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.

In Estonia the advertising of medicinal products is regulated mainly by two legal statutes – the Advertising Act and the Medicinal Product Act (MPA). The Advertising Act provides the requirements, prohibitions, and restrictions established for advertising in general. Specific requirements for advertising of medicinal products are stipulated in the MPA (sections 82–86). The MPA is the main legal Act regulating the field of medicinal products in Estonia and is based on the Directive 2001/83/EC.

The Medical Devices Act (MDA), the Regulation (EU) 2017/745 on Medical Devices (MDR) and the Advertising Act govern the promotion of medical devices. The MDR is directly applicable at the national level.

Furthermore, within the field of pharmaceutical advertising, there are several self-regulatory mechanisms, for example, the Code of Ethics of the Association of Pharmaceutical Manufacturers in Estonia and the Code of Ethics of the Estonian Medical Association, with a particular focus on governing the involvement of physicians in pharmaceutical advertising.

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

According to the Advertising Act 'advertising' means information which is made public in any generally perceived form for a charge or without charge for the purpose of increasing the provision of services or the sale of goods, promoting an event or directing the conduct of a person in public interests.

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 State Agency of Medicines (SAM) regulates and enforces the promotion and advertisement of pharmaceuticals and the Health Board (HB) regulates and enforces the promotion and advertisement of medical devices.

There is no direct relationship between the self-regulatory process and the supervisory and enforcement function of the competent authorities. Self-regulatory codes usually specify requirements of the legal Acts and, in some cases, are even stricter than law or provide additional obligations. Such self-regulations cannot be enforced by the competent authorities.

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

There are specific rules for advertising of food supplements and special nutritional products, however, they are not as strict as the advertising rules for the pharmaceuticals. In general, the standard advertising rules apply, as well as specific rules for the use of health statements (in the same way as in the European Union).

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?

In Estonia, it is prohibited to advertise prescription only products to the general public. The prohibition does not apply to vaccination campaigns approved beforehand by the SAM and the HB.

Under the MPA, only pharmaceuticals classified as over-the-counter medicines can be advertised to the general public. Only the medicinal products for which a marketing authorisation is valid in Estonia may be

advertised. Teleshopping of medicinal products is prohibited. It is also prohibited to supply samples of medicinal products, to sell or give away items connected to medicinal products or to organise raffles or lotteries related to medicinal products for such persons, and to offer such persons other medicinal products, goods or services free of charge or at a discount rate in connection with the purchase of a medicinal product. There are specific requirements and restrictions by type of advertisement to which the advertisement must comply (including the information and warnings that must be included; and specification as to which claims are not allowed, etc).

Additionally, general requirements and restrictions of the Advertising Act apply including:

- prohibition of misleading advertisement;
- prohibition of advertisement of healthcare services;
- the requirement that outdoor advertisements and notices must be in the Estonian language;
- rules for use of comparison in advertising;
- protection of persons and property in advertising;
- advertising of goods and services which are technically complex, contain hazardous substances or require special operating skills;
- advertising directed at children and use of children in advertising; and
- advertising in media services and video-sharing platforms.

Regarding medical devices, there are no specific restrictions (in addition to general principles from the Advertising Act) for advertising of medical devices to the general public in Estonia.

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?

Advertising of medicinal products to the general public over the internet is permitted. However, all requirements for advertising of medicinal products to the general public (see Question 5 above) apply.

The advertising of medicinal products subject to medical prescription over the internet is permitted only if access to the information is limited to persons qualified to prescribe medicinal products, dispensing chemists and pharmacists and must comply with the MPA.

There are no restrictions in the Estonian legislation for advertising pharmaceuticals and medical devices online (in social media, by influencers). All general requirements and restrictions apply to any channel, method or type of advertising.

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)?

Promotion and/or advertisements (excluding vaccination campaigns) do not require prior approval from regulators. The SAM does not approve advertisements before they are made public, however, it can give its interpretation of advertising legislation. The interpretations do not have a legally binding nature and do not exclude liability.

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

The promotion of information on unauthorised pharmaceuticals and off-label information is generally not allowed.

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 advertisements must follow the rules set out in the Advertising Act. The comparison in the advertisement must be based on one or several relevant material and verifiable features of the compared goods or services, which may also include price.

The use of a competitor's trademark, name, goods or other distinguishing marks in comparative advertising is not prohibited, provided that it is intended solely to distinguish between the goods being compared and to highlight objectively the differences between them. Comparative advertising must not cause confusion, exploit the reputation of the trademark, name or other features of a competitor or the designation of origin

of the competing goods, or present goods and services as imitations or copies of the goods and services covered by the protected trademark.

Reference to a competitor's product or indication which has not yet been authorised in Estonia is generally not allowed.

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?

Healthcare professionals (HCPs) are doctors, dentists, nurses and midwives if they are registered with the Health Board. In the context of the MPA, pharmacists and assistant pharmacists providing pharmacy services in a general pharmacy or hospital pharmacy are also considered HCPs, provided that they have been registered in the health administration information system.

The MPA regulates requirements and restrictions of advertisement and other promotional activities (gifts, support, events) directed to HCPs. It also regulates the content, and how such information should be presented to the HCPs about the medicinal products. For example, references taken from scientific works to be used in advertising of medicinal products must be presented without amendments and be supplied with references to the source documents; the up-to-date summary of product characteristics of the medicinal product must be available etc.

Only an authorised representative of a marketing authorisation holder (MAH) in possession of complete information about the properties of the medicinal product is permitted to advertise the medicinal product by means of personal communication or at events. A leaflet advertising a medicinal product must include the summary of the product's characteristics, or at least the information needed for issue of a medical prescription.

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?

General principles regarding the specific promotional and advertising activity apply independent of the means used for communication.

Advertising of medicinal products subject to medical prescription over the internet is permitted only where access to the information is limited to persons qualified to prescribe medicinal products, pharmacists and assistant pharmacists. The advertiser must register users, verify that they belong to the category of persons mentioned above and ensure that only those persons have access to the advertisement. Advertisements for prescription-only medicinal products disclosed in this way must comply with the requirements laid down in the MPA and contain a summary of the product's characteristics.

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?

If the advertisement is addressed to the general public, it is prohibited to include recommendations by scientists or HCPs that encourage the consumption of medicinal products.

There are no explicit rules in this regard for advertisement of medical devices, however, the general prohibition of advertisement of healthcare services and the Code of Ethics of the Estonian Medical Association must be considered.

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

It is permitted to provide HPCs with samples of medicinal products. Only a MAH or an authorised person of the MAH may handle and distribute samples. One HCP may be provided with up to five samples of medicinal products each, no larger than the smallest presentation on the market, and the number of samples provided per year must not exceed 300 within two years as of the provision of the first sample or approval of a new

indication of the medicinal product. All activities regarding samples must be documented and documents retained.

Samples of prescription medicinal products can only be given to qualified prescribers with a signed request. It must be noted that no samples of narcotics, psychotropic drugs, or antibiotics can be provided to anyone.

New strength or size of the packaging of the same active substance without a new indication does not give the right to provide new samples. Each sample of a medicinal product must be marked with the words '*Mitte müügiks*' ('Not for sale'), the package must conform to the marketing authorisation and each sample must be accompanied by a copy of the summary of product characteristics. It is prohibited to sell samples of medicinal products and to transfer them for non-medical purposes.

Provision of samples of medical devices is not restricted, however, general anti-corruption (including private sector corruption) regulations must be considered.

Gifts and donations

MAHs, their authorised persons and third parties are prohibited to give gifts and provide services the value of which exceeds €6.40 to HCPs, pharmacists and assistant pharmacists, and such persons are prohibited from accepting such gifts or services. Pecuniary gifts are prohibited. Gifts must be relevant to the corresponding professional practice of the persons and must not be connected to the sale or prescription of specific medicinal products or medicinal products manufactured by a specific manufacturer.

Provision of gifts the value of which exceeds €6.40 is only permitted for participation in medical or pharmaceutical events organised by a research institution (RI) or professional organisation (PO) as follows:

- compensation for the fee for participating in the scientific part of the event;
- compensation for accommodation and transport costs (to a reasonable extent);
- compensation of the above costs must not extend to other persons except HCPs, pharmacists and assistant pharmacists; and
- such support must be granted exclusively under conditions which must be made public and which must not be connected to the sale or prescription of specific medicinal products or medicinal products manufactured by a specific manufacturer, and the parties are required to enter into a written contract to such effect, precluding any inducement of the sale or prescription of medicinal products.

There are no specific requirements or restrictions for gifts and support by medical device manufacturers or their licensees. General anti-corruption (including private sector corruption) regulations apply.

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

Where a MAH organises a scientific event intended for HCPs, pharmacists or assistant pharmacists, hospitality offered at such events, including entertainment, must remain within reasonable limits, be strictly limited to the main scientific objective of the event, and must not be extended to persons other than those mentioned above. Information provided concerning medicinal products at such events must comply with the requirements set for advertising medicinal products.

Hospitality at other face-to-face interactions is not explicitly regulated, however, general anti-corruption regulations and inducement restrictions apply. If a face-to-face interaction does not qualify as an event (for example, meeting with an HCP), MAHs are prohibited from providing gifts, services and/or other benefits value of which exceeds €6.40.

The Code of Ethics of the Association of Pharmaceutical Manufacturers in Estonia states additional or more detailed requirements and restrictions (for example, cost per meal etc).

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?

The donations made by MAHs to healthcare institutions or organisations are considered as a promotional tool (as it is regulated in the MPA). A MAH has the right to support a medical or pharmaceutical event organised by a RI or PO, provided that a contract is concluded between the MAH and the organiser of the event, precluding any influence that the MAH might have over the program.

Donations are also mentioned in the Code of Ethics of the Association of Pharmaceutical Manufacturers in Estonia. General anti-corruption (including private sector corruption) regulations apply.

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?

Pharmaceutical laboratories or their licensees have the right to support scientific or educational meetings. General anti-corruption (including private sector corruption) regulations apply. In case information about pharmaceutical products are shared at the event, advertisement rules for medicinal products must be considered, independent of the organiser of the event.

There are no specific restrictions for the promotion of medical devices via supporting scientific or educational meetings by medical device manufacturers or their licensees. General anti-corruption (including private sector corruption) regulations apply. There is no significant difference between these two sectors from the perspective of rules on the provision of support.

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

General anti-corruption (including private sector corruption) regulations and rules of advertisement of medicinal products apply.

Members of the Association of Pharmaceutical Manufacturers in Estonia (APME), their subsidiaries, and any companies affiliated with APME member companies or their subsidiaries must adhere to principles agreed upon by the European Federation of Pharmaceutical Industries and Associations and pan-European patient organisations. These principles ensure:

- the independence of patient organisations in political judgement and activities;
- cooperation based on mutual respect;
- no promotion of specific products by patient organisations, nor requests for such promotion from pharmaceutical companies/MAHs;
- transparency in cooperation objectives and scope, with clear acknowledgment of financial support; and
- encouragement of diverse funding sources for patient organisations.

If pharmaceutical companies/MAHs grant financial support, indirect support, and/or support in kind to a patient organisation, the companies must have a written contract regarding the granted support. The amount and objective of the support (eg, general support, support for a specific meeting or publication, etc) must be set out in the contract. The contract must also include a description of the indirect and support in kind.

Pharmaceutical companies/MAHs sponsoring patient organisations must not influence sponsored materials to promote their business interests. Upon request, pharmaceutical companies/MAHs can participate in text preparation from a fair and balanced scientific standpoint.

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?

Under Estonian legislation, it is possible to delegate promotional advertising activities to a third party through a service agreement. Co-promotion specifically is not explicitly regulated, however, all parties involved in providing and/or publishing advertisement of medicinal products can be held liable for violations.

It must be mentioned that the third party must follow all the restrictions and requirements set for the advertisement of medicinal products and medical devices in the Advertising Act, MPA and other legal Acts.

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

Recently, the yearly reporting obligation of transfers of value was dropped, therefore, it is no longer mandatory to report transfers of value to the SAM. All support granted to HCPs, pharmacists, or assistant pharmacists as well as the expenses made in connection to the events specified above must be still recorded in the documentation of the local representative or local branch of the MAH. Upon respective request by the SAM, the MAH must submit all documents and information related to the transfers of value.

Under the Code of Ethics of the APME, transfers of value by pharma companies must be published on the website of the MAH. The Code of Ethics does not apply to medical device manufacturers.

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?

The placing, producing or publicising of advertising which violates the requirements for advertising of medicinal products, or for violation of the prohibition on inducement designed to promote prescription or sales of medicinal products, if committed by a legal person, is punishable by a fine of up to €32,000. The supervisory authority may issue administrative orders and, upon failure to comply with an administrative order, impose the non-compliance levy, upper limit of which is €9,600 (which may be imposed repeatedly).

According to the Advertising Act, the placing, producing or publication of advertising which violates the general requirements for advertising, if committed by a legal person, is punishable by a fine of up to €400,000. The supervisory authority may issue administrative orders and, upon failure to comply with an administrative order, impose the non-compliance levy, upper limit of which is €3,200 (which may be imposed repeatedly).

Supervisory authorities do not impose penalties and other sanctions very actively. Usually, penalties and other sanctions are not announced publicly, however, public information is available in the document registry of the authority and upon 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 SAM is responsible for enforcement of promotion and advertisement regulations of pharmaceuticals and the HB is responsible for promotion and advertisement regulations of medical devices. The rules are enforced strictly, however, sanctions are imposed dependent on circumstances. Often warnings and administrative orders for ensuring compliance are issued, fines and other more serious sanctions are usually imposed in case of intentional and serious violations.

The competitors have the possibility to take direct action through the courts in relation to promotional infringements, however, this is rather rare and is not a widespread practice. To ensure the compatibility of the rules, the competitors can, and do, lodge complaints to the relevant state supervisory authority.

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?

As the last amendments to the MPA regarding the advertisement of medicinal products came in force in 2023 and some amendments enter into force in 2024, there is no significant development to be expected in the next year.

The amendments in relation to advertisement of medicinal products were aimed at modernising the conditions for advertising and promotion of medicinal products: liability for compliance was extended to publishers and service providers involved in advertising of medicinal products; and the yearly reporting obligation of advertisement and promotion activities (including transfers of value) was dropped.