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 pharmaceuticals is governed by:

- the Advertising Law;
- Regulation No 378, 'Procedures for Advertising Medicinal Products and Procedures by Which a Medicinal Product Manufacturer is Entitled to Give Free Samples of Medicinal Products to Physicians'; and
- Association of International Research-based Pharmaceuticals Manufacturers (Starptautisko inovatīvo farmaceitisko firmu asociācija or 'SIFFA') code.

The advertising of medical devices is governed by:

- the Advertising Law; and
- the Regulation (EU) 2017/745 on Medical Devices (the 'MDR').

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 defined in the Advertising Law, Article 1: 'Advertising is any form, or any mode of announcement or endeavour associated with economic or professional activity, intended to promote the popularity of or demand for goods or services (including immovable property, rights and obligations)'.

The advertising of pharmaceuticals or medical devices is not further defined under Latvian law.

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 authority in the field of pharmaceutical and medical devices advertising is the Health Inspectorate of the Republic of Latvia. The function of the Health Inspectorate is to supervise compliance with regulatory enactments.

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 the requirements of legal acts and, in some cases, are even stricter than the law or provide additional obligations. Such self-regulation 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, such as 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 the advertising of food supplements and special nutritional products; however, they are not as strict as the advertising rules for pharmaceuticals. In general, the standard advertising rules apply, as well as specific rules for the use of health statements (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 (advertisements) in your country and, if so, which ones?

No, only non-prescription medicinal products can be advertised to the general public. The advertising of medicinal products to the general public shall be designed in such a way that there could be no doubt that the information distributed is an advertisement and the product being advertised is a medicinal product. It is prohibited to distribute medicinal products to the general public for promotional purposes. The

advertising of medicinal products intended for the general public shall include at least the following information, if particular medicinal products are advertised:

- the name of the medicinal product, as well as the general name specified in the laws and regulations regarding the procedures for the labelling of medicinal products and the requirements to be met for the package leaflet of medicinal products, if the medicinal product contains only one active substance;
- information that is necessary for the correct use of the medicinal product;
- an express and legible invitation to carefully read the package leaflet or relevant information on the packaging;
- an invitation to consult with a physician or pharmacist regarding the use of the medicinal product;
- the warning '*Zāļu nepamatota lietošana ir kaitīga veselībai*' (Unreasonable use of medicinal products is harmful for your health), which shall take up not less than ten per cent of the visual amount of the advertising, and the size of letters shall be such that the title would take up the largest technically available part of the area intended for warning text; in video advertising, such a warning shall be retained throughout advertising, and, in audio advertising, the warning shall be expressed at the end of the advertising text; and
- the advertiser.

It is also prohibited to include in the advertising of medicinal products intended for the general public information that:

- suggests treatment by mail or provides advice in a similar way, and which gives the impression that a diagnosis may be determined without involving a physician;
- suggests that the effects of the medicinal product are guaranteed, the use of the medicinal product is unaccompanied by adverse reactions and the effects of the medicinal product are equivalent to, or better than, those of another method of medical treatment or another medicinal product;
- suggests that the overall health condition of the patient will improve significantly if he/she takes the medicine product;
- suggests that the health of the patient may deteriorate if he/she does not taking the relevant medicinal product; this condition shall not apply to the advertising of vaccines;
- is directed exclusively or principally at children;
- refers to recommendations by scientists, healthcare professionals or persons who are not part of any of the aforementioned categories, but could encourage the consumption of medicinal products because of their celebrity;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggests that the safety and efficacy of the medicinal product is due to the fact that it is natural;
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refers, in improper, alarming or misleading terms, to claims of recovery;
- uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of the medicinal product on the human body or parts thereof; and
- promotes the purchase of the medicinal product, justifying the necessity of the purchase of the medicinal product with the price of the medicinal product by announcing a special clearance sale or providing notification that the medicinal product is sold together with another medicinal product (including for a lowered price) or goods.

As regards medical devices, there are no such restrictions.

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?

It is possible to advertise pharmaceuticals and medical devices through the internet and social media, if the general requirements are observed (see the response to Question 5).

The advertising of prescription pharmaceuticals over the internet is permitted only if access to the information is limited to persons qualified to prescribe medicinal products. It is also prohibited to advertise pharmaceuticals using celebrities or influencers; however, such restrictions do not apply to medical devices.

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)?

The promotion and/or advertisement of pharmaceuticals or medical devices do not require prior approval from regulators. However, the advertisement of vaccines and vaccine campaigns are subject to obtaining prior permission from the Health Inspectorate and the Centre for Disease Prevention and Control.

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 advertising, insofar as it pertains to a comparison, shall be permitted if all of the following conditions are conformed to:

- it shall not be misleading;
- it compares goods or services that are intended for one and the same needs or for one and the same purposes;
- it objectively compares one or more material, related, verifiable and characteristic features of the relevant good or service, which may also include price;
- it does not create confusion for market participants in relation to the advertiser and a competitor, or in relation to the advertiser and the trademark, name (firm name) or other distinguishing marks, goods or services of a competitor;
- it does not bring into disrepute the trademarks, trade names, other distinguishing marks, goods, services or operations of a competitor and does not defame them;
- it does not unfairly use the name (firm name), trademark, trade name or other distinguishing marks of a competitor, or the reputation of the designation of origin of a competing good;
- it does not display goods or services as an imitation or copy of such good or services as there is a protected trademark or trade name; and
- in advertising goods with a designation of origin, the comparative advertising pertains to goods with the same designation of origin.

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?

According to section 2.2. of the Regulation No 378, 'Procedures for Advertising Medicinal Products and Procedures by Which a Medicinal Product Manufacturer is Entitled to Give Free Samples of Medicinal Products to Physicians', healthcare professionals are persons who have the right to prescribe or distribute medicinal products.

The advertising of pharmaceuticals intended for healthcare professionals shall be placed only in scientific and informative press publications intended for specialists, in specially prepared advertising materials or in electronic mass media intended only for specialists, ensuring that there is a warning prior to opening the advertising that the content of the site is intended only for specialists. The warning must appear every time on opening the relevant website. Healthcare professionals in medical treatment institutions may be informed regarding pharmaceuticals only outside office hours for accepting patients, co-ordinating the time of the visit with healthcare professionals beforehand and complying with the procedures stipulated by the head of the medical treatment institution. In pharmacies, informing healthcare professionals regarding pharmaceuticals is permitted, co-ordinating the time of the visit with the head of the pharmacy beforehand.

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 rules for virtual/online interactions with healthcare professionals.

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?

If the advertisement is meant for the general public, it is prohibited to include recommendations by scientists or healthcare professionals that encourage the consumption of medicinal products.

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.

Free samples may be distributed if the following conditions are met:

- the packaging of the free sample is the smallest trade unit;
- the labelling of the free sample conforms to the laws and regulations regarding procedures for labelling;
- a copy of the description of the medicinal product is appended to each free sample of the medicinal product;
- the term for storage is specified in the labelling and package leaflet;
- free samples, for the purpose of introduction, are supplied only to persons who have the right to prescribe the particular medicinal products; and
- free samples may be distributed only according to a written request signed and dated by a healthcare professional or the head of the medical treatment institution, in which the name, strength or concentration of the medicinal products, the pharmaceutical form and number of packages are indicated.

It is prohibited to supply more than four samples to each healthcare professional per year, and together, no more than 1,000 free samples of prescription medicinal products of the same name within a year.
The distribution of free samples of medicinal products is prohibited, if:

- the medicinal product contains narcotic and psychotropic substances that are controlled in Latvia;
- the medicinal product contains doping substances;
- the State Agency of Medicines has recognised the medicinal product as a narcotic analgesic preparation; and
- the medicinal product contains isotretinoin, thalidomide or lenalidomide.

It is prohibited to offer inducements to healthcare professionals as a means of encouraging them to prescribe, supply, sell or dispense medical products. In advertising pharmaceuticals to healthcare specialists, it is also prohibited to offer gifts either related or not related to the professional activities of the professionals. This includes remuneration in either cash or kind. Moreover, healthcare professionals may not solicit, request or accept any material or other kind of benefit that is prohibited.

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 and the requirements of applicable codes of ethics apply.

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

Regulation No 378, 'Procedures for Advertising Medicinal Products and Procedures by Which a Medicinal Product Manufacturer is Entitled to Give Free Samples of Medicinal Products to Physicians' sets out that, in organising and sponsoring events with professional and scientific orientation, as well as providing material or other support to associations, foundations and medical treatment institutions for participation of specialists in such events, the owner of marketing authorisation for medicinal products or an authorised representative thereof, or another person who is the advertiser or distributor of advertising shall ensure the storage of documents and information, and shall conform to the following conditions:

- it is not a sports, tourism or recreational event, or an entertainment event of another kind;
- the event is directly related to a benefit to the development of science and medicine, and improvement of healthcare;
- if the event is organised outside Latvia, the justification of the association, foundation or medical treatment institutions for the participation of the specialist in the event has been received;
- for specialists who are registered for participation in an event (also in an event where medicinal products are not advertised), it is only permitted to cover the registration fee, study materials, travel and accommodation expenses, including catering expenses within the scope of the event

programme; and
- material or other support does not promote prescribing or using a medicinal product with a specific name.

However, more specific rules are set out in the SIFFA local code, which establishes the same rules as the European Federation of Pharmaceutical Industries and Associations (EFPIA) code.

There are no special regulatory requirements applicable to hospitality at promotional or scientific events for medical devices. However, certain requirements apply under relevant code of ethics.

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?

In general, no, if the donation has a professional and scientific orientation.

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?

It is possible to support scientific and educational meetings. The local laws and rules do not distinguish between scientific or educational events.

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

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

The SIFFA local code requires pharmaceutical companies to observe the following principles in interactions with patient organisations: (1) the independence of patient organisations in political judgment and activities; (2) cooperation based on mutual respect; (3) no promotion of specific products by patient organisations, nor requests for such promotion from pharmaceutical companies/marketing authorisation holders (MAHs); (4) transparency in cooperation objectives and scope, with a clear acknowledgment of financial support; and (5) encouragement of diverse funding sources for patient organisations.

The SIFFA local code also sets the same restrictions on hospitality, financing of participation in events, gifts, donations and so on, as applicable to healthcare institutions and specialists. In addition, no company may require that it be the sole funder or sponsor of a patient organisation or any of its programmes. The SIFFA local code also sets additional requirements for contacting representatives of patient organisations for the provision of services, including that such services may only be provided for the purpose of supporting healthcare, research or education, and may not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific pharmaceuticals.

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 and general cooperation rules apply. Please note that assigning certain service provisions to third parties does not exclude the responsibility of MAH or the organiser.

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

Yes, it is mandatory. Each year (by 31 March) notification shall be submitted to the Health Inspectorate regarding the material or other support provided to associations, foundations, medical treatment institutions and healthcare professionals in the previous year, in writing.

There is no requirement to report transfers of value for the manufacturers of medical devices.

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 Health Inspectorate can initiate administrative proceedings in the case in which the rules for advertising are violated. Depending on the subject of the advertisement, there is a difference in which law would be applied. In the case in which consumers/the general public are concerned, the authority would apply Unfair Commercial Practices law; the fines can be up to four per cent of the company’s net turnover

for the last financial year, but not exceeding €300,000. If the healthcare professionals or medical institutions are concerned, then the Advertising Law would be applied; the fines can go up to €14,000. The sanctions are not applied actively and usually are not announced publicly.

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 Health Inspectorate supervises and enforces the rules. Competitors can submit an application to the Health Inspectorate to initiate a case, but they cannot go directly to court and claim that there is an advertising/promotion law violation. Under Latvian law, such claims would be inadmissible. There has to be direct infringement of the competitors rights (eg, intellectual property violations and reputational damage).

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?

No, there are no developments expected in the near future. The general practice and enforcement trends haven't changed or shifted for a while. Usually the Health Inspectorate would only initiate cases when advertising violates rules for the advertising of pharmaceuticals to the general public (ie, advertising prescription medicinal products to consumers).