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 advertising of medicinal products and medical devices in Poland is governed by both statutory law and soft law.

With respect to statutory law, the advertising of medicinal products and medical devices is governed by:

- The Pharmaceutical Law Act of 6 September 2001;
- The Regulation of the Minister of Health of 21 November 2008 on the advertising of medicinal products;
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices;
- The Medical Devices Act of 7 April 2022; and
- The Regulation of the Minister of Health of 21 April 2022 on the advertising of medical devices.

With respect to soft law, the following self-regulatory codes are in force regarding the advertising of medicinal products included in codes of conduct adopted by industry associations:

- The Code of Good Practice of INFARMA (the Employers' Association of Innovative Pharmaceutical Companies) – Polish adaptation of the EFPIA Code of Practice;
- The Ethical Code of the Polish Association of Pharmaceutical Industry Employers – Polish adaptation of Medicines for Europe Code of Conduct;
- The Code of Ethical Business Practice of Medtech Poland and POLMED Chamber of Commerce – Polish adaptation of Medtech Europe Code of Ethical Business Practice.

Codes of conduct are only binding on members of the relevant associations, but in practice, they have an impact on setting market standards.

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

Generally, the approach towards advertising is broad and covers a wide spectrum of activities which may lead to an increase in demand and/or consumption.

With respect to pharmaceuticals, the Pharmaceutical Law Act defines advertising as 'any activity that involves providing information about or encouraging the use of a medicinal product with the aim of increasing the number of prescriptions written and the supply, sale or consumption of medicinal products.'

Regarding medical devices, Polish statutory law does not define advertising separately. Therefore, in this context, it should be defined in accordance with the meaning attributed to it in administrative courts jurisprudence ie, as any action that is intended to encourage potential customers to make a purchase decision. In practice, a statement is treated as an advertisement when the information is dominated by an incentive to purchase the product and this is how it is perceived by the average person to whom it was addressed.

Polish law does not distinguish between 'advertising' and 'promotion' either with regard to pharmaceuticals or medicinal devices. Consequently, promotional activities are subject to the rules concerning advertising.

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?

Regarding the advertisement of pharmaceuticals, the relevant authority is the Chief Pharmaceutical Inspector and with respect to advertising of medical devices – the President of the Office for Registration of Medicinal Products and Medical Devices.

Industry organisations introduce verification procedures and may impose sanctions, however only on their members. Such sanctions are agreed beforehand by the members of a given organisation and introduced in a self-regulatory code, so that members know what to expect in case of a violation.

The Chief Pharmaceutical Inspector and the President of the Office for Registration of Medicinal Products and Medical Devices are independent public authorities overseeing the market and imposing statutory sanctions regardless of whether the sanctioned entity is a member of any organisation. As a rule, public authorities and industry associations act independently. However in some cases, industry associations may notify the authorities about detected irregularities which violate the law.

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?

The advertising of other health-related products such as food supplements falls under a separate regime in Polish law. At this point, the rules for advertising and promoting food supplements have not been codified and they are only partly regulated by the Food and Nutrition Safety Act of 25 August 2006. Due to the rapid growth of the market, in the first quarter of 2023 the Polish government presented a draft of new regulations regarding advertising of dietary supplements. However, work on this project has not been completed and there to date, no reports for continuing legislative work in this regard (the project appears to have been abandoned). Advertising of dietary supplements is, however, subject to industry self-regulation, for example, included in the Code of Good Practices of the National Council of Supplements and Nutritional Foods (KRSiO).

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?

Polish law narrows the entities to which advertising of certain healthcare products can be directed. Pharmaceutical Law provides that advertising may not be directed to the public for medicinal products, which are:

- prescription only;
- controlled substances (narcotics or psychotropic substances); or
- reimbursed from public funds.

These medicinal products may only be advertised to professionals, that is, persons authorised to issue prescriptions or persons trading in medicinal products.

The Medical Devices Act bans the advertising to the public of medical devices intended for use by users other than laypersons. Such medical devices may only be advertised to professionals.

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?

Although Polish law does not include specific rules for promoting pharmaceuticals and medical devices online, general regulations for advertising such products apply to online promotional activities. For example, the use of images of healthcare professionals in medical device adverts and medicinal products directed at the public is not permitted. In addition, all mandatory warnings (eg, on the need to read the patient information leaflet and consult a doctor, if needed) must be included.

Self-regulatory industry codes acknowledge the use of online advertising channels and urge members to follow the general advertising rules. Such codes emphasise that companies should pay special attention to site security if these are to be targeted only at professionals. The Medicines for Europe Code requires having an internal policy for employees' use of social media, to control the target of the advertising. In September 2022, the President of the Competition and Consumer Protection Office published guidelines (soft law) regarding cooperation with social media influencers, where good practices are specified for the clear designation of influencer content sponsorship. Following these guidelines is helpful as regards the statutory requirement to provide information about sponsorship where users provide their opinions about for example, a medical device in connection with a received benefit.

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)?

Polish law does not require any prior approval of promotional materials from regulatory authorities, both in respect of pharmaceuticals and medical devices. Polish law does require that outsourced medical device promotion, such as adverts, must be approved by the outsourcing entity prior to dissemination. Industry codes of good practice regulate the requirement of introducing systems of internal company approvals of advertising materials before they are disseminated.

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

No, unauthorised medicinal products (eg, prior to obtaining marketing authorisation) can be the subject of advertising in Poland, and advertising the medicines for off-label use is prohibited. Information on unauthorised medicines and off-label information may be published only provided such information does not have the characteristics of medicinal product advertising. Data must come from medical or scientific literature, published research or scientific evidence presented at conferences, conventions or scientific congresses.

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 allowed, yet extreme caution must be taken when preparing such adverts because they are subject to more stringent rules than for other forms of advertising. Using another company's brand name for comparative advertising is permissible only if it is not contrary to good practice. The regulations list the requirements which must be met in order to determine that the advert is not contrary to good practice. In brief, the characteristics of the product must be compared in an objective and verifiable way. The specific rules concerning comparative advertising also apply even if a brand name is not used but it is still possible to identify the competitor's product.

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?

Under the Pharmaceutical Law Act, healthcare professionals are to be understood as persons authorised to issue prescriptions or persons trading in medicinal products. There are specific requirements regarding medicines promotional communication to professionals. Such communications must contain the required scope of information regarding the product characteristics. Information regarding the product must be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicinal product.

Under the Medical Devices Act, healthcare professionals should be understood as persons who have a formal education in a relevant field of healthcare or medical discipline. Medical devices promotional communication addressed to such persons must not be misleading, must be consistent with the instructions for use and contain the required scope of information regarding the device.

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 statutory rules regarding virtual interactions with healthcare professionals – general rules on advertising of medicinal products and medical devices apply. The Medicines for Europe Code of Conduct mentions that companies must not provide or fund any food or drinks for individual virtual attendees at a meeting.

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?

Yes, such restrictions exist regarding both advertising of pharmaceuticals and medical devices. The Pharmaceutical Law Act stipulates that advertising of a medicinal product to the general public cannot include references to recommendations of scientists and persons with medical or pharmaceutical education or suggest that they have such an education.

The Medical Devices Act mentions that advertisement of a medical device cannot include an image of a healthcare professional, person claiming to be a healthcare professional, or person presenting a medical device in a way suggesting that they practice such a profession.

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.

Both the Pharmaceutical Law Act and the Medical Devices Act allow the supply of free samples, provided certain conditions are met.

Regarding pharmaceuticals, such samples may not be of medicinal products containing narcotic drugs, psychotropic substances and chemicals with potential use in narcotic drug production. Where the recipient of such advertising is a pharmacist, it can also only involve medicinal products issued without a prescription. Provision of such samples can only be directed to persons authorised to write prescriptions, provided that:

- a person authorised to write prescriptions has sent a written request to a medical or sales representative to supply samples of a medicinal product;
- the person supplying samples keeps documentation of the samples supplied;
- each sample supplied is not larger than the smallest package of a medicinal product approved for sale in Poland;
- each sample supplied is marked 'free sample – not for sale';
- the summary of product characteristics ('SmPC') or the Veterinary SmPC for a veterinary medicinal product is attached to each sample; and
- the number of samples of the same medicinal product supplied to the same person is not more than five packages in one year.

Gifts are only allowed on an exceptional basis, provided that they are valued at under PLN 100 and relevant to the practice of medicine or pharmacy and bear the logo of a company or of a medicinal product.

With respect to medical devices, the supply of free samples is permitted, however, subject to the general requirements on advertising of such products.

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

General rules governing the offering of hospitality to healthcare professionals are stipulated in the Pharmaceutical Law Act. These state that manifestations of hospitality must not exceed the main purpose of the meeting. It makes no difference whether the hospitality takes place in Poland or abroad. Also, the law does not require approval to be obtained from the company affiliate in the country where the healthcare professionals reside for offering such hospitality. Codes of good practice regulate the limit of costs for hospitality or meals. For example, the INFARMA Code of Good Practice specifies a limit of PLN200 (approximately US$50) to cover costs of meals at meetings in Poland and €100 abroad.

The Medical Devices Act does not include any specific rules regarding offering hospitality to healthcare professionals.

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?

Statutory law does not provide for a specific regulation on donations to healthcare organisations, however general anti-bribery regulations must be taken into consideration. The Pharmaceutical Law Act does not specify donations as not being a promotional tool. However, the INFARMA Code of Good Practice states that they must not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicinal products. It also specifies that such donations are only allowed if: (1) they are made for the purpose of supporting healthcare, research or education; and (2) they are documented and kept on record by the donor.

According to the Medtech Code of Ethical Business Practice, a member company cannot make a charitable donation to support the general running of a hospital or other healthcare organisation. A charitable donation may only be given to a legal entity or body which has charitable and/or philanthropic purposes as its main objects.

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?

Both pharmaceutical companies and medical device manufacturers can sponsor scientific or educational meetings.

Regarding pharmaceutical companies, such activity is specified in the Pharmaceutical Law Act as a form of advertising.

Regulations regarding medical devices also allow sponsoring of educational events as a form of advertising. Where medical devices are advertised during such an event, it must be indicated that the communication is an advert, unless it is obvious.

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

Neither the pharmaceutical nor medical device industry are regulated by statutory law, as regards this area.

With respect to pharmaceutical companies, the codes of good practice are of crucial significance. For example, the INFARMA Code of Good Practice states that donations for patient organisations (in cash or in kind or otherwise) are only allowed if: (1) they are made for the purpose of supporting healthcare, research or education; (2) they are documented and kept on record by the donor; and (3) they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicinal products.

According to Medtech Europe Guidance on interactions between the medical technology industry and Patients' Organisations, all collaborations should have a legitimate need. This includes a clearly identified patient benefit, and should never be used to induce or encourage the use of MedTech Europe member companies' products or services, nor to seek confidential information.

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 activities to a third party through a service agreement both with regard to the pharmaceutical and medical device industry. When it comes to advertising of medicinal products, the Pharmaceutical Law Act does not specify the form in which advertising is to be delegated. On the other hand, outsourcing of advertising requires written approval of adverts by the operator concerned.

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

No, there is no specific statutory requirement to report information about transfers of value to healthcare professionals and organisations (operating in both the pharmaceutical and medical device industry). However, with respect to transfers of value by the entities operating within the pharmaceutical industry, self-regulatory organisational principles often impose obligations.

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?

In the event of a breach of the rules regulating the advertising of medicinal products, the Chief Pharmaceutical Inspector may issue a decision ordering the company:

- to cease the showing or running of medicinal product advertisements that violate applicable regulations;
- to publish the decision in places where such was shown and provide a correction of the misleading advertisement; or
- to rectify the infringements.

Furthermore, pharmaceutical advertising breaches may result in fines.

Similarly, in the event of a breach of the rules regulating the advertising of medical devices, the President of the Office for Registration of Medicinal Products and Medical Devices may issue a decision ordering:

- the rectification of the infringements found; or
- the cessation of the publication, appearance or conduct of the advertising in question; or
- publication of the issued decision in places or media in which the given advertisement appeared.

The relevant authority may impose very high administrative fines for violating the medical devices advertising regulations (up to PLN5m ie, €1.2m).

Furthermore, the President of the Competition and Consumer Protection Office may impose administrative fines which may be severe. For example, in August 2023, in a case of the surreptitious advertising of dietary supplements through social media, one such fine amounted to PLN5m. Such decisions are publicised.

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 authority responsible for enforcing regulations regarding advertising of medicinal products is the Chief Pharmaceutical Inspector, who tends to interpret the regulations strictly. Competitors may report irregularities to this authority to initiate proceedings or pursue claims in court for advertising which violates competition law. The President of the Office for Registration of Medicinal Products and Medical Devices enforces medical devices advertising regulations. So far, no enforcement decisions have been issued as the medical devices advertising regulations are new, coming into force in mid-2023.

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?

The most noteworthy development in the area of enforcing rules on advertising of medicines is the practice of stopping the dissemination of advertisements while proceedings are still ongoing and before the Chief Pharmaceutical Inspector issues its decision, due to the fear of any negative impact on the company's image as a result of the publication of an infringement decision.

Last year brought an amendment to some of the regulation's provisions, introducing a new warning about the safety of medicinal products. Previous warnings had been on the market for 15 years and advertising recipients were accustomed to their content, with weak reactions when reading these warnings. The new warnings, with three different versions, are intended to build a desirable habit among the public of having to read patient information leaflets. Also, market practice reveals a tendency for pharmaceutical companies to make public data on the benefits provided to healthcare professionals, which has not been required by Polish law so far but is mainly self-regulated by the pharmaceutical industry.

The medical devices advertising regulations have only been in force since mid-2023. Consequently, the industry awaits the first decisions regarding advertising of medical devices to be issued by the President of the Office for Registration of Medicinal Products and Medical Devices.

Advertising of health-related products on social media is under scrutiny of the President of the Competition and Consumer Protection Office and the fines are high. For example, in August 2023, in connection with a case of surreptitious advertising of dietary supplements through social media, one such fine amounted to PLN5m.