PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

The following laws govern the promotion and advertising of pharmaceuticals and medical devices in the Czech jurisdiction:

- Act No 40/1995 Coll on the Regulation of Advertising (the 'Advertising Act');
- Act No 378/2007 Coll on Pharmaceuticals (the 'Pharmaceuticals Act');
- Act No 375/2022 Coll on Medical Devices (the 'Medical Devices Act').

The State Institute for Drug Control (SUKL) has published the following guidelines in relation to the advertising of medicinal products and medical devices:

- UST-38: Non-interventional, non-safety post-registration studies – evaluation of promotional material;
- UST-35 version 2: Non-interventional post-registration studies, method of reporting;
- UST-27 version 3: Regulation of Advertising of Human Medicines and Human Tissues and Cells;
- UST-23 version 3: Provision of Advertising Samples of Human Medicines;
- UST-16 version 2: Sponsorship and provision of gifts and other benefits to professionals under the Advertising Act.

Additionally, pharmaceutical industry associations often have their own guidelines or codes that also cover the advertising of medicinal products and medical devices. However, these are not legally enforceable.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

Advertising is generally defined by the Advertising Act – 'advertising' means any announcement, demonstration or other presentation disseminated by means of the communication media, with the aim of promoting a commercial activity, in particular the consumption or sale of goods, the construction, rental or sale of immovable property, the sale or exercise of rights or obligations, the provision of services, the promotion of a trade mark, unless otherwise provided for by law.

More specifically, the advertising of medicinal products for human use means any information, persuasion or inducement intended to promote the prescription, supply, sale, dispensing or consumption of medicinal products for human use. This includes in particular: (1) visits by sales representatives to persons authorised to prescribe, supply or dispense medicinal products for human use; (2) the supply of samples of medicinal products for human use; (3) promoting the prescription, supply and sale of medicinal products for human use by means of a gift, a consumer competition and the offer or promise of any benefit or financial or material reward; (4) sponsoring meetings held to promote the prescription, sale, dispensing or consumption of medicinal products for human use and attended by professionals; (5) the sponsorship of scientific congresses attended by experts and reimbursement of travel and accommodation costs related to their participation.

A similar definition is used also for the advertising of medical devices.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

The competent regulatory body for advertisements of both medicinal products and medical devices in the Czech Republic is the SUKL (see Question 1 above).

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, for exampke food supplements, special nutritional

products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

The Advertising Act specifically addresses advertising of different types of products or services, including foodstuffs, food supplements and infant nutrition products. The rules in this regard in particular cover labelling, providing information to consumers and meeting other requirements laid down in national or European Union (EU) legislation on food and tobacco products, nutrition and so forth. The rules tend to be less stringent than the regulations governing the advertising of medicinal products or medical devices.

In addition, these rules are supervised and enforced by a different competent regulatory body than the advertising of medicinal products and medical devices, namely the State Agricultural and Food Inspectorate.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisement) in your country and if so, which ones?

Advertising to the general public is only permitted for authorised non-prescription medicines for human use that do not require a diagnosis specification or that can be used according to the advice of a pharmacist.

Additionally, medicinal products for human use that contain narcotic or psychotropic substances are prohibited from being advertised to the general public.

On the other hand, advertising a prescription vaccine for which the Czech Ministry of Health has approved a vaccination campaign, towards the general public, is permitted.

Additional requirements for advertising medicinal products to the general public mandate that advertising must:

- be worded in such a way as to make it clear that the product is a medicinal product for human use;
- include the name of the medicinal product as provided in the marketing authorisation;
- contain the necessary information for the correct use of the medicinal product; and
- contain a clear invitation to read the package leaflet carefully.

Advertising to the general public must not, in particular:

- suggest that medical advice, intervention or treatment is not necessary;
- imply that the effects of taking a medicinal product are guaranteed;
- imply that the use of the medicinal product will improve health;
- imply that non-use of the medicinal product may adversely affect the health of individuals (except for vaccines);
- be intended exclusively for persons under 15 years of age;
- recommend a medicinal product by reference to scientists or health professionals;
- imply that a medicinal product is a foodstuff, cosmetic or other product for daily use; and/or
- imply that the safety or efficacy of a medicinal product is guaranteed solely by its natural origin.

Medical devices, or in vitro diagnostic medical devices which, according to the manufacturer's instructions, are intended only for use by a healthcare professional, or may be dispensed only on the basis of a voucher (prescription) or request form issued by a healthcare professional, are prohibited from being advertised to the general public.

Similar conditions to those applicable to the advertising of medicinal products to the general public (see above) also apply to the advertising of medical devices to the general public.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

The general rules on the advertising of medicinal products and medical devices apply equally to advertising via the internet and social media.

For pharmacies selling products online, only non-prescription products may be offered and sold in this way. The general terms and conditions must be displayed on the relevant websites and each medicinal product offered must be identified by its specific registration code.

It is also possible to provide information about prescription-only medicinal products on the internet, provided that the information on a given prescription-only product is accessible only by self-reference (ie, a person

looks it up by themselves) and the advertisement consists only of an accurate representation of the packaging of the given prescription-only product and contains a verbatim and complete version of the information contained in the package leaflet or summary of product characteristics approved under the marketing authorisation.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

No. Prior approval is not necessary. Advertisements may be used freely, provided that they comply with applicable rules.

It is possible to schedule a paid consultation with the SUKL to obtain a statement on the compliance of a promotional activity with the applicable rules. This practice is widely used by healthcare companies, as it provides them with an additional layer of certainty, especially in non-clear-cut cases.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

No. Only medicinal products with a marketing authorisation valid in Czech Republic may be advertised (to healthcare professionals as well as to the general public).

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

Comparative advertising is permitted only if it is addressed to healthcare professionals.

In addition, it must comply with the general requirements for comparative advertising set out in the Czech Civil Code, including:

- it must not be misleading;
- it may compare only products/services meeting the same needs or intended for the same purpose;
- it objectively compares one or more relevant, verifiable and material features of products/services, including the price;
- if comparing products indicated with a designation of origin, it may only compare products of the same designation of origin;
- it does not discredit or take unfair advantage of another competitor, its position, activities or results; and
- it does not offer imitation or replica products/services bearing the competitor's trademark or name.

Since only authorised medicinal products may be advertised, it is not possible to refer to a competitor's product or indication which has not yet been authorised in the Czech Republic, even if such a product has been authorised in another country.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

For the purposes of the rules and requirements on the advertising of medicinal products, healthcare professionals are persons authorised to prescribe or dispense medicinal products (ie, doctors, pharmacists and pharmacy technicians). A similar definition applies to healthcare professionals in relation to the promotion of medical devices.

The Advertising Act imposes the following restrictions on advertisements directed at healthcare professionals:

- Such advertising may only be disseminated through means of communication intended primarily for healthcare professionals (eg, non-periodic professional publications, professional periodicals, professional audiovisual programs).
- The information contained in such advertisements must be accurate, up-to-date, verifiable and complete to enable healthcare professionals to form their own opinion about the therapeutic value

of a given medicinal product (or any clinical benefit or safety and effectiveness of a particular medical device); where appropriate, reference must be made to the relevant publications.
- The advertising must contain information on the authorisation of the particular medicinal product, on its dispensing and on reimbursement by public health insurance.

Furthermore, the Advertising Act prohibits offering, promising or giving gifts or other benefits to healthcare professionals (except for gifts or other benefits of negligible value, which is up to CZK 1,500 per year per professional, or free samples that are not available for sale, provided that these samples are labelled accordingly, and the additional conditions stated below are met).

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

No specific rules in relation to virtual meetings, congresses or symposia are stipulated in the Advertising Act.

However, in its 'Guidelines on Sponsorship and the Provision of Gifts and Other Benefits to Professionals', SUKL states that the participation of experts in virtual scientific congresses, that is, those that take place via remote access and replace or complement the professional events held with the physical participation of experts, is only possible upon paying a participation fee, or by providing a sponsorship contribution to the organiser or promoter of such an event.

Other online interactions are governed by the same rules as the general advertising of medicinal products or medical devices towards healthcare professionals. However, as noted above, advertising toward healthcare professionals may only be disseminated through means of communication intended primarily for them. According to the SUKL, the internet cannot be regarded as one of such means of communication intended primarily for healthcare professionals. If advertising directed at healthcare professionals is carried out through a website, it must be ensured that such a website is mainly visited by healthcare professionals, at least by declaring that the person accessing the website is a healthcare professional within the meaning of the Advertising Act and by confirming that he/she has read the legal definition of a healthcare professional and accepts any associated risks in this regard.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?

The inclusion of endorsements by healthcare professionals, their recommendations or other reference to them in promotional (advertising) materials is prohibited. In particular advertisements to the general public cannot contain recommendations by healthcare professionals, scientists or other persons with a similar role.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

It is possible to provide healthcare professionals with samples of medicinal products, but subject to the conditions below.

Samples of medicinal products or medical devices must be labelled as 'Sample – not for sale' or similar.

Samples of medicinal products may only be provided to persons authorised to prescribe such medicinal products and only upon their written request. In addition, samples may only be provided in their smallest packaging on the market and in limited quantities. SUKL assesses the quantity on a case-by-case basis.

The following medicinal products may not be used for the creation of samples:

- medicinal products containing narcotics and psychotropic substances;
- unauthorised medicinal products, including those whose authorisation has been revoked or has expired;
- authorised medicinal products which have not yet been placed on the market or which have been subject to a prolonged interruption or withdrawal from the market;
- medicinal products for which the conditions and amount of reimbursement have been applied but have not yet been determined.

Marketing authorisation holders are obliged to establish a system to guarantee the records and traceability of each sample provided.

Distributors are obliged to report to the SUKL the supply of samples of medicinal products to marketing authorisation holders or their sales representatives.

Samples of medical devices and in vitro diagnostic medical devices may be provided only in quantities necessary to test these devices in accordance with their intended use.

Gifts and donations to healthcare professionals are prohibited unless their value does not exceed a negligible value (which is, according to the SUKL, up to CZK 1,500) and are relevant to their professional activities.

14. What rules govern the offering of hospitality to healthcare professionals?

The offering of hospitality to healthcare professionals is governed by the Advertising Act and the SUKL 'Guidelines on the Sponsorship and Provision of Gifts and Other Benefits'.

In particular, any hospitality offered to healthcare professionals at a meeting intended to promote medicinal products, or at a meeting held for professional or scientific purposes, must be proportionate. Accordingly, it must be limited to the place and time of the meeting and to the extent necessary for its main purpose. The provision of hospitality must not be extended to persons other than healthcare professionals (ie, family members of the healthcare professionals or other healthcare workers, such as nurses).

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

Any donation in connection with the promotion of the prescription, supply, sale, distribution or consumption of medicinal products for human use (or medical devices) is considered advertising and is subject to applicable requirements. No special regulation exists in this regard, as this is also governed by the Advertising Act.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

No differences exist between the medicinal products and medical devices sectors – any hospitality must be limited to the place and time of the meeting and the extent necessary for its purpose. For more details see Question 14 above.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

Industry associations are typically created as associations representing the interests of legal persons according to the Czech Civil Code. They are funded by the contributions of their pharmaceutical company members. Some industry associations have adopted their ethical codes that also include requirements in relation to the promotion of products. Most notably, the Association of Innovative Pharmaceutical Industry (AIFP) adopted its Code of Practice, which is a collection of ethical rules agreed upon by AIFP members for the promotion of medicinal products to healthcare professionals and interactions with healthcare professionals, healthcare facilities and patient organisations. This Code of Practice implements the Code of Practice adopted by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Patient organisations are associations created in line with the Act on Health Services and are funded by the contributions of their members or by donations.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

Yes. It is possible to subcontract a third party for promotional (advertising) services. The applicable rules in the Advertising Act include the division of liability between the processor of the advertising (the third party) and the advertiser, as well as the obligations to cooperate with the supervisory authority reviewing the compliance.

In case the processor of any advertising creates an advertisement solely for an advertiser, the processor and the advertiser are jointly and severally liable for any violations connected with such advertisements.

The processor may be exempted from liability for the content of the advertisement if the advertisement contains information, the accuracy of which, the processor is unable to assess.

Co-promotion is not regulated under Czech law.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

No. As noted above, transfers of value made by permit/authorisation holders to healthcare professionals are limited to CZK 1,500 per year, per healthcare professional.

In addition, each AIFP member company must disclose and clearly identify any amounts of transfers of value made to healthcare professionals (or healthcare institutions) during a particular reporting period. Value transfers should be classified either as: (1) a contribution to event-related costs (eg, registration fees, travel and accommodation costs); or (2) service and consultancy fees.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

For the provision of gifts or other benefits of more than negligible value (ie, more than CZK 1,500), or for breaching the rules on the provision of hospitality to healthcare professionals, a penalty up to CZK 1m (approximately €40,000) may be imposed.

For violations of rules regarding the content of the advertising of a medicinal product or a medical device a penalty up to CZK 2m (approximately €80,000) may be imposed.

Penalty decisions are typically not published. However, the SUKL regularly publishes an overview of its inspections, stating which company was inspected and whether a violation was found.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

The SUKL is responsible for the enforcement of advertising regulations for both medicines and medical devices, with the exception of television and radio advertising, which is under the supervision of the Council for Radio and Television Broadcasting.

In 2023, the SUKL imposed more than CZK 4.5m in fines for advertising violations, which was significantly higher than in the previous three years.

A competitor whose rights have been threatened or infringed by another competitor's unfair competition may bring a civil action against that competitor for an infringement of the rules on unfair competition, in particular misleading or comparative advertising.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

There are currently no proposed amendments to the Advertising Act or other announced developments in this area.

Recent trends indicate that the SUKL tends to impose higher sanctions in relation to the enforcement of advertising rules in comparison with previous years. The SUKL has been quite active in conducting inspections of pharmaceutical companies for compliance with advertising rules. Moreover, case law regarding the advertising of medical devices is not yet particularly settled in the Czech Republic. Regulations in this respect were only adopted relatively recently and the approach of the SUKL is not yet particularly predictable. Medical device companies should be more cautious and consult with the SUKL on any advertising issues on a regular basis.