

<b>PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES</b>
<b>Authors:</b> Morta Putaite
<b>GENERAL</b>
<b>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.</b>
<p>The main Lithuanian legal acts that govern the promotion and advertising of pharmaceuticals and medical devices are:</p> <ul style="list-style-type: none"><li>• Law on Health System of the Republic of Lithuania; and</li><li>• Law of Advertising of the Republic of Lithuania.</li></ul> <p>The advertising of pharmaceuticals is also specifically governed by:</p> <ul style="list-style-type: none"><li>• Law on Pharmacy of the Republic of Lithuania; and</li><li>• Rules on Advertising of Medicinal Products approved by Order No V-1128 of the Minister of Health of the Republic of Lithuania, dated 28 December 2006.</li></ul> <p>Regulation (EU) 2017/745 on Medical Devices (the 'MDR') also governs the promotion of medical devices. The MDR is directly applicable at the national level.</p> <p>Furthermore, there are several self-regulatory mechanisms, for example, the Code of Ethics for Pharmaceutical Marketing adopted by the Lithuanian Innovative Pharmaceutical Industry Association and Medicinal Products Manufacturers' Association, as well as the Code of Ethics adopted by the Lithuanian Association of Medical Devices' Manufacturers.</p>
<b>2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?</b>
<p>Advertising is generally defined as the dissemination of information in any form and by any means related to a person's economic, commercial, financial or professional activities, encouraging the purchase of goods or the use of services, including the acquisition of real estate, the assumption of property rights and obligations.</p> <p>The advertising of pharmaceuticals is more specifically defined as the spreading of purposive information about pharmaceuticals among the public, and healthcare and pharmaceutical professionals qualified to prescribe or supply pharmaceuticals in any form and by any means, canvassing activity or inducement, each designed to promote the prescription, supply, sale or consumption of pharmaceuticals, including:</p> <ul style="list-style-type: none"><li>• visits by medical sales representatives;</li><li>• the supply of pharmaceutical samples;</li><li>• inducements by the gift, offer or promise of a benefit or bonus;</li><li>• sponsorship in promotional meetings;</li><li>• sponsorship of scientific congresses, including the payment of travelling and accommodation expenses for professionals; and</li><li>• the support of radio, television broadcasts and/or programmes presenting information about pharmaceuticals.</li></ul> <p>There is no specific distinction between the definitions of advertising and promotion in Lithuania.</p>
<b>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?</b>
<p>Key authorities for the regulation and enforcement of promotion and advertisement are:</p> <ul style="list-style-type: none"><li>• Ministry of Health (MoH) and State Medicines Control Agency of Lithuania (SMCA) for pharmaceuticals (except in relation to misleading advertising); and</li><li>• State Consumer Rights Protection Authority (SCRPA) for medical devices and in relation to the misleading advertising of pharmaceuticals.</li></ul>

Each self-regulatory body must have a collegial body for assessing and issuing decisions on breaches of codes of ethics. Such bodies operate under applicable codes for pharmaceuticals and medical devices. The range of possible measures in a self-regulatory process is broader, for example, recommendation, notices, information to central management, publication of breaches and removal from membership. In certain cases, self-regulatory bodies must also inform relevant supervisory authorities of the breach.

**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, for example, the advertising of food supplements must contain an indication of food supplements. However, the rules are not as strict as the advertising rules for pharmaceuticals. In general, standard advertising rules apply, with some additional rules, as well as specific rules for the use of health statements (same as in the European Union).

In addition, inserting an unrelated advertisement between the advertising of pharmaceutical and food supplements during television and radio broadcasts is also specifically required.

### **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 pharmaceuticals can be advertised to the general public. In addition, vaccines may be advertised to the general public subject to additional requirements. Distributing pharmaceuticals to the general public for promotional purposes is prohibited. When selling (dispensing) non-prescription pharmaceuticals, additionally offering analgesic products is prohibited.

Advertising to the general public may not include:

- reference to a recommendation by scientists, health professionals or persons who, because of their celebrity, could encourage the consumption of the pharmaceutical;
- a detailed description or representation of a case that could lead to erroneous self-diagnosis;
- reference, in improper, alarming or misleading terms, to claims of recovery;
- misleading terms or an improper pictorial representation of changes in a human or animal body caused by disease or injury, or of the action of the advertised pharmaceutical;
- material directed exclusively or principally at children;
- the impression that a medical consultation or surgical operation is unnecessary, in particular, by offering a diagnosis or by suggesting treatment by mail and by other information media;
- a suggestion that the effects of taking the medicine are guaranteed and are unaccompanied by adverse reactions;
- a suggestion that the effects of the advertised pharmaceutical are better than or equivalent to those of another product or treatment;
- a suggestion that health may be enhanced by taking the advertised pharmaceutical;
- a suggestion that health could be affected by not taking the pharmaceutical (except for vaccines);
- a suggestion that the pharmaceutical is food, cosmetic or another consumer product;
- a suggestion that the safety or efficacy of the pharmaceutical is due to the fact that is natural; and
- influence through persistent offers, indicating alleged price reductions on price lists, price labels, pharmacy premises, or other means or measures contrary to good morals and public order.

The advertising of medical devices may not include the name, last name or image of the patient, as well as recommendations by healthcare institutions, professionals or their professional organisations.

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

The advertising of pharmaceuticals to the general public over the internet and in social media is generally permitted. However, all requirements for the advertising of medicinal products to the general public (see

the response to Question 5) apply, including the prohibition on celebrities advertising pharmaceuticals. In addition, internet advertisements of a pharmaceutical must include reference to its leaflet or labelling information available on the internet. Finally, it is generally required to clearly identify that the provided information constitutes advertising of a pharmaceutical.

The advertising of prescription pharmaceuticals over the internet is permitted only on specialised websites not accessible to the public. Such websites should be reported and registered in the list of websites where prescription pharmaceuticals may be advertised. Registration is performed by SMCA. In addition, certain additional requirements apply to the advertising of prescription pharmaceuticals over the internet.

The advertising of medical devices through the internet and social media is subject to compliance with general requirements.

**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. The advertisement of vaccines is subject to obtaining prior permission to perform a vaccination programme and within the measures of such a programme.

However, it is possible to apply to SMCA for expertise on the compliance of the advertising of pharmaceuticals (except for misleading advertising) with the requirements of the Law on Pharmacy and other legal acts. The conclusions by SMCA are issued within one month.

**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 in Lithuania is allowed, as long as it is not misleading. In addition, the following requirements should be met.

- advertisements shall contain comparable goods that meet the same needs or are intended for the same purposes;
- one or more significant product features should be compared objectively;
- advertising shall not cause confusion between brands, names or other signs;
- advertisements shall not disparage the competitor's trademarks, name or other signs;
- goods with an indication of origin shall be compared with goods with the same indication of origin;
- the reputation of a competitor's trademark, name or other distinctive signs or reference to the origin of a competing product may not be used unfairly; and
- goods are not presented as imitations or copies of goods marked with a protected trademark or name.

Referring to a competitor's product or indication that has not yet been authorised 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?**

Lithuanian legal acts do not provide for a specific definition of healthcare professionals. However, in general, it is understood broadly and includes all types of healthcare and pharmaceutical professionals.

All registered pharmaceuticals (both prescription and non-prescription) may be advertised to healthcare professionals subject to compliance with applicable requirements. Prescription pharmaceuticals may only be advertised in special publications or on special websites included on a positive list and not accessible

to the public. The promotion of pharmaceuticals at a healthcare institution is only allowed during events organised at the healthcare institution following a procedure approved by the healthcare institution and legal acts. Promotional events outside healthcare institutions are subject to prior registration with SMCA.

Special requirements also apply to the content of advertising of pharmaceuticals.

There are no special rules governing promotional communications on medical devices.

**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?**

Generally, the national law stipulates the requirements for websites on which prescription-only medicinal products may be advertised to healthcare professionals (eg, such websites shall be included on a positive list approved by the Minister of Health, such websites shall not be accessible to the general public and such websites shall contain particular mandatory information).

In the case of online promotional pharmaceutical events organised by marketing authorisation holders (MAHs) and (or) their local representatives (LOCs), specific rules shall be followed besides general anti-bribery, advertising and other relevant requirements.

MAHs and LOCs organising online promotional events shall register the event to the database managed by the SMCA at least 15 business days prior to the planned date of the event.

MAHs or LOCs, after registering a promotional event in the SMCA's electronic registration form for promotional events, must: (1) ensure the registration of participants of the promotional event; (2) enter confirmation that the promotional event took place no later than within three business days from the date of the online promotional event on the electronic form for registering promotional events; and (3) in the case in which the online promotional event is cancelled, notification must be provided on the electronic form for registering promotional events no later than one business day before the planned promotional event, and three business days after the planned date of the online promotional event if the event does not take place due to other reasons.

There are no specific requirements in the national law for online scientific (professional) events and online promotional events organised by members of the medical device industry, and interactions with healthcare professionals. Therefore, in such cases, general anti-bribery, data protection and other relevant requirements must be followed.

The rules of relevant self-regulatory codes should be also considered, if applicable.

**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?**

Including recommendations by scientists or healthcare professionals in the advertising of pharmaceuticals addressed to the general public or medical devices is prohibited.

**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 of pharmaceuticals may be used in advertising addressed to healthcare professionals subject to the following requirements:

- the sample shall be identical to the smallest packaging of a pharmaceutical of the same name, form and strength as available on the market;
- packaging shall be marked 'free sample not for sale';
- leaving free samples with healthcare professionals, or distributing them among pharmaceutical specialists or the general public, as well as using them for healthcare purposes, is prohibited;
- samples must be stored in separate premises with restricted access; and
- all operations with samples must be recorded in writing.

The provision of samples of medical devices is not restricted, however, general anti-corruption (including private sector corruption) regulations and the requirements of applicable codes of ethics must be considered.

It is prohibited to offer inducements to healthcare professionals and pharmaceutical specialists 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 professional. This includes remuneration in either cash or kind. These requirements do not apply to hospitality and support in relation to events (see the response to Question 14).

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?**

At promotional events, hospitality may only be offered to healthcare and pharmaceutical professionals participating in the event and should not overwhelm the main purpose of the event. In addition, such hospitality should not impact the prescription of pharmaceuticals, their selling prices or any discounts. Hospitality at scientific events may also be offered to participants only, and should remain within reasonable limits and be conducive to the main purpose of the event. Additional requirements apply in accordance with relevant codes of ethics.

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

Lithuanian law has a broad interpretation of the term 'advertising'. However, usually, donations to healthcare institutions or organisations should not be considered advertising. It depends on whether the information disseminated is related to the economic, commercial, financial or professional activities of the advertiser. It is important to evaluate each specific donation on a case-by-case basis.

**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?**

There is no prohibition on manufacturers of medicinal products or manufacturers of medical devices supporting scientific or educational meetings, provided such support meets the general anti-bribery, tax and other relevant requirements.

Hospitality at professional/scientific pharmaceutical congresses (ie, also those supported by the pharmaceutical industry) shall be secondary to the main purpose of the meeting. Only the payment of the travelling, accommodation, catering and/or registration expenses of healthcare professionals shall be authorised.

National law does not provide for any specific requirements relating to medical device industry members' support for scientific or educational meetings.

The rules of relevant self-regulatory codes should be also considered, if applicable.

**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 for the advertisement of pharmaceuticals and medical devices apply.

Codes of ethics for pharmaceutical marketing require 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/MAHs; (4) transparency in cooperation objectives and scope, with the clear acknowledgment of financial support; and (5) encouragement of diverse funding sources for patient organisations.

The 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 Code of

Ethics 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?**

Only a MAH or LOC may act as an organiser of advertising. It is possible, however, to delegate promotional advertising activities to a third party through a written service agreement. Such delegation does not exclude/reduce the liability of the MAH/organiser of advertising.

The law also specifically provides that the MAH and one or more legal entities authorised by it may carry out joint marketing activities of pharmaceuticals (eg, sales promotion, advertising and other marketing activities).

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

Yes, in Lithuania it is mandatory for pharmaceutical MAHs to report to SMCA all transfers of value to healthcare institutions, and healthcare and pharmaceutical professionals, as well as organisations representing the interests of healthcare or pharmaceutical professionals, or institutions. Information on transfers of value is provided to SMCA and published by it once a year.

In addition, codes of ethics for pharmaceutical companies provide for the disclosure of transfers of value to patient organisations.

There is no requirement to report transfers of value for 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?**

According to the general Law on Advertising, a penalty of up to three per cent, but not exceeding €100,000 (six per cent and €200,000 in the case of a repeated breach) may be imposed on a breach of promotion (advertising) requirements. These rules are applicable to medical devices, food supplements and so on, as well as misleading advertising. In addition, administrative penalties from €140 to €560 may be imposed on managers of legal entities or other responsible persons for the violation of requirements on advertising.

Administrative penalties from €800 to €3,000 may be imposed for managers of legal entities or other responsible persons for the violation of requirements on the advertising of pharmaceuticals.

In addition, authorities may prohibit advertising or instruct entities to publicly deny the information.

The fact of a breach of advertising rules for pharmaceuticals is made public on the SMCA website. Sanctions for a breach of other advertising requirements are not necessarily, but are quite often, made public.

Authorities perform supervision and impose measures quite actively.

**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?**

SMCA is responsible for the enforcement of promotion and advertisement regulations of pharmaceuticals (except for misleading advertising), and SCRPA is respectively responsible for medical devices and misleading advertising. The rules are enforced strictly, however, sanctions are imposed depending on the circumstances. Often warnings and administrative orders for ensuring compliance are issued, fines and other more serious sanctions are usually imposed in cases of intentional and serious violations.

It is possible for competitors to take direct action through the courts in relation to promotional infringements subject to proving their interests. Although it is still rather rare and not widespread practice, it is becoming more frequent. To ensure the compatibility of the rules, 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?**

Certain draft legal acts suggest that, in the future, new regulations may be expected in relation to the use of new technological solutions (eg, QR code) in the advertising of pharmaceuticals and a clearer distinction between scientific and advertising events, as well as the provision of education materials to healthcare and pharmaceutical specialists. Nonetheless, particular drafts governing these matters are not yet available.

No particular developments are expected in relation to the advertising or promotion of medical devices.