

<b>PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES</b>
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<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 promotion and advertising of pharmaceuticals are primarily regulated by the Medicines Act (395/1987) and the Medicines Decree (1987/693). Pharma Industry Finland (PIF) has adopted the PIF Code of Ethics (last revised in 2023). It contains complementary self-regulation on the marketing of medicines and includes the core principles and ethics of the code of the European Federation of Pharmaceutical Industries and Association (EFPIA).</p> <p>Medical devices are nationally regulated under the Medical Devices Act (719/2021), which supplements Regulation (EU) 2017/745 on medical devices (the 'MD Regulation') and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (the 'IVD Regulation'). Furthermore, the Act on Certain Medical Devices Specified in European Union Directive (629/2010) lays down provisions on the national implementation of the Directive 98/79/EC on in vitro diagnostic medical devices (the 'IVD Directive'). The national laws contain additional rules on marketing. Sailab – MedTech Finland ('MedTech Finland') has adopted the MedTech Finland Ethical Code that is essentially aligned with MedTech Europe's Ethical Code.</p> <p>The promotion and advertising of pharmaceuticals and medical devices are also subject to general marketing legislation, such as the Consumer Protection Act (38/1978), which applies to consumer advertising, and the Unfair Business Practices Act (1061/1978), which applies both to business-to-business marketing and to any marketing that concerns another business, even if it is intended for consumers. The Electronic Communications Services Act (917/2014) contains rules on direct electronic marketing.</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>There is no meaningful difference between promotion and advertising under Finnish law as they both fall under the broad concept of marketing.</p> <p>The concept of marketing of pharmaceuticals is very broad. According to the Medicines Decree, marketing covers all advertising regardless of the target group, all kinds of marketing and promotional activities, the distribution of samples, and the activities of medicinal product sales representatives. The Finnish Supreme Administrative Court has confirmed that the definition is substantially the same as that in the Medicines Directive 2001/83/EC.</p> <p>For medical devices, article 7 of the MD Regulation and article 7 of the IVD Regulation contain provisions on prohibited claims in the labelling, instructions for use, making available, putting into service, and advertising of devices which may be misleading as to the intended purpose, safety, or performance of the device. According to the Medical Devices Act, these provisions apply to all forms of marketing, that is, of commercial communications, regarding medical devices.</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>The Finnish Medicines Agency (Fimea) monitors and enforces the rules concerning the marketing of medicinal products and devices. The National Supervisory Authority for Welfare and Health and the Regional State Administrative Agencies supervise the rule that the healthcare professionals should not ask for or accept any inappropriate inducements, benefits, or gifts.</p> <p>The PIF's ethical rules complement Fimea's supervisory activities for pharmaceuticals. The PIF Code of Ethics has its own compliance order and monitoring system, and disputes between companies bound by the PIF Code of Ethics should be resolved in accordance with its rules before submitting the case to the authorities. If the matter is already pending before the competent authorities, the self-regulatory process is not usually initiated before the authorities have issued a final decision.</p> <p>MedTech Finland, an advocacy and lobbying organisation for health technology companies, self-regulates ethical practices in relation to co-operation with the healthcare sector. The Ethical Committee oversees</p>

<p>compliance with the MedTech Finland Ethical Code, regardless of any legal proceedings the companies may initiate.</p>
<p><b>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?</b></p>
<p>According to the Medicines Act, any product or substance which, considering all its properties, is intended for internal or external use to cure, alleviate, or prevent disease or its symptoms in humans or animals is considered a medicinal product and is therefore subject to the regulations on the marketing of pharmaceuticals. For example, vitamin supplements are medicinal products when used for the aforementioned purposes (Fimea's decision on the list of medicinal products 183/2022).</p> <p>The Medicines Act states that in cases of ambiguity, the product should be interpreted as falling within the scope of the legislation on medicinal products, unless there are specific reasons for a different interpretation.</p>
<p><b>CONSUMER MARKETING</b></p>
<p><b>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?</b></p>
<p>Pursuant to the Medicines Act, prescription medicines or medicines containing narcotic or psychotropic substances (listed in the Government Decree 1130/2014 and the Government Decree 543/2008) must not be marketed to the public. Marketing must never be directed at children. It is forbidden to distribute free medicinal product samples to the general public. Thus, as stated in the PIF Code of Ethics, prize-winning competitions and lotteries targeted at consumers are prohibited in the marketing of pharmaceuticals. Pursuant to the Medicines Decree, the marketing of products prepared in a pharmacy for an individual patient is prohibited.</p> <p>Under the Medical Devices Act, CE-marked medical devices may be marketed to the public. It is, however, forbidden to associate non-existent functions and features with the device or create false impressions regarding it, and the marketing must be aligned with the intended use and target group of users. Therefore, for example, a device intended for professionals may not be marketed for home use. Accordingly, the pre-marketing of medical devices that are not yet CE-marked, which is permitted under certain conditions, is primarily intended for marketing to professional users. Moreover, the MedTech Finland Ethical Code prohibits providing free demonstration products and samples to the public.</p> <p>The Medicines Act, the Medicines Decree, and the Medical Devices Act also lay down specific requirements on the minimum information that must be given in the marketing to the public and, on the other hand, material and claims that may not be used. Chapter 2 of the Consumer Protection Act also regulates marketing to consumers. Disguised advertising of medicines is prohibited, as explicitly stated in the PIF Code of Ethics.</p>
<p><b>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?</b></p>
<p>According to the Medicines Act, when marketing medicines by electronic means, consumers must be protected from marketing that should not be directed at them. Otherwise, the general rules on marketing of pharmaceuticals and medical devices apply.</p> <p>The PIF Code of Ethics and the MedTech Finland Ethical Code apply equally to marketing via the internet and social media. The former also includes specific stipulations concerning internet sites, which must be complied with if the internet site containing health awareness information includes links. For example, the links must not lead directly to pharmaceutical marketing.</p>
<p><b>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)?</b></p>
<p>There is no obligation to obtain prior approval from Fimea or any other public authority for promotions or advertisements.</p> <p>The companies committed to the PIF Code of Ethics must submit their television or radio spots advertising self-care medicines for preliminary inspection. In the preliminary inspection, the planned advert is either</p>

approved with or without modifications or rejected. For other forms of consumer advertising, such preliminary inspection is voluntary.

The MedTech Finland Ethical Code does not have a similar procedure for advertisements of medical devices.

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

The Medicines Act prohibits the marketing of a medicinal product without a valid marketing authorisation or registration in Finland, and the marketing information must be in accordance with the approved product characteristics description. The Medicines Decree stipulates that information provided in conjunction with the marketing must comply in all respects with the special information listed in the summary of product characteristics.

However, the PIF Code of Ethics clarifies that unauthorised products can be mentioned in the company's product portfolio in connection with corporate image marketing. It is also allowed to provide information on the results of the company's research programmes without brand names and therapeutic claims.

**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 marketing is generally regulated under the Consumer Protection Act (38/1978) and the Unfair Business Practices Act (1061/1978). Comparative marketing must not create a likelihood of confusion with a competitor's product or indication that may influence consumers' decision-making. It is prohibited to use false or misleading expressions concerning a competitor's business which are likely to affect the demand for, or supply of, a product or harm the business of another.

The PIF Code of Ethics stresses the requirement of factual and accurate information in comparative marketing of medicines. Only prices of comparable packages and doses can be compared. Comparisons of active ingredients must be evidence-based, and the date of comparison or study report must be indicated. Advertising must avoid implying equal or superior effects of a medicine compared to another.

The main rule is, as stated above, that unauthorised products may not be marketed. Referring to a competitor's unauthorised product may be deemed non-essential or unjustified, and such references may be seen as inappropriate and prohibited.

**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?**

A 'healthcare professional' is defined under the Health Care Professionals Act (559/1994) as a licensed or authorised professional or a professional with a protected occupational title as laid down in the Health Care Professionals Decree (564/1994), and who is therefore entitled to use the occupational title and practice the profession in question.

Prescription medicinal products and medicinal products containing narcotic drugs or psychotropic substances may, under the Medicines Act, be marketed only to persons entitled to prescribe or supply them. Under the Health Care Professionals Act (559/1994), those professionals include physicians, dentists, veterinarians, students of these professions to a limited extent, and (senior) pharmacists. Moreover, nurses, opticians, and dental hygienists have a limited right to prescribe certain medicines.

Under the Medicines Act, the advertising must contain essential information about the medicine and its use, and the Medicines Decree and the PIF Code of Ethics list the information that must always be provided. The marketing can take place only in medicinal product demonstrations arranged for these professionals, in publications intended for them, and in electronic communication media in a secure format. Under the Electronic Communications Services Act and the PIF Code of Ethics, healthcare professionals must be able to effectively refuse to receive direct marketing.

<b>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?</b>
<p>Most of the general rules, the main content of which is explained under the following headings, applicable to offline interactions also apply to corresponding virtual activities.</p> <p>The Pharma Industry Finland is a member of EFPIA, and therefore member companies are bound to use the 'e4ethics' platform to pre-assess virtual events. Under the MedTech Finland Ethical Code, virtual events organised by a third party and attended by participants from more than one country must be approved by the International Conference Vetting System (CVS).</p>
<b>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?</b>
<p>The Medicines Decree prohibits recommendations made by healthcare professionals in marketing directed at the general public. Also, under the PIF Code of Ethics, pharmaceutical marketing must not contain direct and active recommendations to use the medicine given by healthcare professionals.</p> <p>Under the MedTech Finland Ethical Code, the principle of independence requires that interactions between the industry and healthcare professionals must not be dependent on the recommendations of medical devices. Co-operation and other interactions between member companies and healthcare professionals must not be linked in any way to the recommendations of healthcare professionals.</p>
<b>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.</b>
<p>Under the Medicines Act, free medicinal product samples may be provided to physicians, dentists, veterinary surgeons, licensed pharmacists, and managers of hospital pharmacies and dispensaries. Sample packs of prescription medicines may only be supplied to persons authorised to prescribe them. The Medicines Decree prohibits providing sample packs of narcotics or substances primarily affecting the central nervous system or medicinal products containing a psychotropic substance. The sample must be equal to the smallest package size of the medicinal product available on the market. Only one sample pack per calendar year may be supplied to a single recipient for introduction to the medicinal product on written, signed, and dated request accompanied with a summary of product characteristics.</p> <p>The legislation on medical devices does not contain provisions on samples. The MedTech Finland Ethical Code allows providing a reasonable number of free samples to healthcare professionals. Multiple-use samples shall be returned to the company immediately after a reasonable familiarisation period. The PIF Code of Ethics mentions that dosage devices may be provided.</p> <p>Inexpensive gifts directly related to the recipients' professional activities are allowed under the Medicines Act, the PIF Code of Ethics and the MedTech Finland Ethical Code. However, the PIF Code of Ethics prohibits promotional gifts related to prescription medicines. Pursuant to the MedTech Finland Ethical Code, gifts and other similar acknowledgements to healthcare professionals may not be given in cash or on request. Both codes of ethics stipulate that the provision of promotional items must not, directly or indirectly, in the pursuit of commercial interests, influence decisions or actions of healthcare professionals.</p> <p>Under the PIF Code of Ethics, making donations to individual healthcare professionals is only permitted for certain clinical trials or when approved by the regulatory authority and ethics committee. The MedTech Finland Ethical Code forbids donations to individual healthcare professionals.</p>
<b>14. What rules govern the offering of hospitality to healthcare professionals?</b>
<p>Under the Medicines Act, hospitality must be moderate and secondary to the purpose of the event. Promotional activities must not be inappropriate or undermine public trust. The PIF Code of Ethics includes more specific rules on hospitality. In connection with events, hospitality can extend only to the registration costs and to the travelling, accommodation, and limited meal expenses.</p> <p>For medical devices companies, hospitality must respect the principles of reasonableness and transparency, and not compromise the integrity of healthcare professionals according to the MedTech Finland Ethical Code. The hospitality must be related to the purpose of the event and can only last for its duration, covering reasonable and pre-agreed accommodation and meal expenses, and reasonable actual</p>

travel expenses. For sales, promotional or other business meetings, member companies may reimburse travel or accommodation expenses for healthcare professionals when a new product is launched, or the presented medical device is non-transferable.

**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 public authorities' practice, it has been interpreted that using charity donations in the marketing of medicines is inappropriate within the meaning of the Medicines Act. Healthcare institutions or organisations that collect money for non-profit purposes must have a fundraising permit in accordance with the Money Collection Act (863/2019) to receive donations.

Under the PIF Code of Ethics, donations must not constitute a commercial incentive regarding a particular medicinal product. Therefore, donations that are effectively considered as marketing tools are prohibited. Only donations for supporting healthcare or research are allowed. Similarly, under the MedTech Finland Ethical Code, charity donations are allowed but they may not be used in any way to promote sales.

**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?**

Under the PIF Code of Ethics, pharmaceutical companies can only sponsor events that focus on research or medical training. The program must be mainly scientific or educational. The sponsoring must be clearly disclosed and is subject to the marketing guidelines of the PIF Code of Ethics. For events that are part of the systematic continuing education and training of doctors, the financing from commercial companies should principally focus on the general costs of the event through the organising organisation, as required by the Doctors and Commercial Enterprises Guidelines (2014) of the Finnish Medical Association.

For medical devices companies, the MedTech Finland Ethical Code allows the sponsorship of third-party meetings when the professional program is the main focus of the event, and the program is sufficiently relevant to the professional knowledge or practice of the healthcare professionals. To be eligible for support, international conferences organised by third parties must be approved in MedTech Europe's CVS. The support and educational grants must be addressed to healthcare organisations. However, in the case of methodological training organised by a third party, the participation of individual professionals may be directly supported. The MedTech Finland Ethical Code allows the purchasing of exhibition and advertising space and the conclusion of agreements on sponsorship or any promotional services in connection with third-party training and events.

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

The PIF Code of Ethics must be followed in cooperation between pharmaceutical companies and patient organisations. The same obligations regarding cooperation and hospitality apply as in relation to healthcare professionals. The representatives of patient organisations are subject to the same rules on incentives, gifts, and other support measures. Pharmaceutical companies can fund patient organisations for healthcare, research, or education, but not to promote specific medications. They must not influence the organisation's materials for commercial gain, and marketing prescription-only medicines through such collaborations is strictly prohibited. A written agreement specifying financial support or sponsorship is required. The companies must have an approval process for such agreements, maintain a list of sponsored organisations, and disclose the funding.

MedTech Finland Ethical Code also aims to foster relationships between medical devices companies and patient organisations. MedTech Europe, of which MedTech Finland is a member, has published Guidance on the Interactions between the Medical Technology Industry and Patient Organisations (2021). According to this Guidance, agreements with patient organisations should be in writing and all interactions should be based on the principles of transparency, independence, integrity, trust, and equivalence.

**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 Finnish law in general, the company is always responsible for its marketing, regardless of the party that conducts it. Under the Unfair Business Practices Act and the Consumer Protection Act, the party on whose behalf the marketing is done shall clearly appear on the marketing.

<p>Under the PIF Code of Ethics, a pharmaceutical company's responsibilities extend to tasks carried out in collaboration with third parties. If the company fails to ensure that the third party complies with the PIF Code of Ethics, the company may be sanctioned for the violations that have occurred.</p> <p>The rules on the marketing of medical devices are explicitly stated to apply to all operators conducting the marketing. MedTech Finland recommends concluding a written agreement on compliance with the MedTech Finland Ethical Code with relevant third parties, as the liability of companies to comply with the rules also extends to activities delegated to third parties.</p>
<p><b>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</b></p>
<p>The Medicines Act obliges maintaining, for public review, an up-to-date list of all direct and indirect financial and comparable support given to associations in the fields of medicine and healthcare and to patient organisations. However, the PIF Code of Ethics additionally includes a Code for the Disclosure of Transfers of Value, under which the company must document and publish the economic benefits targeted at healthcare professionals.</p> <p>Under the MedTech Finland Ethical Code, the principle of transparency must be respected in all interactions between medical devices companies and healthcare professionals. MedTech Finland's member companies document and publish all grants awarded in accordance with the publication guidelines of the MedTech Finland Ethical Code.</p> <p>Both codes of ethics allow giving donations and grants directly to healthcare professionals only in non-commercial contexts (see the responses to Questions 13 and 16).</p>
<p><b>ENFORCEMENT</b></p>
<p><b>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?</b></p>
<p>In the event of significant infringements, Fimea may impose a marketing ban to prohibit the continuation or renewal of unlawful marketing. In connection with such a ban, Fimea may also give an order to correct information. The ban may also be reinforced by a conditional fine. Marketing bans have been imposed approximately once a year and are publicly announced.</p> <p>The Medicines Act mandates fines for a medicinal product offence if the provisions on the marketing of medicinal products are violated intentionally or negligently. Under the Criminal Code (39/1889), a person who intentionally or through gross negligence acts in violation of the Medicines Act or Decree or Fimea's prohibition or order may be sentenced for a medicine offence to fines or imprisonment for at most one year. Criminal convictions are in principle public.</p> <p>A company committed to the PIF Code of Ethics may be sanctioned by a warning, a request to abstain from incorrect activity, a processing charge, a compensation or sanction payment, or an order to rectify and correct the measures taken. These enforcement decisions are public information. In 2022, in eight cases out of nine, the Inspection Board imposed a sanction payment of €8,000 and a processing charge of €2,000 on the companies involved.</p> <p>The Ethical Committee of MedTech Finland has the right to impose sanctions and penalties, such as a written warning or a written requirement to implement the ethical rules, a fine, a requirement to recall products, and a requirement to publish a correction. The Ethical Committee publishes its decisions and sanctions if it considers it necessary.</p>
<p><b>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?</b></p>
<p>Fimea is responsible for the enforcement of the rules concerning the marketing of medicinal products and devices. Every year, Fimea handles around 35 cases related to the monitoring of the marketing of medicines (Fimea, 17 June 2022). Criminal proceedings are initiated by the National Prosecution Authority and handled by the general courts. The Consumer Ombudsman supervises marketing measures aimed at consumers.</p> <p>If a company's practices violate the Unfair Commercial Practices Act, competitors can take direct legal action through the courts. Most of the detected improprieties in the marketing of medicines are, however, dealt with by the pharmaceutical industry's self-regulatory system. The companies committed to the PIF Code</p>

must try to solve their disputes primarily in amicable negotiations, and ultimately the compliance with the PIF Code of Ethics is enforced by two Inspection Boards and the Supervisory Commission. Similarly, the Ethical Committee of the MedTech Finland enforces the MedTech Finland Ethical Code, and the procedure starts with mediation.

#### **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?**

Finnish legislation on the marketing of medicines is fairly strict and is not expected to be loosened in the future (Publications of the Government's analysis, assessment and research activities 2021:19). Nonetheless, the Ministry of Social Affairs and Health (01/2024) has set up a working group to prepare the release of some of the most commonly used over-the-counter medicines for sale outside pharmacies, which, if implemented, would most likely indirectly affect the marketing of these medicines.

More than half of the respondents to the Health Technology Industry Survey (2023) said that the sales and marketing costs of their health technology business have increased.