PANORAMIC

PHARMA & MEDICAL DEVICE REGULATION

Switzerland

LEXOLOGY

Pharma & Medical Device Regulation

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REGULATORY FRAMEWORK

Competent authorities for authorisation

Identify the competent authorities for approval of the marketing of medicinal products and medical devices. What rules apply to deciding whether a product falls into either category or other regulated categories?

The competent authority for granting marketing authorisations for medicinal products is the Swiss Agency for Therapeutic Products (Swissmedic).

For medical devices, the same system applies as in the European Union, in that there is no marketing authorisation for medical devices, but a conformity assessment procedure. The supervisory authority for medical devices is also Swissmedic.

Medicinal products are defined as products of chemical or biological origin that are intended to have or are presented as having a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and disabilities. Blood and blood products are also considered to be medicinal products. Medical devices are defined as products that are intended to have, or are presented as having, a medical use and whose principal effect is not obtained with a medicinal product. For some products, the purpose given to them by the manufacturer is decisive for their categorisation as a medicinal product or medical device. For medical devices, the Medical Device Coordination Group guidelines and the Manual on Borderline between Medical Devices and Medicinal Products of September 2023 are referred to. Products without a medical purpose may also fall into other product categories, such as foodstuffs, cosmetics and personal protective equipment.

Law stated - 1 Oktober 2024

Approval framework

Describe the general legislative and regulatory framework for approval of marketing of medicinal products and medical devices.

The rules on the granting of marketing authorisations and the placing of medicinal products on the market are set out in the Law on Therapeutic Products and various ordinances depending on it; in particular:

- the Ordinance on the Requirements for Marketing Authorisation of Medicinal Products;
- the Ordinance on the Simplified Marketing Authorisation of Medicinal Products and Authorisation by Way of Notification
- the Ordinance on the Simplified Marketing Authorisation of Complementary and Herbal Medicinal Products;
- the Medicinal Products Licensing Ordinance; and
- the Ordinance on Medicinal Products.

The relevant procedures are the ordinary, pre-announcement, fast-track and simplified procedures. A marketing authorisation can only be granted to a company or person having

its domicile, registered office or branch office in Switzerland. The applicant must also have a manufacturing, import or wholesale licence.

The conditions for granting a marketing authorisation for a medicinal product are that it is of high quality, safe and effective. Detailed rules apply concerning the labelling of medicinal products and the wording of the information to professionals and the patient information leaflet.

For medical devices, in principle, the EU rules on market access apply. However, as the mutual recognition agreement with the European Union has not been updated, Switzerland has established measures designed to limit the negative consequences of this development and the lack of cooperation in market monitoring. These include the staggered timelines for appointing an authorised representative, the need for economic operators to register with Swissmedic, the reporting of serious incidents to Swissmedic and the recognition of EU certificates of conformity in Switzerland.

As a consequence of the inability of the Swiss authorities to access the European database for medical devices (EUDAMED3), Swissmedic is, since the beginning of August 2024, gradually introducing a Swiss database on medical devices (swissdamed).

To sell a medical device in Switzerland, its product information must be given in German, French and Italian. Deviations from this requirement are permissible if the following criteria are met:

- the device is supplied exclusively to professionals or is a custom-made device or a medical device manufactured and used in a healthcare institution;
- it is certain that the user meets the necessary professional and linguistic requirements and qualifications, and is in agreement;
- the protection of patients, users and third parties is ensured; and
- the efficacy and performance of the medical device are not placed at risk.

Manufacturers of medical devices that have their registered office outside Switzerland must appoint an authorised representative in Switzerland. This representative must be indicated on the packaging of the product.

Law stated - 1 Oktober 2024

CLINICAL PRACTICE

Applicable rules

What legislation controls and which rules apply to ethics committee approval and performance of clinical trials in your territory for medicinal products and medical devices?

Clinical trials are mainly regulated by:

- the Law on Therapeutic Products;
- the Human Research Act (HRA);
- ordinances related to the HRA;

- the Ordinance on Medical Devices;
- certain provisions of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices;
- the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use Guidelines on Good Clinical Practice of 1996 (ICH-GCP E6(R2)); and
- the World Medical Association Declaration of Helsinki.

In principle, clinical trials require authorisation from the Swiss Agency for Therapeutic Products (Swissmedic) and the competent ethics committee. Clinical trials of medicinal products authorised in Switzerland and administered according to the authorised use, as well as compliant medical devices used within the scope of the purpose designated by the conformity assessment, do not need authorisation by Swissmedic.

The ethics committee examines compliance with legal requirements and verifies the scientific quality of the trial. The committee ensures the safety of the trial subjects. Swissmedic examines whether the product used in the trial complies with the requirements of good manufacturing practice and with safety requirements.

Applications to the ethics committee are submitted through the Business Administration System for Ethics Committees' web portal. The committee should issue its decision within 30 days. If the committee requests additional documents, this time limit is suspended until the complete information has been received. In the case of multicentre trials, the lead ethics committee should issue its decision within 45 days. Essential changes in the trial must also be approved by the ethics committee prior to their implementation.

Law stated - 1 Oktober 2024

Reporting requirements

What requirements exist for reporting the commencement of a trial and its results to the competent authorities or the public?

The reporting requirements will be amended as per 1 November 2024. Hereafter, the new regulation is described. Most clinical trials require prior authorisation by Swissmedic. Essential changes in the trial must be approved by Swissmedic prior to their implementation. Generally, a final report with a summary of the outcome must be filed with Swissmedic and the competent ethics committee within one year of the completion or discontinuation of the trial. For trials for which Swissmedic approval was not necessary, this notification has to be made solely to the competent ethics committee.

The publication requirements will be amended as per 1 March 2025. Hereafter, the new regulation is described. The Human Research Act provides for mandatory public registration of authorised clinical trials by the sponsor either with a primary registry accredited by the World Health Organization or with the registry of the US National Library of Medicine, as well as in the public database of the Swiss National Clinical Trials Portal. The sponsor must make sure that a summary of the results of the trial is published therein within one year from the completion or discontinuation of the trial. An interruption of more than two years is considered as discontinuation. For the publication in the public database of the Swiss

National Clinical Trials Portal, a lay summary of the trial results must be added. In the case of clinical trials for phase I exclusively with adult participants, the publication of the results can take place at the latest 30 months from the completion or discontinuation of the trial. If for scientific reasons it is not possible to publish the trial results within the time limit, the sponsor must justify this in the application documents and state when publication will take place.

Law stated - 1 Oktober 2024

Consent and insurance

Are there mandatory rules for obtaining trial subjects' consent to participate? Must sponsors arrange personal injury insurance to a particular limit?

Trial subjects must give their free informed consent for their participation in the trial. Clause 4.8 of the ICH-GCP applies. Different types of informed consent are required for the future use of collected health data, genetic data and biological samples for research purposes. Subject to certain exceptions, the consent for the participation in the trial so far had to be given in writing. From the revision, which comes into force on 1 November 2024, consent can now also be given in electronic form. The consent requirements are different for uncoded, coded (ie, pseudonymised) and anonymised data. The revision as per 1 November 2024 will provide for new specific consent requirements for genetic testing and prenatal risk assessment. For the further use of coded health data and coded biological material for research purposes, a 'general consent' is possible; that is, a consent that does not need to be specific with regard to a particular research project. Swissethics provides templates for the consent.

The HRA provides for the liability of the sponsor for injuries suffered by trial subjects in connection with the trial (with certain exceptions). The liability is for any damage caused by the trial, occurring during the trial and within 10 years of its completion. The liability has to be secured by insurance or comparable securities up to a certain amount. The amount of insurance coverage is generally at least 10 million Swiss francs for the whole trial, 1 million Swiss francs for each case of personal injury and 50,000 Swiss francs for each case of material damage. The insurance or security has to cover damages occurring during the trial or within 10 years of its completion. The statute of limitations for damages caused by a trial is generally 20 years.

Law stated - 1 Oktober 2024

MARKETING AUTHORISATION

Time frame

How long does it take, in general, to obtain an authorisation from application to grant, what fees are payable and what is the normal period of validity of the authorisation?

In general, the ordinary marketing authorisation for medicinal products proceedings takes about a year at minimum. The Swiss Agency for Therapeutic Products (Swissmedic) has issued a guideline setting out its internal targeted time periods and milestones. If

Swissmedic has queries, or requests further information or documents, the internal targeted time periods are stopped and the authorisation process can take longer.

If the applicant informs Swissmedic well in advance (three to six months) of the date of filing the application for marketing authorisation, Swissmedic offers, under certain conditions, a 20 per cent faster process (procedure with pre-announcement). The fees for the proceedings are then doubled.

If there is no treatment, satisfactory or otherwise, against a perilous or heavily disabling disease, and if the medical preparation is of a high therapeutic value, a fast-track procedure is available upon the applicant's request. The fast-track procedure must be applied for at least three months before the application for the marketing authorisation is filed. The marketing authorisation procedure can then be completed within about five months. If Swissmedic has queries, the proceedings may take longer.

The fees of Swissmedic for examining applications for marketing authorisations vary depending on the type of application. They are:

- 80,000 Swiss francs for a new active substance;
- 30,000 Swiss francs for a product containing an already registered active substance with innovation (simplified procedure);
- 15,000 Swiss francs for a product containing an already registered active substance without innovation (simplified procedure); and
- 500 Swiss francs for renewing an existing authorisation.

In addition to these fees, Swissmedic charges an annual supervisory fee that is calculated based on the ex-factory price of the medicinal product. The fee amounts to 6.5 per 1,000 of the ex-factory price.

The marketing authorisation is initially valid for five years. Swissmedic is entitled to grant a shorter authorisation period in the case of temporary authorisations or for health protection reasons. The authorisation is then renewed upon application if the conditions for authorisation are still fulfilled. The renewed authorisation is generally valid for an unlimited period. Swissmedic may, however, also limit the term of the renewed authorisation if necessary.

Law stated - 1 Oktober 2024

Marketing exclusivity

What protections or exclusivities apply to the marketing period of an approved medicinal product or variation?

The Law on Therapeutic Products does not provide for marketing exclusivities, but only for regulatory data protection in line with the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights 1994, article 39(3).

Law stated - 1 Oktober 2024

Protecting research data

What protections or exclusivities apply to the data submitted by originators to gain initial approval and, on variation or new application, to add indications or pharmaceutical forms?

Data submitted to Swissmedic are protected as follows against use by other applicants.

The protection period is 10 years for a medicinal product containing a new active substance.

Data protection is granted for three years for data filed in support of an authorisation for a medicinal product (original or not) for a new:

- indication;
- method of administration;
- Galenic form; or
- dosage.

For new indications, Swissmedic may grant 10 years of data protection on request when a significant clinical benefit can be expected over existing therapies and the indication is supported by extensive clinical trials.

For a medicinal product specifically and exclusively for paediatric use in accordance with the paediatric investigation plan, Swissmedic may grant data protection for 10 years on request.

For an important medicinal product for a rare disease, Swissmedic may grant data protection of 15 years on request.

Law stated - 1 Oktober 2024

Freedom of information

To what extent and when can third parties make freedom of information applications for copies of research data submitted by applicants for authorisation to market medicinal products or medical devices?

After an administrative decision has been taken, third parties, in principle, can ask for copies of authorities' documents based on the Federal Act on Freedom of Information in the Administration. Excepted are, among others, business secrets. Research data submitted by applicants for authorisation to market medicinal products or medical devices that have not been published can, in most situations, be business secrets. The four conditions for information to be a business secret are analysed in detail by Swissmedic and the courts. Regulatory data protection does not per se provide protection against freedom of information requests as the Swiss Federal Court has ruled in recent years (Case 1C_562/2017 E3.2).

With regard to research data regarding medical devices that are under the control of the authorities, the situation is as described above. Conformity assessment bodies are, however, not subject to the Federal Act on Freedom of Information in the Administration.

Law stated - 1 Oktober 2024

Regulation of specific medicinal products

What are the specific requirements and processes for marketing approval of the major categories of regulated products?

A simplified marketing authorisation procedure is available for certain types of medicinal products, such as:

- complementary and herbal medicinal products;
- orphan drugs;
- medicinal products with active substances that have already been authorised in Switzerland;
- parallel imports from a country with an equivalent marketing authorisation system;
- medicinal products of which the active substance has been used in a medicinal product authorised in one or more EU or European Free Trade Association (EFTA) countries for at least 10 years and that are comparable with regard to indication, dosage and mode of application;
- non-prescription medicinal products that, at the time of submission of the application, are proven to have been used medically for at least 30 years, at least 15 years of which have been in EU and EFTA countries; and
- certain radiopharmaceuticals and antidotes.

The simplified marketing authorisation procedure does not apply to biosimilars. However, Swissmedic may grant exemptions from the documentation and evidence requirements in the context of a biosimilar marketing authorisation procedure.

For certain medicinal products (eg, certain homeopathic and anthroposophical products), authorisation by way of a mere notification procedure is possible.

Swissmedic may grant a marketing authorisation of limited duration based on reduced requirements for medicinal products against life-threatening or seriously disabling diseases if this is compatible with the protection of health, if a significant therapeutic benefit can be expected from the administration of these products, and if no equivalent medicinal product is available in Switzerland.

For biologicals containing genetically modified organisms, additional authorisation requirements apply. Swissmedic assesses the product not only in accordance with the regulations of the Law on Therapeutic Products (LTP) but also of the Gene Technology Act and the Ordinance on the Handling of Organisms in the Environment.

For medical devices, in principle, the EU rules on market access apply. Specific rules exist for the obligation to appoint an authorised Swiss representative, the need for economic operators to register with Swissmedic and the reporting of serious incidents to Swissmedic.

Law stated - 1 Oktober 2024

Rewards and incentives

What rewards or incentives for approval are applicable to the major product categories, including orphan drugs, drugs for paediatric use, generic drugs and biosimilars?

Rewards in respect of regulatory data protection are granted to certain medicinal products, such as products specifically and exclusively for paediatric use or against orphan diseases.

If the approved product information of a medicinal product reflects all studies performed according to the approved paediatric investigation plan, an extension of the patent protection for six months is furthermore available upon application. The extension can be in the form of an extension of the supplementary protection certificate (SPC) (the Patent Act, article 140n) or, if there is no SPC, in the form of a paediatric supplementary protection certificate (the Patent Act, article 140t).

Law stated - 1 Oktober 2024

Post-marketing surveillance of safety

What pharmacovigilance or device vigilance obligations apply to the holder of a relevant authorisation once the product is placed on the market?

Marketing authorisation holders must include a risk management plan, including a pharmacovigilance plan, in applications for marketing authorisation for medicinal products with a new active substance and for new indications of new active substances. A risk management plan is also required for medical devices.

Marketing authorisation holders for medicinal products with a new active substance or biosimilars have to submit periodic safety update reports to Swissmedic during the four years following authorisation and in certain other situations.

Generally, the manufacturer or distributor of therapeutic products must maintain a pharmacovigilance system. The manufacturer or marketing authorisation holder of a medicinal product must notify Swissmedic of any of the following risks relating to medicinal products, which have been observed in Switzerland:

- serious adverse events;
- previously unknown adverse events;
- accumulation of known or previously unknown adverse events, including serious misuse and serious cases of intoxication;
- quality defects; and
- unusual distribution restrictions.

In relation to risks observed abroad, the following must be notified to Swissmedic:

- previously unknown risks or new aspects of known risks that are clarified further with regard to risk mitigation measures, that require risk mitigation measures or that have led to risk mitigation measures abroad;
- accumulation of known or previously unknown adverse events, including serious misuse and serious cases of intoxication; and

- quality defects if batches that were put on the Swiss market are affected.

The person placing a medical device on the market for the first time must notify Swissmedic of serious adverse events in Switzerland. Serious adverse events that occur in other treaty countries have to be notified to the competent authority in the applicable country.

In addition, the manufacturer, marketing authorisation holder or distributor of therapeutic products must report suspicion of illegal trade of therapeutic products by third parties, which it discovers in connection with its activities, with one of its products or with its components.

Law stated - 1 Oktober 2024

Other authorisations

What authorisations are required to manufacture, import, export or conduct wholesale distribution and storage of medicinal products and medical devices? What type of information needs to be provided to the authorities with an application, what are the fees, and what is the normal period of validity?

Medicinal products

Manufacturing is, in principle, subject to a manufacturing licence from Swissmedic. Hospital pharmacies and other organisations holding a retailing licence may have to apply for the licence to the canton.

The criteria for obtaining a manufacturing licence from Swissmedic, in accordance with the Medicinal Products Licensing Ordinance of 14 November 2018, article 3 et seq, are:

- the applicant is located in Switzerland;
- the applicant's facilities operate a system ensuring the pharmaceutical quality of medicinal products and the management and staff in the departments concerned must be actively involved in this system;
- each department has a sufficient number of qualified and competent staff members to enable it to achieve its quality targets;
- a qualified person has been appointed for the facilities;
- the facilities are organised in an appropriate way;
- the facilities are designed, structured, maintained and modernised regularly to guarantee the safe manufacture of medicinal products, and the premises and equipment that can influence the quality of the medicinal products is approved;
- a document system is available to provide the working instructions, procedure descriptions and protocols of the relevant manufacturing processes;
- manufacturing, testing and cleaning procedures are validated;
- quality control is independent of manufacture;
- applicable duties of care are fulfilled in the manufacturing process (in particular, manufacture is carried out in accordance with EU good manufacturing practices, as

set out in Commission Directive 2003/94/EC on good manufacturing practice for medicinal products); and

- the work of all persons occupying key positions in the company is set out in job descriptions and their positions in the hierarchy are shown in organisation charts.

Swissmedic performs an inspection with regard to these conditions.

The fee for the examination of an application for a licence is 1,500 Swiss francs. Additional fees for the inspection (depending on the time needed) apply. Swissmedic requests additional fees for the examination of inspection reports of regional inspectorates (200 Swiss francs), for the update of the database (100 Swiss francs) and the issuance of the licence certificate (200 Swiss francs; each attachment: 100 Swiss francs).

Licences granted since 1 January 2019 do not have a limited duration. Licences granted previously remain valid at least until their expiry date. Swissmedic may withdraw the licence if the conditions for its grant are no longer met or if the licensed activity is not performed for more than 12 months.

The requirements for licences for import, export or conduct of wholesale distribution of medicinal products are similar to those listed above for some variations (the Medicinal Products Licensing Ordinance, articles 11-18). Reduced requirements apply for licences for trading medicinal products abroad or brokerage or agency activities with medicinal products (the Medicinal Products Licensing Ordinance, articles 21-26).

Medical devices

Swiss law does not require licences for manufacturing, importing, exporting or conducting wholesale distribution and storage of medical devices. The principle of self-monitoring applies. Conformity assessment bodies need to be accredited or recognised by an international treaty.

Law stated - 1 Oktober 2024

Sanctions

What civil, administrative or criminal sanctions can authorities impose on entities or their directors and officers for breach of the requirements concerning controlled activities?

Swissmedic and the cantonal authorities monitor compliance in their respective areas of competence, which are defined in the LTP and related ordinances. They can generally take any administrative measure necessary to enforce the LTP, subject to the principles of proportionality and of public interest. The LTP lists certain possible measures in this regard. For breaches of a licence, Swissmedic can:

- raise objections and set an appropriate period for re-establishment of the lawful situation;
- suspend or revoke the licence;
- close down the establishment;

- seize, hold in official storage or destroy medicinal products that endanger health or that do not conform to the LTP; and
- prohibit the distribution, supply, import, export and trade of medicinal products, order their immediate recall from the market, or order the publication of recommendations of conduct to prevent damage.

Swissmedic and the competent cantonal courts can also impose criminal sanctions on entities or their directors, including the confiscation of assets or compensatory claims. Articles 86 and 87 list the breaches of the LTP for which criminal sanctions are foreseen. The criminal sanctions include up to 10 years of imprisonment and a fine (eg, for dealing or distributing unlicensed medicinal products that put the health of patients in danger).

Law stated - 1 Oktober 2024

Exemptions

What, if any, manufacture and supply of medicinal products is exempt from the requirement to obtain an approval to market?

There are some exceptions to the requirement to obtain marketing authorisation for medicinal products. The following medicines may be marketed without marketing authorisation:

1. medicinal products manufactured by hospitals or public pharmacies based on a prescription by a physician for a specific person or a specific circle of persons (magistral formula): the medicinal product can be manufactured ad hoc or for stockpiling, but only dispensed based on a prescription by a physician;
2. medicinal products manufactured ad hoc or for stockpiling by hospitals, public pharmacies, drugstores or other establishments with a manufacturing licence based on a special monograph of the pharmacopoeia or another recognised dispensary for dispensing to their own clients (officinal formula);
3. non-prescription medicinal products manufactured ad hoc or for stockpiling by hospitals, public pharmacies, drugstores or other establishments with a manufacturing licence based on their own formula or on a formula published in learned literature and within the dispensing competence of the person responsible for the manufacturing and for dispensing to his or her own clients;
4. medicinal products for which no alternative equivalent medicinal product is authorised or available and that are manufactured for stockpiling by hospitals based on a hospital's internal list of medicinal products and for dispensing to their own clients;
5. medicinal products for clinical trials; and
6. medicinal products that cannot be standardised.

Manufacturing of the medicinal products listed under items (1) to (4) can be delegated to an establishment with a manufacturing licence, and there are qualitative and quantitative limits on the manufacturing of these medicinal products.

Law stated - 1 Oktober 2024

Parallel trade

Are imports allowed into your jurisdiction of finished products already authorised in another jurisdiction, without the importer having to provide the full particulars normally required to obtain an authorisation to market? What are the requirements?

A company wishing to make parallel imports of medicinal products can apply for a special type of marketing authorisation, which is granted in a simplified procedure. The following conditions must be met:

- the medicinal product must originate from a country with an authorisation system equivalent to that of Switzerland;
- the medicinal product must satisfy the same requirements as products already approved in Switzerland; in particular, in relation to labelling and product information; and
- the parallel importer must be in a position to meet the same safety and quality requirements for the products as the holder of the marketing authorisation for Switzerland.

Swissmedic does not consider whether the medicinal product is still patent-protected. The defence of patent rights is upon the patent holder.

Law stated - 1 Oktober 2024

AMENDING AUTHORISATIONS

Variation

What are the main requirements relating to variation of authorisations for medicinal products and medical devices?

With the revision of the Law on Therapeutic Products (LTP), as of 1 January 2019, the regulations regarding variations of marketing authorisations for medicinal products were aligned with the EU regulations in this field. In the field of medical devices, including variations, Swiss law generally refers to EU regulations.

Law stated - 1 Oktober 2024

Renewal

What are the main requirements relating to renewal of authorisations for medicinal products and medical devices?

The marketing authorisation for a medicinal product is granted for the first time for five years. The Swiss Agency for Therapeutic Products (Swissmedic) may grant a shorter marketing authorisation period in the case of temporary authorisations or for health protection reasons.

The marketing authorisation is thereafter renewed upon application if the conditions for authorisation are still fulfilled. The renewed authorisation is generally valid for an unlimited period. Swissmedic may limit the duration of the renewed marketing authorisation if necessary.

For medical devices, there is no marketing authorisation necessary. For the conformity assessment, Swiss law generally refers to EU law.

Law stated - 1 Oktober 2024

Transfer

How easy is it to transfer the existing approvals or rights to market medicines and medical devices? How long does this take in general?

Marketing authorisations for medicinal products can be transferred by the marketing authorisation holder to another entity or person. The transfer is normally easy. It must be applied for at Swissmedic at least three months in advance. The current marketing authorisation holder must sign a declaration of assignment of the marketing authorisation and the new marketing authorisation holder must assume all rights and obligations related to the marketing authorisation. The new marketing authorisation holder must hold an appropriate licence for its activities.

For medical devices, there is no marketing authorisation that needs to be or can be transferred. The 'CE' mark cannot be transferred from one owner to another in an asset deal. A new conformity assessment must be made. Depending on the class of the medical devices and the changes in the production process, the costs and efforts needed for the new conformity assessment process can be very different. In a share deal, there would be no transfer of rights.

Law stated - 1 Oktober 2024

RECALL

Defective and unsafe products

What are the normal requirements for handling cases of defective or possibly unsafe products, including approvals required for recall and communication with health professionals?

The Swiss Agency for Therapeutic Products (Swissmedic) must be notified of quality defects. Swissmedic collects pharmacovigilance notifications and analyses them, and it can also order appropriate measures. If required and appropriate, Swissmedic can order administrative measures, including warning letters and product recalls. Most often, the measures are agreed between the company concerned and Swissmedic. The company concerned may also decide to execute a recall on its own.

Law stated - 1 Oktober 2024

ADVERTISING AND PROMOTION

Regulation

Summarise the rules relating to advertising and promotion of medicinal products and medical devices, explaining when the provision of information will be treated as promotional. Do special rules apply to online advertising?

Advertising aimed at healthcare professionals is generally allowed for all medicinal products authorised in Switzerland. Advertising must not be misleading, inaccurate, against public policy or unethical, or incite excessive, abusive or inappropriate use of medicinal products. Advertising aimed at healthcare professionals must be in line with the latest product information approved by the Swiss Agency for Therapeutic Products (Swissmedic), the Swiss regulatory agency. Advertising must be accurate, balanced and provable. The claims must be based on and reflect the current state of scientific knowledge. They may only refer to clinical studies conducted in accordance with good clinical practice that are published or accepted for publication, or to meta-analyses or observational studies that are published in a scientifically recognised scientific journal. Publications must be quoted literally, completely and with the exact reference. Advertisements must not indicate that a medicinal product does not have adverse effects or is without risk or harmless; appear to be an editorial; or indicate that a human medicinal product does not lead to dependency. Advertising for prescription-only medicinal products on the internet must be limited to healthcare professionals by means of password protection.

Information about illnesses and treatment options, in general, is permissible. Advertising for the company as such is also permissible, as is ad hoc publicity of quoted companies. For deciding whether information is illegal product advertising or admissible information, all circumstances of the particular case need to be taken into account. The sole mention of a brand name does not necessarily make information advertising.

Advertising of medical devices and collaboration with patient organisations with regard to medical devices are currently not as rigorously regulated as advertising for medicinal products. The Ordinance on Medical Devices contains one provision on advertising that sets out the following rules (article 69):

- advertising must be limited to statements that correspond to the product information;
- misleading claims, in particular on the intended use, safety and efficacy of a medical device, are prohibited; and
- advertising to the general public is prohibited for medical devices that are exclusively intended for use by healthcare professionals.

Law stated - 1 Oktober 2024

Inducement

What regulations exist to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of a particular medicinal product or medical device?

Mainly, the following regulations discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend the use of a particular medical product or medical device:

- the Law on Therapeutic Products, especially article 55, and the Ordinance on Integrity and Transparency in the Field of Therapeutic Products;
- the Ordinance on Advertising for Medicinal Products, especially article 11 on scientific congresses and promotional events;
- the anti-bribery provisions of the Swiss Criminal Code, articles 322-ter to 322-decies, and of the Act against Unfair Competition, article 4a;
- the rules governing the employment and function of healthcare professionals;
- the Federal Act on Academic Medicinal Professions;
- the Pharma Code and the Pharma Cooperation Code issued by scienceindustries; and
- the Swiss MedTech Code issued by Swiss MedTech.

Law stated - 1 Oktober 2024

Reporting transfers of value

What requirements apply to recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices?

The Pharma Cooperation Code issued by scienceindustries and the Swiss MedTech Code and the Transparency Guidelines issued by Swiss MedTech require that transfers of value to healthcare professionals and organisations are published on a company website; if possible, on a named basis and, if the healthcare professional or organisation does not consent, in aggregate form. Full details of transfers of value to healthcare professionals and organisations that are in connection with prescription-only medicinal products must further be disclosed to the Federal Office of Public Health upon request.

Law stated - 1 Oktober 2024

Enforcers

Describe the bodies involved in monitoring and ensuring compliance with advertising controls for medicinal products and medical devices, distinguishing between any self-regulatory framework and control by the authorities.

Swissmedic is the authority competent for monitoring and enforcing compliance with the rules for advertising therapeutic products (medicinal products and medical devices) to professionals and to the public. Advertising of medicinal products to professionals is also and mainly supervised by the Secretariat of the Pharma Code based on the advertising provisions of the (self-regulatory) Pharma Code. If a company does not comply with or refuses to follow the ruling of the Pharma Code Secretariat, the Pharma Code Secretariat

may, if it considers the violation of the Pharma Code a possible health risk, transmit the matter to Swissmedic.

Law stated - 1 Oktober 2024

Sanctions

What are the possible financial or other sanctions for breach of advertising and promotional controls for medicinal products or medical devices?

The intentional breach of advertising rules for medicinal products may be sanctioned by Swissmedic with fines of up to 50,000 Swiss francs, and breaches by negligence with fines of up to 20,000 Swiss francs. In the case of the commission of a breach on a professional basis, the fine may be higher. There is no equivalent provision for breaches of advertising rules for medical devices.

Swissmedic may also prohibit certain advertising in administrative proceedings and order that a future breach would incur fines.

The breach of the provisions on granting of financial benefits may be punished with a term of imprisonment of up to three years or a fine.

Law stated - 1 Oktober 2024

OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

May health professionals prescribe or use products for 'off-label' indications? May pharmaceutical companies draw health professionals' attention to potential off-label uses?

Doctors may prescribe and use products for off-label indications. This is part of the freedom of the doctor. He or she must have the informed consent of the patient and is solely responsible for the off-label use. In certain therapeutic areas, off-label use occurs very often.

Advertising for off-label use is not allowed. According to the Pharma Code, pharmaceutical companies are, however, allowed to inform healthcare professionals and the media about new indications, fields of use or dosages, Galenic formulations or packages that have not yet been authorised in Switzerland, without direct or indirect advertising. The trade name may be used, but always in connection with the international non-proprietary name of the active substance. The companies must make it clear that the medicinal product, new indication, field of use, dosage, Galenic formulation or package has not yet been authorised by the Swiss Agency for Therapeutic Products (Swissmedic) in Switzerland.

Law stated - 1 Oktober 2024

Unlicensed products

What rules apply to the manufacture and importation and supply to healthcare providers of unlicensed medicines or medical devices?

Unlicensed medicinal products, in principle, may not be imported or distributed. The same applies to medical devices that are not in conformity with the applicable requirements.

Under certain conditions, physicians, pharmacists and certain other healthcare professionals can import medicinal products that are not authorised in Switzerland for the treatment of named patients or for emergency situations (Medicinal Products Licensing Ordinance, article 49). The conditions are that the medicinal product is authorised in a country with a comparable marketing authorisation system (currently Australia, Canada, member states of the European Economic Area, Japan, New Zealand, Singapore and the United States) and that there is no medicinal product authorised or available in Switzerland that can be used as an alternative, or a change of the medication to a medicinal product that is authorised and available in Switzerland is not appropriate.

In addition, physicians are also allowed to import medicinal products that have not (yet) obtained marketing authorisation in such a country but are authorised for use in a clinical trial. In this situation, a risk analysis has to be established and reported to the competent cantonal authorities before importation.

The law also provides for specific provisions on compassionate use programmes authorised by Swissmedic. According to the new article 9b, paragraph 1 of the Law on Therapeutic Products (LTP), Swissmedic may temporarily authorise the sponsor of a clinical trial in Switzerland to use trial medication (that has not yet received a marketing authorisation) on certain persons or certain categories of persons outside the clinical trial.

Medical devices that are not in conformity with the requirements of the LTP may generally not be brought into circulation or used (LTP, article 86). As an exception, individual medical devices for which the relevant conformity assessment procedure has not been carried out may be placed on the market and used under the following conditions (the Ordinance on Medical Devices, article 22):

- they serve to remedy life-threatening conditions or to eliminate permanent impairments of a bodily function;
- no conforming medical device is available for the specific indication;
- they are used exclusively by medical personnel on individuals;
- the medical practitioner has informed the individual concerned of the non-compliance of the medical device and the risks involved; and
- the individual concerned has consented to the use of the medical device.

Also, Swissmedic may authorise the bringing into circulation and the putting into service of a specific medical device if the use of the medical device is in the interest of public health or patient safety or health (Ordinance on Medical Devices, article 22, paragraph 1).

Law stated - 1 Oktober 2024

Compassionate use

What rules apply to the establishment of compassionate use programmes for unlicensed products?

Until the end of 2018, there was no specific regulation on named patient programmes initiated by pharmaceutical manufacturers before a marketing authorisation was granted. Under certain conditions, physicians and pharmacists could import medicinal products that were not authorised in Switzerland, but in a country with a comparable marketing authorisation system for the treatment of named patients or for emergency situations. This possibility has been maintained and expanded to medicinal products that are (only) authorised for use in a clinical trial in such a country.

Since 1 January 2019, the law also contains a provision for certain compassionate use programmes authorised by Swissmedic. According to the LTP, article 9b, paragraph 1, Swissmedic may temporarily authorise the sponsor of a clinical trial in Switzerland to use trial medication (that has not yet received a marketing authorisation) on certain persons or certain categories of persons outside the clinical trial.

Law stated - 1 Oktober 2024

SALE AND SUPPLY

Regulation
Are there special rules governing the dispensing or sale of particular types of medicinal products or medical devices?

For certain types of medicinal products and medical devices, special rules governing the dispensing or sale exist. The basic rule is that prescription-only medicinal products (dispensing category A and B) may only be dispensed by pharmacists or doctors with an authorisation for self-dispensation which is granted by certain Cantons. Non-prescription medicinal products (dispensing categories D and E) may also be dispensed by drugstores.

One other important category is narcotic medicinal products. In addition to the rules on medicinal products, the rules on narcotic products apply. These rules require a special licence and strict controls of each step in the supply and dispensing process. They provide special rules regarding separate secured storage, transportation, destruction, retention of documents for at least 10 years, special authorisation for off-label use of certain substances, etc.

Special rules also exist for blood and blood products. These rules provide special licensing obligations and recording and archiving obligations (30 years).

In respect of medical devices, it must be taken into consideration that, for example, the dispensing of certain medical devices requires a prescription or that in vitro diagnostics for the detection of communicable diseases in humans cannot be dispensed to the public (with the exception of HIV tests).

Law stated - 1 Oktober 2024

Online supply

What laws and guidelines govern online dispensing, sale and supply of medicinal products and medical devices?

While online sale and supply of medicinal products in principle is prohibited, the cantons can grant authorisations to operate mail-order pharmacies. According to the Law on Therapeutic Products (LTP) and the Therapeutic Products Ordinance, article 55, in particular, the following conditions must be met for such an authorisation.

- the pharmacy must own a cantonal retailing licence;
- the pharmacy must operate a quality assurance system, assuring among other requirements:
    - the identification of the patient;
    - a check for adverse interactions with other medicinal products; and
    - proper advice to patients; and
    - the patient must supply a doctor's prescription with the order, whether it is a prescription or non-prescription drug.

Online dispensing, sale and supply of medical devices is governed by the LTP, article 48, and the Medical Devices Ordinance, article 7. Medical devices that can be dispensed to the public and that are intended by the manufacturer for self-service can be offered and sold to the public via the Internet. Professional advice must also be assured (except for Class I devices).

Law stated - 1 Oktober 2024

Pricing and reimbursement

What are the controls imposed on pricing of medicines and medical devices and reimbursement by national social security systems that are applicable to manufacturers, distributors and pharmacists?

Medicinal products that are reimbursed by basic health insurance are subject to government price control. The prices of non-reimbursed products are free and are not government-controlled. A finished medicinal product must, in principle, be listed on the speciality list (SL) established by the Federal Office of Public Health (FOPH) to be reimbursed in the outpatient sector of basic health insurance. When deciding on the admission of a medicinal product to the SL, the FOPH determines its list price. This price is the maximum price that can be invoiced by healthcare providers and that will be reimbursed by health insurance companies. About 80 per cent of the sales of pharmaceutical products in Switzerland relate to products listed on the SL.

The relevant criteria for fixing the SL price of an original product are the prices of drugs having the same indication or a similar mode of action and the average price of the product in other countries. Currently, the prices in nine reference countries – Austria, Belgium, Denmark, Finland, France, Germany, the Netherlands, Sweden and the United Kingdom – are used for this comparison. For determining the SL price, the FOPH adds a distribution margin to the ex-factory price determined according to the two criteria described above.

The fulfilment of the conditions for admission to the SL is, in principle, reviewed every three years. A review of the conditions for admission to the SL also takes place immediately after the expiry of the patent protection, as well as in the following situations: extension of an indication by the Swiss Agency for Therapeutic Products, request for changing a limitation of reimbursement and request for a price increase. The SL prices of generics and biosimilars are determined depending on the prices of their reference products.

Price increases may be applied based on the above-mentioned pricing criteria. They are, however, generally rare and can be excluded for specific years based on certain criteria.

In 2015, the FOPH launched a health technology assessment (HTA) programme that evaluates medical services and therapies already reimbursed by mandatory health insurance. The HTA is intended to assess the effectiveness, appropriateness and cost-effectiveness of certain individual medical services and therapies. After completion of an HTA procedure, the FOPH or Federal Department of Home Affairs decides on the continuation or a possible restriction or cancellation of the reimbursement.

If a medicinal product is not listed on the SL or is listed on the SL but used off-label or outside a limitation of reimbursement, it must be taken over by the health insurance companies under basic health insurance if there is no effective and authorised treatment alternative and a high therapeutic benefit can be expected from its use. In this situation, after consultation with the marketing authorisation holder, the insurer determines the amount of compensation depending on the (expected) therapeutic benefit of the medicinal product. Binding price reductions from the ex-factory price apply.

In the inpatient sector, basic health insurance pays hospitals certain lump sums depending on the diagnosis of the patient (the DRG system). The lump sum also covers the costs of medicinal products and medical devices. For certain expensive medicinal products, additional remunerations are foreseen in the DRG system. An additional remuneration of a certain defined amount is only available if the product has been listed in the SL.

The reimbursement of medical devices applied by medical practitioners is regulated by tariff agreements. For medical devices that are directly used by patients, or prescribed by a doctor and used by nursing institutions or nursing staff, the medical aid and device list, MiGeL, lists the maximum prices that are reimbursed by the health insurance companies. The MiGeL does not impose a price control (ie, the distributors of medical devices are free to determine their own price).

Law stated - 1 Oktober 2024

UPDATE AND TRENDS

Forthcoming legislation and regulation

Is there any current or foreseeable draft legislation or other rules that will affect the regulation of pharmaceuticals and medical devices? What is likely to change, and what steps need to be taken in preparation?

A revision of the pricing rules for reimbursed medicinal products came into effect on 1 January 2024. In this context, the FOPH announced that a revision of the Handbook for the List of Specialties (SL Handbook) will be published (most probably at the end of the year or in early 2025). The SL Handbook describes the FOPH's practice in this field.

Furthermore, under the title 'Cost containment package 2', several measures to reduce the cost increase of mandatory health insurance are currently being discussed in parliament. These measures also relate to the pricing of medicinal products.

On 1 November 2024 and 1 March 2025, revisions of the ordinances to the Human Research Act will come into force. The revisions intend to strengthen the protection of participants in research projects and improve the framework conditions for research. For example, the current requirements of EU law for the documentation and notification of side effects and reporting in research projects will be implemented. Furthermore, the revision is aiming to take account of scientific and technological progress and improve the framework conditions for research in the area of digitalisation.

Law stated - 1 Oktober 2024