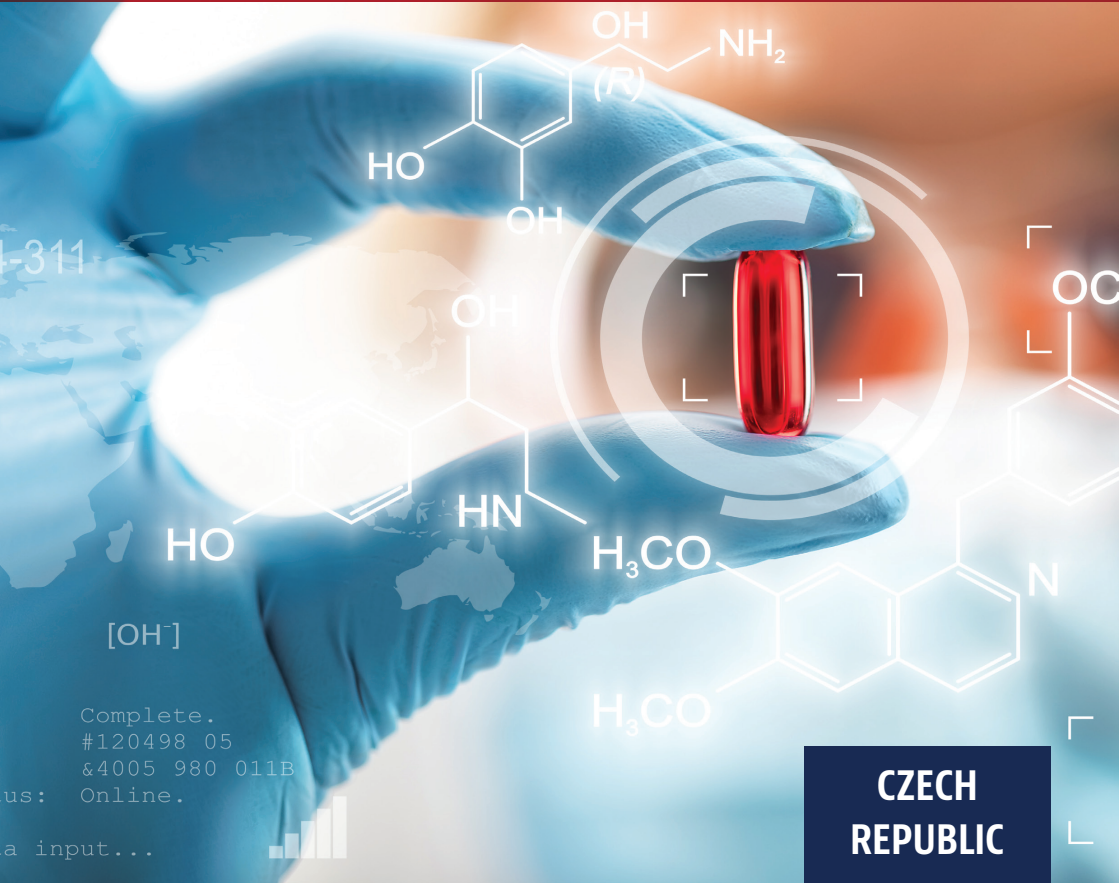


# Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



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# Czech Republic

Milena Hoffmanová

## Introduction

The Czech Republic during recent years has taken a number of important steps towards harmonizing its legal norms and regulations with legislation of the European Union (EU), including relevant laws and regulations covering the pharmaceutical industry. As a result, laws and regulations applicable to pharmaceutical advertising in the Czech Republic are generally in line with relevant EU directives. The stated objective of the Czech legislator is compliance with ethics and norms in the pharmaceutical industry, including professional and objective provision of healthcare to consumers/patients.

Accordingly, the principal EU directives in the pharmaceutical field have been implemented into Czech law, including the Directive on Advertising of Medicinal Products for Human Use, which has since been integrated into the Directive on Community Code relating to medicinal products for human use (as amended), and concerning misleading and comparative advertising (as amended). Thus, Czech law generally satisfies the requirements set forth in the relevant European legislation.

## Restrictions Under Advertising Law

### The Regulatory Framework

The principal rules governing the advertising of human pharmaceuticals (as defined below) are set out in Act No. 40/1995 Coll., on the Regulation of Advertising, as amended (the “Act on Advertising”); Act No. 378/2007 Coll., on Pharmaceuticals and Changes and Amendments to Certain Related Laws, as amended (the “Act on Pharmaceuticals”); and in Act No. 89/2012 Coll., Civil Code, as amended (the “Civil Code”). In addition, the relevant provisions of Act No. 143/2001 Coll., on the Protection of Economic Competition (the “Competition Act”), as amended, are applicable in the event that

the advertising of pharmaceuticals or other conduct in the pharmaceutical industry is likely to have a negative effect on economic competition.

## Act on Advertising

The Act on Advertising provides general advertising rules applicable to any goods and services, and also contains special regulations for the advertising of pharmaceutical products. Such special provisions of the Act on Advertising are applicable to any advertising (including advertising aimed at healthcare professionals and the general public) of pharmaceuticals, including proprietary as well as generic and homeopathic drugs. In addition, these rules also apply to the advertising of reserved pharmaceuticals, which can be promoted only if duly registered with the State Institute for Drug Control (the “Authority”), under the Act on Pharmaceuticals. Moreover, regulations of the Act on Advertising are to be considered regarding food products and food additives if advertising statements refer to diagnosis, prevention, removal or alleviation of diseases, conditions or bodily injury in humans.

Since the former provision of the Act on Advertising regarding the advertising of medical devices was deleted from the Act on Advertising as of 26 January 2006, the advertising of medical devices is now only governed by the general provisions of the Act on Advertising and other applicable laws.

The Act on Advertising has been amended to include a new section on the advertising of veterinary medicines, which introduced certain new limitations on the advertising of this category of medicines (see section on “Permitted and prohibited practices”).

“Advertising” means any announcement, demonstration or other presentation, circulated primarily through communications media, intended to support economic activity, in particular, consumption or sale of goods; construction, lease or sale of real estate; sale or use of rights or obligations; provision of services; or promotion of a trademark.



In addition, the Act on Advertising extends the definition of advertising in relation to pharmaceuticals as follows: “advertising of human pharmaceuticals” means, in addition to the activities included in the definition of advertising, any information, persuasion or incentive provided in order to support the prescription, supply, sale, dispensing or consumption of pharmaceuticals in the form of visits by commercial representatives of persons authorized to prescribe, supply or dispense human pharmaceuticals; supply of samples of pharmaceuticals; a gift, consumer’s lottery or offer of any benefit or financial or other reward; sponsoring of meetings organized for the purpose of support of the prescription, sale, dispensing or consumption of human pharmaceuticals and attended by healthcare professionals; and sponsoring of scientific congresses attended by healthcare professionals and reimbursement of travelling and accommodation expenses relating to their attendance.

The concept of advertising under the Act on Advertising also includes objectively presented factual information, such as scientific publications, if used by companies to promote the sale, prescription or consumption of their human pharmaceuticals products. Regulations and restrictions of the Act on Advertising are only applicable, however, with regard to the advertising of certain or identifiable medicinal products. If a company advertises its products or services in general or by its reputation, or emphasizes in a non-specific manner the quality and good value of its products without drawing attention (either to healthcare professionals or, as the case may be, the general public) to a certain or identifiable pharmaceutical product, such advertising is not regulated by the special provisions of the Act on Advertising but is subject only to the general provisions of this law. The same applies to publication of information regarding a disease, without mentioning a particular or identifiable medicinal product.

Moreover, the Act on Advertising does not apply to labeling of medicinal products and information included in patient information leaflets, according to applicable laws; correspondence and documents that do not serve advertising purposes, but are used in order to respond to an individual inquiry regarding a particular medicine; sales catalog

and price lists, unless they include a description of the pharmaceuticals' characteristics, announcements, notices and provision of information relating, *inter alia*, to changes in packaging, or to warnings against adverse effects of any human medicine; and information on human health or disease, unless it contains any reference (even a hidden reference) to a human medicinal product.

It should also be noted that, according to the Act on Advertising, comparative advertising of medical products is permissible under general conditions stipulated in the Civil Code, as long as it is addressed only to healthcare professionals.

According to the Act on Advertising, the State Institute for Drug Control is the regulatory authority in the area of advertising medicinal products, with the exception, however, of advertising on radio and television, which is supervised by the Council for Radio and Television Broadcasting.

In connection with its practice and supervising role, the Authority has issued a number of guidelines and instructions interpreting the abovementioned laws concerning advertising medicinal products.

### Terms and Definitions

In addition to the terms already used above, the following basic definitions are relevant to advertising activities in the pharmaceutical industry, and significant to the analysis included in this chapter:

“Healthcare professional,” for the purposes of advertising pharmaceuticals, means any person authorized to prescribe or dispense human pharmaceuticals. According to the Authority’s current interpretation, “healthcare profession” may also include legal entities (see more detailed discussion in “Gifts” below).

“Human pharmaceutical” means any medicinal substance intended for administration to humans; “medicinal substance” means any substance or combination of substances that is intended for the treatment or



prevention of human or veterinary diseases, for making a diagnosis, or for the regeneration or modification of physiological functions.

“Medical device” means any tool, device, instrument, equipment, material or other object or product utilized separately or in combination, including any requisite software, which is intended by its manufacturer or importer for use on humans in connection with: making a diagnosis, or the prevention, monitoring, treatment or moderation of a disease; making a diagnosis, or the monitoring, treatment, moderation of or compensation for injury or health handicap; the examination, replacement or modification of an anatomic structure or physiological process; or contraception.

“Reserved pharmaceuticals” means human pharmaceuticals that can, according to a registration decision, be sold without a medical prescription outside pharmacies.

## Competition Law

As of the date of accession of the Czech Republic to the EU on 1 May 2004, the system of concurrent application of EU competition rules and national rules was put in place. The Community competition rules prevail over national rules (by excluding the application of national rules), provided that the anti-competitive conduct of an undertaking could potentially affect trade between member states and distort competition in the Common Market.

As the pharmaceutical industry represents a highly competitive market that at the same time is quickly evolving and whose structure is also changing due to continuing research and development of new products and devices, as well as mergers between competitors, the competition rules must be observed in connection with both marketing (distribution) as well as promotional activities conducted by pharmaceutical companies.

In particular, pharmaceutical companies should carefully prepare and apply any pricing schemes and discount systems offered to their customers. This applies, in particular, in the situation where a



company's product reaches (or is even close to<sup>1</sup>) the threshold of dominance in the relevant market, in order to avoid infringement of the provisions of the EC Treaty and the Competition Act, which restrict abusive behavior to the detriment of consumers or competitors by one or more undertakings in a dominant position. In this context, it is usually of crucial importance for purposes of verifying the existence of a dominant position on the part of a company to correctly define the relevant market.<sup>2</sup>

Where the market share constantly reaches or even slightly exceeds the threshold-representing dominance, it is necessary to consider whether any discounts provided do not have illegal loyalty-inducing effects and do not foreclose the market to other competitors by tying up the customers.

Furthermore, any interactions between competitors in the pharmaceutical market should be made in strict compliance with the relevant competition rules restricting agreements (whether in written form or otherwise) that result or may result in the distortion of competition (e.g., cartels, fixing of prices or discriminating commercial terms).

## Permitted and Prohibited Practices

The following section outlines permitted and prohibited practices relating to the advertising of human pharmaceuticals in the context of relationships between pharmaceutical companies and distributors on the one hand, and medical facilities and individual healthcare professionals on the other. This summary is based on an analysis of

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<sup>1</sup> Please note that according to the Commission's practice, undertakings with market shares of no more than 25 percent are not likely to enjoy a single dominant position in the market concerned. When assessing the existence of dominance, it is necessary to take this into account.

<sup>2</sup> Consistently with the decision-making practice of the European Commission, a relevant pharmaceutical product market should be defined by reference to the third ATC level, which reflects the therapeutical/pharmacological subgroups of drugs. Ultimately, however, substitutability of products depends on the indication for which they are approved and used.



the laws and regulations referred to above, as well as the application of the relevant laws by the Authority.

## Gifts

According to the general principle stipulated in the Act on Advertising, gifts or other benefits can be promised or provided to individual healthcare professionals in connection with the advertising of human pharmaceuticals only if the gift or other benefit is of a small nominal value and related to the healthcare professional's expert activities. According to a resolution by the Authority,<sup>3</sup> "small nominal value" means CZK1,500 (approximately EUR55), including all gifts provided by the particular donor (pharmaceutical company, distributor, etc.) to an individual healthcare professional in a particular calendar year.<sup>4</sup> Concerning the requirement for relevance of the gift to the healthcare professional's expert activity, it is generally understood and approved by the Authority that items including, *inter alia*, stationery, diaries or calendars, professional literature or small instruments, are acceptable. These rules also apply to gifts provided in the form of prizes in various competitions or lotteries aimed at or participated in by healthcare professionals.

Provision of gifts and other benefits to individual healthcare professionals includes, according to the Authority's interpretation of the Act on Advertising, gifts, donations or other support (collectively referred to as "support") provided to a hospital or other medical

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<sup>3</sup> In general, please note that the Authority is not explicitly authorized in the Act on Advertising to issue any decrees or other generally binding regulations that would implement the provision of the law (including the term "small nominal value"). Thus, from a strictly technical-legal point of view, general resolutions of the Authority (as opposed to decisions adopted in concrete administrative proceedings) are not legally binding; however, since the Authority is vested with the competence to supervise any pharmaceuticals advertising activities, its resolutions and published opinions are commonly respected and viewed as binding.

<sup>4</sup> The prohibitions summarized in this paragraph are implemented in detailed regulations governing the promotion of human pharmaceuticals promulgated by the Authority (the regulatory body supervising the promotion of human pharmaceuticals in the Czech Republic).

facility as a legal entity. However, such interpretation is subject to strong criticism by the professional public and it needs to be mentioned that the interpretation is not generally binding. Nonetheless, a sanction has been imposed for such a breach.

If the term “healthcare professional” is construed exclusively as including only natural persons, it would be possible to provide support to state-owned hospitals or a private medical facility conducting its activity on the basis of Act No. 372/2011 Sb., on Healthcare Services.

Furthermore, support can also be provided to a private hospital operated by a single physician without breaching the Act on Advertising. This is possible because, although a physician cannot have the status of a private hospital, he or she can be an operator of a private hospital, and therefore be viewed as separate and distinct from the private hospital itself. Nevertheless, in the case of a private hospital operated by a single physician (or a small group of physicians), the donor must ensure that the support is indeed provided to the private hospital and not to the physician(s) operating the hospital. It should be noted, in this context, that the Authority tends to be more conservative and pays more attention to support provided to private hospitals operated by one physician or a small group of physicians.

### Seminars and Promotional Events

For the purposes of the description of allowed activities concerning seminars and other scientific events as well as promotional meetings, it is crucial to define the term “sponsoring.” According to the Act on Advertising, “sponsoring” means a contribution that is made in order to support the production or sale of the products of, or the provision of services by, the sponsor. Any legal entity or individual can be a sponsor. According to the interpretation of “sponsoring activities” by the Authority in the pharmaceutical sector, “sponsoring” shall mean the provision of a financial or other contribution to the organizer of: a seminar, scientific congress or symposium; or a meeting organized in



order to support the prescription, sale, supply or consumption of human pharmaceuticals, attended by pharmaceutical professionals.

According to the Act on Advertising, it is lawful to sponsor the organization of seminars, scientific congresses or symposia and to reimburse healthcare professionals for the costs of transport, accommodation and admission fees incurred as a result of attending such scientific events.

It is also legally permissible to sponsor promotional meetings organized in order to support the prescription, sale, supply or consumption of pharmaceuticals. The amount of the donor's contribution to the organizer of the meeting is not limited by law. However, in connection with such sponsorship of promotional meetings, companies are not allowed to reimburse healthcare professionals for transport, accommodation or admission fees, or provide them with other advantages. A sponsor may provide healthcare professionals attending a promotional event with gifts of a small nominal value as well as refreshments, provided that the rules that apply to the provision of these advantages are met.

In addition, a pharmaceutical company may sponsor other independent activities or events concerning social life (e.g., cultural or sporting events), including events that happen to be attended by healthcare professionals. However, such support must not be provided in such a way that it could be viewed as a gift or other benefit provided by a pharmaceutical company to a healthcare professional in connection with promoting medicine products.

Finally, educational grants to state or privately owned hospitals are generally permitted if the purpose of the grant is not to serve as an incentive or promotional tool for the prescription of medicinal products by the particular physician, or a reward for the same. Grants may only be paid to institutions and not to individual healthcare professionals. In relation to the interpretation of the definition of "professional" by the Authority, it is for now unclear whether it is possible to provide such support to legal entities without limitation.

## Hospitality and Entertainment

Although the Act on Advertising does not specify the term “hospitality,” the interpretation generally accepted by the supervising Authority, as well as professional commentators on the law, includes refreshments (i.e., food and drink) and accommodation. Such refreshments and accommodation for individual healthcare professionals provided in connection with promotional meetings organized in order to support the prescription, sale, supply or consumption of human pharmaceuticals, or scientific congresses or symposia attended by healthcare professionals, are legally permissible if commensurate with the nature of the meeting, secondary to the main (i.e., scientific or business) purpose of the meeting, and extended only to healthcare professionals (e.g., not to their spouses or families). Provided that these conditions are met, the “small value” threshold of CZK1,500 (approximately EUR55, as specified above) does not apply to the provision of refreshments.

Subject to the exemption concerning gifts of small nominal value, organization of entertainment for (or the provision of other advantages to) healthcare professionals in connection with advertising pharmaceuticals, including during the promotional or scientific meetings described above, is prohibited.

## Advertising and Other Promotional Activities

### General Limitations

In general, the Act on Advertising allows advertising of medicinal products that have been registered according to the Act on Pharmaceuticals, that is, medicines with valid marketing authorization.<sup>5</sup> Accordingly, advertising of non-registered products (including products in their manufacturing process) is prohibited. This provision is based on the regulation in the Act on Pharmaceuticals, which stipulates that, subject to a few exceptions (e.g., special

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<sup>5</sup> According to the Act on Advertising, human medicines may be registered under the national registration procedure with the Authority or via the EU centralized procedure with the European Medicines Agency (EMA).



treatment programs), only duly registered pharmaceuticals can be placed on the Czech market and prescribed and provided to patients in relation to the provision of healthcare in the Czech Republic.

In line with the EU human medicines directive, the Act on Advertising distinguishes between advertising prescription-only pharmaceuticals and pharmaceuticals that may be bought and applied by consumers without the need to obtain prescription from a physician, or over-the-counter (OTC) pharmaceuticals.

Prescription-only pharmaceuticals may only be advertised to healthcare professionals (i.e., persons authorized to prescribe or dispense such products) and not to the general public. Such advertising aimed at healthcare professionals may not be carried out through information channels and communication means other than those dedicated mainly to experts (e.g., professional magazines and professional audiovisual documents). In the case of Internet advertising intended for healthcare professionals, information about prescription-only pharmaceuticals of a promotional nature must be clearly designated.

The advertising of prescription-only pharmaceuticals aimed at healthcare professionals must include: accurate, current and verifiable information enabling the professionals to formulate their own opinion about the therapeutic value of the advertised product; basic information according to the summary of product characteristics (SPC), including the date of approval or latest revision; information about the manner of dispensing the product according to the registration; and information about the reimbursement status of the product under the public health insurance system.

In connection with each visit to a healthcare professional made for the purpose of advertising human medicines, a sales representative<sup>6</sup> must provide the visited professional with a summary of the product

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<sup>6</sup> The institute of sales representation is defined in Section 2483 and following of Act No. 89/2012 Coll., the Civil Code.

characteristics and information about the reimbursement status of the product under the public health insurance system.

Any advertising of OTC pharmaceuticals aimed at the general public must be: formulated in such a way that it is clear that the product is a human medicine; include the brand name of the product according to the marketing authorization; include information necessary for the proper use of the product; and include clear and visible instructions to read in the patient information leaflet.

OTC pharmaceuticals may be advertised to the general public, provided that such advertising does not:

- concern pharmaceuticals that comprise narcotic or psychotropic substances;
- induce patients to conclude that consultation with a physician or treatment is not necessary, namely, by an offer of remote diagnosis or treatment;
- focus solely on persons younger than 15 years of age;
- recommend human pharmaceuticals with reference to recommendations of scientists, healthcare professionals or persons who are not in such position but who could support the consumption of pharmaceuticals due to their actual or presumed social status; or
- indicate that the human pharmaceutical is a food or cosmetic product or other kinds of consumer goods.

If the advertisement of a pharmaceutical product is intended to serve as a reminder of such product, it must not include information other than the brand name of the product approved in the marketing authorization, or its International Nonproprietary Name (INN), or a trademark. This rule applies to reminders of prescription-only medicines as well as to OTCs.



According to the Act on Advertising, the advertising of any goods, services or other performance or values whose sale, provision or distribution is in conflict with applicable laws<sup>7</sup> is prohibited. Therefore, the advertising of medical devices that do not meet the requirements for placement on the market according to the relevant laws is prohibited.

The Act on Advertising further stipulates that a person who ordered the particular advertising (in the case of advertising medicinal products, such person would most often be a pharmaceutical company) must store a copy thereof for at least five years following its final distribution.

#### Special Offers and Discounts

Pharmaceutical companies (and also pharmacies) may use various marketing tools in order to promote human medicines and support their sale, including, *inter alia*, special offers and discounts. In this regard, it is important to mention that, due to the strict regulation of provision of samples of medicines, companies are not allowed to organize special offers in the form of, for example, 2 + 1 (i.e., if you buy two products, you receive one additional product for free). Such a special offer would contravene the restriction on provision of samples to the general public, and if focused on healthcare professionals, the limitations on provision of samples to healthcare professionals (see section on “Samples”). In contrast, a special offer structured as “3 products for the price of 2” would be acceptable, as there is no product provided for free under this scheme; all three products are discounted, and the provision of discounts is legally permissible.

#### Comparative Advertising

According to the Act on Advertising, comparative advertising concerning pharmaceuticals or healthcare is legally permissible if addressed to persons authorized to prescribe or dispense such

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<sup>7</sup> Namely, Act No. 268/2014 Coll., on Medical Devices, as amended, and Act No. 22/1997 Coll., on Technical Requirements on Products, as amended.



pharmaceuticals or provide such healthcare, and if conducted in accordance with the provisions of the Civil Code.

The Civil Code sets out the general rules for comparative advertising, which is defined (rather improperly) in the chapter dedicated to unfair competition and recognized, under certain conditions, as one of the special cases of unfair competition. According to the Civil Code, comparative advertising is “any advertising which explicitly or by implication identifies a competitor or goods or services offered by a competitor.” The Civil Code implements the relevant provisions of Council Directive 84/450/EEC, as amended by Directive 97/55/EC.

According to the Civil Code, comparative advertising is permitted only when it meets all of the following criteria:

- It is not misleading.<sup>8</sup>
- It compares only goods or services meeting the same needs or intended for the same purpose.
- It objectively compares only such features of the goods or services that are fundamental (material), relevant, verifiable and representative; as a rule, several features must be compared and these may include the price; only exceptionally may a comparison of one feature be permitted, provided that such comparison fully meets all the stipulated conditions.
- It does not create confusion in the marketplace between the advertiser and a competitor or between their enterprises, goods or services, or trademarks, commercial names or other distinguishing marks typical of one or the other.

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<sup>8</sup> According to Section 2977 (1) of the Civil Code, “misleading advertising” is advertising that pertains to someone’s enterprise or occupation, with the aim of increasing sales of goods or services, including rights and obligations, and is deceptive or is capable of being deceptive for persons to whom it is addressed or who come into contact with it, and thereby is capable of influencing economic behavior of such persons.



- It is not disparaging<sup>9</sup> with respect to other competitors' enterprises, products, trademarks and/or other designations.
- It relates only to products with the same designation, if the competitor is entitled to use a protected designation of origin.
- It does not take unfair advantage of the reputation of another competitor's trademark, trade name and/or other designation.
- It does not present goods or services as imitations or replicas of goods or services bearing a protected trademark or trade name.

Comparative advertising must therefore be limited to objectively assessable features, qualities or characteristics of the compared pharmaceutical products and must be carried out in a way that does not, even potentially, meet the conditions of other unfair competition conduct.

#### Veterinary Medicines

According to the Act on Advertising, as amended, veterinary medicines may be advertised to the general public, provided, however, that such advertising does not: concern veterinary medicines that may be dispensed only on the basis of a prescription according to the marketing authorization; or concern veterinary pharmaceuticals that comprise narcotic or psychotropic substances.

#### Samples

According to the Act on Advertising, free samples of human pharmaceuticals can be distributed exceptionally, in a limited amount,

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<sup>9</sup> According to the Civil Code, “disparagement” means conduct whereby one competitor states or disseminates false information about the circumstances, products or services of another competitor, with such false information being likely to be detrimental. Disparagement also involves stating and disseminating truthful information about the circumstances, products or services of another competitor, if such information is capable of causing detriment to that competitor.

to persons who are authorized to prescribe them.<sup>10</sup> Each sample must represent the smallest registered package available in the market and must be labeled “free sample” or “not for sale.” Free samples of pharmaceuticals can only be provided where there is a dated and signed written request from the authorized person. However, distribution of free samples of pharmaceuticals that comprise narcotic or psychotropic substances is prohibited, even to persons authorized to prescribe them.

Distribution of free samples of pharmaceuticals to the general public or to individual persons who are not authorized to prescribe them is prohibited.

#### Consequences of Breach

According to the Act on Advertising, the Authority may order removal or termination of advertising that contravenes the provisions thereof. In addition, the Authority may specifically suspend commencement of distribution of a misleading pharmaceutical advertising if, in its view, damage could be caused to human health or life by distribution of such advertising. For such measure, the Authority’s suspicion is sufficient and no evidence of occurrence of damage is required.

Furthermore, the Authority can impose a penalty amounting up to CZK5 million (approximately EUR185,000) on an individual entrepreneur or a legal entity for breaches of the provisions of the Act on Advertising relating, *inter alia*, to the distribution of prohibited advertising and to sponsoring activities in the pharmaceutical industry.

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<sup>10</sup> Please note that since pharmacists are not generally qualified to prescribe human pharmaceuticals in the Czech Republic, no free samples of human pharmaceuticals may be distributed to them.



## Professional Codes of Conduct

### Professional Code of Conduct for Physicians

The Czech Medical Chamber, the Czech Chamber of Pharmacists and the Czech Chamber of Dentists are the existing associations for all physicians, pharmacists and dentists, respectively, practicing in the Czech Republic. According to a special law under which the chambers were established, each physician, pharmacist and dentist practicing or providing healthcare services in the territory of the Czech Republic must be a member of the relevant chamber according to his profession (the “Chamber”).

By way of illustration, the Czech Medical Chamber has issued a set of rules, including a code of ethics, organizational rules and a disciplinary code, which apply to all its members and which broadly set out the rules for provision of healthcare services.

The following passages from the Chamber’s code of ethics deal with the use of pharmaceutical and diagnostic products:

- “A physician may not, on his own or upon agreement with others, prescribe purposeless therapeutic and diagnostic or other treatment for motives of self-interest.”
- “If a physician recommends, in his therapeutic practice, drugs, medical remedies or medical aids, he may not pursue commercial goals but only his conscience and the benefit of the patient.”

Under the organizational rules, the Chamber supervises physicians’ activities and imposes sanctions in the event of a breach of relevant legislation or of the Chamber’s rules and codes.

In the event of a breach of obligations under the Chamber’s rules or under other relevant legislation, a physician may face monetary penalty, reprimand or expulsion from the Chamber (which effectively results in a ban on such physician’s further medical practice).

## Professional Code of Conduct for Pharmaceutical Companies

The Association of the Innovative Pharmaceutical Industry in the Czech Republic (AIFP) is a voluntary national association of research and development-based pharmaceutical companies. Founded in 1993 and formerly known as the International Association of Pharmaceutical Companies, AIFP is a member of the European Federation of Pharmaceutical Industry and Associations (EFPIA).

Members of the AIFP have committed to market and promote their products in compliance with strict ethical principles that have been embodied in the Code of Conduct. In this context, AIFP members have undertaken in the Code of Conduct not to implement any practice or activity that would lock prescribing physicians into schemes aimed at generating prescriptions in exchange for incentives. In addition, no gifts, donations or other benefits or advantages may be provided or offered to a healthcare professional in exchange for prescribing products or on conditions that would otherwise interfere with the independence of a healthcare professional's prescribing practices.

The AIFP Code of Conduct covers the advertising of prescription-only medicinal products aimed at healthcare professionals (as opposed to the general public). Promotion, as used in the AIFP Code, includes any activity undertaken, organized or sponsored by a pharmaceutical company, or with its authority, which promotes the prescription, supply, sale, administration or consumption of its medicinal product(s).

The AIFP Code covers (in special chapters) all methods of promotion, including, but not limited to, oral and written promotional activities and communications; journal and direct mail advertising; the activities of medical sales representatives; the Internet and other electronic communications; the use of audio-visual systems such as films, video recordings, data storage services and the like; and the provision of samples, sponsorships, gifts and hospitality.



In relation to the co-existence of the general legal regulations of advertising and the provisions included in the AIFP Code of Conduct, the rules adopted by AIFP are, in many cases, stricter than the general legislation, as the Code of Conduct takes the laws as a basis and further aspires to create an even more ethical environment in the area of pharmaceutical advertising by implementing more demanding rules.

By way of example, in addition to the general rule concerning the CZK1,500 threshold for any and all gifts provided by a pharmaceutical company to one healthcare professional during a calendar year, the AIFP Code of Conduct generally prohibits provision of gifts, with certain limited exceptions, such as informational or educational materials up to the value of the abovementioned threshold and as long as directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.

Another example may be a new 4x2 rule, setting more strict conditions for provision of free samples of medicines, stipulating that no healthcare professional should receive annually more than four samples of a specified new drug that he or she is authorized to prescribe. Giving samples of a specified drug is allowed only for two years after the medical professional's request for the given drug sample. The term of two years applies to samples of a generally specified drug, that is, on the whole market and not only in relation to individual healthcare professionals.

Also, in addition to the general rule on sponsoring laid down in the Act on Advertising, the Code of Conduct contains a detailed description of the terms under which an AIFP member may organize or sponsor a congress or other scientific meeting attended by healthcare professionals, including specific limitations on the number of days, scope of agenda or types of venues.

## Liability Under Criminal and Civil Law

### The Regulatory Framework

There is no special Act in force that regulates bribery and corruption practices in the Czech Republic. Czech anti-corruption legislation consists of a number of provisions set out, among others, in the Criminal Code, the Civil Code, the Act on Procurement of Public Orders and the Labour Code. The Czech Republic is also party to a number of international treaties and conventions aimed at combating bribery and corruption, including, the OECD convention against bribery of foreign public officials in international business transactions (the “OECD Convention”),<sup>11</sup> the Civil Law Convention on Corruption,<sup>12</sup> and the Criminal Law Convention on Corruption.<sup>13</sup>

In relation to the pharmaceutical industry, the principal objective of the application of anti-corruption provisions is to secure objectivity and professional impartiality concerning the sale, supply and, above all, prescription of medicinal products by healthcare professionals, as well as to prevent any influences on the conduct of healthcare professionals.

### Criminal Code

Bribery and corrupt practices are generally prohibited under Act No. 40/2009 Coll., Criminal Code, as amended (the “Criminal Code”). The Criminal Code regulates three bribery-related criminal offenses (the acceptance of bribes, the offering of bribes and indirect bribery involving public officials).

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<sup>11</sup> The Czech Republic signed the OECD convention on 17 December 1997. The instrument of ratification was deposited with the OECD on 21 January 2000, and in accordance with Article 15(1) of the OECD convention, became effective in the Czech Republic as of 21 March 2000.

<sup>12</sup> The Convention was signed by the Czech Republic in 2000, ratified two years later and became effective in the Czech Republic as of 1 January 2004.

<sup>13</sup> The Convention was signed by the Czech Republic in 1999, ratified the following year and became effective in the Czech Republic as of 1 July 2002.



The Criminal Code refers to the consequences of the acceptance of a bribe:

“Whoever, himself or using another one in relation to procurement of the matters of public interest for himself or for another one accepts, allows himself to be promised a bribe, or whoever himself or using another one in relation to a conduct of his business or someone else’s for himself or for another one accepts or allows himself to be promised a bribe, will be punished by imprisonment for a term of up to four years or by the banning of his activity.”

Similarly, the Criminal Code addresses the consequences of offering a bribe:

“Whoever, in connection with the procurement of a matter of public interest, affords, offers or promises anyone, or for anyone, a bribe, or whoever affords, offers or promises anyone, or for anyone, in relation to a conduct of business, will be punished by imprisonment of up to two years or with a fine.”

There are three basic elements that a prosecutor would need to prove in order to successfully indict an individual under the anti-bribery provisions in the Criminal Code:

1. The payment (or other gratuity) given or accepted must constitute a “bribe.” According to of the Criminal Code, a bribe is an unjust benefit consisting of direct material enrichment or other advantage being provided, or to be provided, to the person being bribed, or, with this person’s consent, to another person, to which the person is not entitled. A bribe can be in monetary or non-monetary form and does not necessarily have to have a monetary value attributable to it. According to precedents in the Czech courts, the amount of a payment (or value of gratuity) is irrelevant with respect to



the criminal liability once the payment (or gratuity) qualifies as a bribe, as defined in the Criminal Code.

2. The bribe must be offered and accepted in connection with the “procurement of a matter of public interest.” The Criminal Code is silent on the meaning of the term “procuring a matter of public interest,” but the Supreme Court of the Czech Republic has ruled that the activity of a physician (healthcare professional) relating to the protection of a patient’s health falls within the purview of a “matter of public interest” for the purposes of the Criminal Code.<sup>14</sup>

In connection, it should be noted that according to the Criminal Code, physicians are not considered public officials solely by virtue of their profession, that is, the provision of medical treatment and other health services in a state hospital, private practice or otherwise, in the Czech Republic. Nevertheless, a physician (healthcare professional) can become a public official if he or she is elected or appointed to a function, such as being a member of the local council or a responsible officer of the local government, or a member of the body of the civil service or other bodies of public administration (e.g., director of the Authority). Furthermore, as indicated below, a physician (healthcare professional) can be held criminally liable for corrupt activities, even if he or she is not deemed to be a public official for the purposes of Czech law, where the physician (healthcare professional) accepts a bribe in connection with a matter of public interest, which, for the purposes of this analysis, would include the provision of healthcare services to the public.

3. The bribe-offering and bribe-taking must be committed intentionally (as opposed to crimes committed by omission). In order for a payment or other benefit to constitute a bribe

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<sup>14</sup> Decision of the Supreme Court no. Rt 13/90 4 TZ 45/88, dated 16 January 1989 (Coll. SC 90,1: 59).



under the Criminal Code, it must be demonstrated that there was intent on the part of the individual participant (or donor) under the circumstances. That is, it would have to be proved to the court that, at the moment of making the payment (or providing another benefit), the person making the payment (or conferring the benefit) expected (and intended) that, in doing so, he or she would be able to influence a matter of public interest.

#### Criminal Liability of Legal Entities Act

Act No. 418/2011 Coll., on Criminal Liability of Legal Entities and Proceedings Against Them (the “Criminal Liability of Legal Entities Act”), sets out selected behavior for which a legal entity may be criminally liable; please note that these are the same criminal acts that are discussed previously in more detail. The Criminal Liability of Legal Entities Act refers to facts in the Criminal Code. This law replaced the long-standing principle of Czech law, under which only natural persons were criminally liable.

A legal entity may be criminally liable for committing criminal acts relating to bribery if the crime is committed in the name, or interest, or in relation to the activity, of the legal entity and if such actions are referable to the legal entity. The actions are referable to the legal entity if the crime was committed by the acting of a body of the legal entity; a person exercising control activities; a person authorized to act on behalf of the legal entity; a person having a controlling influence; or an employee or a person in a similar position (person working on the basis of contracts of work outside of employment) during performance of working tasks ordered by the employer, if the compulsory or necessary checks on the employee’s work or their supervisors and precautions for preventing or averting consequences of the committed crime were not made.

Criminal liability of a legal entity does not exclude criminal liability of a natural person.

## Civil Code

The provisions defining and regulating unfair competition are contained in the Civil Code. The term “unfair competition” is defined as conduct in economic competition that conflicts with good morals of competition and which may be detrimental to other competitors or customers. Such unfair competition is prohibited.

The Civil Code also includes a definition of bribery; however, this definition applies only for the purposes of unfair competition. Accordingly, for the purposes of the Civil Code, bribery does not involve public officials, matters of public interest, or other conditions stipulated in the Criminal Code. Please note that bribery under the Civil Code is not a criminal offense and is not prosecuted by public authorities.

The definition of bribery under the Civil Code means conduct whereby:

- “a competitor offers, promises or renders, directly or indirectly, benefits to an individual who is a member of a competitor’s statutory body (or similar body), or a competitor’s employee (or an individual of a similar status) in order to gain, by means of unfair conduct, an advantage for himself or for another person (competitor) to the detriment of another competitor, or an illegal advantage in competition; or
- the individual referred to above directly or indirectly demands, solicits the promise of, or accepts, any type of benefit for the same purpose.”

## Permitted and Prohibited Practices

### Criminal Code

Given the foregoing, a payment, gift or other benefit provided to a healthcare professional by a distributor of human pharmaceuticals or medical devices, under circumstances where the healthcare



professional prescribes or dispenses the donor's product to patients, could constitute a criminal offense of bribe-offering and/or acceptance of a bribe, provided that the other conditions specified in the Criminal Code (see the discussion under the section on "Criminal Code") are met. It should be noted that the criminal offence of bribery can be committed by both an individual as well as a legal entity.

#### Civil Code

An argument can be made that the provision of payments, gifts or other benefits to healthcare professionals by a distributor of human pharmaceuticals or medical devices, for the purpose of inducing the healthcare professional to recommend or otherwise prescribe such products (as distinct from competing products) to patients, could be considered unfair competition under the provisions of the Civil Code.

#### Public Procurement and Fraud

There is no special criminal offense defined in the Criminal Code in relation to public procurement. However, Section 257 of the Criminal Code prohibits machinations in relation to ordering public procurement and public tendering – which is the prevailing form in which public procurements are organized in the Czech Republic. In addition, persons deciding on tenders organized in relation to public procurement usually hold a public official position and, therefore, can be punished according of the Criminal Code for abusing the function of a public official. Also, the criminal offense of acceptance of a bribe, as earlier defined, would apply to a public official accepting an unjust payment or other benefit in relation to public procurement.

#### Sanctions

##### Criminal Code

In the absence of specific legislation on the issue, only the Criminal Code governs bribery and corruption practices. The punishment of these practices depends on whether the offer of a bribe, or the acceptance of a bribe, was committed (please see the discussion under the section on "Criminal Code").

With respect to the criminal offense of bribery regarding public officials, the Criminal Code describes the consequences of indirect bribery: “Whoever asks for or accepts a bribe to use his influence to affect the exercise of a public official’s powers, or for having done so, will be punished by imprisonment of up to three years.”

#### Civil Law

According to the general rules of Czech contract law, any contract that has been concluded unethically or in violation of a valid law or regulation will be void and unenforceable under Czech law.

#### Civil Code

Under the Civil Code, a person whose rights have been violated or threatened as a result of unfair competition may demand that the violator desist from and immediately cease such improper conduct. This person may also demand appropriate remedy, which may be rendered monetarily, as compensation for damages, and by surrendering any unjust enrichment.

### Contracts with Healthcare Professionals and Medical Institutions

Rendering various professional services by healthcare professionals to pharmaceutical companies is a standard part of interactions between these two groups which include, *inter alia*, lecturing and proctorships, ad hoc expert’s advice and assistance with research. Provision of such services is, in principle, permissible. However, any such agreement on provision of services must not serve as an undue influence of healthcare professionals when prescribing or dispensing human pharmaceuticals.

Further payment of speaker fees to physicians or administrators at scientific congresses or symposia is legally permissible if the compensation is *bona fide* for the actual services rendered by healthcare professionals competent in their field. In this regard, it is important to mention that no such agreements on speaker fees should



be awarded for promotional purposes, as such agreements would be viewed as hidden advertising, prohibited by the Act on Advertising and the Civil Code.

The general rules of the Civil Code regarding contractual law will apply to all agreements between healthcare professionals and pharmaceutical companies and their distributors in the same way as those general rules apply to contracts in any other industry. However, the principles and prohibitions contained in the additional legislation, as described above, also apply to such agreements. Accordingly, the rules representing good clinical practice will apply to any agreement with a healthcare professional in relation to the activities of an investigator in a clinical trial.

However, any contractual relationship between a pharmaceutical company and a healthcare professional in the Czech Republic, the purpose of which is to promote the company and its products or even to induce a particular healthcare professional to prescribe, use, or dispense its products, will be subject to the restrictions and prohibitions mentioned above. Accordingly, a payment (or other benefit) provided to a healthcare professional by a producer or distributor of pharmaceuticals or medical devices on the basis of such an agreement, under circumstances where the pharmaceutical professional prescribes and/or dispenses to patients the particular pharmaceutical or medical device manufactured or distributed by the donor, could constitute a criminal offense of bribe-offering and/or acceptance of a bribe, as the case may be, provided that the other conditions specified in the Criminal Code (see the discussion under the section on “Criminal Code”) are met.

Payment of compensation to physicians for the conduct of clinical or non-clinical studies is lawful if the clinical study complies with the extensive provisions in the Act on Pharmaceuticals and regulation of good clinical practice. Clinical studies must be pre-approved by the Authority, the ethics committee for multi-centric studies, and the ethics committee of the relevant trial site (hospital), and written consent must be obtained from the subjects of the study. Physicians

(investigators) may be compensated, but a written agreement should be entered into between the sponsor of the study and the investigator or hospital, and the relevant ethics committee(s) should review the amount of compensation.

In addition, payments made (or other benefits provided) to healthcare professionals by a manufacturer or distributor of human pharmaceuticals or medical devices, for the purpose of inducing the healthcare professional to recommend or otherwise prescribe such products (as distinct from competing products) to patients, could be considered unfair competition under the provisions of the Civil Code and also a breach of the Chamber rules or other relevant legislation.

## Recommendations

In the event of uncertainty about the legal consequences of any proposed or ongoing advertisement, sponsorship, donation or agreement with healthcare professionals, or any promotional activity directed at healthcare professionals in the Czech Republic, it is strongly recommended that the advertisement be reviewed for compliance with applicable laws and regulations and/or that appropriate, prior consultation be undertaken with the relevant department of the Authority.

As highlighted above, the restrictions and prohibitions regarding promotional activities consisting of the provision of gifts and other benefits to healthcare professionals do not apply when such gifts or benefits are provided to hospitals or other medical facilities as legal entities. However, please see the discussion on the term “healthcare profession” by the Authority, which, if binding, would restrict provision of gifts and benefits to legal entities.

It is strongly recommended that pharmaceutical companies (and their distributors, if applicable) keep accurate and detailed records and accounts of promotional expenditures, and that management should institute measures to ensure that they are advised and kept informed of



any proposed sponsorship, donation or 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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