Baker McKenzie.

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

BELGIUM

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Belgium

Geert Bovy

Introduction

The success of the sale of a product depends on a whole range of factors, including, among others, the price and the quality of the product, the usefulness and the necessity of the product, and the advertising and promotion of the product. Successful promotion and advertising campaigns offer the customer a particular reason to select a product. This is true in any market with the Belgian healthcare market being no exception.

However, due to the nature of and the risks associated with medical products, their promotion is subject to rather strict European and Belgian regulations. The purpose of this chapter is to provide guidance for pharmaceutical and medical device companies in the promotion of their products to the public and to healthcare professionals, and in their contacts with healthcare professionals, by giving an overview of the legal and ethical rules in Belgium, which may form the basis of ethical, civil and even criminal liability.

The Regulatory Framework

The promotion of medical products in Belgium is regulated by a complex amalgam of acts, royal decrees, circulars, and industry and professional codes of conduct, the content of which are not always very clear and can be subject to various interpretations.

A distinction needs to be made under Belgian law between medicinal products and medical devices:

- A medicinal product is "*any substance or combination of substances, presented as having curative or preventive qualities with regard to diseases in human beings or animals*." According to the same definition, "*any substance or combination of substances which may be used in, or*

administered to, human beings or animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis" is likewise considered a medicinal product.

- A medical device is defined as follows:

  "*any instrument, apparatus, equipment, software, material or other article, whether used alone or in combination, including the software intended by the manufacturer to be used specifically for diagnosis and/or therapeutic purposes, and 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,*
  - *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 Act of March 25, 1964 on Medicinal Products

The promotion of medical products is mainly governed by the Act of March 25, 1964 on Medicinal Products (the "Act"), and more specifically by its Article. 10. This article applies to medicinal products and medical devices.

According to Article 10 of the Act, "*it is prohibited in the context of the supply, prescription, delivery or administration of medicinal products to promise, offer or grant, directly or indirectly, premiums, monetary benefits or benefits in kind to wholesalers, to persons engaged in brokering activities, to persons entitled to prescribe, deliver or administer medicinal products as well as to institutions where the prescription, delivery or administration of medicinal products takes place.*"

However, this prohibition does not apply:

- to premiums or benefits of a negligible value and which relate to the practice of medicine, dentistry, pharmacy or veterinary medicine;
- to hospitality and participation costs at scientific events provided that specific conditions are met; and
- to compensation for legitimate services of a scientific nature provided that it remains within reasonable limits.

The scope of these exceptions is further explained in the section on "Permitted and Prohibited Practices."

For the sake of completeness, it should be noted that Article 9 of the Act further regulates the advertising of medicinal products and medical devices to the general public. It lays down several prohibitions and restrictions regarding the advertising of medicinal products and implantable medical devices to the general public.

Other Legal Provisions

In addition to the Act, the following legal provisions also govern the promotion of medical products:

- Article 18, §2 of the Royal Decree of November 10, 1967 on the Performance of Medical Profession explicitly prohibits "*agreements between practitioners, i.e., physicians, dentists,*

pharmacists, midwifes, and physiotherapists or between such practitioners and third parties, particularly, manufacturers of medical products and suppliers of medical or prosthesis equipment, if said agreements relate to their profession and aim at providing any direct or indirect benefit or advantage for either party."

Agreements are thus only prohibited if they have an influence on the practitioner's profession and if they bring a direct or indirect benefit to the practitioner.

- The Royal Decree of April 7, 1995 on the Information on and the Advertising of Medicinal Products contains rules on advertising medicinal products that is aimed at the general public and healthcare professionals. This royal decree also includes rules on disease awareness campaign[1]. It further provides rules for the activities of medical representatives. This royal decree applies to medicinal products only.

- The Royal Decree of January 11, 1993, which regulates the distribution of samples for human use also deserves brief mention. According to Article 2 of this royal decree, medicinal samples can only be distributed on an exceptional basis to persons qualified to prescribe on specific written, dated and signed requests. Article 3 of this royal decree also stipulates that persons who are entitled to prescribe medicinal products may not receive, from all marketing authorization holders, more than 600 samples per civil year. It also stipulates that only eight samples of each medicinal product per year can be given by the marketing authorization holder per person qualified to prescribe.

[1] According to Article 2, §1, 3° of the Royal Decree of April 7, 1995 as amended by the Royal Decree of November 22, 2006, information campaign means "*the information campaign to the public on human disease or human health which refers directly or indirectly to a medicinal product or to a group of medicinal products broadcasted by one or more broadcasting means*."

Permitted and Prohibited Practices

Gifts, Seminars, Hospitality and Entertainment

The practice of offering gifts and inviting healthcare professionals to restaurants and scientific events such as seminars, congresses, roundtable discussions and workshops is a customary practice in the pharmaceutical sector. The limitations that apply to these practices are summarized below.

Gifts

From the legal provisions mentioned in "The Regulatory Framework" section, it can be concluded that as a general rule, it is prohibited to offer any benefits, advantages or premiums to healthcare professionals or to institutions where the prescription, delivery or administration of medical products takes place. This prohibition applies regardless of whether such offering is made pursuant to an agreement and whatever the nature or purpose of the gift may be (charity, continuous training, etc.).

Consequently, pharmaceutical and medical device companies are not allowed to give vouchers or cash, computers, TV or DVD players, wine, chocolates or flowers to healthcare professionals.[2]

The only exception to the abovementioned prohibition is the offering of gifts and advantages of negligible value which are relevant to the practice of medicine, dentistry, pharmacy or veterinary medicine. The Act does not provide a definition of what is meant by "*negligible value*," but such a definition may be provided later on by way of a royal decree. The notion of negligible value is discussed in the preparatory works of the Act of December 16, 2004, which has amended Article 10 of the Act. The preparatory works suggest taking the tax criteria into account. The preparatory works list examples of

[2] It is to be noted that the term healthcare professional is very broadly defined and includes not only physicians (working both in public and private hospital, under an employee status or a self-employed status) but also nurses, dentists, pharmacists, wholesalers, private and public hospitals, revalidation centers and rest homes.

authorized gifts, such as subscriptions to scientific reviews, scientific books, scientific CD-ROMs, stethoscopes and spatulas.

Seminars and Hospitality

Based on the legal provisions mentioned in "The Regulatory Framework" section, pharmaceutical and medical device companies may offer hospitality and participation costs at scientific events, provided that the five following conditions are met:

- The event has an exclusive scientific nature.
- The hospitality offered is strictly limited to the scientific scope of the event. This means that majority of the time must be dedicated to activities of a scientific nature.
- The place, date and duration of the event does not create confusion as to the scientific nature of the event.
- The hospitality and participation costs are limited to the duration of the event; this means that if the healthcare professional wishes to extend his/her stay, he/she will have to bear all the costs related thereto.
- The hospitality and participation costs cannot be extended to any person other than the healthcare professional involved. This means that if the spouse, partner or any person other than the invited healthcare professional wishes to accompany the healthcare professional, he/she will have to bear all the costs related to his/her stay.

Neither the Act, nor the Royal Decree of April 7, 1995 on the Information on and the Advertising of Medicinal Products has defined the term "*hospitality*." However, the term "*hospitality*" is discussed in the preparatory works of the Act of 16 December 2004, which has amended Article 10 of the Act. According to the preparatory works, hospitality includes notably welcome costs, meals and lodging.

Article 10, §3 of the Act puts in place a visa procedure for hospitality and participation costs offered at scientific events (i.e., congresses, symposia, technical meetings, seminars, training sessions, information sessions, advisory boards, investigators' meetings, etc.) taking place during several calendar days. Prior to any such event, pharmaceutical and medical device companies must obtain a visa (authorization) from Mdeon for the hospitality and participation costs it wishes to offer to healthcare professionals practicing in Belgium. If the visa is not granted, the participation costs in the event, including the hospitality, cannot be offered.

While agreements entered into with healthcare professionals do not have to be submitted to the approval of Mdeon, pharmaceutical and medical device companies entering into agreements which provide for reimbursement of transportation costs, lodging, meals, etc., with a healthcare professional practicing in Belgium, must file a visa request for the scientific event to which the healthcare professional will participate. Such requests shall contain information on the various costs to be reimbursed but not on the fees paid for the services performed.[3]

Entertainment

It may be derived from the legal provisions mentioned in "The Regulatory Framework" section that pharmaceutical and medical device companies are allowed to entertain healthcare professionals, provided that the entertainment is:

- reasonable in cost;
- secondary to the main purpose of a scientific meeting; and
- restricted to heath professionals (the spouse or partner of the healthcare professional may not be invited).

[3] For more information on the visa procedure, see https://www.mdeon.be/index.php?id=48&L=2 and for practical directives, see https://www.mdeon.be/fileadmin/templates/media/pdf/directives_en.pdf

Consequently, it would not be acceptable, for example, to offer free tickets to healthcare professionals to attend a sports event, a concert, or the like. However, it would, in principle, be acceptable to invite healthcare professionals to a scientific meeting followed by a dinner.

Promotional Activities

Promotional sales to healthcare professionals such as "*buy ten, get twelve*" are prohibited by Article 10 of the Act.

There is no specific provision governing the granting of price rebates or discounts to healthcare professionals. However, in practice and as a general rule, price rebates are allowed by case law and by the Belgian Federal Agency for Medicines and Health Products provided that the following conditions are met:

- Principle of non-discrimination: A rebate scheme that would be offered only to selected hospitals/clinics (as opposed to all hospitals/clinics) would constitute a prohibited advantage under Article 10 of the Act. In order to be acceptable under pharmaceutical law, the rebate scheme must be offered to all hospital/clinics. In addition, the rebate scheme must be the same for all hospital/clinics (no individually tailored rebate scheme) and apply objective standardized purchase targets that apply equally to all hospital/clinics.

- The price rebates may not provide a direct or indirect prohibited advantage under Article 10 of the Act to the beneficiary of the rebate. There is a prohibited indirect advantage when a hospital/clinic benefits from rebates and does not pass the rebates to the health reimbursement agency (*riziv/inami*) in case of refundable medical devices.

Samples

According to the Royal Decree of January 11, 1993, pharmaceutical companies may only distribute medicinal samples for human use to

persons qualified to prescribe medicinal products if said persons have specifically requested so in writing.

Furthermore, a physician is not allowed to request more than 600 samples from pharmaceutical companies per year and he/she may only directly distribute samples to patients when this is absolutely necessary due to urgent medical circumstances or social distress.

However, it should be noted that certain medicinal products – specifically those containing narcotics, anesthetics or hallucinogens, such as tranquilizers and soporifics – may not be distributed at all by way of sample.

Drug samples must also be supplied in the smallest packaging available. In addition, drug samples may of course not be sold. The indication "*free sample - may not be sold*" must be clearly printed on the outer packaging. In addition, the royal decree restricts the distribution of samples by stating that only eight samples of a given medicinal product a year can be given per product and per person qualified to prescribe.

This restriction does not apply to the distribution of samples which have been requested to test the efficiency of a given medicinal product in the framework of an application for retribution by the government.

The marketing authorization holder must establish a controlling system supervising the distribution of samples within its company. A list must be drawn up, indicating which samples (identification numbers) have been distributed to which prescribers (name and address). In addition, the marketing authorization holder has to keep the written requests for the receipts of samples for a period of 10 years and must communicate before 1 March of each year to the Federal Agency for Medicines and Health Products specific information relating to the medicinal product delivered as sample as well as the total number of samples per product it has given to persons qualified to prescribe medicinal products.

The royal decree furthermore indicates that each medicinal sample should be accompanied by a copy of the Summary of Product Characteristics, as provided by Article 6, §1*quinquies*, of the Act.

Consequences of Breach

As a preliminary remark, it should be noted that the Royal Decree of June 10, 2006, implementing Article 10, §5 of the Act, has created a contact point within the Federal Agency for Medicinal and Health Products, which aims to centralize all information regarding behaviors and acts that could potentially constitute an infringement to Article 10 of the Act. Anyone having information/knowledge on a potential infringement to Article 10 of the Act can communicate such information to the contact point, who will then investigate if deemed necessary.

Criminal Sanctions

Article 16 of the Act and Article 38, §1, 5° of the Royal Decree of November 10, 1967 on the Performance of Medical Profession contain criminal sanctions that may apply in case of a breach of certain legal provisions in connection with the promotion of medical products to healthcare professionals.

The following criminal sanctions apply in the case of a violation of the rules applicable to gifts, seminars, hospitality, entertainment and promotional activities:

- To any person violating Article 10 of the Act (including, amongst others, health professionals and officers of pharmaceutical and medical device companies) – imprisonment from one month to one year and/or a fine from EUR1,200 up to EUR90,000
- To pharmaceutical and medical device companies (in their capacity as legal entities) violating Article 10 of the Act – a fine ranging from EUR3,000 up to EUR180,000

- To healthcare professionals infringing Article 18, §2 of the Royal Decree of November 10, 1967 – a fine in the amount of EUR156 to EUR3,000

The following criminal sanctions apply in the case of a violation of the rules applicable to samples:

- To any person violating the provisions of the Royal Decree of January 11, 1993 (including, among others, health professionals and officers of pharmaceutical and medical device companies) – imprisonment from eight days to one month and/or a fine ranging from EUR600 up to EUR6,000
- To pharmaceutical and medical device companies (in their capacity as legal entities) violating the provisions of the Royal Decree of January 11, 1993 – a fine ranging from EUR600 up to EUR12,000

General Commercial Liability

Pharmaceutical and medical device companies that violate legal provisions in connection with the promotion of medical products to healthcare professionals can also be sued by competitors to cease and desist unfair trade practices.

Such a lawsuit is to be filed with the president of the Court of First Instance. In addition to an injunction to cease the so challenged unfair trade practice (possibly with an amount to be paid per breach to this injunction), the president of the Court of First Instance may order that the judgment be publicized.

Professional Codes of Conduct

In Belgium, the promotion of medicinal products is also governed by a code of conduct for pharmaceutical companies. The provisions of the code of conduct are self-regulatory rules adopted by "pharma.be", the Belgian association of the pharmaceutical industry. Over 90 percent of

Belgian pharmaceutical companies are members of pharma.be and must therefore comply with the code of conduct.

The pharma.be code of conduct contains general rules with respect to the promotion of medicinal products. The most important are the following:

- Any communication that presents the properties of a medicinal product may only encourage a rational use of the product and must be based on observations that are correct, true, objective, sufficient, fair and verifiable; are in accordance with the most recent content of the approved dossier concerning marketing authorization; reflect generally accepted scientific knowledge; and where appropriate, are backed up by bibliographical references, which are to be mentioned in the communication. Any communications (except for "reminder" advertising) shall mention the composition of the product, therapeutic indications, contra-indications and precautionary measures, adverse reactions, dosage and method of administration, available packaging, and the name and address of the company responsible for marketing the product. Promotional material for medicinal products must always be identifiable as such. Whenever published studies are mentioned, clear references shall be given. Where quotations and visual materials are used, the source must always be mentioned.

- Comparisons with competing medicinal 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. They shall be based on the most recently available data.

- The terms "safe" and "without danger" or any other term expressing a similar concept cannot be used unless clearly defined. It cannot be said that a medicinal product presents neither adverse reactions nor risk of dependency.

- All communications with respect to medicinal products must be internally examined and approved by professionally and scientifically qualified persons.
- Information or promotion relating to medicinal products may only be aimed at persons who can reasonably be assumed to need them or to be interested in them. The frequency of the promotion will depend on real needs and may not in any way inconvenience the recipient.
- Information or promotion from abroad is treated in the same way as that which originates in Belgium and must comply with the same regulations.

With respect to a number of practices regarded as promotional activities, the pharma.be code of conduct contains notably the following specific rules:

Samples – Article 29 stipulates that drug samples can only be given to persons qualified to prescribe medicinal products if they have submitted a written, signed and dated request to the company. It furthermore states that companies must have an appropriate system for controlling the distribution of samples. The words "*free sample- may not be offered for sale*" or any other words of similar meaning must appear on the outer packaging of the sample. It is to be noted that the pharma.be code of conduct does not implement the "4x2 standard" of Article 16 of the EFPIA HCP Code, this provision being more restrictive than that of the Belgian Royal Decree of January 11, 1993 (see section on "Samples").

Collective scientific meetings – Articles 30 to 37 regulate the organization of scientific events, such as scientific seminars, congresses, symposia and visits to pharmaceutical companies.

Pharmaceutical companies are authorized to organize or support such events, provided that: the event is of an exclusively scientific and professional nature; the hospitality offered at the event is restricted to

healthcare professionals; the hospitality is limited to the duration of the event and secondary to the principal scientific purpose of the meeting; and the costs for travel, accommodation and registration remain at a reasonable level. The value of meals may under no circumstances exceed the limits laid down in the pharma.be guidelines.[4]

The hospitality offered will not under any circumstances include payment for the organization of sporting or leisure activities or indeed any other form of entertainment. Spouses or partners may join the event, provided that they make an explicit request and bear all the costs of joining the event.

Sponsoring and donations – Article 38 allows pharmaceutical companies to make any financial or other operational resources available to third parties, provided that this is laid down in writing and that they take all useful measures to be informed of the destination and use of the means available. "Financial means or other operating means" are understood to be subsidies, grants, allowances, scientific prizes, sponsoring and provision of services for humanitarian purposes.

Premium and benefits – Article 40 mirrors Article 10 of the Act of March 25, 1964 on Medicinal Products with respect to over-the-counter medicines. However, the pharma.be code provides for a much more restrictive approach towards prescription-only medicines as it prohibits any gifts to HCPs in that respect (including pens, notepads,

[4] 4 For events that take place over several successive days, including the related hospitality, which according to Article 72 of the code are subject to a visa procedure:

- The value of a lunch (drinks included) may not exceed EUR40.
- The value of a dinner (drinks included) may not exceed EUR80.
- For events that run for one day only and that are not subject to a visa procedure:
- The value of the meals may not exceed EUR40 per lunch and EUR80 per dinner, all included (drinks, tax, room hire, etc.), at the market price.
- The maximum hospitality of EUR40 (lunch) + EUR80 (dinner) can only be offered if the program includes at least six hours of scientific activities (http://www.pharma.be/assets/files/4286/4286_130577714666758889.pdf).

post-it notes, etc.). This "ban on gifts" for prescription-only medicines will, however, not apply to:

(i) informative or educational materials, provided that these materials are:

- of limited value[5];
- directly relevant to the practice of medicine or pharmacy; and
- directly beneficial to the care of patients

(e.g., brochures and USB sticks for information or educational purposes will be allowed);

(ii) items of medical utility, provided that these items are:

- intended directly for the training of HCP and the care of patients;
- of limited value; and
- not part of the basic material or basic equipment that every HCP needs for his or her routine practice.

The prohibition of Article 40 does not, however, apply to remuneration for legitimate services of a scientific nature, provided that this remuneration remains within reasonable limits.

Non-interventional studies – The code also establishes specific rules for non- interventional studies carried out by pharmaceutical companies (Articles 43 and 44 of the code), with the assistance of

[5] The pharma.be guidelines set forth cumulative conditions for gifts to qualify as gifts of "limited value": (i) no influence on any therapeutic choice; (ii) value of not more than EUR50 (market value, VAT included); and (iii) cumulative value of not more than EUR125 per year, per HCP and per pharmaceutical company (VAT included).

healthcare professionals. For these kind of studies, specific requirements listed under Article 44 must be complied with.

Transparency obligations – Articles 44*bis* to 44*quinquies* provide that pharmaceutical companies are required from the year 2015 to document and disclose transfers of value made, directly or indirectly, to an HCP/HCO in connection with the development and sale of prescription-only medical products for human use. The first disclosure will take place in June 2016 regarding the transfers of value in 2015. Such transfers will be disclosed via the central platform website managed by pharma.be (www.betransparent.be.) on an individual basis. Aggregate disclosure will nevertheless be applicable where transfers of value (i) cannot be disclosed on an individual basis for legal reasons, or (ii) relate to research and development. Information on transfers shall in principle remain accessible to the public for at least three years after the date when such information is first disclosed. It is noted that pharmaceutical companies must retain the relevant proof that they have respected their disclosure obligations correctly and in full for a minimum of five years after the end of the relevant reporting period.

Although such disclosure obligations do not apply to transfers of value solely related to over-the-counter medicines, pharmaceutical companies are strongly encouraged to comply with these obligations with regard to any of their products.

Violations of the abovementioned rules are subject to the following sanctions:

- Reprimand
- Injunction to take corrective measures
- Supervisory measures
- Financial indemnification measures

- Publication of the decision of pharma.be in a review having a scientific or economic importance in the pharmaceutical industry
- Exclusion from pharma.be

In addition, it must be noted that pharma.be may inform the Belgian Federal Agency for Medicines and Health Products of substantial infringements. The Federal Agency for Medicines and Health Products has the power to take further measures including filing a criminal complaint with the public prosecutor.

The pharma.be code of conduct supplements the EFPIA Code on the Promotion of Prescription-only Medicines to, and interaction with, Healthcare Professionals; the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations; the IFPMA Code of Pharmaceutical Marketing Practices; and the Code of Ethics of the non-profit association Mdeon. In case of inconsistency, the most constraining provision will prevail.

Professional Code of Conduct for Medical Devices

In Belgium, the promotion of medical devices is also governed by a code of conduct for medical device companies. The provisions of the code of conduct are self-regulatory rules adopted by the *Association des fabricants, importateurs et distributeurs des dispositifs médicaux ASBL/Beroepsvereniging van fabrikanten, invoerders en verdelers van medische hulpmiddelen VZW* (UNAMEC).

The UNAMEC Code of Conduct contains, *mutatis mutandis*, the same general rules with respect to the promotion of medical devices as the pharma.be code of conduct. Those rules are set forth in the section on "Professional Codes of Conduct."

With respect to a number of practices regarded as promotional activities, the UNAMEC code of conduct also contains specific rules. Those rules are generally similar to the rules set forth in the pharma.be

code of conduct. However, some minor differences exist, notably the following:

Samples – Article 21 of the code states that samples can only be given to persons that have submitted a written request to the company, and provided that the samples are given to obtain an opinion on the quality of the product as well as being supplied in limited quantity.

Loan or putting at disposal of equipment – Article 22 of the code provides that equipment for medical, scientific or technical use can only be lent or put at the disposal of medical or paramedical institutions in limited quantity and to the benefit of patients, the medical community and medical or paramedical institutions. Such loan or putting at disposal must be compliant with Article 10 of the Act of March 25, 1964 on Medicinal Products.

Collective scientific meetings – Articles 23 to 32 of the code define the rules for individual and collective scientific meetings. Except for some details, these rules are similar to the rules provided in the pharma.be code of conduct.

Transparency obligations – Articles 40 to 43 of the code contain similar disclosure obligations as those found under the pharma.be code with respect to transfers of value made in connection with the development and sale of medical devices. Such rules are expected to enter into force in 2016 and the first disclosure is expected to take place in June 2017 (regarding transfers of value of 2016). As for pharmaceutical products, such disclosures will also take place via the central platform website managed by pharma.be (www.betransparent.be).

Violations of the abovementioned rules subject the guilty party to the following sanctions: reprimand; corrective measures; injunction to cease some practices; publication; or, if the case arises, exclusion from the UNAMEC. In addition, it must be noted that UNAMEC may decide to inform the Belgian Federal Agency for Medicines and Health Products, who have the power to take further measures

including filing a criminal complaint with the public prosecutor for substantial infringements.

Professional Code of Conduct for Physicians

The Code of Conduct for Physicians contains self-regulatory rules adopted by the *Ordre des Medécins/Orde van geneesheren* (i.e., Physicians Association). Each physician must comply with the code of conduct and is subject to disciplinary sanctions (warning, censure, reprimand, maximum of two years of suspension, disbarment) in case of noncompliance.

The code of conduct does not contain any specific rules which regulate the promotion of medicinal products or medical devices and the relationship between physicians and the healthcare industry.

However, as a general rule, Article 9 stipulates that "*physicians must refrain from acting in a way that would jeopardise the honour and the dignity of his/her profession.*"

According to Article 173, any agreement between a physician (private/public employee and self-employed) or a physician organization and a non-physician that could have an impact on the deontological aspects of the physician's profession must be submitted in writing to the relevant provincial authority (i.e., *Ordre des médecins/Orde van geneesheren*)[6] prior to its signing.

Article 174 further prohibits any agreement between a physician and a third party that may restrict the "*diagnostic or therapeutic freedom of the physician*." As a result, any agreement that provides for a pecuniary advantage for the physician (in case he/she would decide on the use of medical devices/pharmaceutical products of a specific brand) could be considered as a restriction of the physician's freedom to determine, in the exclusive interest of his/her patients, whether or not certain medical devices/medicinal products must be used.

[6] With the exception of medical experiment protocols, provided that the latter are submitted to an ethics committee for approval.

Mdeon's Code of Ethics

Mdeon became operational on 15 November 2006. Mdeon is the common deontological platform created on 23 May 2006, by the associations of physicians and pharmacists together with the pharmaceutical and medical device industries.

Mdeon's mission is to proactively determine the principles of a modern, transparent and effective self-regulatory instrument for the information on and promotion of drugs and medical devices, as well as to ensure compliance.

In this respect, Mdeon has adopted a code of conduct that relates to premiums and benefits, collective scientific meetings and services of a scientific nature. The Mdeon Code of Conduct also provides for visas and consultation procedures:

- Visas procedure – Mdeon has been appointed to handle visa applications as provided in Article 10, §3 of the Act of March 25, 1964 on Medicinal Products. This legal provision puts in place a visa procedure for hospitality and participation costs offered at scientific events taking place during several calendar days. Prior to an event, pharmaceutical and medical device companies must obtain a visa from Mdeon for the hospitality and participation costs it wishes to offer to healthcare professionals practicing in Belgium. The procedure has been laid down in Mdeon's Code of Ethics.
- Consultation procedure – The healthcare industry and healthcare professionals can seek Mdeon's advice on questions regarding premiums and benefits, collective scientific meetings and services of a scientific nature.

Liability Under Criminal Law

The Regulatory Framework

Anti-bribery rules apply potentially to everyone. The Belgian Criminal Code makes a distinction between public bribery (Articles 246 to 252 of the Belgian Criminal Code) and private bribery (Articles 504*bis* and 504*ter* of the Belgian Criminal Code). While the provisions on public bribery (see below) apply to individuals/legal entities exercising a public function,[7] the provisions on private bribery (see below) apply to private individuals and legal entities of the private sector.

Public Bribery

According to Article 246 of the Belgian Criminal Code, any person holding a public office who accepts an offer, a gift or a promise in compensation of any act or decision made in the framework of his/her function (even if the act or decision is, as such, legal and/or justified), commits public bribery.

According to the same article, any offer, gift or benefit granted or promised to a person holding a public office with a view to encouraging the latter to adopt a particular attitude within the scope of his/her responsibilities, may be qualified as public bribery.

Furthermore, Article 247, §4 of the Belgian Criminal Code prohibits influence peddling. Influence peddling may be defined as a tripartite process whereby one person exercises his/her influence on another person in order to obtain a favor for a third person.

For the purpose of applying public bribery regulations, a distinction must be made between healthcare professionals working in municipal

[7] The following legal entities are, however, not criminally liable under Belgian law: the federal state, the regions, the communities, the provinces, Brussels and its suburbs, the municipalities (multi-district zones), intra-local territorial organs, the French Community Commission, the Flemish Community Commission, the Joint Community Commission and the public centers for social welfare.

hospitals ("CPAS-OCMW") or in hospitals run by state-owned universities, and healthcare professionals working in private university hospitals subsidized by the government on the one hand, and healthcare professionals working for private hospitals on the other.

The regulations on public bribery only apply to the first category of healthcare professionals as they are considered to hold a public office.

Private Bribery

According to Article 504*bis* and 504*ter* of the Belgian Criminal Code, any person who:

- in his/her capacity as director or manager of a legal entity, proxy holder or employee of a legal entity, or proxy holder or employee of a natural person;
- requests or accepts an offer, promise or benefit, on his/her own or on behalf of a third party, in exchange for adopting a particular attitude within the scope of his/her responsibilities; and
- without the authorization and knowledge of the board of directors, the general meeting of shareholders, the principal, or the employer, whichever case applies.

Commits Private Bribery

The same is possibly committed by any person offering a bribe to a private person, provided that the former is acting without authorization or knowledge of his/her superior(s).

Contrary to the regulations on public bribery, regulations on private bribery do apply to healthcare professionals working for private hospitals.

Permitted and Prohibited Activities

Gifts

Based on the legal provisions on public and private bribery mentioned above, any offer, gift or benefit granted or promised by a pharmaceutical company to a healthcare professional, with a view to encouraging him/her to cause the hospital to purchase certain medical products is prohibited.

It must be noted that public and private bribery provisions will apply even if the gift, offer or benefit is given to a third party (such as patient, medical association, family member).

However, customary gifts remain acceptable under the bribery regulations, provided that they are of a negligible value and relevant to the practice of medicine, dentistry, pharmacy or veterinary medicine. Neither in the law nor in the case law is there any indication as to what the value limit could be in order for a customary gift to be considered inexpensive. Due to the criminal nature of the offense, it can be assumed that the gift should in any case be of a very small value (e.g., diaries, calendars, pencils, post-its, writing paper).

Seminars and Hospitality

Based on the provisions on public bribery, healthcare professionals holding a public office (see "Public Bribery" above) may be invited to scientific seminars or conferences and may be offered the same seminar materials, writing materials, ordinary meals or refreshments as provided to all attendees. However, healthcare professionals holding a public office may not be offered travel and living expenses incurred for attending a seminar or conference, unless they are invited to speak at such seminar or conference. If permitted at all, travel and living expenses are subject to the prior approval of the public official's supervisor. The expenses must not be for any extended stay, side trips, etc. They must also be reasonable in level, restricted to healthcare professionals and directly related to the seminar or conference.

Based on the provisions on private bribery, healthcare professionals working for private hospitals (see section on "Private Bribery") may be invited to scientific seminars or conferences and may be provided with the same seminar materials, writing materials, ordinary meals or refreshments as provided to all attendees. Contrary to healthcare professionals holding a public office, healthcare professionals working for private hospitals may be reimbursed for travel expenses related to seminars or conferences. However, the travel and living expenses must still remain reasonable in level, restricted to healthcare professionals and related to the seminar or conference.

With respect to scientific events taking place during several calendar days, reference is made to the information in the sections on "Seminars and Hospitality" and "Professional Codes of Conduct."

Entertainment

Based on the legal provisions on public and private bribery, pharmaceutical and medical device companies are allowed to invite healthcare professionals for entertainment if reasonably priced (e.g., business breakfast or business dinner following a scientific meeting).

However, it would not be considered appropriate to invite healthcare professionals to locations such as a cabaret or night club. Entertainment must be customary, business-orientated and infrequent.

Public Procurement and Fraud

Pharmaceutical and medical device companies that are involved in public procurement procedures and commit public bribery may be excluded from participating in any present or future public procurement.

Furthermore, healthcare professionals involved in public procurement fraud may be dismissed from their function and barred from any public function for a period of five to 10 years and/or any other function listed in Article 31 of the Criminal Code.

Article 314 of the Belgian Criminal Code should also be briefly mentioned. This provision sanctions the individuals who, in adjudicating procedure, perturb the freedom of auctions and/or submissions by way of violence, force, gifts, promises or any other fraudulent means, by imprisonment of 15 days to six months and a fine from EUR600 up to EUR18,000.

Pharmaceutical and medical device companies (in their capacity of legal entities) who, in adjudicating procedure, perturb the freedom of auctions and/or submissions by way of violence, force, gifts, promises or any other fraudulent means, are punishable with a fine from EUR3,000 to EUR72,000.

Sanctions

Public Bribery

Public bribery committed by an individual is punishable with imprisonment from six months to 15 years and/or fines up to EUR600,000.

Public bribery committed by pharmaceutical and medical device companies (in their capacity as legal entities) is punishable with a fine from EUR 18,000 up to EUR2,160,000.

Private Bribery

Private bribery committed by an individual is punishable with imprisonment from six months to three years and/or fines up to EUR300,000.

Private bribery committed by pharmaceutical and medical device companies (in their capacity of legal entities) is punishable with a fine from EUR18,000 up to EUR600,000.

Contracts with Healthcare Professionals and Medical Institutions

The Regulatory Framework

Article 18, §2 of the Royal Decree of November 10, 1967 on the Performance of Medical Profession explicitly prohibits agreements between practitioners (i.e., physicians, dentists, pharmacists, midwives and physiotherapists) or between such practitioners and third parties, particularly, manufacturers of medical products and suppliers of medical or prosthetic equipment, if said agreements relate to their profession and aim at providing any direct or indirect benefit or advantage for either party.

Although the royal decree does not give any indication as to what exactly is meant by "*relate to their profession*," one may reasonably assume that any influence on the prescription behavior of a physician is intended to be encompassed.

A physician who violates the above rule risks being fined an amount ranging between EUR156 and EUR3,000. Moreover, the contracting party (e.g., the pharmaceutical company) can be deemed an accomplice to said offense.

Any excessive compensation paid to a healthcare professional or medical institution for research or consultancy work shall also be caught by the prohibition of Article 10 of the Act of March 25, 1964 on Medicinal Products.

According to Article 173 Code of the Conduct for Physicians, any agreement between a physician and a non-physician which could have an impact on the ethical aspects of the physician's profession must, prior to its signing, be submitted in writing to the relevant provincial

authority of the Physicians' Association (i.e., *Ordre des médecins/Orde van geneesheren*).[8]

Article 174 further prohibits any agreement between a physician and a third party which may restrict the "*diagnostic or therapeutic freedom of the physician.*"

Any agreement that provides for a pecuniary advantage for the physician in case he/she would prescribe the use of medical products from a specific brand, or decide on the use of medical devices of a specific brand, could be considered as a restriction of the physician's freedom to determine, in the exclusive interest of his/her patient, whether or not certain medical products/medical devices must be prescribed or used.

The provisions of the Act of May 7, 2004, concerning experiments on the human person, shall apply in case the contract with a healthcare professional or medical institution relates to an experiment or a clinical trial as defined in this Act.

Permitted and Prohibited Agreements

Although the wording of Article 18, §2 of the Royal Decree of November 10, 1967 on the Performance of Medical Profession can be viewed as ambiguous, it cannot be interpreted as prohibiting all kind of agreements.

In this respect, a pharmaceutical company is allowed under Belgian law to enter into speaker agreements, consultancy agreements, research agreements proctorship agreements and/or clinical trial agreements with physicians, provided that the following principles are taken into consideration:

[8] This is an obligation of the physician, not of the pharmaceutical/medical device company. There is no sanction for the pharmaceutical/medical device company in the event the physician does not submit his/her agreement to the Physicians' Association. In practice, most of the Belgian physicians have a tendency to "conveniently" not submit such agreements, the approval procedure being extremely slow.

- The physician must remain free to determine his/her prescription behavior and in his/her use of medical devices. The compensation paid to the physician would be deemed illegal if, and to the extent that, it induces the physician to prescribe or use certain products, as it could possibly be linked to a purchase undertaking. Consequently, agreements should be drafted with due care, emphasizing the freedom of the physician as much as possible.

- The compensation paid to the physician for his/her research work, the services rendered and/or the clinical trial conducted must be reasonable and represent the fair market value.

- Before entering into any agreement with a physician, it is very important to take into account the possible employment contract the latter could have entered into with a hospital and to obtain sufficient confirmation that no provision in such employment contract prohibits or restricts such agreement.

There exists a case in which an agreement between a physician and a third party was voided on the basis of Article 18, §2 of the Royal Decree of November 10, 1967 on the Performance of Medical Profession. The Belgian Supreme Court held that an agreement between a pathology laboratory and a physician, pursuant to which the latter was entitled to a commission on every blood test that was carried out by the laboratory upon the physician's prescription, violates Article 18, §2 of the royal decree.

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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