

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.

Swiss legislation provides the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) as a basis.

The law differentiates between rules for the advertising/promotion of pharmaceuticals and medical devices. Whereas the law provides a framework for the rules on promotion/advertising of pharmaceuticals bans advertising/promotion of prescription-only pharmaceuticals to the public, any misleading or contrary to public order and morality. The main purpose of these regulations is to avoid any excessive, abusive or inappropriate use of medicinal products. As a general principle, any advertising for pharmaceutical use must correspond with the medical indications approved in the pharmaceutical's authorisation. The purpose of these regulations is the protection of public health.

TPA also provides the legal basis for the ordinance on advertising of pharmaceuticals which specifies above-mentioned provisions in the law, also covering topics such as advertising during events and sponsoring of events and visits of sales personnel.

There are further rules in the Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code) by Science Industries Switzerland (Business Association Chemistry Pharma Life Sciences). The Pharma Code must be understood in the context of the Code of Practice of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the EFPIA Code of Practice by the European Federations of Pharmaceutical Industries and Associations. The Pharma Code is more specific than the laws with a focus on providing a level playing field within the industry concerning the advertising and promotion of pharmaceuticals, any communications addressed to healthcare professionals and corresponding reference material, events (including sponsoring of events), the cooperation of pharmaceutical companies with healthcare professionals, healthcare organisations and patient organisations, the support (sponsorship) by pharmaceutical companies for clinical trials and finally the cooperation with service providers. The Pharma Code is not applicable to the promotion by pharmaceutical companies of over-the-counter medicinal products. It is only binding for signatories, but most of the pharmaceutical companies have signed. The Pharma Code also includes rules on interpretation and mediation procedures.

TPA states different rules for the advertising and promotion of medical devices. The respective provision just authorises the administration (executive power) to adopt further rules in order to protect health and prevent fraud, restrict or prohibit the advertising of certain medical devices and enact regulations concerning cross-border advertising in an ordinance. The definition of medical devices in the TPA includes in vitro diagnostics.

The administration has regulated the advertising of medical devices in the Medical Devices Ordinance (MedDO) and for in vitro diagnostics in the Ordinance on In Vitro Diagnostic Medical Devices (IvDO). Both provisions have an identical wording. With regard to the scope of this survey, there is no difference between medical devices and in vitro diagnostics including the applicable legal framework. Therefore, any reference made to medical devices hereinafter also applies to in vitro diagnostics, and any reference made to the MedDO also includes the respective provisions in the IvDO.

Any claims that do not comply with the product information (approved as part of the certification of the medical devices) and any misleading statements, particularly concerning the intended purpose, safety and performance of a device, are banned. Further, advertising for medical devices for use by professionals only is also strictly prohibited.

The industry has prepared the Code of Ethical Business Practice (Ethics Code) in line with the Code of Ethical Business Practice of MedTech Europe with the purpose of increased transparency and protect integrity in relation to all interactions between member companies of Swiss Medtech and healthcare professionals and organisations, and also to ensure that medical treatment decisions are made independently.

<p>Even though the restrictions for advertising and promotion of medical devices including in vitro diagnostics provided by the TPA and the MedDO/IvDO are very limited, the scope of the Medtech industrial Ethics Code is more or less identical with the scope of the pharma codex, meaning the scope is much broader than the restrictions provided by legal frameworks (TPA/MedDO/IvDO). This Code is also only binding to signatories.</p>
<p>2. How is ‘advertising’ defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?</p>
<p>Advertising for pharmaceuticals is specifically defined. It includes all information, marketing and incentivisation measures aimed at promoting the prescription, dispensing, sale, consumption or use of pharmaceuticals.</p> <p>There is no specific definition of advertising for medical devices in the legal framework. However, the broad definition applicable to advertising of pharmaceuticals would also apply for the advertising of medical devices.</p>
<p>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?</p>
<p>Related to pharmaceuticals and medical devices the federal authority (Swiss Agency for Therapeutic Products, Swissmedic), is the competent authority to regulate promotion/advertising (of course within the limits of the law) and to enforce the legal framework.</p> <p>If a procedure concerning the same conduct has already been brought before a state authority or to a court the Pharma Code Secretariat will not open a procedure. In case of a pending procedure under the Pharma Code the Code Secretariat will suspend any proceedings, which have already been opened for as long as none of the participating pharmaceutical companies ask for the proceedings to be terminated.</p> <p>The Swiss Medtech Code of Ethical Business Practice does not refer to procedure before state authorities or courts. However, the Code only provides a mediation procedure. If a member/competitor lodges a procedure before a state administration or a court this would be inconsistent with a mediation.</p>
<p>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?</p>
<p>Under Swiss Law, there are no other products that fall under the same regulations on promotion/advertising.</p> <p>However, the legal framework for pharmaceuticals or medical devices can apply to a product (eg, food or cosmetic product) in case indications which attribute to such product the properties of preventing, treating or curing a human disease or which give the impression that such properties are present. In such a case advertising must be stopped with immediate effect to eliminate any statements which do not comply with the laws.</p>
<p>CONSUMER MARKETING</p>
<p>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?</p>
<p>Prescription-only medications and medical devices which are intended solely for use by healthcare professionals to the public must not be advertised.</p>
<p>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?</p>
<p>Swiss law provides no specific rules for the advertising of pharmaceuticals through the internet, except for advertising of pharmaceuticals for oral administration containing alcohol, which is only permitted if the product contains less than 0.5 g of pure alcohol in the maximum single dose according to the recommended dosage.</p>

There are also some specific challenges relating to advertising pharmaceuticals on the internet. If prescription-only pharmaceuticals are advertised, it must be secured that the advertising is not made available to the public. As in advertising on television there is a mandatory information that must be provided confirming the nature as pharmaceutical and advice to read the product information or seek the advice of a healthcare professional.

There are also no specific rules for advertising of pharmaceuticals or medical devices on social media. It is still challenging because of the multiple restrictions for advertising of pharmaceuticals which are very difficult to comply with on social media. For example, advertising must be recognisable as such. Advertising for pharmaceuticals must be clearly separate from editorial contributions. This can be very challenging on a social media account. Advertisers with a social media account must also provide a channel to report adverse events.

Neither the TPA nor the MedDo provide rules for the advertising of medical devices on the internet or on social media. As long as the advertising does not include misleading statements, particularly concerning its intended purpose, safety and performance of a device, it is considered legal.

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)?

Advertising in printed media or by means of audiovisual media (eg, the internet, screen presentations, electronic display boards, etc.) is subject to prior approval from regulators. However, this restriction only applies to specific products (ie, analgesics, sleeping pills, sedatives, laxatives and anorexics), and only if the product information mentions a potential for abuse or addiction.

Either the advertising project or the final produced advertising must be submitted to Swissmedic which required five copies, and in all languages in which the advertising is to be distributed. These documents should provide a precise picture of the planned advertising.

If an advertising project is assessed favourably by Swissmedic, the applicant of a final produced advertising will receive a final approval. In the case of a favourable assessment of an advertising project, a positive preliminary decision will be received. The produced advertising can then be finalised, which will be finally approved if compliant with the legal framework.

If Swissmedic considers an advertising project or final produced advertising not to be compliant with the legal requirements a negative preliminary decision will be received, providing the reasons for the negative assessment. The advertising project or final produced advertising may then be amended for approval if compliant with legal requirements. Otherwise, a further negative preliminary decision will be received, providing the opportunity for amendments to the advertising.

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

Such advertising is prohibited, with no exceptions.

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?

Statements on comparisons with other pharmaceuticals are only permissible if they are scientifically correct and are based on equivalent clinical trials or data collections that fulfil the requirements of good clinical practice etc.

There is no similar rule for medical devices. However, the Swiss Federal Act on Unfair Competition provides very similar standards in line with the pharma legal framework. Consequently there is relevant difference.

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?

Swiss law makes the distinction between: (1) medical health professionals, ie, medical doctors, dentists, pharmacists, chiropractors and veterinary surgeons; and (2) psychological health professionals, and tertiary health professionals (no university level), such as nurses, physiotherapists, midwives, ergo therapist, osteopath, etc. Any health professional who wants to practice under their own professional responsibility must obtain a licence from the canton in which they want to practice.

Pharmaceutical laws and regulations relate to healthcare professionals: medical doctors, dentists and pharmacists who work in particular in a practice or hospital, as well as pharmacists and druggists in retail businesses and persons who are authorised by Swiss law on therapeutic products to prescribe, deliver, use or purchase medicinal products for humans. This definition also includes official representatives and persons with a public-law employment contract or mandate if they perform or are authorised to perform such activities.

For medical devices, it is a matter of product certification to define whether use is limited to health professionals and which health professionals, in accordance with the intended purpose and the information provided by the manufacturer.

Further, there is a specific rule relating to devices for injection intended to remain in the human body for more than 30 days (long-term injectable devices) which may only be used by a doctor or a qualified nurse with appropriate training in the injection of long-term implantable 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?

There are no specific rules for such activities.

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?

Endorsements by healthcare professionals in promotional (advertising) materials for health professionals are permitted. However, it is prohibited to show persons in professional clothing of medical personnel, chemists or medical assistants or when carrying out profession-specific medical activities in promotional (advertising) materials for the public.

There are no similar provisions for the advertising (promotion) of medical devices but depending on the context endorsing advertising/promotion of medical devices to the public by inclusion of healthcare professionals could be considered misleading and, therefore violate laws on advertising/promotion of medical devices.

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.

TPA and the Pharma Codex provide quite detailed rules on transparency and integrity related to prescription-only pharmaceuticals.

Healthcare professionals can be provided with samples of pharmaceuticals on the written request of the healthcare professional but only in small quantities. Such quantities are understood as a maximum of five packages per healthcare professional per year and pharmaceutical form and dosage in the first two years following market launch, and thereafter a maximum of two packages. These packages must comply with the smallest size of the package approved, and must be visibly and permanently marked 'free sample' (so they cannot be sold).

The TPA and the MedDO do not state any restrictions to the providing of free samples of medical devices to healthcare professionals. The Ethics Code regulates that free samples are only permitted to the extent the healthcare professional needs them to get used to a new medical device and to decide whether and when they wish to use such devices in their daily work.

Manufacturers/suppliers of pharmaceuticals are not allowed to give gifts or monetary donations to healthcare professionals, other than a modest value (maximum 300CHF (approx. US\$335 per year) which are of relevance to medical or pharmaceutical practice, that is, they are directly connected with the practice of the profession by the professional or of direct benefit to the professional's customers.

There is no restriction in the law for gifts and donations of manufacturers/suppliers of medical devices to healthcare professionals. However, the Ethics Code prohibits gifts and donations to healthcare professionals. They are only allowed if made to healthcare organisations and institutions.

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

Pharmaceutical companies may offer hospitality to healthcare professionals relating to education and training based on a written agreement with the healthcare professional and only if the healthcare professional pays at least one fifth education and at least one third of the cost of the training related to registration fees, travel costs, hospitality and framework programme, which must be of minor importance.

The legal framework on medical devices provides no rules on offering hospitality to healthcare professionals. The Ethics Code allows medical device companies to offer hospitality (meals and accommodation), as long as it is reasonable only for the duration of the event and of the appropriate standard.

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?

Donations of pharmaceutical manufacturers/suppliers meaning payment of money without a specified purpose compliant with the law are not permitted. Permit/authorisation holders may support healthcare providers (organisations, not healthcare providers) related to research, teaching, and infrastructure based on a written agreement stating the purpose of such payment, are used exclusively for the said purpose, and are not subject to conditions or requirements relating to the prescription, dispensing, use or purchase of certain prescription-only pharmaceuticals. Such payment must be made to a designated account held by the organisation to which healthcare professionals do not have sole access and they must be duly recorded in the organisation's accounts. Considering the aforementioned, the applicable legislation leaves no room for donations as a promotional (advertising) tool. It also seems more appropriate to speak of 'support' rather than 'donations'. The Pharma Code also differentiates between support related to the aforementioned purposes and donations, which are not permitted.

The laws on medical devices do not state any restrictions relating to donations. The Ethics Code provides rules which are binding to Swiss Medtech members. This Code does not allow donations to healthcare institutions or organisations for promotional (advertising) purposes, but only for charitable and philanthropic purposes. Under certain conditions, donations to non-profit-making hospitals may be permissible in cases of demonstrated financial hardship. Also, as related to pharmaceutical educational grants to support educational events, scholarships or fellowships, general medical education topics, etc.

Even though donations by medical devices suppliers/manufacturers to healthcare institutions or organisations are not prohibited according to the Swiss legal framework on medical devices, and the restrictions under the Ethics Code are only binding to members of Swiss Medtech, there are still restrictions for donations which are generally applicable. The anti-corruption laws in the Swiss Criminal Code prohibits bribing (offering, promising, giving an undue advantage or accepting the same). A donation for promotional (advertising) purposes would have to be considered as an 'undue advantage' and as such would constitute a criminal offence.

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?

A laboratory is not specifically pharmaceutical. Laboratories even face fewer restrictions than pharmaceutical companies or Medtech companies.

There is a difference between pharmaceutical companies and MedTech companies. The former is bound by legal restrictions in the TPA and the Ordinance on Integrity and Transparency in relation to Therapeutic Products (TPITO) at least relating to prescription-only pharmaceuticals. Medtech companies are only restricted by the rules provided in the Ethics Code, and only if they are members of Swiss Medtech. Third Parties (service providers) are bound by the same rules as their clients.

In both sectors the primary purpose of the support must be the education and not the promotion of products. There is a difference between consulting, where the health professional supports the company with their specialised knowledge and scientific/educational meetings for the benefit of the health professional.

See also the response to Question 14.
17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.
<p>The legal framework does not provide any rules regarding relationships including funding of patient organisations. The reason is simple. The patient organisations have no influence on the amount of medication prescribed or used. Therefore, the scope of the rules is very limited in the pharmaceutical sector and non-existing in the medical device sector.</p> <p>The Pharma Code only safeguards the independence of patient organisations with reference to their political attitude, their mode of action and their activity. The Code bans requests to patient organisations to promote prescription-only pharmaceuticals and to consider requests made by patient organisations. Further, pharmaceutical companies shall not support a patient organisation on an exclusive basis, and they shall not require patient organisations to provide financial or other support for them as a sole pharmaceutical company, either overall or for their individual projects.</p> <p>The Ethics Code of Swiss Medtech explicitly excludes patient organisations from the definition of healthcare organisations. It only refers to patient organisations in relation to educational events organised by or staged with.</p>
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, this is possible on the basis of agreements that secure compliance of such third party with all applicable rules and regulations. From a regulatory point of view the marketing authorisation holder, who has outsourced the services remains responsible for strict compliance with the rules and regulations including all restrictions (in addition to the service provider).
19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?
The Swiss regulatory framework is not entirely consistent. While the advertising rules apply to prescription-only pharmaceuticals, the transparency rules apply to discounts and refunds related to all pharmaceuticals (including non-prescription pharmaceuticals) except for over-the-counter medicinal products and all medical devices except Class I devices. There is also no mandatory reporting but just the obligation to make the data/information available to the Federal Office of Public Health on request.
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?
<p>The Swiss law provides fines of up to CHF50,000 (approx. US\$55,900) for wilfully contravening the regulations on the advertising of pharmaceuticals. If the person concerned acts in a professional capacity a monetary penalty of up to CHF540,000 (approx. US\$600,000) may be imposed. Negligent violations may be subject to a fine of up to CHF20,000.</p> <p>Neither fines nor monetary PenFines and monetary penalties are published. Only court decisions are publicly available, but on a no-name basis.</p>
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?
<p>Swissmedic is responsible for the enforcement of the rules on advertising/promotion. Swissmedic enforces the rules related to all violations they notice strictly or, which is often the case, made aware of by competitors.</p> <p>The Swiss Federal Act on Unfair Competition allows competitors to take civil action, but this is hardly ever carried out.</p>
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?

To date, there is an extensive legal framework for advertising and promotion of pharmaceuticals, whereas neither advertising nor promotion of medical devices is subject to similar legal provisions.

The Swiss parliament decided in 2019 to extend the scope of Article 55 TPA on integrity, and of the Ordinance on Integrity and Transparency in relation to Therapeutic Products (TPITO) to 'advantages provided relating to the prescription, dispensing and use of medical devices'. To date, there is no definite timeline for the amendments. Any changes are not expected to come into effect before 2025.