Pharma & Medical Device Regulation 2022

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Getting The Deal Through

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Lexology Getting The Deal Through is delighted to publish the third edition of *Pharma & Medical Device Regulation*, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on Armenia.

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Alexander Ehlers of Ehlers, Ehlers & Partner and Ian Dodds-Smith of Arnold & Porter, for their continued assistance with this volume.

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Getting The Deal Through

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Switzerland

Frank Scherrer and Marcel Boller

Wenger Vieli Ltd

HEALTH SERVICES FRAMEWORK AND COMPETENT AUTHORITIES

Healthcare bodies

1 | Describe the bodies and their responsibilities (public and private sector) concerned with the delivery of healthcare and appropriate products for treatment.

Healthcare services and appropriate products for treatment are mainly delivered by public and private hospitals, resident physicians and pharmacies. A broad catalogue of healthcare services and products for treatment are reimbursed to patients by health insurances under the mandatory health insurance scheme. Each resident in Switzerland must contract basic health insurance with a health insurance company of his or her choice. There is the possibility of contracting additional private insurance. Besides health insurance, there are other types of social insurance.

Competent authorities for authorisation

2 | 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.

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. 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. 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 MEDDEV guidelines and the Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices of December 2017 are referred to. Products without a medical purpose may also fall into other product categories, such as foodstuffs, cosmetics and personal protective equipment.

Approval framework

3 | 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 Ordinance on Establishment Licences; 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 a branch office in Switzerland. The applicant must also have a manufacturing, import or wholesale licence.

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

For medical devices, as a principle, the EU rules on market access apply. For sale of a device in Switzerland, the 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.

CLINICAL PRACTICE

Applicable rules

4 | 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;
- 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));
- the World Medical Association Declaration of Helsinki; and
- Annexes VIII and X of Council Directive 93/42/EC concerning medical devices (the Medical Devices Directive) and Annexes 6 and 7 of Council Directive 90/385/EC and EN ISO 14155:20116, if clinical trials involve medical devices.

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 a web portal (ie, Business Administration System for Ethics Committees (BASEC)). 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.

Reporting requirements

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

Most clinical trials require prior authorisation by Swissmedic. Essential changes in the trial must also be approved by Swissmedic prior to their implementation. The sponsor must also notify Swissmedic of an interruption of the trial within 15 days, and of the trial's completion within 90 days. Generally, a final report with a summary of the outcome must be filed with Swissmedic within one year of the interruption or completion of the trial. For trials for which Swissmedic approval was not necessary, this notification has to be made to the competent ethics committee.

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 Switzerland SNCTP portal. The results of the trial do not need to be published.

Consent and insurance

6 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. The consent requirements are different for uncoded, coded (ie, pseudonymised) and anonymised data. For the general further use of coded health data and coded biological material for research purposes, 'general consent' is possible; that is, consent that does not need to be specific with regard to a particular research project. Swissethics provides templates for consent.

The HRA provides for 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 cover 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.

MARKETING AUTHORISATION

Time frame

7 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 take 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 eight per 1000 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 of time. Swissmedic may, however, also limit the term of the renewed authorisation if necessary.

Protecting research data

8 What protection 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?

Undisclosed data that has been submitted to the authorities for obtaining a marketing authorisation, the origination of which involves a considerable effort, is protected against unfair commercial use (article 39(3) of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights 1994). In line with this principle, the Law on Therapeutic Products (LTP) provides 10 years of data exclusivity for original preparations.

Data exclusivity 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 of 10 years on request.

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

Freedom of information

9 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 the respective 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 for 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 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.

Regulation of specific medicinal products

10 Are there specific rules for approval, and rewards or incentives for approval, of particular types of medicinal products, such as traditional herbal and homeopathic products, biologicals and biosimilars, controlled drugs, orphan drugs and those for paediatric use?

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 LTP but also of the Gene Technology Act and the Ordinance on the Handling of Organisms in the Environment.

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) (article 140n of the Patent Act) or, if there is no SPC, in the form of a paediatric supplementary protection certificate (article 140t of the Patent Act).

Post-marketing surveillance of safety

11 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 respective 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.

Other authorisations

12 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 to the canton.

The criteria for obtaining a manufacturing licence from Swissmedic, in accordance with article 3 et seq of the Ordinance on Establishment Licences of 14 November 2018, 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 for the issuance of the licence certificate (200 Swiss francs; each attachment: 100 Swiss francs).

Licences granted under the revised LTP do not have a limited duration. Licences granted under the previous law 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 for some variations (articles 11 to 18 of the Ordinance on Establishment Licences). Reduced requirements apply for licences for trading medicinal products abroad or brokerage or agency activities with medicinal products (articles 21 to 26 of the Ordinance on Establishment Licences).

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.

Sanctions

13 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 time 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).

Exemptions

14 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 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 for manufacture of these medicinal products.

Parallel trade

15 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.

AMENDING AUTHORISATIONS

Variation

16 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, Swiss law already referred to the EU regulations. The adaptation of Swiss medical device law to the EU regulations on medical devices and in vitro diagnostic medical devices is currently under way.

Renewal

17 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.

Transfer

18 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.

RECALL

Defective and unsafe products

19 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 a recall on its own.

PROMOTION

Regulation

20 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 (HCPs) 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 HCPs 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 HCPs 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 are taken into account. The sole mention of a brand name does not necessarily make information advertising.

Advertising aimed at the general public is not allowed for prescription-only medicinal products. It is furthermore not allowed for medicinal products that are reimbursed by the mandatory basic health insurance. Advertising aimed at the general public must not be misleading, inaccurate, against public policy or unethical, or incite excessive, abusive or inappropriate use of medicinal products. It must be in line with the latest Swissmedic-approved product information. It must be objective and without exaggeration and contain an invitation to consult the patient leaflet. Pharmaceutical products must be clearly presented as such. Quizzes, vouchers, testimonials and invitations to contact the marketing authorisation holder are not permitted. Advertisements in a printed form or via electronic media for analgesics, sedatives, sleeping tablets, laxatives and anorectics must be submitted to Swissmedic for prior approval if the product information mentions a potential for abuse or addiction.

Advertising of medical devices and collaboration with patient organisations 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 HCPs.

Inducement

21 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 HCPs to prescribe, sell, supply or recommend 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, article 322ter to 322decies, and of the Act against Unfair Competition, article 4a;
- the rules governing the employment and function of HCPs;
- the Federal Act on Academic Medicinal Professions; and
- the Pharma Code and the Pharma Cooperation Code issued by Scienceindustries, and the Swiss MedTech Code issued by Swiss MedTech.

Reporting transfers of value

22 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?

Details of transfers of value to HCPs and healthcare organisations (HCOs) that are in connection with prescription-only medicinal products need to be recorded and disclosed upon request to the Federal Office of Public Health. 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 are published on a company website; if possible, on a named basis and, if the HCP or HCO does not consent, in aggregate form.

ENFORCEMENT OF ADVERTISING RULES

Enforcers

23 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.

The Swiss Agency for Therapeutic Products (Swissmedic) is the authority competent for monitoring and enforcing compliance with the rules for advertising therapeutic products 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.

Sanctions

24 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 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 imprisonment up to three years or a fine.

PRICING AND REIMBURSEMENT

Pricing

25 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 the 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 for based on the above-mentioned pricing criteria. They are, however, generally rare.

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, the health insurance companies determine the reimbursed amount and negotiate a cost participation with the pharmaceutical company concerned.

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. Additional remuneration of a certain defined amount is only available if the product has been listed in the SL.

For medical devices that are directly used by patients, 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). As of 1 October 2021, MiGeL will also govern the reimbursement of medical devices prescribed by a doctor and used by nursing institutions or nursing staff. The reimbursement of medical devices applied by medical practitioners continues to be regulated by tariff agreements.

OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

26 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 is, however, 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 (HCPs) 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.

Unlicensed products

27 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 respective requirements.

Under certain conditions, physicians, pharmacists and certain other HCPs can import medicinal products that are not authorised in Switzerland for the treatment of named patients or for emergency situations (article 49 of the Ordinance on Establishment Licences). 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 prior to 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 nor used (article 86 of the LTP). 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 (article 9, paragraph 5 of the Ordinance on Medical Devices):

- 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 (article 9, paragraph 4 of the Ordinance on Medical Devices).

Compassionate use

28 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 compassionate use programmes authorised by Swissmedic. According to article 9b, paragraph 1 of the 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.

SALE AND SUPPLY

Regulation

29 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. One 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 for 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 for 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).

Online supply

30 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 article 55 of the Ordinance on Pharmaceutical Products, 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:
  1. the identification of the patient;
  2. a check of adverse interactions with other medicinal products; and
  3. 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 article 48 of the LTP and article 17 of the Medical Devices Ordinance. Medical devices that can be dispensed to the public and that are intended by the manufacturer for self-service can be offered and sold via the internet. Professional advice must also be assured (except for Class I devices).

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UPDATE AND TRENDS

Forthcoming legislation and regulation

31 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 major revision of the law on medical devices aligned Swiss law with the EU regulations on medical devices and in vitro diagnostic medical devices. This revision became effective on 26 May 2021. In respect of in vitro diagnostics, this revision will become effective on 26 May 2022.

Parliament is currently discussing various projects for a revision of the pricing and reimbursement rules, especially for generic products.

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