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 promotion and advertising of pharmaceuticals (medicinal products) and medical devices is chiefly regulated via the following laws:

- Act No 147/2001 Coll on advertising, as amended (Act on Advertising);
- Act No 362/2011 Coll on medicinal products and medical devices, as amended (Act on Medicinal Products);
- EU Directive 2001/83/EC on the Community Code relating to medicinal products for human use;
- Regulation (EU) 2017/745 on medical devices;
- Act No 578/2004 Coll on healthcare providers, health workers, professional organisations in health and on amendment to certain acts, as amended (Act on Healthcare Providers);
- Act No 250/2007 Coll on consumer protection, as amended;
- Act No 513/1991 Coll on Commercial Code, as amended (Commercial Code);
- Act No 595/2003 Coll on income tax, as amended (Income Tax Act);
- Act No 18/2018 Coll on personal data protection, as amended;
- Act No 452/2021 Coll on electronic communications, as amended (Act on Electronic Communications);
- Act No 40/2015 Coll on audio-visual output, as amended (Act on Audio-visual Output);
- Act No 264/2022 Z z on media services, as amended; and
- Act No 187/2021 Z z on the Protection of Competition, as amended.

The relevant industry and self-regulatory codes are as follows:

- Code of Practice of the European Federation of Pharmaceutical Industries and Associations (EFPIA);
- Code of Conduct of the Association for Generic and Biosimilar Medicines (GENAS);
- Ethical Code of Association of the Innovative Pharmaceutical Industry (AIFP);
- Ethical Code of the Association of Medicinal Products and Medical Devices Suppliers (ADL); and
- Ethical Code for Healthcare Professionals attached as Annex 4 to the Act on Healthcare Providers (HCP Ethical Code).

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

The promotion and advertisement of medicinal products falls under the same definition of advertisement of medicinal products as defined under the Act on Advertising, which includes:

a) advertising which targets the public;
b) advertising which targets persons authorised to prescribe and issue medicinal products (healthcare professionals (HCPs));
c) visits aimed at promoting medicinal products by sales representatives of the holders of a marketing authorisation (MAH);
d) offering samples of medicinal products to the public or persons authorised to prescribe and issue medicinal products;
e) the provision of incentives (other than those of negligible value) to HCPs, such as donations, offers and pledges; and
f) the sponsorship of promotional events and scientific congresses attended by persons authorised to prescribe or issue medicinal products.

The advertising of medical devices is not explicitly regulated under Slovak law, as the definition of medicinal products under the Act on Advertising includes: (1) medicinal products intended for protection against disease, for the diagnosis of disease, for the treatment of disease or for influencing physiological functions; (2) veterinary medicinal products; (3) herbal medicinal products; and (4) herbal veterinary medicinal products.

The advertising of medical devices is subject only to the general advertising rules set out in the Act on Advertising (ie, advertising must comply with competition rules, must not endanger people's mental and physical health, or promote violence). In addition, the general rules on advertising set out in the laws and codes of conduct referenced in the response to Question 1 must be observed (ie, advertising must include

the name of the medical device, and advertising of medical devices must not include data that could lead to a false self-assessment of the state of health).

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 main public authorities responsible for monitoring compliance with the rules on the promotion and advertising of medicinal products and medical devices are:

- the State Institute for Drug Control (SIDC), which supervises the advertising of medicines in accordance with the Act on Advertising;
- the Ministry of Health also monitors compliance with the relevant provisions of the Medicines Act;
- the Media Services Council supervises the broadcasting of advertising, and the sanctions it can impose include a fine or the broadcast of a notice of violation; and
- the Slovak Trade Inspection monitors product placement pursuant to the Act on Audio-visual Output.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

Regulations on the promotion and advertising of medicinal products apply only to products defined as medicinal products under the Act on Advertising, see the response to Question 2.

Similarly, advertising for infant formulae and follow-on formulae is only permitted in publications on infant and young child care and in scientific publications. It must contain scientifically validated and factually correct data.

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 (advertisements) in your country and, if so, which ones?

The advertising of the following medicinal products is prohibited;

- those not registered in the Slovak Republic;
- those containing narcotics, psychotropic substances and preparations;
- the supply of which is subject to a medical or veterinary prescription; and
- the supply of which is not subject to a medical prescription but which are reimbursed by the public health insurance system in Slovakia.

The above ban does not apply to vaccination campaigns authorised by the Ministry of Health or to advertising directed at HCPs.

It is also forbidden to distribute medicines directly to the public for advertising purposes and to distribute antimicrobial veterinary medicines for advertising purposes in any form, including the distribution of samples.

In addition, the advertising of medicinal products must not:

- contain any content that is offensive to human dignity, that hurts national or religious feelings, or that discriminates on grounds of gender, race or social origin;
- promote violence, vandalism or profanity, or incite or condone illegal behaviour;
- depict the nudity of the human body in an offensive manner;
- depict products that are harmful to the environment or to the life or health of humans, animals or plants without explicitly and clearly stating that they are harmful;
- endanger the physical or mental health of citizens;
- present foodstuffs and food supplements as having the effects of medicinal products;
- contain personal data or data relating to the property of persons without their prior consent;
- refer to the statements of other persons without their prior consent;
- interfere with the rights of other persons without their consent; and

- abuse the trust of minors, in particular by (1) encouraging behaviour that could endanger their health, psychological or moral development or (2) showing them in dangerous situations.

Compliance must also be ensured with the general rules on advertising set out in the legislation referenced in the response to Question 1.

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?

There are no specific restrictions and requirements for the electronic marketing of medicinal products and medical devices, and such advertising must comply with the requirements set out in the Act on Advertising. In addition, under the Act on Electronic Communications and the Act on Advertising, the sending of commercial communications by electronic means without prior customer consent is banned (subject to the exceptions provided for in the Act on Electronic Communications).

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)?

Yes, the SIDC monitors the distribution of advertising on the basis of advertising reports submitted by the distributor together with information on the target group and the start date of the advertising campaign (also possible via SIDC's electronic storage). The SIDC requires advertising notifications for all future planned activities on a quarterly basis or at the latest by the start of the advertising campaign.

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

Please see the response to Question 5 above –advertising of medicinal products not registered in the Slovak Republic is banned. This does not apply to vaccination campaigns authorised by the Ministry of Health or advertising directed at HCPs.

Off-label use of medicinal products in Slovakia is possible only following Ministry of Health approval. Off-label use of pharmaceutical products by HCP or healthcare providers without such approval is liable to be sanctioned as an administrative offence under the Act on Medicinal Products.

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 if it complies with the restrictions set out in Section 4 of the Act on Advertising, ensuring it is not misleading, avoids confusion between companies and compares products or services for similar needs or purposes. This applies to advertising aimed at both the general public and HCPs, and requires objective comparisons of products for similar purposes, including the assessment of specific, typical, essential and verifiable characteristics, with the possibility of price comparisons.

Company information (including the brand name) may be used in competitive advertising, but it must not cause confusion, discredit or defame the competitor or take unfair advantage of the competitor's reputation. The advertising of medicinal products which are not registered in the Slovak Republic is banned (see the response to Question 5, above); therefore, it is not possible to refer to a competitor's product or indication that is not yet registered in the Slovak Republic.

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 medicinal product advertising, HCPs are defined as persons qualified to prescribe medicinal products and persons qualified to dispense medicinal products.

The advertising of medicinal products to HCPs must include: (1) essential information on the medicinal product according to the summary of product characteristics; (2) classification of the medicinal product according to the method of administration; and (3) the date of manufacture or update of the material.

When promoting medicinal products to HCPs, the following actions are prohibited:

- visiting HCPs during their working hours for the purpose of promoting medicinal products;
- for HCPs to accept visits from medical sales representatives during the HCP's working hours for the purpose of promoting medicinal products; and
- giving, offering or promising gifts, financial or material advantages or benefits to such persons.

A medical sales representative who promotes medicinal products to HCPs must be trained and have sufficient scientific knowledge to provide the most accurate and complete information about the medicinal product they are promoting. The holder of the marketing authorisation decision is required to provide this training.

During each visit, medical representatives must provide or make available to HCPs a summary of the characteristics of the medicinal product they are promoting. They may also provide information on the price of the medicinal product and the amount and conditions of payment of the medicinal product under public health insurance.

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?

There are no specific restrictions. Online activities are also considered to be advertising for medicinal products and advertising conducted virtually must comply with the above-specified provisions of the Act on Advertising. In addition, under the Act on Electronic Communications and the Act on Advertising, sending commercial communications by electronic means without prior customer consent is banned (subject to the exceptions provided for in the Act on Electronic Communications).

According to the AIFP recommendations for virtual events, advertising activities and the presentation of advertising in virtual professional events is only permitted outside the hours of the virtual professional event.

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

According to the Act on Advertising, the advertising of medicinal products to the general public may not include any element containing a recommendation by scientists, health professionals or well-known persons whose popularity may encourage the consumption of medicinal products.

HCPs may recommend medicinal products as part of their medical practice. However, this recommendation must be made only to the patient concerned, in private and in accordance with the above-specified provisions of the Act on Advertising and other applicable regulations. If an HCP were to recommend a medicinal product to a patient for the purpose of promoting or selling that medicinal product, this would constitute advertising of medicinal products and such conduct would be in breach of the Act on Advertising.

Furthermore, under the HCP's ethical code, which is legally binding for each HCP, when prescribing and recommending medicinal products, medical devices the HCP must not be guided by commercial considerations, but exclusively by science, professional judgement, their conscience and the needs of the patient.

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.

Samples of medicinal products may be provided by the holder of a decision on registration, on the basis of a written request, to HCPs only, up to a maximum of two samples per year of the smallest packaging of the registered medicinal product, marked 'FREE MEDICAL SAMPLE – NOT FOR SALE' and accompanied by a summary of the medicinal product's characteristics.

It is prohibited to: (1) provide samples of medicinal products containing narcotics or psychotropic substances; and (2) provide samples of medicinal products directly to patients. Samples may only be provided to a person authorised to prescribe the medicinal product in question, provided that the detailed requirements set out in the applicable legislation are met.

Medical devices

We are not aware of any specific regulations that permit or prohibit the distribution of medical device samples to patients or HCPs.

Gifts

The provision of gifts or donations to HCPs is very strictly regulated. According to the Act on Medicinal Products, holders of a marketing authorisation for medicinal products, holders of a licence for wholesale distribution of medicinal products, and holders of a licence to provide pharmaceutical care are banned from granting or receiving rebates in kind and banned from directly or indirectly encouraging, inducing or influencing the prescribing of HCPs in any way when prescribing medicinal products, medical devices or dietetic foods.

HCPs are also required to comply with the HCP Ethical Code, as Section 9 of the Ethical Code stipulates: 'When prescribing and recommending medicinal products, medical devices and dietetic foods, the HCP shall not be guided by commercial considerations but solely by science, professional judgement, his/her conscience and the needs of the patient'.

In addition, the relevant provisions on corruption, passive bribery and active bribery under Act No 300/20005 Coll of the Slovak Criminal Code, as amended, apply.

The provision of monetary and non-monetary benefits to HCPs, including benefits in the form of gifts, is also subject to income tax for both natural and legal persons. According to the Methodological Instruction of the Financial Administration of the Slovak Republic, the provision of medicinal products and medical devices is also taxable income.

Under the Income Tax Act, manufacturers and distributors of medicinal products and medical devices are required to report to the tax authority the amount (value) of benefits in kind provided to HCPs and healthcare organisations (HCOs).

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

Hospitality at promotional events must be strictly limited to the purpose of the promotional event and may only be provided to HCPs. However, this provision does not prevent the direct or indirect provision of hospitality at events intended solely for professional and scientific purposes, provided that such hospitality is always strictly limited to the main scientific purpose of the event and is not provided to persons other than HCPs (maximum 20 per cent of the total time of the event and must comply with the provisions of the Act on Advertising). The time required for travel and overnight accommodation is not included in the total time of the event.

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?

Yes, donations can be considered a promotional (advertising) activity, as according to Section 8(2) of the Advertising Act, the advertising of medicinal products also includes: (1) offering samples of medicinal products to the public or to persons authorised to prescribe and dispense medicinal products; (2) providing incentives (other than those of negligible value) to HCPs, such as donations, offers and promises; and (3) sponsoring promotional events and scientific congresses attended by HCPs.

Please refer to our response to Question 13 above, on gifts and income tax obligations.

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?

The sponsorship of promotional events and scientific congresses attended by persons authorised to prescribe or dispense medicinal products falls under the definition of advertising of medicinal products and must comply with the rules of the Act on Advertising. There is no difference between these two sectors from the point of view of advertising rules.

Please refer to our response to Question 14 above, on hospitality at scientific and educational meetings.

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

The relationships between the pharmaceutical industry and patient organisations must be conducted ethically and transparently. Where applicable, the reporting rules outlined in our response to Question 15 apply. Otherwise, the applicable rules follow the relevant industry and self-regulatory codes. The tax liability of the organisation depends on its legal form.

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 delegate promotional (advertising) activities to a third party through a service agreement. In such an agreement, the MAH has to follow the rules on the documentation of a medicinal product or medical device, rules on gifts, hospitality, samples and ensure other compliance.
Co-promotion is not explicitly regulated. The MAH must follow the rules on promotion of medicinal products set out in the Advertising Act (as referenced above in our responses to questions 5, 6, 8 and 9).

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

Yes, please refer to our responses to questions 13 and 15, above.

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?

Penalties include a ban on advertising and a fine of up to €166,000, which can be imposed for various misdemeanours, such as the illegal use of comparative advertising, violating the ban on advertising medical products (Article 8(4) of the Advertising Act), violations of the formal rules for advertising medicinal products, and violations of the rules on objective information and false advertising.

The supervisory authorities tend not to be particularly aggressive, but they do impose several penalties and sanctions each year, depending on the severity of the uncovered breach. Decisions are not public, but can be obtained through an access to information request.

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 SIDC supervises the advertising of medical products in accordance with the Act on Advertisement. The Ministry of Health also monitors compliance with the relevant provisions of the Act on Medicines (some of which also cover advertising). The Council for Media Services supervises the broadcasting of advertising, and the sanctions it can impose include a fine or the broadcasting of a notice of violation. The Slovak Trade Inspectorate monitors product placement under the Act on Audio-visual Output.

The rules set out in the relevant laws are enforced and, in the event of evidence of damage, competitors can take direct action through the courts in relation to promotion (advertising) infringements.

It is also worth noting that in Slovakia, major media outlets and broadcasters are members of *Rada pre reklamu* (the Advertising Standards Council), an independent advertising self-regulatory organisation (SRO). The main objective of the SRO is to enforce and promote honest, decent and truthful advertising in Slovakia. This SRO can, on any third-party petition, declare advertising to be unethical by a decision of the Arbitration Commission. Such advertising may then no longer be published or broadcast by Advertising Standards Council members, effectively resulting in a ban.

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?

New medical device legislation is planned, but details are yet to be published.

In terms of enforcement trends, it is evident that due to understaffing issues, the main focus of regulators has been on issuing notifications to competitors and other parties.