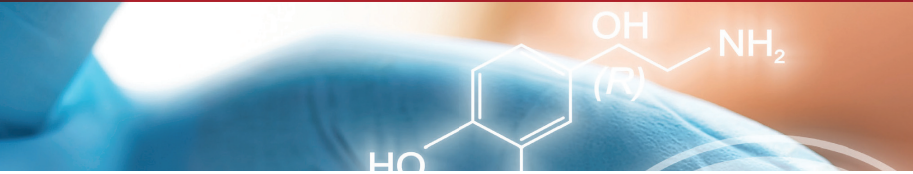


Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



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Hungary

Helga Bíró

Introduction

Hungary became a member of the European Union (EU) on 1 May 2004, and the laws and regulations applicable to pharmaceutical advertising are generally in line with the relevant EU directives. However, in some cases, Hungarian legislation contains regulations that are more detailed or stringent than those of EU directives governing the promotional activities of pharmaceutical manufacturers and distributors. The underlying goal of this legislation appears to be to attain a high level of consumer protection.

The periodic amendments of the legislation also aim to restrict promotions directed towards healthcare professionals in order to reduce the expenditures of the health insurance budget.

The Regulatory Framework

The following laws contain the basic rules regarding pharmaceutical advertising:

- Act XCVIII of 2006 on the Safe and Economic Supply and Distribution of Medicines and Therapeutic Medical Devices (the “Gyftv.”)
- Act XLVII of 2008 on the Prohibition of Unfair Commercial Practices to Consumers (the “Fttv.”)
- Act XLVIII of 2008 on Basic Conditions and Limits of Economic Advertising Activities (the “Advertising Act”)
- Act XCV of 2005 on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products (the “Medicines Act”)

- Decree 3/2009. (II. 25.) of the Minister of Health on the Detailed Rules of the Promotion of Medicinal Products and Therapeutic Medical Devices, the Registration of Medical Sales Representatives and Commercial Practices Targeted to Consumers (the “Promotion Decree”)

If the promotional commercial practice is likely to have negative effects on economic competition, the relevant provisions of Act LVII of 1996 on the Prohibition of Unfair and Restrictive Market Practices (the “Competition Act”) are also applicable.

Furthermore, the ethical rules to be considered by both healthcare professionals and companies advertising or promoting pharmaceuticals within Hungary are contained in the Code of Ethics for Pharmaceutical Communication (the “Industry Code”) signed by the Hungarian Pharmaceutical Manufacturers Association, the Association of Innovative Pharmaceutical Manufacturers, the Association “Immunity” of Vaccine and Immunobiological Product Manufacturers and Distributors, and the Association of Hungarian Generic Product Manufacturers and Distributors; the Transparency Code on the Transfers of Value from Association of Innovative Pharmaceutical Manufacturers Companies to Healthcare Professionals and Healthcare Organizations (“Transparency Code”); the Hungarian Code of Ethics for Advertising issued by the Hungarian Association for Advertising (the “HAA Code”); the Code of Ethics issued by the Hungarian Chamber of Medical Practitioners (the “HCMP Code”); and the Code of Ethics of the Hungarian Chamber of Pharmacists (the “HCP Code”).

Categories and Basic Principles of the Legislation

Hungarian legislation distinguishes between medicinal products, medical devices, therapeutic medical devices, quasi-medicinal products and herbal medicinal products.

Medicinal product: According to the Medicines Act, a medicinal product is any substance or combination of substances offered for treating or preventing disease in human beings, or any substance or



combination of substances that may be used in or administered to human beings for restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or for making a medical diagnosis.

Medical device: According to Decree 4/2009. (III.17.) of the Minister of Health on Medical Devices, a medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, as well as custom-made devices and devices intended for clinical investigation that are intended by the manufacturer to be used for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process; or
- 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 advertising of medical devices not qualifying as therapeutic medical devices is not subject to special regulatory restrictions.

Therapeutic medical device: A therapeutic medical device is a medical device for the personal use of patients suffering from temporary or permanent health detriment or deficiency (including *in vitro* diagnostic devices intended for self-use), or care technical devices not qualifying as medical devices during the use of which there is no need for permanent supervision of a healthcare professional. The Gyftv.

contains detailed rules on the advertising of therapeutic medical devices, whether supplied with or without a reimbursement. Furthermore, the Gyftv. extends the scope of the promotional rules regarding gift-giving, promotional hospitality and sponsorship to the persons entitled to prescribe or supply therapeutic medical devices.

Quasi-medicinal products: According to Decree 10/1987. (VIII.19.) of the Minister of Health, a quasi-medicinal product is a product containing substances of a natural origin that have favorable biological effects and are not detrimental to health if the product is used consistent with its user instructions. Quasi-medicinal products may be used without a prescription but must be registered with the National Institute of Pharmacy and Nutrition (the “OGYÉI”) prior to being marketed in Hungary. The same rules apply to the advertising of quasi-medicinal products as to the advertising of medicines that may be used without a prescription. Quasi-medicinal products will be gradually withdrawn from commerce. A new application for the registration of a quasi-medicinal product is no longer allowed to be submitted to the OGYÉI since 30 October 2005. Furthermore, manufacturers and distributors of quasi-medicinal products were required to apply for the re-qualification of their products containing a herbal ingredient (for example, as a medicinal product, cosmetic product or a food supplement) by 31 March 2011. Decree 53/2005. (XI.18.) of the Minister of Health sets out the conditions for the re-qualification of quasi-medicinal products. Quasi-medicinal products that are on the market by 31 March 2011 and that could be categorized as traditional herbal medicine based on their characteristics were allowed to be distributed until their expiry date, but only until 1 April 2013.

The concept of herbal medicinal products is defined in Decree 52/2005. (XI. 18.) of the Minister of Health on the Marketing of Medicinal Products. According to this decree, herbal medicinal products are herbal ingredients or a combination thereof that: are intended and designed for use without the supervision of a medical practitioner and exclusively for administration in accordance with a specified strength and dosage; are an oral, external and/or inhalation



preparation; and have been in medicinal use for a period of at least 30 years preceding the date of the application, including at least 15 years within the EEA. Herbal medicinal products are subject to a special, simplified registration procedure with the OGYÉI. As the use of these products does not require medical supervision, they can be advertised according to the rules applicable to OTC medicinal products. The following warning must be indicated in the advertisement of traditional herbal medicinal products: “Traditional herbal medicinal product. Regarding the therapeutic indications, its application is solely based on long-standing use.”

Furthermore, in line with the relevant EU legislation, Hungarian law makes a distinction between infant milk and follow-on milk, as well as dietary foods for special medical purposes (Decree 24/2003. (V. 9.) of the Minister of Health and Decree 20/2008. (V. 14.) of the Minister of Health contain these rules). According to these rules, the advertisement of infant formulae, in particular, may only contain information of a scientific and factual nature. Such information may not imply or create a belief that bottle feeding is equivalent or superior to breast-feeding. The advertising rules applicable to food products and food supplements apply to dietary foods for special medical purposes.

The Advertising Act, the Medicines Act, the Promotion Decree and the Gyftv. contain restrictions regarding every aspect of the advertising and promotion of medicinal products and therapeutic medical devices.

The Definition of Medicinal Product and Therapeutic Medical Device Advertising

The Gyftv. and the Promotion Decree contain the sector-specific regulation of commercial practices related to medicinal products and therapeutic medical devices.

Based on the Gyftv., the definition of commercial practice is very broad and includes any information, activity, commercial communication, including advertising, that aims at fostering the

prescription, procurement, sale or consumption of a medicinal product or a therapeutic medical device.

The Advertising Act defines the term “advertisement” broadly to include any information, communication or manner of presentation intended:

- to foster the sale or use in any way of products, services, real estate, rights of pecuniary value; and
- in connection with the abovementioned purpose, to facilitate the popularization of the name, designation or activity of an undertaking or the identification of goods.

Given this broad definition, almost every communication from an undertaking might qualify as an advertisement if it contains the name of the medicinal product/therapeutic medical device or a reference identifying the product (for example, a parallel indication of the international common name or the active substance together with the name of the manufacturing company or other reference).

Consistent with the provisions of the European legislation, the Gyftv. unambiguously lists the cases that do not qualify as advertisement of medicinal products, being: the product label and the patient information leaflet of medicines; the instructions for use of therapeutic medical devices; and factual, informational materials on the modification of the packaging, or on adverse effects or the commercial price list, provided that they do not contain statements regarding the effects of the medicinal product or the application of the therapeutic medical device.

Advertisements of Prescription-Only Medicines and Therapeutic Medical Devices and of Medicines and Therapeutic Medical Devices that may be Purchased and Applied without a Prescription

In line with the relevant EU directive, Hungarian pharmaceutical advertising rules also distinguish between prescription medicines and medicines that may be bought and applied without a formal



prescription or over-the-counter (OTC) medicines. The Gyftv. extended the scope of the provisions regarding the advertisements of OTC medicines to include therapeutic medical devices that may be bought and applied without a formal prescription. Furthermore, the Gyftv. extended the rules regarding the promotion of prescription-only, reimbursed medicines to reimbursed therapeutic medical devices.

The promotion of prescription-only or reimbursed medicines and reimbursed therapeutic medical devices is permitted solely to the specified group of healthcare professionals entitled to prescribe or supply medicinal products and therapeutic medical devices. It is prohibited to advertise the product to the general public. This prohibition does not apply to information conveyed in connection with campaigns for the promotion of vaccination programs that are authorized by the government body in charge of the healthcare system, and to information on the medicinal products connected to these campaigns.

According to the Gyftv., the persons authorized to prescribe and distribute medicinal products and therapeutic medical devices are medical doctors, pharmacists, and manufacturers and distributors of medical products or therapeutic medical devices.

Although permitted, several restrictions apply to the advertising of OTC products and non-reimbursed therapeutic medical devices. For example, certain specific items of information – the name of the medicinal product or therapeutic medical device; the information required for its correct use; and an express, legible invitation to read the package leaflet – must be indicated in the advertisement. Furthermore, the advertisement must contain the following warnings:

- In the case of medicinal products – “For information on risks and adverse effects, please read the patient leaflet or consult with your doctor or pharmacist.”

- In the case of therapeutic medical devices – “For information on risks, please read the instructions for use or consult with your doctor.”

Furthermore, advertisements concerning the following are prohibited:

- Medicinal products or therapeutic medical devices that are not permitted to be distributed or applied in Hungary
- Medicinal products that contain certain psychotropic or narcotic substances
- Investigational medicinal products
- Directed towards children
- An OTC medicine if there is a prescription-only medicinal product in circulation under the same name
- An OTC medicine if the product receives reimbursement upon ordering by prescription
- A therapeutic medical device if a reimbursed therapeutic medical device is in circulation under the same name

In addition to the above, the general rules on advertising must also be considered in the advertisement of medicinal products or therapeutic medical devices to consumers/patients (Fttv., Advertising Act). These rules prohibit unfair commercial practices (especially misleading or aggressive commercial practices) and provide for strict requirements applicable to comparative advertisements.

The Gyftv. allows the distribution of certain OTC medicinal products outside of pharmacies. The rules on the promotion of OTC medicines must also be applied in the case of the non-pharmacy sale of medicines.



Permitted and Prohibited Practices

Gifts, Seminars, Hospitality and Entertainment

Section 14 (1) of the Gyftv. prohibits a company or person engaged in the advertising of medicinal products from giving, offering or promising gifts, pecuniary advantages or benefits in kind to persons qualified to prescribe or supply medicinal products, unless the gifts are inexpensive and relevant to the practice of medicine.

According to the Gyftv., a gift qualifies as inexpensive if its value does not exceed 5 percent of the current statutory minimum income (in 2016, HUF111,000, 5 percent of which is HUF5,550 or approximately EUR17). Inexpensive gifts (such as notepad paper, pens and books) may be given to those who are authorized to prescribe or distribute medicinal products and therapeutic medical devices. The logo of the company may be indicated on the gift. However, any item bearing the company logo is deemed by the Advertising Act to be given for the purpose of advertising. The aggregate annual value (inclusive of VAT) of the provided gifts may not exceed 60 percent of the statutory monthly minimum income (in 2016, HUF66,600 per year).

The advertiser may in no case give, offer or promise a monetary benefit. Hungarian legislation sets out rules stricter than comparable EU directives concerning sponsorship of promotional and professional meetings.

According to the Gyftv., events enhancing the promotion of medicinal products or therapeutic medical devices may only be organized for professional, scientific or educational purposes. The hospitality provided at such events may not exceed the threshold limit regarding inexpensive gifts as detailed above (in 2016, HUF5,550 or approximately EUR17 per day), and such hospitality must be subordinate to the main purpose of the event. Only professionals active in the healthcare system or in the supply of medicinal products or therapeutic medical devices may be invited to these events.

Sponsorship offered, directly or indirectly, at events for purely professional and scientific purposes must always be reasonable in degree and remain subordinate to the main scientific objective of the meeting.

According to the Gyftv., the amount of “reasonable sponsorship” of scientific conferences for one participant shall be 5 percent of the monthly amount of the statutory minimum income (in 2016 HUF5,550 or approximately EUR17 per day).

The promotional purpose must always remain subordinate to the scientific purpose of the conference. According to the Gyftv., promotional activities are only allowed at scientific events if the direct or indirect promotion (e.g., the presentation of the application of a particular product, the hiring of exhibition stands and the purchasing of advertising space in the conference materials) is clearly separate in the conference program.

According to the Gyftv., in-kind sponsorship may be granted to persons who are engaged in medical or scientific activities in order to make it possible for them to attend professional conferences and courses. The in-kind sponsorship may only cover the costs directly associated with the conference (e.g., travel and accommodation expenses, as well as registration fees).

The group of persons who may be invited to promotional and scientific events is rather broad as it includes all healthcare professionals engaged in healthcare activities and in the distribution and supply of medical products or therapeutic medical devices (such as doctors, pharmacists, nurses, laboratory assistants and distributors of medical products).

Only in-kind sponsorship may be granted to healthcare professionals. In practice, this means that pharmaceutical companies and the distributors of therapeutic medical devices may not transfer money to individual healthcare professionals, but they are required to organize, either through their internal department or a travel agent, the



attendance of the medical doctor at the conference (registration fee, accommodation, travel and meals); that is, companies may only provide the plane ticket and the hotel booking confirmation to the medical doctor.

Contrary to previous legislation, the Gyftv. does not require that sponsorship to attend scientific events be provided through a public tender. Recent case law of the OGYÉI highlights the requirement to set uniformly applied eligibility criteria for sponsorship of HCPs to attend scientific events to ensure that only doctors properly qualified can attend an event (e.g. sponsorship to attend an English-language event may only be provided to HCPs who speak English, and GPs should not be sponsored to attend specialist events on, for instance, cardiology or diabetes care).

Pursuant to the Gyftv., participation of a healthcare professional in a conference or the organization of an event at a given location may only be sponsored by a pharmaceutical company if the necessary means or eligibility can be ensured at such location, or if the organization of the conference at a closer location to the participants' workplace would cause unreasonable additional costs.

In addition, the organization of supplementary scientific programs is only allowed for those healthcare professionals who are entitled to prescribe medicinal products or therapeutic medical devices with reimbursement, and the healthcare professionals' participation in such supplementary scientific programs may only be sponsored by a pharmaceutical company if such program takes place during the scientific event.

The Gyftv. clearly states that persons entitled to prescribe or supply medicinal products and therapeutic medical devices may not solicit or accept any inducement that is not compliant with those described above.

The Gyftv. requires that pharmaceutical companies notify the OGYÉI of the organization and any direct or indirect sponsorship of

professional events and training courses, as well as the sponsorship of healthcare professionals' participation in professional events, by submitting to the authority the data listed in the Gyftv. no later than 15 days before the date of the event or training course.

Promotion of Medicinal Products to Healthcare Professionals

Pursuant to the Gyftv. Act, the promotion of medicinal products and therapeutic medical devices shall comprise commercial practices pertaining to the composition, efficacy or application of medicinal products and therapeutic medical devices targeted solely at healthcare professionals authorized to prescribe, supply or educate on the use of medicinal products and therapeutic medical devices (i.e. doctors, pharmacists, manufacturers and distributors of medicinal products or therapeutic medical devices).

A marketing authorization holder of a medicinal product, a person licensed to engage in pharmaceutical wholesale, a manufacturer or distributor of a therapeutic medical device or the authorized representative of such companies (company engaged in medicine promotion) may only promote the products subject to prior notification filed at the OGYÉI.

Companies engaged in medicine promotion may only perform promotional activities through a natural person employee or contractor who complies with the qualification requirements provided for in the Promotion Decree, who has been registered by the OGYÉI, and who has obtained an ID card from the OGYÉI.

The position of a medical sales representative (MSR) for medicines may only be held by a person who is employed/contracted by the company engaged in medicine promotion, or by the OGYÉI, and who is professionally qualified as a medical doctor, a dental surgeon, a pharmacist, a biologist, a chemist or a graduate of the college for healthcare workers, or who has been exempt from the above qualification requirements before 14 March 2007. The applicable laws



do not provide for any qualification requirements concerning sales representatives engaged in the promotion of therapeutic medical devices.

Pharmaceutical companies engaged in promotion must pay a special tax of HUF832,000 (approximately EUR2,800) for each MSR employed by them on a monthly basis. This payment obligation is less for medical device companies: HUF83,000 (approximately EUR280) per month per MSR. If the MSR is admitted to or removed from the register during the month, the company's payment obligation shall be proportionate to the number of days during which the MSR was engaged in promotional activities in the given month.

The Gyftv. contains a list of periods during which the company will be exempt from payment of the sales rep tax (e.g. the duration of the MSR's sick leave, maternity leave or the period of unpaid vacation).

If the manufacturer gives a mandate to a marketing company to engage in promotional activities and the MSRs are also employed by the marketing company, the mandated person will be obliged to pay the tax in respect of the MSRs. However, the mandated marketing company will very likely pass the payment obligation onto the pharmaceutical/medical device manufacturer in their contract for services as it is in the pharmaceutical/medical device manufacturer's interest that the products be promoted.

MSRs may only promote medicinal products to medical doctors upon a previously scheduled appointment. A medical representative may not in any case come in during consultation hours or hinder the activities of a doctor engaged in providing healthcare. According to the Promotion Decree, MSRs may only visit medical doctors when the medical doctor is not engaged in providing healthcare or preventive care.

Pursuant to the Gyftv. and the Promotion Decree, the promotion of medicinal products must always be in compliance with the summary

of product characteristics of the medicinal product or the instructions for use of the therapeutic medical device.

The Industry Code states that promotional information presented to healthcare professionals must include, clearly and legibly, essential information consistent with the summary of product characteristics (specifying the date on which such essential information was generated or last revised) with special regard to the conditions of safe use (counter indications). Furthermore, promotional materials distributed by MSRs must call for a detailed study of the summary of product characteristics of a given product.

All the information given by MSRs, including written documentation, must be precise, accessible, verifiable and up-to-date, and they must be presented in such detail that enables the person qualified to prescribe or supply medicine or medical device to form an opinion about the product's application, advantages and disadvantages. Quotations taken from medical journals or other scientific works for use in promotional documents must be faithfully reproduced and the precise source referenced. According to the Promotion Decree, each written document must state the date on which it was finalized or last revised. If the medicinal product or therapeutic medical device is reimbursed, the information provided by MSRs during their visits must include the price serving as the basis for reimbursement, the amount of reimbursement and the consumer price of the product.

The HCMP Code provides that a medical doctor may only consider MSR-communicated information that is professional, scientifically grounded and based on proper statistical data. The doctor must insist on a full-scope representation and require the MSR to indicate the scientific sources of all the information communicated.

Free Medical Samples

Each MSR may supply a limited number of free samples of medicines and disposable medical devices to persons qualified to prescribe or supply medicine or therapeutic medical devices until the end of the year following that in which the product has been placed on the



Hungarian market, to enable people to familiarize themselves with the product, in response to a written request signed by the recipient. Free samples may be given:

- in the case of a healthcare service provider offering inpatient care, through the chief institutional pharmacist (in which case, the supply of samples must be recorded in the registry of the institution's pharmacy); or
- in the case of any other healthcare service providers, directly to the person qualified to prescribe medicine or therapeutic medical devices.

The sample must include a summary of product characteristics for medicines and the instructions for use of therapeutic medical devices.

Pursuant to the Promotion Decree, two packaging units may be provided per year per medicinal product or per disposable therapeutic medical device for those who are authorized to prescribe and distribute medicinal products, provided that the two packaging units do not exceed the amount sufficient for a one-month treatment. In the case of reimbursed medicines, free samples may only be provided until the end of the year following the date of placement of the product on the market.

Furthermore, a protocol must be prepared for each delivery of samples. The protocols must be retained for five years and - in case of reimbursed medicinal products or therapeutic medical devices - they must be submitted to OGYÉI quarterly. Each sample must be identical with the smallest package presentation in the market of the medicine or disposable medical device. The packaging must contain the words: "free medical sample, not for sale." In the case of disposable therapeutic medical devices, the packaging must contain the words: "free therapeutic medical device sample, not for sale."

Samples of medicinal products containing psychotropic or narcotic substances may not be provided.

A medical sample or therapeutic medical device sample may only be given directly to patients for therapeutic or rehabilitation purposes.

Besides the provision of a medical sample for therapeutic purpose, doctors, pharmacists or suppliers of medical devices may not give or offer directly to patients any gift, sample or coupon enabling the purchase of the product, with the aim of enhancing the consumption or use of a medical product or products of a given pharmaceutical manufacturer or a reimbursed therapeutic medical device. Furthermore, pharmaceutical or medical device companies may not make the provision of the above benefits conditional upon the use of the product.

Moreover, any reduction, refund or reimbursement of the price that the patient is required to pay for reimbursed medical products is also prohibited in any direct or indirect way or form (by means of, for example, offering gifts, samples, vouchers, coupons and discounts that are contingent upon the collection of points or by other similar means).

Any benefit provided in connection with dispensing any medicinal products that is not reimbursed - other than price discounts - may solely be used for pharmaceutical consultation services offered by the pharmacist in the pharmacy.

The dispensing of medical products or any other products that may be sold in pharmacies, or consultation services offered by the pharmacists, may not serve as a basis for granting any discount or any other advantage to the patient by the pharmacy or any other entity.

In the case of infant formulae, the product may not be advertised at the sales point, either by the giving of samples or any other promotional device aimed at inducing the sale of infant formulae directly to the consumer at the retail level (e.g., special displays, discount coupons, premiums, special sales and tie-in sales). Manufacturers and distributors of infant formulae may not provide to the general public, to pregnant or breastfeeding women or to members of their families,



free or low-priced products, samples or any other promotional gifts, even if via healthcare institutions or employees of healthcare institutions. OGYÉI must be notified when manufacturers or distributors of infant formulae donate informational or educational equipment or materials.

Medicine and Medical Device Donations

Medicinal products and therapeutic medical devices may only be donated for charitable purposes to healthcare or social institutions or charitable organizations if the professional conditions and the control of the application of the medicine and the use of the medical device are ensured.

The Decree on the Establishment and Operation of the Charity Council (Decree 65/2000. (V. 9.) of the Government) provides the definition of “charitable activity.” Pursuant to this definition, charitable activity covers the humanitarian, non-pecuniary aid granted to socially deprived people (e.g., elderly, children, handicapped and homeless people) if the assistance is: offered without discrimination in relation to race, gender, nationality or religious belief; necessary for the fulfillment of basic needs; not related to political aims; and granted solely on the basis of a means test. In our view, the definition of “charitable activity” also determines the scope and limits of the charitable purposes for which medicine and medical device donations may be granted.

According to the Healthcare Act (Act CLIV of 1997), the following are considered healthcare institutions: hospitals engaged in inpatient care and outpatient clinics; the National Ambulance Service; institutions of the national blood bank; and the national institutes under the Ministry of Health that provide healthcare. Based on the Social Allowances Act (Act III of 1993), a social institution is an institution providing personal social care, particularly, social basic care (e.g., provision of meals and family care) and specialized care (e.g., nursing homes). The law does not define the notion of charitable organization; however, organizations that engage in charitable

activities (e.g., public interest companies and foundations) are likely to qualify as charitable organizations.

A protocol must be prepared upon the delivery of donated medicine and medical devices. The persons authorized to prescribe or supply medicinal products and medical devices, as well as the company promoting the products, must keep the protocols for five years after the delivery of the donation and - in the case of reimbursed medicinal products or therapeutic medical devices - they must be submitted to the OGYÉI quarterly.

Medicines and therapeutic medical devices may only be donated if the expiry date allows the donee to use the donation for a reasonable time prior to expiration. The following statement must be indicated on each presentation of the donation: “Medicine donation, not for sale!” or “Therapeutic medical device donation, not for sale!”

Other Donations

Pharmaceutical or medical device companies may also grant donations other than medicine or medical devices (e.g., money and equipment). In the case of donations other than medicinal products, there is no statutory requirement that such donation may only be granted to healthcare institutions. However, we suggest providing donations only to healthcare or social institutions or foundations. Companies should not grant donations to individual healthcare professionals (or companies of individual professionals, i.e., partnerships or limited companies of medical doctors) in order to mitigate the risk that the donations may be regarded as unlawful gifts/benefits offered to them.

Further recommendations are as follows:

- Donations should only be granted upon written request of the institution/foundation in question. The request should clearly state the reason why the institution/foundation needs the donation granted by the pharmaceutical or medical device company.



- A written donation agreement should be signed in each case. The agreement may only be executed by the authorized representatives of both parties.
- Monetary donations must not be made in the form of cash.

Consequences of Breach

Administrative Proceedings Advertising Supervisory Proceedings

The Consumer Protection Inspectorates (NFH) or the Competition Authority (“GVH”) may initiate proceedings in cases of infringing advertising of OTC medicines or non-reimbursed therapeutic medical devices.

As a general rule, the NFH may initiate proceedings in cases of infringing advertising activities directed towards consumers/patients, except if the advertisement can restrict economic competition, in which case the GVH may initiate proceedings.

Advertisement is considered capable of restricting economic competition without any further consideration if, for example, the advertisement was broadcast nationally or if it was published in a nationally circulated newspaper or in a daily paper circulated in at least three counties.

In certain cases as defined by the Gyftv. (e.g., illegal advertising of a prescription-only or reimbursed medicinal product or therapeutic medical device to patients), regardless of the commercial practice’s capability of restricting economic competition, the NFH may initiate proceedings.

The GVH (or in certain cases, the court) may initiate proceedings in case of infringing comparative advertising activities.

OGYÉI can act as an expert authority in the procedures of the NFH for certain professional questions defined by law. An administrative procedure may not be initiated more than three years after the

publication of the illegal advertisement. In the case of continuous illegal advertising, the three-year limitation period is counted from the date of the last publication of the advertisement.

An advertising supervisory proceeding may be initiated not only *ex officio*, but also upon request. Anyone may request the commencement of an advertising supervisory proceeding if a person's right, legal interest or legal status may be affected by the illegal advertising. Consequently, competitors of advertisers may also turn to the abovementioned authorities.

If the NFH establishes an infringement of the law, the authority may, *inter alia*, issue a cease-and-desist order or impose a fine on the infringing company. The amount of the fine that can be imposed ranges from HUF15,000 (approximately EUR50) to:

- five percent of the annual net sales revenue, up to a maximum of HUF100 million (approximately EUR340,000), of business entities falling under Act C of 2000 on Accounting (and not falling under Act XXXIV of 2004 on Small and Medium-sized Enterprises), whose annual net sales revenue is in excess of HUF100 million (approximately EUR340,000); up to a maximum of HUF2 billion (approximately EUR6.8 million) if the infringement concerns the lives, health, physical integrity of a broad range of consumers, or if it results in substantial financial injury to a broad range of consumers; or
- HUF500,000 (approximately EUR1,700) for business entities not included above; or up to 5 percent of the annual net sales revenue of the business entity if the infringement concerns the lives, health and physical integrity of a broad range of consumers; or if it results in substantial financial injury to a broad range of consumers; or up to HUF5 million (approximately EUR17,000) for business entities to whom the Accounting Act does not apply.



The decision of the NFH may be appealed before the head of the NFH and judicial review is available against the decision of the head of the NFH.

If the GVH establishes an infringement of the law, the authority may, *inter alia*, issue a cease-and-desist order or impose a fine that may amount to 10 percent of the group net turnover obtained in the preceding year by the companies involved in the infringement. The GVH's practice regarding misleading advertising activities has become more and more stringent in the past few years. For instance, it imposed increasingly higher fines due to misleading medicine advertising (e.g., in the case Vj-68/2004, the Competition Office imposed a fine of HUF100 million or approximately EUR340,000).

There is no appeal against the GVH's decision; however, a court review of such decision may be requested.

Illegal Promotional Activities - Proceedings of the OGYÉI

The OGYÉI has authority to proceed against cases of illegal promotion of prescription-only or reimbursed medicines or reimbursed therapeutic medical devices to healthcare professionals. If the GYEMSZi- OGYI establishes infringement of the applicable laws on medicine promotion, the OGYÉI may:

- initiate ethics proceedings at the competent ethics committee;
- call upon the person in breach (by indicating the deadline for correction) to correct the deficiencies and to suspend its activities;
- issue a cease-and-desist order;
- impose a fine the amount of which ranges between HUF500,000 (approximately EUR1,700) and HUF25 million (approximately EUR86,000) in case of authorized distributors; in the case of marketing authorization holders and manufacturers, the amount of the fine that can be imposed on

the company ranges between HUF500,000 (approximately EUR1,700) and HUF500 million (approximately EUR1.7 million); and in case of MSRs, between HUF500,000 (approximately EUR1,700) and HUF5 million (approximately EUR17 million);

- if in case of a repeated or grave breach:
 - prohibit the company from promoting the medicinal product for a definitive period of time (from six months up to three years); or
 - initiate at the Health Insurance Fund Administration the suspension of the agreement that entitles the infringing company to dispense medicinal products with reimbursement, or the suspension of the agreement that entitles the infringing healthcare professional to order medicinal products with reimbursement for no longer than one month; and
- for reimbursed medicinal products, if the competent authority establishes the infringement of the applicable laws on medicine promotion by a marketing authorization holder or its representative twice within one year, and the amount of the fines imposed on such company reaches HUF5 million (approximately EUR17,000), the Health Insurance Fund Administration shall exclude the medicinal product concerned from reimbursement if there is another reimbursed medicinal product with the same indication that can be purchased by patients for a price not more than 50 percent higher than the medicinal product concerned.

A repeated breach is one that is at least twice as determined in final and enforceable decisions of the competent authorities within the past two years. A serious breach is when the usual market value of the unlawful promotion of the medicinal products or medical devices



exceeds HUF25,000,000 (approximately EUR85,000) for repeated breaches. A fine may be imposed cumulatively.

For pharmacies already existing on 1 January 2011, and for pharmacies established after the entry into force of the Gyftv. in which a healthcare professional entitled to prescribe medicinal products with reimbursement has an ownership share, the government body in charge of the healthcare system shall determine whether any agreement exists among pharmacies marketing medicinal products with reimbursement under a contract with the Health Insurance Fund Administration, manufacturers and distributors of medicinal products, and healthcare professionals entitled to prescribe medicinal products with reimbursement that may jeopardize or endanger the safe and efficient supply of medicinal products to patients. If it can be established that the existence of such agreement endangers the efficient and safe supply of medicines, the government body in charge of the healthcare system shall approach the Health Insurance Fund Administration to terminate the contract that entitles the pharmacy to supply products with reimbursement.

Special Supervisory Powers of the OGYÉI

The Gyftv. confers significant powers on the inspectorate to investigate breaches of the rules on promotion.

In order to discover the relevant facts of the case, the OGYÉI may request that any person or organization provide the OGYÉI with the documents handled or possessed by the person or organization. The OGYÉI may make a forensic copy of computer databases and may inspect the stored data. The OGYÉI is authorized to obtain and process the personal data of the person under investigation or any person related to it. However, when investigating practices of gift-giving, promotional hospitality and the sponsorship of scientific events, the OGYÉI may not have access to, and may not use as evidence, attorney-client privileged information. The OGYÉI may inspect any premises where evidence is suspected to be located. It may enter the business premises of the company under investigation,

search business premises, and may also search private homes and cars, provided that such private property belongs to a current or previous employee of the company. The OGYÉI may only conduct this sort of search if it has obtained in advance an order of the Metropolitan Court to do so. The order of the Metropolitan Court may not be challenged. The court will only approve such “raid” if the authority can establish that less intrusive investigational measures would not be successful and if it is reasonable to assume that the evidence would not be voluntarily provided. The OGYÉI may request police assistance in carrying out the abovementioned investigational measures.

The Promotion Decree contains specific duties imposed on marketing authorization holders of medical product device companies, as well as their authorized representatives, to cooperate with the competent authorities. Under these provisions, the marketing authorization holder or its authorized representative carrying out promotional activities must ensure the control of commercial communication and promotional activities by establishing a scientific organizational unit within the company.

Furthermore, the marketing authorization holder and the manufacturer of therapeutic medical devices or its authorized representative must archive samples of all advertisements and the mode of distribution and the starting date of distribution of the advertisement. They must supply the authorities with information, assist them during investigations, and verify that the medical sales representatives have been adequately trained and satisfy the relevant requirements.

Unfair Competition

A competitor may, among other remedies, bring an action before a civil court for unfair competition if it can prove that a company gained an unlawful competitive advantage as a result of the infringement of the law or industry ethical rules on advertising and promotion. Such action may lead to an injunction or claim for damages. The court can also impose a fine on the defendant based on the Competition Act.



Ethics Proceedings

Furthermore, violation of the various ethical codes may also incur serious sanctions on the persons or companies whose activities fall under the scope of the codes.

The Industry Code has been harmonized to a great extent with the code of ethics of the European Federation of Pharmaceutical Industries and Associations (EFPIA). The Industry Code establishes a Communication Ethics Committee (the “Committee”), which reviews ethics complaints and disputes by applying the provisions of the Industry Code. The Industry Code permits anyone, including a competitor or a healthcare professional, to make a complaint about a member company. The Committee also may start proceedings *ex officio*. However, if the applicant turns to any authority prior to or in parallel with the complaint submitted to the Committee, the Committee will not start its proceedings until a decision is made by the competent authority because the Committee does not want to influence the regulatory actions of the relevant authorities. If the Committee concludes that a member company committed an ethical offense, its proceedings may result in temporary membership suspension or, in the most serious cases, expulsion. The Committee may also order the withdrawal of promotional material, issue a written notice on the execution of the order, or request that a rectification be circulated to HCPs if the misleading communication may lead to the improper application of the product or may result in any risk to patients. Both the HCMP and HCP may conduct ethical procedures against their members.

The HAA Code establishes the primary liability of advertisers for compliance with the code’s provisions. If the advertiser cannot be identified or the advertiser proves that the breach is not attributable to its improper conduct, act or omission, the advertisement provider or publisher is liable for an advertisement that constitutes a violation of ethics rules. However, application of the rules of the HAA Code is only voluntary.

Professional Codes of Conduct

The Industry Code's provisions are in line with, or in some cases, even more stringent than the relevant statutory norms of the Advertising Act and the Promotion Decree. Thus, the Industry Code prohibits the giving of gifts, benefits or sponsorships to doctors, pharmacists or healthcare workers, unless it is inexpensive and related to the practice of medicine. The category of healthcare professionals is wider than the group of persons entitled to prescribe or supply medical products under the Gyftv. (i.e., the category of healthcare professionals comprises any healthcare workers or staff members of healthcare service providers who take part in healthcare and in the ordering, procuring or use of medicinal products, including, for example, nurses). The Industry Code, in line with the EFPIA Code, contains detailed rules regarding sponsorship and hospitality. No company or representative office may organize or sponsor an event that takes place outside its home country unless some of the invitees are from abroad and it makes greater sense to hold the event in another country. Hospitality may not include entertainment programs. Companies should avoid using venues that are renowned for their entertainment facilities.

The Transparency Code's provisions are in line with the provisions of the EFPIA Transparency Code.

The HCMP Code currently contains the primary ethical rules governing the work of medical doctors and seeks to set a high standard of ethics and professional responsibility to maintain confidence in the healthcare industry. A doctor shall not accept any gift or other promised material benefit that is provided with a condition that a particular product should be prescribed, used or recommended to patients. Infringement of such rules is an ethical offense. It is an ethical offense if a doctor recommends similar products of different companies as their first choice product within a short period of time. It is also an ethical offense to favor medicines, medical devices or other products as opposed to other similar products in exchange for any support or gift. The HCMP Code declares any



relationship between a doctor and a pharmacist that is aimed at gaining profits or increasing turnover as unethical.

Similarly, the HCP Code prohibits pharmacists from engaging in any kind of advertising activity that would conflict with the rules of professional conduct or ethics, or result in unfair competition among pharmacies. A pharmacist shall not conclude any agreement or accept any benefit that would endanger or infringe his or her professional independence and the independence of his or her decisions or the effective and safe pharmaceutical supply to patients. In particular, contracts and agreements are considered as capable of endangering professional independence if the pharmacist becomes interested in, or seems to be interested in, offering a particular medical product or the products of a particular pharmaceutical or food supplement company in exchange for any fee, gift or other benefit or remuneration. However, this principle does not apply to contracts between the pharmacist as the manager of the pharmacy and a pharmaceutical wholesaler or any other supplier, under which agreement the pharmacy will be entitled to certain benefits depending on the contractual volume or value.

Liability under Criminal (and Civil) Law

Regulatory Framework

Act No C of 2012 on the Criminal Code (the “Criminal Code”) contains rules on bribery. These rules apply to crimes committed by natural persons. Act CIV of 2001 on the Applicable Criminal Sanctions against Legal Persons (the “Criminal Sanctions against Legal Persons Act”) states that in certain cases, legal persons may also be liable for criminal offenses (including bribery).

Permitted and Prohibited Practices and Sanctions

The Criminal Code differentiates between active and passive, as well as official and economic bribery. The subjects of official bribery are “public officials.” The Criminal Code gives the following detailed definition of public officials: members of Parliament; the president of

the Republic; members of government; judges of the Constitutional Court; judges and public prosecutors; the ombudsmen of fundamental rights; members of the local municipality bodies; public notaries; persons on official duty at the Constitutional Court; courts; public prosecutor's offices; administrative bodies; local municipality administrative bodies whose activity belong to the normal functioning of the body in question; and persons engaged in administrative, public executive tasks at bodies that are entrusted by law with administrative or public executive powers (e.g., civil servants who have the authority to make decisions in administrative proceedings).

It is unclear whether doctors, pharmacists or other healthcare workers (for example, nurses) may qualify as public officials. As a general rule, such persons do not fall under the term 'public official.' However, in certain cases, if a doctor acts with administrative authority (e.g., a doctor certifies a person's incapability to work or issues a health certificate), he or she can be considered a public official. Nevertheless, doctors/healthcare workers may be the subject of economic bribery since they are usually employed by a government or local municipality body (e.g., hospital, outpatient surgery) or a company (e.g., Ltd., limited partnership).

Active official bribery is when a person promises or gives an unlawful benefit to a public official or to any other person on account of such public official's actions in order to influence that public official or person. Such a person shall be punished for a felony and can be imprisoned for up to three years. The person may be imprisoned for a duration from one year up to five years if the he or she induces the public official to breach official duty, exceed competence or abuse official position in any way.

Passive official bribery is if a public official requests, demands or accepts any unlawful benefit related to the performance of the public official's duties, or accepts such conduct by another public officer. Passive official bribery is a crime punishable by imprisonment for one year to five years. Passive bribery is more strictly punishable if the public official is in a leading position or has the power to act in more



substantial matters; the crime is committed habitually, as part of a conspiracy or in a business-like manner; or the public official actually breaches official duties, exceeds authority or abuses position in any other way.

The Criminal Code states that active economic bribery is where any person gives or promises unlawful advantage to an employee or member of a budgetary institution, business organization or social organization, or to another person on account of such employee or member, to induce him or her to breach his or her duties. Such action is punishable by imprisonment for up to three years. This form of bribery is more strictly punishable if the unlawful advantage is given or promised to an employee or member who is authorized to act in the name and on behalf of a budgetary agency, business organization or social organization.

Under the provisions on passive economic bribery, it is prohibited for an employee or member of a budgetary institution, business organization or social organization to request any unlawful benefit or to accept such benefit or the promise thereof in return for the breach of his or her duties or to accept that conduct by another employee or member of that budgetary institution, business organization or social organization. This crime is punishable by imprisonment for up to three years. It could be more strictly punished if the breach of duty is actually committed or it is committed in a more substantial matter; as part of a conspiracy or in a business-like manner; the employee breaches his or her official duties; or the employee or member requesting the benefit is empowered to act on behalf of the budgetary institution, business organization or social organization.

Pursuant to the Criminal Sanctions against Legal Persons Act, various sanctions can be applied against a legal person if the crime has been committed: intentionally; for the purpose of achieving a material advantage for the benefit of the legal person, or the crime has resulted in such a benefit; and by a duly authorized representative of the legal person, a member of the supervisory board or a person authorized by them within the scope of activity of the legal person; or the crime has

been committed by a member or employee within the scope of activity of the legal person if the person authorized to supervise such persons could have prevented such an act.

The criminal sanctions that may be applied against legal persons include: the termination of the legal person's activity; the restriction of the activity; and a fine (ranging from HUF500,000 or approximately EUR1,700) of up to three times the material advantage/benefit that was intended to be gained or was actually gained by the crime.

As a general rule, Hungarian anti-bribery rules prohibit any kind of "unlawful benefit." The Criminal Code does not define what constitutes a benefit. The Commentaries of the Criminal Code indicate that a benefit may be either material or personal in nature, and that the term "benefit" should be interpreted broadly. Furthermore, there is no significant jurisprudence interpreting the relevant Criminal Code provisions, and the Curia (the Hungarian Supreme Court) has not yet issued any interpretative rulings on this subject. As a result, whether an advantage or benefit given or promised falls under the scope of the bribery provisions of the Criminal Code must be decided on a case-by-case basis, taking into account the relevant facts and circumstances.

Regarding gifts and benefits granted to persons entitled to prescribe or supply medicinal products and medical devices, in our view, the distinction between "lawful" and "unlawful" advantage may be made according to the statutory provisions. According to the Gyftv., only inexpensive gifts of medical utility may be granted to such persons. "Inexpensive" means 5 percent of the statutory monthly minimum income (in 2015, HUF5,250 or EUR17). If a pharmaceutical company provides a medical doctor with a benefit, the value of which exceeds the above threshold (e.g., the doctor is provided with a more expensive gift or with expensive hospitality) or the benefit does not relate to the practice of medicine (e.g. a gift provided for personal use), it can be considered as an unlawful benefit, and provided the other elements of the Criminal Code's provisions such as an intention



to induce the breach of the person's duties are also fulfilled, the crime of bribery may be established.

Public Procurement and Fraud

Any fraud committed in relation to public procurement proceedings can be sanctioned by civil or criminal laws. No special regulations apply to public procurement by healthcare institutions and fraud committed by healthcare professionals. It is a criminal offense that can be sanctioned with up to five years' imprisonment if companies enter into restrictive agreements in public procurement (and concession) procedures to affect the result of tender and to set prices or other conditions (i.e., bid rigging).

Contracts with Healthcare Professionals and Medical Institutions

The general rules of Act No. V of 2013 on the Civil Code (the "Civil Code") apply to all contracts between healthcare professionals and medical institutions in the same way as in any other industry.

The general rules on contracts for services are regulated in Sections 6:272 - 6:280 of the Civil Code. Pursuant to the Civil Code, the person entrusted with a mandate to provide services must duly provide the services in accordance with the principal's instructions and interests, and the principal must pay a fee for the services. Pursuant to Section 6:276 (4) of the Civil Code, the costs incurred by the person entrusted to provide services must be reimbursed by the principal.

In relation to contracts concluded with doctors, the most important issue is that, under the agreement, the doctor must provide real services/activities proportionate to the remuneration offered for the service under the agreement. An agreement reached with a medical doctor must not disguise any provision of gifts or benefits to the doctor. In the latter case, the contract may be regarded as a hidden contract aimed at circumventing the laws on gifts and benefits that are allowed to be offered to healthcare professionals. According to the Civil Code, such contracts are null and void. Anyone can challenge an

invalid contract without a time limit (Section 6:88 of the Civil Code). Thus, the competent authorities (the OGYÉI, the GVH or the tax authorities) may also initiate proceedings against disguised contracts aimed at circumventing the applicable laws on medicine promotion (or in certain cases, the rules on taxation). Hidden contracts may also be considered bribery under the Criminal Code.

In order to avoid a contract being classified as a hidden contract, the following points should be observed:

- The contracts should precisely define what kind of services the doctor must provide (such as delivering a presentation, writing an article or conducting a study).
- If the contract is concluded with a company, the name of the person who will personally deliver the service (e.g., hold a lecture) should be indicated in the contract. In such a case, this person should also sign (or countersign) the contract.
- Conditions for the completion of the services should be determined in the contract (such as the deadline and manner). The completion of the services should be documented (such as a prepared study, slides of a lecture, summary report, conference material, signed minutes taken from an advisory board meeting), and the relevant documentation regarding the completion of services should be archived.
- The fees may only be paid via bank transfer and only if the fulfilment of the contract is properly documented.
- The fees paid to the healthcare professional under the contract must be commensurate with the services rendered.

Based on recent OGYÉI case law, pharmaceutical companies must ensure that when engaging HCPs to provide services, they enter into documented contractual arrangements for the provision of legitimate services that are needed by, and will be used to support the business



of, the company. Therefore, pharmaceutical companies should particularly be cautious in mandating HCPs for services such as market research and data collection, which are in the forefront of investigations of the OGYÉI. Recent OGYÉI case law also pointed out that in the case of speaker services, presentation materials are the intellectual property of the HCP. The OGYEI has also held that it is unlawful for an HCP to hold a presentation in his or her institution and be paid by a pharmaceutical company for such presentation; the OGYÉI held that HCPs should not be paid twice (i.e., under their employment relationship with the institution and under a service agreement with a pharmaceutical company).

Should the medical professional incur any expenses as a result of the performance under the contract (e.g., the doctor had to participate in meetings, conferences or trainings in connection with the contract), it has to be clear from the contract that these extra costs were necessary for the proper completion of the services under the contract. Reimbursement of extra costs (travel, accommodation, meals) must be reasonable. No luxury costs may be reimbursed.

In the case of contracts with healthcare professionals, pharmaceutical companies must take into account that in certain cases, the healthcare professional's employer must be notified in advance of the establishment of the contractual relationship, or the doctor must seek the prior approval of his or her employer. The duty of notification or the obtaining of prior approval depends on the legal relationship of the healthcare professional, i.e., whether he or she is an employee, a civil servant or a public employee. Therefore, before entering into a contract with a healthcare professional, a pharmaceutical company should check the laws regulating the legal relationship between the doctor and his or her employer, as well as the internal regulations/by-laws of the institution (e.g., internal rules of a hospital). If it is practically possible, it is also advisable to request the employer of the healthcare professional to countersign the contract to verify that the employer is aware of the healthcare professional's additional contractual relationship and approves it.

In any case, it is recommended to include in the contract with the healthcare professional the following (or a similar provision): “the healthcare professional represents and warrants that he or she has the ability under his or her current employment relationship to enter into, and to perform under, the contract; and further, that he or she has made the notifications and has obtained all the approvals required by law and the internal by-laws of the institution to enter into, and to perform under, the contract with the company.”

Recommendations

The legislation on pharmaceutical promotion has changed several times recently. The Gyftv. seems to be a decisive piece of legislation in the long term. Stringent rules apply to the promotional activities of pharmaceutical and medical device companies, and failure to comply with these rules may entail significant authority actions and sanctions. Therefore, it is of utmost importance to properly comply with the relevant laws and ethical rules.

As a general recommendation, always try to comply with the applicable promotional thresholds (e.g., for gifts, sponsorship). Exceeding the thresholds may bring about sanctions and might also be considered as bribery. Benefits granted to healthcare professionals may not be of a personal nature and may in no case relate to the turnover of a particular product (e.g., to the number of prescriptions). It is advisable to keep detailed records on promotional activities (e.g., contracts, certificates of performance, invoices). Regarding contracts concluded with healthcare professionals, the remuneration provided to healthcare professionals must be proportionate to the value of the service provided, and performance must be properly documented. Where possible, it should also be ensured that the relevant institution’s management is aware of the agreement with an individual healthcare professional.



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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