damage nor malicious intent or negligence by the advertiser. At the same time the Minister can request the publication in a form he deems adequate of the entire decision or a part thereof, and/or request a rectification.

If the measures relate to a television or radio advertisement, the Minister must solicit the opinion of the Commission for the Control on Advertising for medicinal products for human use ("Advertising Commission"), except in case of urgency.

The procedures mentioned above explicitly foresee the right for the advertiser to be heard before any decision is taken. Any decision taken by the Minister can be appealed with the competent administrative or civil courts.

1.6 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?

There are various means to enforce compliance with the advertising provisions, consisting of criminal, administrative and civil sanctions.

Under article 16, §3 BMA, infringement of the advertising provisions are in theory punishable by criminal sanctions of one month to one year imprisonment and fines ranging from 1,100 Euro up to 82,500 Euro, which can be doubled in case of recidivism. The common practice is that the inspectors of the Agency which are competent to trace and establish offences usually draft a report of the infringement, after which an administrative fine of the same range mentioned above is proposed to the advertiser. If the administrative fine is not settled, the reports are sent to the public prosecutor, who has to decide autonomously on the opportunity to prosecute the advertiser. Usually the Agency reacts following a complaint by an individual or a competitor, or if a manifest violation has been given a lot of public attention. A recent example of action taken by the Agency against a pharmaceutical company concerned the grant of laptops to health care professionals.

The self-regulated body Pharma.be mentioned under question 1.1 can also take binding decisions against its members in case of violation of their Code of Practice.

Pursuant to the Fair Trade Practices Act of 14 July 1991, competitors can initiate accelerated proceedings on the merits before the competent President of the Commercial Courts to act against advertisements that are deemed illegal and that hurt the professional interest of the complainant.

Very few examples of actions against pharmaceutical companies are publicly available due to a lack of transparency. The Agency's reports and fines are not made publicly available, nor are the decisions of Pharma.be and Mdeon. However, a general contact point has been established with the Agency which is *inter alia* responsible for the publication of all decisions and for the drafting of a two-yearly report. The first report is expected in 2009.

1.7 What is the relationship between any self regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self- regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The self-regulatory bodies on the one hand and the Agency on the other hand do not have a systematic form of cooperation. The Code of Practice of Pharma.be provides that all cases which concern facts liable to constitute a violation of the laws and regulations on medicinal product, are referred to the Agency if certain conditions are fulfilled. Mdeon must keep a register with all decisions on the granting of visas (see question 1.4) for three years at the disposal of the Agency. Mdeon also must inform the Agency immediately of all refusal decisions, all late applications, all decisions reformed in appeal and all established irregularities in the visa procedure.

In practice, the self-regulated bodies and the Agency each perform their duties independently from one another. Decisions of the self-regulated bodies cannot be appealed to the Agency.

1.8 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?

Competitors can file summary proceedings, accelerated proceedings on the merits or common proceedings on the merits before the competent courts pursuant to the Fair Trade Practices Act

of 14 July 1991 and/or common tort law. The most commonly used action is the accelerated proceedings on the merits, which is similar to the summary proceedings as regards timing without having to establish the formal requirement of "urgency". As opposed to the summary proceedings, which can only lead to provisional measures, the accelerated proceedings on the merits lead to an actual decision on the merits of the case, granting an enforceable injunction if needed accompanied by a publication measure or rectification. Actual damages can only be obtained through proceedings on the merits. These measures are not only open to competitors of the advertiser, but also to the Minister.

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?

Under article 9, § 1, 1st paragraph BMA, advertising for medicinal products for which no marketing authorisation is granted in Belgium is explicitly prohibited. Therefore it is also prohibited to promote such unauthorised medicinal products at scientific meetings. However, if the aim of the scientific meeting is clearly not to promote the prescription, supply, sale or consumption of unauthorised medicinal products once they actually are registered, these meetings are to be considered as purely scientific information instead of forbidden advertising. Such meetings would not fall within the scope of article 9 BMA. This would apply for instance to meetings at which the results of important clinical trials or studies are discussed, if this event is not sponsored by a pharmaceutical company that has a direct or indirect link with the product used at these trials or studies.

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

The same rules apply as mentioned under question 2.1. In principle, advertising for unauthorised medicinal products is prohibited. Only in the event that the publications take place from a purely scientific or informative perspective, without any ulterior commercial motive, are such publications allowed.

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

Press releases by companies with regard to unauthorised products is - given the broadly worded scope of "advertising for medicinal products" - most likely to be considered prohibited. By analogy, there is case law from the Brussels court of appeals considering press releases and press articles regarding an *authorised* medicinal product to be prohibited direct-to-consumer advertising.

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

Article 9, § 1, 6th paragraph BMA explicitly allows for correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product. Therefore, under these exceptional circumstances, information about an unauthorised medicinal product may be sent to a health care professional at his explicit request (e.g. scientific studies).

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?

The answer to this question has to be assessed on a case by case approach. Since the general principle is the ban on advertising of unauthorised medicinal products, any communication on unauthorised medicinal products between a vendor of medicinal products on the one hand and a buyer on the other hand is most likely to be considered prohibited advertising. If the question relates to government institutions, e.g. health care institutions, needing to determine the health care budget for the next year(s) to come, such communication by the pharmaceutical company is less likely to be considered advertising given the non-commercial nature of such communication.

2.6 Is it possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

The same rules mentioned above apply. There are no guidelines dealing with this particular issue, but given the *per se* commercial nature of involving health care professionals in exercises regarding launch materials for unauthorised products, such practice is to be considered prohibited advertising.

3 Advertisements to Health Professionals

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

Without prejudice to the common rules applicable both for advertising towards health care professionals and to the general public (articles 4 and 5 of the Advertising Decree), advertisements directed solely to health care professionals must carry the following information in a legible form, pursuant to article 9 of the Advertising Decree:

- the name of the product, its qualitative and quantitative composition in terms of active substance(s) and its pharmaceutical form;
- all information contained in the SmPC, public information leaflet ("PIL") or labelling regarding the therapeutic indications, dosage, counter indications and side effects of the product;
- the name of the MA holder and the product authorisation number;
- the supply classification; and
- for each package form marketed, the retail price of the product (mentioned clearly in bold in the upper right-hand corner of the advertisement, and taking up 0.50% of the total advertisement surface).

The first three requirements mentioned above must cover at least 50% of the total surface area of the advertisement.

3.2 Is it a requirement that there be data from any or a particular number of "head to head" clinical trials before comparative claims are made?

There is no such legal requirement in place regarding comparative claims. In general, article 4 of the Advertising Decree states that all elements of the advertisement have to be correct, recent and verifiable, while article 9, § 1, 7th paragraph BMA states that all the elements of the advertisement have to be in accordance with the SmPC. Furthermore the general rules regarding comparative advertising laid down in the Fair Trade Practices Act of 14 July 1991 apply.

3.3 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 Belgium?

There is no legislation on comparative advertising specifically adopted for medicinal products. The general provisions mentioned under question 3.2 also apply in the case of comparative advertising.

Under article 9 of the Code of Practice of the self-regulated body Pharma.be, comparisons with competing products - if necessary or useful - must establish the particular characteristics of the product with which it is compared in a manner that is fair, complete and scientific. However, since not all pharmaceutical companies are member of Pharma.be, e.g. the majority generic companies are member of trade association FeBelGen, the practical relevance of these specific provisions is limited.

In most cases, reference is made to the general rules on comparative advertising of the Fair Trade Practices Act of 14 July 1991. Comparative advertising under article 94/1 of this Act is allowed, insofar the advertisement (a selection of conditions which may be relevant for medicinal products follows):

- is not misleading;
- compares products that satisfy the same needs or are intended for the same purpose;
- objectively compares one or more substantial, relevant, verifiable and representative characteristics of the products, which may include the price;
- does not create confusion between the advertiser and the competitor, nor between the advertiser's trademarks, trade names, other distinguishing features or products and those of a competitor;
- does not discredit or denigrate the trademarks, trade names, other distinguishing features, products or circumstances of a competitor;
- does not take unfair advantage of the reputation of a trademark, trade name or other distinguishing feature of a competitor; and
- does not present products as imitations or replicas of products protected by a trademark or trade name.

Established Belgian case law confirms that a competitor's trademark and brand name may be used in a comparative advertisement for a competing product, and that the name and trademark of the reference product may be used to compare the corresponding generic product provided that the above principles are fulfilled.

With regard to comparative advertising between an authorised and an unauthorised product, such advertisement is forbidden given the general ban on advertising for unauthorised medicinal products (see question 2.1).

3.4 What rules govern the distribution of scientific papers and/or proceedings of congresses to doctors?

The general rules on advertising mentioned above under question 2.1 apply. If the distribution of information is related to yet unauthorised medicinal products, it would only be allowed if they are distributed for purely scientific reasons without any underlying commercial motive, which can also depend on the quality of the distributor. If the distribution of information is related to authorised medicinal products, the mandatory information mentioned in question 3.1, regarding advertising to health care professionals, needs to be provided. This would however not be required in certain case specific conditions if the information is provided at the specific request of the health care professional (see question 2.4).

3.5 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)?

There are no specific rules for so-called "teaser" advertisements for medicinal products. It has to be borne in mind that advertising for a non-authorised product is forbidden, while advertising for authorised medicinal products, both to health care professionals and to the general public, is subject to a serious number of restrictions and mandatory information (except for so-called "reminder advertising", which is however intended as a *reminder* of the name of the product and is therefore not reconcilable with the concept of teaser advertisements). Teaser advertisements therefore only seem to be allowed if no direct or indirect link with an identifiable medicinal product can be established.

4 Gifts and Financial Incentives

4.1 It is possible to provide health professionals with samples of products? If so, what restrictions apply?

Pursuant to the Sample Decree, only the MA Holders can provide samples of a product to health care professionals. Only samples of medicinal products of which at least one package form is actually marketed can be distributed. Samples of narcotics, psychotropics, or medicinal products containing isotretinoin cannot be provided.

Samples can furthermore only be exceptionally provided to prescribers following a prior written, dated and signed request of the prescriber. The request must mention the name, address, number of the prescriber's professional organisation, and the name and number of samples of each medicinal product he wishes to receive. The prescriber must keep a complete list of all samples he received over the past year for a period of five years.

The maximum amount of samples per prescriber cannot exceed the total of 600 per calendar year. Each MA Holder can only provide a maximum amount of eight samples per medicinal product, per year and per prescriber. It is explicitly stated that the dispensing of samples to patients by the prescriber is strictly limited to meet an urgent medical or social need.

Pursuant to article 4 of the Sample Decree, a sample may not be taller than the smallest package form available in the market.

The MA Holder also must apply some mandatory information to the (outer) packaging of the sample (e.g. "free sample - not for sale"), and the sample must be accompanied by the SmPC of the medicinal product. The MA Holder is required to put into place a system to control and trace the distribution of samples to health care professionals for a period of 10 years.

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

Article 10, § 1 BMA explicitly prohibits the direct or indirect *promise, offer or award* of gifts, pecuniary advantages or benefits in kind, to *inter alia* health care practitioners. The following three exceptions to this broadly worded prohibition are explicitly set out in the BMA:

- gifts or benefits with a very limited value (the preparatory documents for the BMA indicate that the relevant value would be around 50 Euro per healthcare professional with a maximum of around 125 Euro per year) that are related to the practice of medicine, dentistry, medicinal preparation or veterinary medicine (e.g. wine is explicitly mentioned in the preparatory works as not related to the practice of medicines, as opposed to office equipment, spatula's, etc.);
- invitations to and financing of attendance at scientific events, including hospitality, under a number of cumulative conditions, namely (i) the event is of a purely scientific nature, (ii) the hospitality is strictly limited to the scientific purpose of the event, (iii) the place, date and duration of the event do not create confusion with regard to the scientific nature of the event, (iv) financing of attendance (including hospitality) does not extend beyond the official duration of the event, and (v) financing of attendance (including hospitality) is not provided to persons other than the healthcare professionals; and
- payment or remuneration for legitimate services of a scientific nature, in particular clinical tests, provided that such remuneration is within reasonable limits.

Article 10, § 6 BMA also prohibits the *soliciting* or *accepting* of gifts, pecuniary advantages, invitations or hospitality in the same circumstances. This reciprocal side of the prohibition is also reflected in article 18, § 2 the Royal Decree No. 78 of 10 November 1967 regarding the organisation of health care professions, which provides that in the framework of their profession, it is forbidden for doctors to directly or indirectly ask for or accept any gifts, advantages, invitations or hospitality. The provision also states that any agreement both between health care professionals and third parties (including manufacturers of medicinal products) are forbidden if the agreement provides them with any direct or indirect advantage or profit.

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?

Article 10, § 1 BMA not only forbids the promise, offer or award of gifts and benefits to health care professionals, but also to "institutions where medicinal products are prescribed, dispensed or administered", which includes hospitals. Therefore pharmaceutical companies are in principle not allowed to donate anything to hospitals. However, the rationale behind the general prohibition is that the donations may not lead to the increased prescription of medicinal products of the sponsor of these financial donations or donations in kind. Therefore, it can be argued that donations of a genuine scientific nature are not forbidden under article 10 BMA.

It has to be stressed that the remuneration for legitimate services of a scientific nature, such as in the framework of a clinical trial or study, a lecture at a conference, consultancy services, etc. are explicitly allowed under the third exception to article 10 BMA as long as the remuneration is considered within reasonable limits. Donations granted for philanthropic or humanitarian purposes would also be excluded from the scope of article 10 BMA.

The pure and simple donation of equipment to institutions would also fall under the scope of article 10 BMA. Therefore, such practice would only be allowed if fits within a purely scientific frame, e.g. to provide equipment for a clinical trial or study, provided that the equipment is either returned or bought by the institution after the trial or study is completed.

Given the lack of legal certainty the broadly worded scope of article 10 BMA entails, every donation has to be considered on a case by case approach. The increased awareness and inspections of the Agency with regard to gifts and benefits to hospitals should incite companies to be as transparent as possible and to record the purpose, amount and addressee of any donation to hospitals.

4.4 Is it possible to provide medical or educational goods and services to doctors that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

As explained under question 4.3, such practice would absolutely be forbidden if it actually affects prescribing patterns. The rationale behind article 10 BMA is indeed that gifts and benefits in kind should not influence the prescribing behaviour of health care professionals.

4.5 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?

Even though article 10 BMA does not explicitly provide for this exception, the Minister has acknowledged that, in accordance with article 94.4 of Directive 2001/83/EC, common trade practices relating to prices, margins and discounts are not affected by the prohibition of article 10 BMA. Specifically with regard to hospitals, the Minister stated in the preparatory parliamentary works that volume-related discounts to hospitals are allowed (Parl. Prep. Doc., House of Repres., 2003-2004, nr. 1272/004, p. 27).

4.6 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?

In this respect, reference can be made to article 17 of the Royal Decree of 10 November 1967 mentioned above, which states that third parties, including pharmaceutical companies, can place at the disposal of health care professionals premises or equipment if the conditions of this use are explicitly set out in a written agreement. Furthermore, the provision of equipment or premises is also subject to article 10 BMA and article 18 of the Royal Decree of 10 November 1967 (see question 4.3).

4.7 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?

Article 5, § 1, 10 of the Advertising Decree explicitly disallows any advertising for a medicinal product, whether to the general public or to health care professionals, promising, offering or allowing, directly or indirectly, to refund a medicinal product in part or in

whole if the patient would be unsatisfied with the product. This applies to both OTC and prescription only medicinal products.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

The Minister expressly stated during the parliamentary preparatory works that training and educational activities relating to the appropriate use of medicinal products are not to be considered gifts or pecuniary advantages prohibited under article 10 BMA (Parl. Prep. Doc., House of Repres., 2003-2004, nr. 1272/004, p. 27-28). However, given the broadly worded scope of article 10 BMA, such sponsorship may still be prohibited if the sponsorship of the continuing medical education is not mainly scientific but used instead to promote the prescription or sales of the concerned product.

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?

The rules governing the offering of hospitality to health care professionals are detailed in question 4.2. Any hospitality offered by a pharmaceutical company or accepted by a Belgian health care professional, which would not be compliant with the conditions of article 10 BMA, can lead to sanctions for either party, whether the hospitality is offered abroad or not. Furthermore, scientific events organised abroad will usually include at least one overnight stay for which a prior visa is required (see question 1.4).

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?

Article 10, § 1 BMA allows the financing of attendance at scientific events, including hospitality, under a number of cumulative conditions, namely if (i) the event is of a purely scientific nature, (ii) the hospitality is strictly limited to the scientific purpose of the event, (iii) the place, date and duration of the event does not create confusion with regard to the scientific nature of the event, (iv) financing of attendance (including hospitality) does not extend beyond the official duration of the event, and (v) financing of attendance (including hospitality) is not provided to persons other than the healthcare professionals (see question 4.2).

Remuneration for legitimate services of a scientific nature, such as in the framework of a clinical trial or study, a lecture at a conference, consultancy services, etc. are explicitly allowed under the third exception to article 10 BMA as long as the remuneration is considered within reasonable limits (see question 4.3).

The organisation or sponsorship of a scientific event including at least one overnight stay requires a request for a prior visa from Mdeon, in which the amount of the hospitality must be provided in detail. Article 9.3 of the Mdeon Code of Practice explicitly states that health care professionals cannot be paid merely for attending a scientific event.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

The Agency is competent to fine any company violating the provisions of article 10 BMA or to refer an infringement to the public prosecutor's office (fines ranging from 1,100 Euro up to 82,500 Euro; see question 1.6).

Mdeon is not competent to sanction companies that are not in compliance with the prior visa requirements, but will most likely inform the Agency of any irregularities which comes to its attention.

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

See question 5.2.

5.5 Is it possible to pay doctors to take part in post marketing surveillance studies? What rules govern such studies?

As mentioned under questions 4.3 and 5.2, health care professionals are entitled to receive remuneration for scientific services provided, if such remuneration is within reasonable limits. Such services are not only limited to clinical trials *strictu sensu* for instance, but can also apply to post-marketing surveillance if scientifically justified.

5.6 Is it possible to pay doctors to take part in market research involving promotional materials?

Market research involving promotional materials would not be considered purely scientific. Therefore such research would be forbidden under article 10 BMA.

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?

Advertising of OTC products is allowed, subject to the conditions BMA and the Advertising Decree.

Pursuant to article 9 BMA all aspects of the advertising must be in line with the data in the SmPC. Moreover, all advertising of medicinal products must promote the rational use of this medicinal product through an objective representation, without exaggerating its characteristics, and may not be misleading.

Article 5 of the Advertising Decree provides it is prohibited to advertise for any type of medicinal products, including OTC:

- by means of airplanes, ships or billboards on public roads;
- by means of illuminated advertising signs;
- by orally recommending the medicinal product in public, by telephone, by SMS or by email;
- in children's magazines;
- by issuing a prize competition;
- by means of all sorts of objects which are intended in part or in whole for a purpose other than communicating information;
- on cards meant to be torn off;

- on flyers in publications;
- in software; and
- by promising, offering, or allowing, directly or indirectly, to refund a medicinal product in part or in whole if the patient is unsatisfied with the product.

Article 7 of the Advertising Decree provides in particular with regard to OTC medicinal products, that such advertising is prohibited when it contains an element:

- suggesting that medical examination or surgery is superfluous, in particular when it offers a diagnose or recommends a treatment via letter;
- suggesting that the medicinal product has no side effect and is better than another treatment or medicinal product;
- suggesting that use of the medicinal product can improve the average good health;
- suggesting that the average good health will be affected when the medicinal product is not used, unless when such advertising relates to a vaccination campaign approved by the Minister;
- only or mainly aimed at children;
- referring to recommendations from scientists, health care professionals or persons whose reputation could stimulate the use of the medicinal product;
- assimilating the medicinal product to foodstuffs, cosmetic products or other consumption goods;
- suggesting that the safety or efficacy of the medicinal product is the result of the use of a natural substance;
- leading to an incorrect self-diagnosis as a result of a description or a detailed representation of the anamnesis;
- referring to healings in a frightening or misleading manner;
- using frightening or misleading representations of changes to the human body as a result of a disease, an injury, or the use of a medicinal product; or
- using images, drawings, photographs, or representations likely to undermine the essentially informative character and necessary seriousness expected of an advertisement for a medicinal product and, as far as the addressees are concerned, its purpose is not to persuade them to make rational use of the medicinal product in order to heal or prevent an illness, establish a medical diagnosis or restore, correct or modify bodily functions.

Article 8 of the Advertising Decree also provides that the message must clearly be understood to be advertising and the product to be a medicinal product. It also states that the following data must be included:

- the name of the medicinal product, as well as its common name if it contains only one active ingredient;
- data which are indispensable for the rational use of the medicinal product;
- the mention "this is a medicinal product, no long-term use without medical advice";
- an explicit request to carefully read the patient information leaflet or the packaging whichever applies; and
- the name or trade name of the MA Holder.

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

Such advertising is prohibited pursuant to article 9, § 1 BMA.

Vaccination campaigns and campaigns of general interest which have been granted a prior approval from the Minister of health are permitted. This advertising must comply with the requirements mentioned in article 9 BMA and article 5 of the Advertising Decree.

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?

Disease awareness and health campaigns referring directly or indirectly to a medicinal product or a group of medicinal products, are subject to a number of restrictions pursuant to article 9, § 3 BMA. In accordance with article 3 of the Advertising Decree, such campaigns are forbidden if direct or indirect reference is made to prescription-only medicinal products. They are also forbidden if they contain any of the elements mentioned in article 7 of the Advertising Decree (see question 6.1).

All information published in the context of the campaign must:

- be correct, recent and verifiable; and
- comply with the SmPC for the medicinal product to which reference is made.

Furthermore, disease awareness and health campaigns must encourage rational use of the medicinal product by presenting it objectively, without exaggerating its characteristics and may not be misleading.

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

As discussed above under question 1.2, the notion of "advertising" is construed broadly. Therefore any press release with regard to prescription only medicinal products will most likely be considered forbidden advertising. There is case law from the Court of Appeals of Brussels stating that information and press releases on medicinal products in non-scientific journals may have a promotional effect and is therefore to be considered advertising.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Image or company advertising is as such permitted. As general company information is commonly not intended to promote the sales of medicinal products, but only to provide information on the company through a detailed overview of its activities and products, it is in principle not to be considered as advertising. To such an extent such initiatives are permitted.

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

No specific rules apply.

7 The Internet

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

Apart from article 5 of the Advertising Decree which states that medicinal products cannot be advertised via email, no specific rules apply for internet advertising of medicinal products. All general pharmaceutical advertising provisions mentioned under questions 3.1 and 6.1 above apply. The Agency applies these rules in an

online environment but mainly focuses on online pharmacies established in foreign countries but aimed at the Belgian public (see also question 9.1). However, in practice control and enforcement by the Agency are limited due to the differences in legislation between Member States with regard to internet advertising of medicinal products.

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?

As set out above, different rules apply with regard to advertising towards health care professionals and towards the general public. Therefore Belgian pharmaceutical companies generally foresee a website with limited access for the general public and a secured access for health care professionals (username and password, IP recognition).

7.3 What rules apply to the content of independent websites that may be accessed by link from a company sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

As mentioned above, no particular rules are in place with regard to internet advertising for medicinal products. Independent and non-pharmaceutical third parties are allowed to discuss unregistered or prescription-only medicines. However, if a pharmaceutical company conscientiously places a link on its website to such an independent website, this could be considered direct or indirect forbidden advertising. In such case, the pharmaceutical company could be held responsible.

Under all other circumstances, if the pharmaceutical company is unaware of any direct or indirect advertising of its medicinal products by a third and independent party, it is unlikely that the concerned pharmaceutical company will be held liable. In a recent opinion, the Advocate-General of the European Court of Justice (C-421/07) stated that information distributed by a third independent party is only to be considered advertising if the promotion of prescriptions, the dispensing, the sales or the consumption of a medicinal product is intended. The Advocate-General interestingly noted that the absence of a link between the party distributing the information on the one hand and the vendors or manufacturers of the medicinal product on the other hand, may constitute an important indication of the lack of the promotional content of a message. The final judgment of the ECJ in this matter will also be relevant for Belgium.

7.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Any information which is not directly or indirectly related to a medicinal product, such as corporate, investor or contact information, may be placed on the pharmaceutical company website without restrictions.

Information with regard to medicinal products may likely be considered advertising as a result of the broad construction of this notion, and will therefore have to comply to the rules discussed under sections 2, 3 and 6 above.

8 General - Medical Devices

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

Article 9, § 4 BMA prohibits advertising to the general public of implantable medical devices or acts consisting of placing or implanting implantable medical devices. An implantable medical device is a medical device intended to be entirely inserted in the human body or to replace the epithelium or eye surface through surgery and intended to remain there after that surgery. A medical device which is intended to be only partially inserted in the human body through surgery, but is intended to remain there for a period of at least 30 days will also be considered to be an implantable medical device.

Article 10 BMA discussed above under sections 4 and 5, also applies to *all* types of medical devices.

The Code of Practice of Mdeon (including the requirement to apply for a visa prior to organising or sponsoring a scientific event including more than a one night stay) also applies to medical device companies. The Code of Practice of the Belgian medical devices industry association, UNAMEC, also applies to the medical device companies which are member of this association.

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

Since article 10 BMA applies by analogy to all medical devices, the provisions which are detailed under sections 4 and 5 above fully apply.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

There were no significant changes or developments with regard to the rules on pharmaceutical advertising over the past year. However, it is interesting to note that following the publication of a Royal Decree of 21 January 2009 "regarding instructions for pharmacists", detailed rules on the internet sales of medicinal products have entered into force on 9 February 2009. Pursuant to this decree, the online sales of OTC medicinal products are possible under strict reconditions, while the online sales of prescription-only medicinal products are prohibited. Since article 29 *in fine* of this decree explicitly states that the existing rules on advertising of medicinal products equally apply to the internet sites of pharmacies, the expected growth of online pharmacies in Belgium will undoubtedly raise a number of issues with regard to pharmaceutical advertising on websites.

Recently the members of the "Borderline Product Committee" have officially been appointed and the Committee held its first meeting on 17 February 2009. This committee is competent to advise on the qualification of products (or health claims for such product) as medicinal or non-medicinal. Since the qualification of a product has an important impact on the advertising rules, the opinions of the committee will also have an impact on pharmaceutical advertising in Belgium.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

Following a recent restructuring in January 2009, the organisational structure of the Agency was divided in three "pillars" which are each managed by their own Director-general. The Agency now consists of three directorate-generals called "DG PRE" (covering all activities before the marketing authorisation of a medicinal product), "DG POST" (covering all activities after the marketing authorisation of a medicinal product is granted) and "DG Inspection" (covering all inspection activities). The change is meant to increase efficiency and is also expected to lead to more inspections, including those on pharmaceutical advertising.

Secondly, the first report from the general contact point with the Agency responsible for the publication of all decisions on pharmaceutical advertising is expected in 2009 (see question 1.6).

Finally, the recently announced "pharmaceutical package" of the European Commission contains proposals with regard to pharmaceutical advertising. The implementation of the final "package" will of course also affect the rules in Belgium.

9.3 Are there any general practice or enforcement trends that have become apparent in Belgium over the last year or so?

On 21 April 2008, the Agency sent an official circular letter (n° 518) to all health care professionals to recollect that the principles of article 10 BMA not only apply to MA Holders but also to the health care professionals themselves.

In its annual report of 2007, Mdeon already announced that from a statistical point of view, apparently 58% of the Belgian companies did not seem to comply with the mandatory visa procedure. Therefore it had contacted the Agency, which made it clear by circular letter n° 513 that it would closely monitor all pharmaceutical companies that have never submitted any visa application and continue to refuse to do so. In its annual report of 2008, Mdeon confirmed that numerous inspections have been carried out by the Agency, and that additional inspectors were hired for this purpose. It can therefore be expected that in the future more companies that do not submit visa applications risk an inspection in the years to come.

9.4 Has your national code been amended in order to implement the current version of the EFPIA Code of October 2007?

The EFPIA Code of Practice of October 2007 has explicitly been implemented in the Code of Practice of Pharma.be. Article 3, § 2 of the Code of Practice of Pharma.be states that it supplements "the provisions of the EFPIA Code on the Promotion of Prescription-only Medicines to, and interaction with, Healthcare Professionals, of the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations, of the IFPMA Code of Pharmaceutical Marketing Practices and of the Code of Deontology of the non-profit association Mdeon". In case of contradiction between the codes, the most constraining provision shall always apply.

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