Practical Law™
GLOBAL GUIDE 2020
LIFE SCIENCES

Medicinal product regulation and product liability in Switzerland: overview

Frank Scherrer, Andrea Schütz, Claudia Keller and Marcel Boller, Wenger & Vieli AG

global.practicallaw.com/1-500-6812

REGULATORY OVERVIEW

1. What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

Legislation

Medicinal products are regulated by the Federal Law on Medicinal Products and Medical Devices (Law on Therapeutic Products) (*Heilmittelgesetz*) of 2000 (LTP). Several ordinances have been issued based on the LTP. Genetic testing is subject to the Act on Human Genetic Testing of 2004 (AHGT). Clinical trials with medicinal products are regulated by the LTP, the Federal Act on Research involving Human Beings (Human Research Act) (HRA) of 2011 and related ordinances.

Swiss legislation on medicinal products follows EU regulation in many areas.

Placing medicinal products on the market requires a marketing authorisation (with some exceptions). There is no automatic recognition of marketing authorisations granted in the EU. However, marketing authorisations in countries with a comparable marketing authorisation system such as the EU or the US are taken into account.

The LTP and related ordinances set out the conditions for licences required to manufacture, import, sell, trade, broker, or export medicinal products (establishment licences). The LTP also contains rules about the prescription, dispensing and advertising of medicinal products.

The Federal Health Insurance Act (*Krankenversicherungsgesetz*) of 1994 (as amended) and related ordinances regulate reimbursement of medicinal products and medical devices by social health insurance. They also regulate the pricing of medicinal products reimbursed by social health insurance.

Regulatory authorities

Marketing authorisations are granted by the Swiss Agency for Therapeutic Products (*Schweizerisches Heilmittelinstitut*) (Swissmedic) (*www.swissmedic.ch*). Its main areas of responsibility are:

- Marketing authorisations.
- Establishment licences.
- Control of advertising.
- Supervision of clinical trials.
- Market surveillance for medicinal products and medical devices.

Licences to manufacture, import, trade, broker, or export medicinal products are granted by Swissmedic, or in certain exceptional circumstances by the cantons. Authorisations to operate a hospital, a physicians' practice, pharmacy or a drug store and to dispense medicinal products are granted by the cantons.

Reimbursement status for medicinal products is granted by the Swiss Federal Office of Public Health (*Bundesamt für Gesundheit*) (FOPH) (*www.bag.admin.ch*). The FOPH decides on the maximum price for reimbursed medicinal products. Starting from 2020, the FOPH is also responsible for enforcing the provisions on monetary advantages and transparency.

The authorities of the 26 cantons issue licences for the operation of hospitals, physicians' practices, pharmacies (*Apotheke*, lead by a pharmacist who is entitled to dispense presciption-only medicinal products) and drug-stores (*Drogerie*, which can only sell non-prescription medicinal products**).** In that context, they also have competences concerning the supervision of the manufacturing, handling, prescription and dispensation of medicinal products and medical devices. For example, they can check the handling of medicinal products and can verify the ingredients of medicinal products.

2. Briefly outline any additional or alternative regulation of large molecule (biological) medicines, and discuss how combination products and gene therapies are classified and regulated in your jurisdiction.

Biologicals are treated as a sub-category of pharmaceuticals. For pharmaceutical products containing genetically modified organisms (GMO) 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 (*Gentechnikgesetz*) and the Ordinance on the Handling of Organisms in the Environment (*Freisetzungsverordnung*). Product information and labelling must indicate that the product contains genetically modified organisms. Swissmedic requires specific wording to be placed in the product information regarding the traceability of the product. Since 2019 such products are subject to additional monitoring requirements (biovigilance) and stricter regulation on warning labels in accordance with EU law.

There is no simplified procedure for the marketing authorisation regarding products with known active substances (*see Question 11*) containing genetically modified organisms.

The rules of the LTP are also applied to transplant products (TpP) and gene therapy medicinal products (GT). Such products also require a marketing authorisation of Swissmedic. During the authorisation procedure, the entire manufacturing process, intermediate products and end products are reviewed.

Combination products are also subject to certain specific authorisation requirements. In particular, the application for marketing authorisation must contain data concerning specifically the combination product; it is not sufficient to submit data on the individual components only. For a guideline on the documents to be submitted with the application, Swissmedic refers to the WHO Guidelines for registration of fixed-dose combination medicinal products (*WHO Technical report series, No. 929, 2005: Annex 5*) and to the ICH guideline M3. Combination products containing only

known active substances can be granted marketing authorisation in accordance with the simplified procedure for the marketing authorisation for products with known active substances (*see Question 11*).

3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of medical software, health care IT, e-health (such as mobile health apps), or laboratory diagnostic testing kits?

Medical devices, including diagnostics, are regulated by the LTP and related ordinances. In the field of medical devices Switzerland has essentially transposed EU regulations, mainly into the Ordinance on Medical Devices (*Medizinprodukteverordnung*) (MedDO), which has been issued based on the LTP. This together with the Switzerland-EU Mutual Recognition Agreement (MRA) allows free movement of medical devices between Switzerland and the EU. The prerequisite for the MRA is the equivalence of the corresponding legal regulations in Switzerland and the EU. The Ordinance on Medical Devices was partially revised in November 2017 to implement a first set of changes to EU law. In addition, the regulations on medical devices were further revised to ensure EU compatibility. The corresponding changes will come into force on 26 May 2021 and on 26 May 2022 (for in-vitro diagnostics) and will tighten the requirements for medical devices. For example, manufacturers will have to prove the usefulness and expediency of high-risk products in clinical studies to a much greater extent than previously.

There is currently only fragmented regulation of health IT issues and no specific regulation of mobile medical applications. Software and mobile medical applications may fall within the definition of medical devices if they are used for medical purposes.

Laboratory diagnostic testing tools as a combination of a swab and a specimen receptacle are considered as a laboratory diagnostic testing kit. If the principal intended purpose of a kit is to collect and store human specimens for in vitro diagnostic purpose, the kit will be regulated as an in vitro diagnostic medical device under the MedDO. The distribution to the public of in vitro diagnostic medical devices for the detection of transmissible human diseases is prohibited (*Article 17, paragraph 3, MedDO*).

Swissmedic is the authority responsible for monitoring and enforcing compliance with medical devices regulations. Medical devices do not require a marketing authorisation. However, a medical device can only be placed on the market by a manufacturer or importer when the applicable conformity assessment procedure has been successfully completed. The CE mark allows the free movement of medical devices within the European Economic Area (EEA) and Switzerland. With regard to the placing on the market of certain medical devices in Switzerland a duty to notify Swissmedic applies. For sales in Switzerland, the product information must be written in German, French and Italian (with some restrictive exceptions).

Clinical trials with medical devices are regulated by the LTP, the Human Research Act and related ordinances.

Reimbursement of medical devices by social health insurance is also regulated by the Federal Health Insurance Act and related ordinances. Reimbursement status of certain types of medical devices is granted by the Federal Department of Home Affairs.

PRICING, GOVERNMENT FUNDING AND REIMBURSEMENT

4. What is the structure of the national health care system, and how is it funded? Explain briefly how medicines are introduced into that system.

Structure

The healthcare system reflects the federalist structure of Switzerland. Only certain areas are controlled by the confederation, the others by the 26 cantons. For example, most non-private hospitals are regulated and owned by the cantons.

The confederation's competences have grown in recent years. Important areas of the healthcare system are legislated, and are now controlled by the confederation, including:

- Social health insurance (*Soziale Krankenversicherung*).
- Academic professions in the healthcare sector.
- Pharmaceutical products and medical devices.
- Narcotics.
- Research involving humans.
- Reproductive medicine.
- Transplantation.

Legislation on social health insurance provides that individuals must be insured with a sick fund of his choice. Sick funds form the basis of, and are part of, social health insurance. Cover provided by social health insurance, also called basic insurance (*Grundversicherung*), can be supplemented by optional additional private insurance (private *Zusatzversicherung*). The insurance system generally allows a free choice of healthcare provider(s). The basic insurance provides for a quite extensive catalogue of reimbursed treatments, medicinal products and medical devices.

Funding

The healthcare system is mainly financed by:

- Social health insurance.
- Private insurance.
- The Swiss confederation.
- The cantons.
- The communities.
- Direct payments by patients.

Insured individuals contribute to social health insurance through premiums to their sick fund and patient co-payments. The premiums can vary significantly between the different regions, sick funds and type of insurance that can be chosen within certain limits. The social health insurance premiums of low-income individuals are, in addition, subsidised by the cantons and the federal government.

5. How are the prices of medicinal products regulated?

Non-reimbursable products

For non-reimbursable products, there is no price regulation. Swissmedic does not evaluate prices when granting marketing authorisation. However, if there is price abuse by a market dominant company or there are illegal agreements on prices, the Competition Commission or the price surveillance authority can intervene.

Reimbursable products

For reimbursable products, the Federal Health Insurance legislation sets out regulations for determining the maximum price that healthcare providers (that is, pharmacies, drug stores, hospitals and self-dispensing doctors) can charge for reimbursable products. For a pharmaceutical product to be reimbursed within the framework of the social health insurance system, it must generally be within the lists drawn up for this purpose, particularly the Speciality List (SL) issued by the FOPH (*www.bag.admin.ch/kv/gesetze/sl/d/index.htm*). In case of in-patient hospital treatment, reimbursement of medicinal products, with the exception of certain expensive medicinal products, is included in the flat-rate treatment fees for diagnosis related groups (DRG) paid by the insurance companies.

6. When is the cost of a medicinal product funded by the government or reimbursed? How is a pharmacist compensated for dispensing services?

Depending on the applicable insurance system, the costs of ambulatory treatment, including medicinal products, are directly paid for by the sick fund of the patient or reimbursed to him after he has paid the cost. The costs of in-patient treatment are directly paid for by the sick funds. The sick funds are not part of the state administration, but they perform governmental tasks and are supervised by the state administration. Under the basic health insurance regime, medicinal products dispensed in ambulatory treatment are reimbursed if they are prescribed by a physician (or under certain circumstances, by a chiropractor) and listed in one of the lists drawn up for this purpose, particularly the Speciality List (SL). Optional additional private insurances also cover most authorised medicinal products that are not listed in the SL. The costs of medicinal products dispensed in in-patient hospital treatment are covered through the payments for diagnosis related groups (DRG) paid by the sick funds and the contributions of the Cantons; for certain expensive medicinal products additional fees can be charged by the hospitals within DRG.

Applications for a listing in the SL must be made to the Federal Office of Public Health (FOPH). The granting of marketing authorisation does not mean that a pharmaceutical product is automatically reimbursed. The holder of the marketing authorisation can choose whether to apply for reimbursable status. The FOPH can place a pharmaceutical product of great importance for healthcare on the SL without prior application from the marketing authorisation holder. About 67% of all packages of pharmaceutical products registered and sold in Switzerland are listed on the SL. Prescription and non-prescription drugs can be listed on the SL.

A medicinal product is only admitted to the SL if the applicant can show its efficacy, usefulness and economy. The FOPH bases its decision on a recommendation of the Federal Commission for Medicinal Products. The following are the criteria for fixing the SL price:

- The average ex-factory price (without VAT) of the product in Germany, Denmark, the UK, The Netherlands, France, Austria, Belgium, Sweden and Finland. The FOPH can also use other countries for the comparison.
- The prices of other drugs for the treatment of the main indication of the product.

These two criteria are weighted at 50% each.

If the pharmaceutical product constitutes a considerable therapeutic advancement, an innovation premium can be granted. In determining the SL price, the FOPH adds a distribution margin to the ex-factory price determined according to the above criteria. In an application to list a drug in the SL, the applicant must indicate the requested price. If the FOPH considers the price to be too high, it can give an alternative price, which the applicant can accept or reject. If the applicant finally rejects the prices proposed by the FOPH, he/she can ask that a formal decision is issued by the FOPH. The decision can be appealed.

According to the current rules, fulfilment of the admission conditions is reviewed every three years for all pharmaceutical products listed in the SL (about one third of the listed products every year). If the review shows that the price is too high according to the above criteria, the price is decreased. There is also a review of the admission conditions:

- Immediately after expiration of patent protection.
- If an application for a price increase is filed.
- In principle, if a new indication is authorised by Swissmedic for an original medicinal product or if a request for changing or deleting a limitation on reimbursement is filed.

Currently, the following rules apply for the listing of generic products in the SL:

- The ex-factory price of the generic product must be at least 70% lower than the price of the original, if the Swiss market volume of the original (including its co-marketing products) exceeded CHF25 million per year on average during the three years before patent expiry.
- The ex-factory price of the generic product must be at least 60% lower, if the market volume of the original (including its co-marketing products) was between CHF16 million and CHF25 million on average during the three years before patent expiry.
- The ex-factory price of the generic product must be at least 50% lower, if the market volume of the original (including its co-marketing products) was between CHF8 million and CHF16 million on average during the three years before patent expiry.
- The ex-factory price of the generic product must be at least 30% lower, if the market volume of the original (including its co-marketing products) was between CHF4 million and CHF8 million on average during the three years before patent expiry.
- The ex-factory price of the generic product must be at least 20% lower, if the market volume of the original (including its co-marketing products) did not exceed CHF4 million on average during the three years before patent expiry.

In the three-yearly price revisions, the price difference of generics must be between 35% and 10%, depending on the market volume.

The ex-factory price of parallel imports must generally be at least 15% lower than the ordinary ex-factory price, unless the product is already on the generic price level.

Any price increase of a reimbursed product must be approved by the FOPH. An application for a price increase can be submitted at the earliest two years after the listing of the product in the SL or after the last increase. In 2018 and 2019 price increases were excluded.

FOPH decisions relating to listing in the SL can be appealed first to the Federal Administrative Court and then to the Federal Supreme Court.

The SL sets out the maximum price that the healthcare providers can charge for certain medicinal products. The SL price takes into account a distribution margin which is different for prescription and non-prescription products. In relation to prescription medicines, pharmacists can charge for certain services in addition to the SL price (including control of the prescription, information and instructions, and the keeping of a patient file). The reimbursement of these services is based on a contract between the Swiss pharmacists' association and the insurances that must be approved by the Swiss government.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials are mainly regulated by the:

- Law on Therapeutic Products (LTP).
- Human Research Act (HRA).
- Ordinances related to the HRA.
- Ordinance on Medical Devices.
- Data Protection Act (DPA).
- Guidelines on Good Clinical Practice of the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use 1996 (ICH-GCP E6(R2)).
- World Medical Association (WMA) Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, Brazil 2013.
- Annexes VIII and X of Directive 93/42/EC concerning medical devices (Medical Devices Directive), if clinical trials involve medical devices.

Subject to exceptions, both Swissmedic and the competent ethics committee must approve the trial. The Swiss Association of Research Ethics Committees (Swissethics) has published several guidelines and templates with regard to clinical trials (*www.swissethics.ch*).

Authorisations

In principle, clinical trials with therapeutic products need authorisation by Swissmedic and the competent ethics committee. Clinical trials with pharmaceuticals authorised in Switzerland and administered within the scope of 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 assesses the trial from an ethical point of view, examines compliance with legal requirements and verifies its scientific quality, taking into account local conditions. The committee ensures the safety of the trial subjects. The Association of Swiss Ethics' Committees (Swissethics) issues templates and recommendations for the various documents such as study protocols and informed consent forms. Although the templates are declared to be "mandatory" by Swissethics, the ethics committees accept variations if they are materially in line with their templates. The ethics committees are appointed and supervised by the cantons. There are certain rules in federal law relating to their composition. Applications have to be submitted through a web portal (BASEC). The competent ethics committee confirms receipt of the application within seven days and advises of any formal flaws in the file. The committee issues its decision within 30 days after receipt of the application. In case the committee requests additional documents this time limit is suspended until the complete information has been received. In case of multicentre trials, the leading ethics committee issues its decision within 45 days. Authorisation is granted if the trial complies with ethical, legal and scientific requirements.

Swissmedic examines whether the product used in the trial complies with the requirements of Good Manufacturing Practice and with safety requirements. The trial file has to be submitted to Swissmedic by the sponsor. Swissmedic requires one hard copy and one electronic copy of the file containing the documents listed in the annex of the Ordinance on Clinical Trials in Human Research. Swissmedic does not process incomplete files. Receipt of the application is confirmed within seven days and the applicant is informed of any formal flaws in the file. Swissmedic issues its decision within 30 days after receipt of the complete application. This time limit can be extended for another 30 days if the pharmaceutical is for the first time applied to human beings or if it is manufactured in a new process. Swissmedic can inspect compliance with legal rules any time.

The trial file can be submitted to the competent ethics committee and to Swissmedic simultaneously, if both approvals are required. The trial cannot start before both Swissmedic and the competent ethics committee have approved it. Essential changes in the trial plan have to be approved by Swissmedic and the ethics committee prior to their implementation. The same deadlines apply as for the initial trial authorisation.

Consent

Trial subjects must give their free informed consent to participation in the trial. Different levels of consent are required for the future use of collected biological samples, genetic data and regular health data for research purposes. Clause 4.8 of ICH-GCP applies. The consent requirements are different for uncoded, coded (that is, pseudonymised) and anonymised data. For the general 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 to a particular research project. The HRA and the templates of Swissethics provide the necessary content for the consent forms. The complete information given to the trial subjects and the way the informed consent is obtained is reviewed by the competent ethics committee.

Trial pre-conditions

Pre-conditions for the performance of a clinical trial are that:

- The trial project and documentation must be set up according to the applicable rules.
- The sponsor must have its registered office in Switzerland or name a representative located in Switzerland.
- The competent ethics committee has approved the trial.
- Swissmedic has approved the trial, if necessary.
- Trial subjects must be guaranteed full compensation for injuries suffered in the trial. This requires insurance cover or comparable securities up to a certain amount for any damage caused by the trial, occurring both during the trial and within ten years after it ends. The amount of insurance cover is generally at least CHF10 million for the whole trial and CHF1 million for each case of personal injury and CHF50,000 for each case of material damage. In certain cases, involving lower risks for trial subjects the amount of insurance cover can be less or even no security is necessary. Swissethics has issued a template for general terms and conditions of insurance for clinical trials.

Procedural requirements

Procedural requirements are set out in the Ordinance on Clinical Trials in Human Research and the ICH-GCP.

If serious adverse events occur in participating subjects during the conduct of the clinical trial, the investigator must document them in a standardised manner and report them to the sponsor within 24 hours of their discovery. The trial sponsor **must report** a suspected unexpected adverse drug reaction with a fatal outcome to the competent ethics committee within seven days and any other suspected unexpected serious adverse drug reaction within 15 days.

The trial sponsor must notify Swissmedic of an interruption of the trial within 15 days, and of the trial's completion within 90 days. A final report must generally be filed with Swissmedic within one year of the trial's interruption or completion. With regard to trials for which Swissmedic's approval was not necessary, such notification has to be made to the competent ethics committee. In

case safety or health of the trial subjects is endangered, the ethics committee can set additional requirements or suspend or withdraw the authorisation for the trial.

Public registration

The Human Research Act provides for mandatory public registration of authorised clinical trials. The trial must be registered by the sponsor either with a primary registry accredited by the WHO or with the registry of the US National Library of Medicine, as well as in the public database of Switzerland (SNCTP Portal) (*www.kofam.ch/en/*). Registration must be made prior to conducting the trial. An exception are phase I trials which must be registered within one year after completion of the trial. The data must be registered in the version authorised by the competent ethics committee. Data registered in the international registry must be in accordance with the WHO Trial Registration Data Set (Version 1.2.1). Data registered with the national database must contain additional data as stipulated in Annex 5 of the Ordinance on Clinical Trials in Human Research. Trial results do not have to be published.

Transparency and reporting requirements

An Annual Safety Report (ASR) must be submitted for certain clinical trials carried out in Switzerland (categories B and C).

The ASR is submitted once a year, throughout the duration of the clinical trial, and the final ASR submission must cover the Last Patient Last Visit (LPLV) in Switzerland.

Further, after submission of the ASR (covering LPLV), there is no need for further ASR submissions since the information on safety will be captured in the clinical study report. The report can cover a single trial or several trials with the same medicinal product. In that case the individual trials must be clearly identifiable.

MANUFACTURING AND DISTRIBUTION

8. What is the authorisation process for manufacturing and distributing medicinal products?

Application

The manufacturer must in principle obtain a manufacturing licence from Swissmedic. Hospital pharmacies and other establishments holding a retailing licence may have to apply to the canton.

The distribution at wholesale level and the importation and exportation of medicinal products also require a licence from Swissmedic.

The permitted activities are specified in the licence. Generally, the licence does not mention specific medicinal products or classes of products. The holder of a licence can therefore manufacture or distribute different medicinal products and does not have to apply for a new licence for each product. The handling of controlled drugs and drug precursors are specifically regulated.

Distribution at retail level requires a cantonal licence (*see Question 15*).

Conditions

The conditions for obtaining a licence vary depending on the type of licence.

The following criteria must be satisfied to obtain a manufacturing licence from Swissmedic:

- The facilities of the applicant must operate a system to ensure the pharmaceutical quality of medicinal products, and the management and staff in the individual departments concerned must be actively involved in this system.
- Each department must have a sufficient number of qualified and competent staff members to enable it to achieve its quality targets.
- A qualified person must be appointed for the facilities.
- The facilities must be organised in an appropriate way.
- The facilities must be 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 must be approved.
- A document system must be available to provide the working instructions, procedure descriptions and protocols of the relevant manufacturing processes.
- Manufacturing, testing and cleaning procedures must be validated.
- Quality control must be independent of manufacture.
- Applicable duties of care must be fulfilled in the manufacturing process (in particular, manufacture must be according to EU Good Manufacturing Practices (GMP), particularly as set out in Directive 2003/94/EC on good manufacturing practice for medicinal products).
- The work of all persons occupying key positions in the company must be set out in job descriptions and their positions in the hierarchy shown in organisation charts.

(*Article 3 et seq., Ordinance on Establishment Licences of 14 November 2018.*)

The conditions that must be satisfied to obtain a wholesale licence are comparable to those for the manufacturing licence (*Article 11 et seq., Ordinance on Establishment Licences of 14 November 2018*). Applicable duties of care must be fulfilled, in particular the activities must comply with the EU Good Distribution Practice (GDP).

If the required conditions are not met, the licence cannot be granted. The licence can also be withdrawn if the conditions are no longer fulfilled. Compliance with these conditions is inspected by Swissmedic. An inspection is performed before granting the licence and can also be performed any time during a licence term.

A GMP certification and a GDP certification are not conditions to obtain a licence, but the applicant for a licence must prove that their manufacturing and distribution processes are in line with GMP/GDP.

Restrictions on foreign applicants

The applicant must be located in Switzerland. There are no restrictions on foreign ownership.

Key stages and timing

The key stages in the process are:

- Application.
- Inspection.
- Grant of the licence.
- Regular inspections (in principle, every two years).

Fee

The fee for examining an application for a licence is CHF1,500, plus fees for the examination of inspection reports of regional inspectorates (CHF200) and for the update of the database (CHF100). The fee for the issuance of the licence certificate without attachments is CHF 200. Each attachment to a certificate costs CHF100. The fees are listed in the Ordinance of Swissmedic on its fees.

Authorisations, variations, and renewals

Licences granted under the revised provisions of the LTP do not have a limited duration. Licences granted under the previous law remain valid at least until their expiry date.

The activities covered by the licence are described in the licence itself. For example, the holder of an import licence is entitled to commercially import medicinal products, but cannot export medicinal products without an export licence. For the extension of the scope of the licence, a corresponding application must be made.

Swissmedic can withdraw the licence if the conditions for its grant are not fulfilled any more, or if the licensed activity is not performed for more than 12 months.

Monitoring compliance and imposing penalties

Swissmedic and the cantons have powers to monitor compliance with manufacturing and distribution licences in their respective areas of competence, which are defined in the LTP and related ordinances. They must verify by periodic inspection that conditions for the licences are met. The inspectorates can request an operating description (Site Master File), inspect any part of the premises with or without notice, make copies of documents and electronic files, request information and documents, take samples, and take all necessary immediate measures.

Swissmedic and the competent cantonal authorities 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 the manufacturing or distribution licence, Swissmedic can:

- Raise objections and set an appropriate time period for re-establishment of the lawful situation.
- Suspend or revoke the licence (this decision will be published by Swissmedic).
- Close down the establishment.
- Seize, hold in official storage or destroy medicinal products which endanger health or which do not conform to the LTP.
- 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.

Apart from administrative measures, Swissmedic and the competent cantonal courts can also impose criminal sanctions as follows:

A custodial sentence of up to three years or a fine canbe imposed on any person who wilfully manufactures, places on the market, uses, prescribes, imports or exports, or trades in a foreign country medicinal products without the required marketing authorisation or licence.

A custodial sentence of up to ten years, which can be combined with a monetary penalty, can be imposed if the person concerned:

- Knows or must assume that the violation specifically endangers human health.
- Achieves a high turnover or makes substantial profits through commercial activity. If the person concerned acts out of negligence, he/she is liable to a monetary penalty of up to 180 daily penalty units. The daily penalty units are determined based on the personal and economic circumstances of the person concerned. The maximum penalty is 180 x CHF 3,000, that is CHF1,080,000. In minor cases, a fine of up to CHF50,000 can be imposed.

In principle, the decisions of Swissmedic can be appealed to the Federal Administrative Court. Certain decisions of Swissmedic in criminal proceedings can be appealed to the Federal Criminal Court. Decisions of the Federal Administrative Court and the Federal Criminal Court can be appealed to the Federal Supreme Court.

In criminal proceedings, Swissmedic can, against the will of the licensee, obtain access to all documents relevant to the proceedings. Swissmedic can do this, for example, by means of a house search.

MARKETING
Authorisation and abridged procedure

9. What is the authorisation process for marketing medicinal products?

Application

Marketing authorisation is required for placing a pharmaceutical product on the market, whether prescription-only or over-the-counter (OTC), except in certain limited circumstances. The application must be made to Swissmedic using standard forms, and for New Active Substances, using the Common Technical Document (CTD) of the International Conference on Harmonisation. Swissmedic accepts registration documents in the form approved by the EU. It also supports submitting data electronically. The following documents must be included:

- Analytical, chemical, pharmaceutical, pharmacological, toxicological and clinical documents that certify the quality, efficacy and safety of the product.
- Drafts of the product information to be provided to professionals and patients.
- Packaging design.
- Samples of the medicinal product, active and auxiliary agents, intermediate and by-products, if requested by Swissmedic.
- For new active substances and new indications of new active substances a risk management plan, including a pharmacovigilance plan.
- Paediatric investigation plan.

The required documents are listed in detail in the Ordinance on the Requirements for the Marketing Authorisation of Medicinal Products and its Annexes of 9 November 2001 (Ordinance on Marketing Authorisations) and guidelines issued by Swissmedic.

Exceptions

The following medicinal products can be marketed without a marketing authorisation:

- Medicinal products prepared under a physician's prescription by a public or hospital pharmacy, or under mandate to the latter by another establishment holding a manufacturing licence, and for a given person or group of persons or for a given animal or livestock (magistral formula). On the basis of a prescription, the medicinal product can be manufactured by a public or hospital pharmacy as required or on a small industrial scale but can only be dispensed on a physician's prescription.
- Medicinal products prepared as required for a patient or on a small industrial scale by a public pharmacy, a hospital pharmacy, a drugstore or by another establishment holding a manufacturing licence, conforming to a special monograph of the *Pharmacopoeia Europea and Helvetica* or another pharmacopoeia or formulary recognised by Swissmedic, and which are supplied to their own customers (officinal formula).
- Non-prescription medicinal products prepared as required for a patient or on a small industrial scale by a public pharmacy, a hospital pharmacy, a drugstore or by another establishment holding a manufacturing licence, within the limits of the

establishment's right to dispense, according to its own formula or a formula published in the specialised literature, which are intended for dispensing to the establishment's own customers.

- Medicinal products for which there is no authorised or available alternative medicinal product and which are manufactured in a hospital pharmacy in accordance with the hospital's own pharmaceuticals list, on a small industrial scale, and are intended for dispensing to its own customers.
- Medicinal products for clinical trials.
- Medicinal products which cannot be standardised.
- Medicinal products that were authorised in a canton on 1 January 2002 and which were still on the market when the Revision of the LTP of 18 March 2016 came into force; they must be labelled accordingly and can only be placed on the market in the canton concerned and only supplied by persons entitled to supply medicinal products.

Authorisation conditions

The conditions for a marketing authorisation for all medicinal products (including vaccines) are the product's safety, efficacy and high quality. While high quality manufacturing must always be guaranteed, the application is mainly assessed on the drug's efficacy and relative safety (the ratio between benefit and risk). If a drug or process has already been approved in another country that possesses a similar system of drug control, those examination results are considered. Swissmedic does not examine whether there is patent protection.

A marketing authorisation can only be granted to a person or company having its domicile, registered office or branch office in Switzerland. The applicant must also have a manufacturing, import or wholesale licence.

The marketing authorisation is specific to a medicinal product. The holder of the marketing authorisation must have an establishment licence from Swissmedic for manufacturing, import or wholesale of medicinal products including release for the market. The marketing authorisation does not regulate activities like storing, transporting, distributing, selling and advertising.

Pricing regulations and health technology assessments are not relevant for the marketing authorisation and are not examined by Swissmedic during the marketing authorisation process.

Key stages and timing

The normal authorisation procedure takes at least about one year and can take longer, depending on the time the applicant needs for possible corrections of the application and for answering Swissmedic's list of questions and preliminary statement. Swissmedic's targeted internal time periods for first authorisations and major variations are:

- Formal control: 30 days.
- Examination and establishment of the list of questions: 120 days.
- Advance notice of the decision: 90 days.
- Decision: 90 days.

Swissmedic personnel dealing with the application can be contacted and hearings on important points can under certain conditions be held with Swissmedic. If Swissmedic rejects an application, its decision can be appealed to the Federal Administrative Court, and finally to the Federal Supreme Court.

Swissmedic can, in a simplified procedure, temporarily authorise medicinal products for life-threatening or debilitating diseases if:

- This is compatible with the protection of health.
- Their use is expected to have a major therapeutic benefit.
- No authorised alternative and equivalent medicinal product is available in Switzerland.

There are other simplified procedures for the authorisation of certain categories of medicinal products (*see Question 11*).

Fee

The fees related to marketing authorisations can be found in the Ordinance of Swissmedic on fees. The fees for an examination of an application for a marketing authorisation vary considerably, depending on the type of application, including:

- CHF80,000 for a new active substance.
- CHF30,000 for a product containing an already registered active substance with innovation (simplified procedure).
- CHF15,000 for a product containing an already registered active substance without innovation (simplified procedure).
- CHF500 for renewing an existing authorisation.

In addition, Swissmedic charges an annual supervisory fee. The fee is based on the ex-factory price of the medicinal products and transplant products authorised in Switzerland. The fee amounts to eight per thousand of the ex-factory price. In particular, the fee contributes to covering the costs of the following tasks of Swissmedic: market surveillance activities, the preparation and development of standards, notification of the public, and measures against abuse and incorrect use of medicinal products.

Authorisations, variations, and renewals

The authorisation is granted initially for five years. Swissmedic grants a shorter authorisation period in the case of temporary authorisations or for health protection reasons. The authorisation is renewed on application if the conditions for authorisation are still fulfilled. The renewed authorisation is generally valid for an unlimited period. Swissmedic can, however, also limit the duration of the renewed authorisation if necessary. Swissmedic can re-examine the marketing authorisation at any time and amend or revoke it if necessary.

The transfer of a marketing authorisation is possible. At least three months before the planned transfer date, the future marketing authorisation holder must submit to Swissmedic a written application for the transfer of the marketing authorisation from the previous (current) marketing authorisation holder. The transfer is subject to approval.

Monitoring compliance and imposing penalties

Swissmedic must verify and monitor that medicinal products conform to their marketing authorisation. It can, without incurring costs, take samples, request essential information and documents, and ask for any assistance.

Swissmedic can take administrative measures to ensure compliance with a marketing authorisation similar to those for breach of a manufacturing licence (*see Question 8*). If the requirements are no longer met, Swissmedic can cancel the marketing authorisation.

If the marketing authorisation is breached, penalties can apply. Swissmedic does not impose specific licence conditions for breaches of the marketing authorisation. Particular individuals or entities cannot be barred from receiving a marketing authorisation if the legal requirements are fulfilled.

Protection of confidential information

In general, any person has the right to be granted access to official documents. However, the access has to be limited, deferred or refused if such access to an official document is likely to reveal professional, business or manufacturing secrets or if such access to an official document is likely to prejudice the privacy of a third party, unless exceptionally outweighed by public interest.

Release requirements

The marketing authorisation is issued in the form of a decision of Swissmedic. The marketing authorisation decision also determines the sales category (prescription-only/OTC) and approves the product information for professionals.

10. What pharmacovigilance obligations and other commitments apply after a company has obtained marketing authorisation? Are there further conditions on how the medicinal product is distributed and made accessible to patients?

Post-marketing commitments and pharmacovigilance obligations

Marketing authorisation holders for medicinal products with a new active substance or a biosimilar must submit periodic safety update reports (PSURs) (in principle, annually) to Swissmedic, within four years from authorisation, and in certain other situations. Additional guidance is given by Swissmedic publications and the International Council for Harmonsiation of Technical Requirements for Pharmaceuticals for Human Use (ICH) efficacy guidelines.

Marketing authorisation holders must file a risk management plan, including a pharmacovigilance plan, for marketing authorisations for medicinal products with a new active substance, and for new indications of new active substances.

The manufacturer or the marketing authorisation holder must maintain a pharmacovigilance system. They must also notify Swissmedic of any of the following risks relating to pharmaceutical products, which have been observed in Switzerland:

- Serious adverse events.
- So far unknown adverse events.
- Accumulation of known or so far unknown adverse events, including serious abuse and serious intoxications.
- Quality defects.
- Unusual restrictions of distribution.

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

- So far unknown risks or new aspects of known risks that are further clarified with regard to risk mitigation measures, require risk mitigation measures, or have led to risk mitigation measures abroad.
- Accumulation of known or so far unknown adverse events, including serious abuse and serious intoxications.
- Quality defects if batches are affected that were put on the Swiss market.

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

Additional guidance on pharmacovigilance is given by publications of Swissmedic and notably ICH efficacy guidelines.

The marketing authorisation can impose obligations on the marketing authorisation holder to submit further documents such as information on marketing authorisation procedures abroad or on study results.

Other conditions

Marketing authorisation is revoked if a medicinal product is not actually placed on the market within three years of marketing authorisation or if the product is, after placing it on the market, not actually marketed for three consecutive years (with some exceptions).

11. Is there an abridged procedure for marketing authorisation? Which medicinal products can benefit from it and what conditions and procedure apply? What information can the applicant access and rely on?

Simplified authorisation procedure

The Law on Therapeutic Products (LTP) and related ordinances offer simplified procedures for the marketing authorisation of certain medicinal products, including:

- Generics.
- Drugs with active substances that have already been registered.
- Medicinal products whose active substances are used in a medicinal product which, when the application was submitted, has been authorised as a medicinal product for at least ten years in at least one EU or EFTA country, and which is comparable in terms of indications, dosage and method of administration.
- Non-prescription medicinal products with indications which, when the application was submitted, have been proven to have been used medically for at least 30 years, and for at least 15 years in EU and EFTA countries.
- Medicinal products which, when the application was submitted, have been authorised as medicinal products for at least 15 years in a canton.
- Orphan drugs.
- Drugs which are manufactured in a hospital pharmacy or a hospital internal radiopharmaceutical establishment for the needs of the hospital.
- Complementary and herbal medicinal products.
- Drugs containing certain allergens.
- Radiopharmaceuticals and antidotes.
- Medicinal products prepared by the army and used in the context of the co-ordinated medical service.
- Veterinary medicinal products, which are intended exclusively for animals not kept for the production of foodstuffs.

The procedure is mainly regulated by the:

- Ordinance on the Simplified Marketing Authorisation of Medicinal Products and the Marketing Authorisation of Medicinal Products by Notification of 22 June 2006.
- Ordinance on Simplified Marketing Authorisation of Complementary and Herbal Medicinal Products of 7 September 2018.
- Ordinance on Simplified Marketing Authorisation of Medicinal Products containing Allergens of 11 December 2009.

The ordinances in particular specify the conditions the products and the application respectively must meet and which documents need to be submitted. With regard to medicinal products containing active substances that have already been authorised, it is under certain circumstances possible for applicants to rely on data of a product already authorised by Swissmedic and/or on literature. The documents which have to be submitted with the application are specified mainly in the Ordinance on the Simplified Marketing Authorisation of Medicinal Products and Authorisation by Way of Notification.

Fast track authorisation procedure

The fast track procedure is more expensive (increase of 50% of the fee). It is available on the applicant's request and enables registration to be completed within about four months if all of the following apply:

- It is a promising prevention or therapy against a serious, debilitating or life-threatening disease.
- There are no or no satisfactory treatment options with authorised medicinal products.
- A high therapeutic benefit is expected from use of the medicinal product.

However, if Swissmedic has queries or requests further information or documents, the above time period does not apply and the procedure can take over a year. If the application for a fast track authorisation procedure is approved, the application authorisation can then be submitted no earlier than two months and no later than six months.

Temporary authorisation

Swissmedic can, in a simplified procedure, temporarily authorise medicinal products against life-threatening or debilitating diseases if all of the following apply:

- It is compatible with the protection of health.
- Their use is expected to have a major therapeutic benefit.
- No authorised, alternative or equivalent medicinal product is available in Switzerland.

Temporary authorisation is granted for a maximum of two years and is subject to special conditions, such as the obligation to complete ongoing studies or initiate new studies. If a medicinal product is temporarily authorised, this must be clearly stated in the information on the medicinal product. The temporary marketing authorisation can be renewed on a reasoned application. The application must be accompanied by an interim report to Swissmedic on compliance with the special conditions imposed for the temporary marketing authorisation.

12. Are foreign marketing authorisations recognised in your jurisdiction?

For pharmaceutical products, there is no procedure for the automatic recognition of foreign marketing authorisations in Switzerland. Results of tests performed for obtaining marketing authorisation in a country with equivalent medicinal product control must be taken into account in Swiss authorisation proceedings. However, an independent application for marketing authorisation must be made to Swissmedic. Swissmedic has published detailed guidelines in this respect. For medicinal products containing an existing registered substance, Swissmedic generally limits itself to assessing the evaluation reports of the foreign authorities. However, Swissmedic does not assess European Medicines Agency (EMA) or US Food and Drug Administration (FDA) evaluation reports, provided these reports are not contradictory and Swissmedic has no essential concerns about them.

The Swiss-EU Bilateral Agreement on the Mutual Recognition of Conformity Assessments of 21 June 1999 provides for the mutual recognition of EU Good Manufacturing Practices (GMP) inspections and batch certificates, clinical trial results and medical device conformity assessments. Switzerland is also a party to the Pharmaceutical Inspection Convention (PIC), the Pharmaceutical Evaluation Report (PER) Scheme and other international treaties and memoranda of understanding.

Parallel imports and cross-border trade in medicines

13. Are parallel imports of medicinal products into your jurisdiction allowed? What are the general requirements for imports of medicinal products into your jurisdiction? Are particular foreign markets or products favoured?

Under the LTP, a person or company wishing to make parallel imports can apply to Swissmedic for marketing authorisation using the simplified procedure (*see Question 11, Simplified authorisation procedure*). The following conditions must be met:

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

Swissmedic does not consider whether the medicinal products are still patented. The patent owners must monitor the publication of marketing authorisations and defend their patent rights through a civil action.

Switzerland in principle has adopted the regional exhaustion of patent rights system (that is, patent rights are exhausted relating to the parallel imports if products have been put on the market by the patent owner, or with his consent, in Switzerland or the EEA).

If a product has been put on the market by the patent owner, or with his consent, outside Switzerland and the EEA, a patent of subordinate importance to the product's functional properties cannot be used to hinder parallel imports. For example, a patent for a sprayhead could be of subordinate importance if it was possible to reach an equally good spraying effect with a non-patented sprayhead.

As an exception to the principle of regional exhaustion, the patent owner's consent for placing the product on the Swiss market is required if the product price is government fixed in Switzerland and/or in the country where the product has been put into circulation, as is the case for many pharmaceutical products.

Switzerland recognises the principle of international exhaustion in relation to trade marks.

RESTRICTIONS ON DEALINGS WITH HEALTH CARE PROFESSIONALS

14. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for health care establishments or individual medical practitioners?

The Law on Therapeutic Products (LTP) prohibits the offer and acceptance of monetary advantages to individual medical practitioners or healthcare establishments. Revised **rules** entered into force on 1 January 2020. According to the new rules offering, requesting, granting or accepting undue financial advantages in relation to prescription-only medicinal products is prohibited. The following exceptions apply:

- Gifts of a modest value, relevant for the professional activity of the recipient (for example, prescription pads or any other article for daily professional use). Gifts are considered to be of a modest value if their total value is not more than CHF300 per year per healthcare professional. Industry codes, which are based on the EFPIA-Codes, are more restrictive and prohibit any

gifts to healthcare professionals, with the following reservations:

- objects, information and training materials of moderate value, which are also beneficial to patients;
- writing implements and pads of modest value, provided to healthcare professionals on the occasion of an educational event, which must not bear any references to the company or to particular medicinal products.

- Support contributions for research, further education and training, provided that certain criteria are met.
- Compensation for equivalent services in return, in particular for such services in connection with orders and deliveries of therapeutic products.
- Price discounts or refunds granted on the purchase of therapeutic products, provided that they do not affect the choice of treatment.

These rules are further detailed by the Ordinance on Integrity and Transparency (VITH) that also came into effect on 1 January 2020.

The above rules will be extended to certain medical devices determined by the Federal Council in 2022.

According to the Health Insurance Act, if a healthcare service provider receives a discount on therapeutic products which are reimbursable, he/she must pass the reduction on to the patient or insurer that pays for the product. Under the revised law, there is the possibility to only pass on a part of the rebates granted, provided there is an agreement between the healthcare service provider and the health insurance company that provides that the rebates retained be used for improving the quality of treatment. The LTP contains penalties for breaches of the ban on granting prohibited discounts and the Federal Health Insurance Act contains penalties for not passing on discounts received.

Penal provisions on bribery of the Swiss Criminal Code and the Federal Act against Unfair Competition may also apply. There is little case law in this area.

The above provisions are in principle intended to apply to practices performed in or having an effect in Switzerland.

SELLING RESTRICTIONS

15. What are the restrictions on selling medicinal products? Are there specific regulations for the sale of medicinal products on the internet, by e-mail and by mail order?

Medicinal products can only be sold to patients by a person or institution in possession of a licence to dispense such products. The products are categorised. Some categories of products can only be sold by pharmacists (and, depending on the cantonal law, doctors and possibly other professionals). Other categories can also be sold by chemists. Previously, pharmacists were only allowed to dispense prescription medicines on medical prescription. As of 2019, pharmacists can also dispense medicinal products without prescription if they have direct contact with the person concerned, if they document the product dispensed, and if either:

- The medicinal product and indication has been designated by the Federal Council.
- The case is justified and exceptional.

The LTP in principle bans mail order distribution. This applies to all forms of orders at distance (order in writing, by e-mail or over the internet). However, the cantons can grant exceptions through authorisations to operate a mail order pharmacy. To obtain an authorisation for mail order distribution, the following conditions must be met in particular:

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

The advertising rules apply to advertising of medicinal products through the internet and e-mail (*see Question 16*).

ADVERTISING AND PROMOTION

16. What restrictions apply to the advertising and promotion of medicinal products and the provision of samples, and how are adverts and promotional activity regulated?

Legislation and regulatory authority

Advertising of medicinal products is defined as all measures of information, market development and incentives aimed at promoting the prescription, supply, sale, consumption or use of medicinal products. This includes not only advertising on printed materials and on objects but also, for example, visits by pharmaceutical representatives and the supply of samples of medicinal products.

The advertising of medicinal products is regulated by the:

- Law on Therapeutic Products (LTP).
- Ordinance on Advertising for Medicinal Products.
- Article 65 and 68 of the Ordinance on Health Insurance.
- Federal Act against Unfair Competition.
- Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code), which:
  - is operated by science industries (the Swiss professional association of the chemical, pharma and biotech industries);
  - applies to advertising to professionals (including doctors, dentists and chemists).

Swissmedic supervises advertising and enforces the rules for advertising to professionals and to the public using governmental powers. Advertising to professionals is also and mainly supervised by the Secretariat of the Pharma Code based on the advertising provisions of the Pharma Code. If a company does not comply with or refuses to follow the ruling of the Pharma Code Secretariat, the Pharma Code Secretariat will, if it considers the violation of the Pharma Code a possible health risk, transmit the matter to Swissmedic for evaluation and further procedures.

Restrictions

Advertising to professionals is allowed for all medicinal products registered in Switzerland. Advertising to the general public is only allowed for non-prescription drugs which are not listed on the SL.

Advertising to professionals and to the general public must not:

- Be misleading.
- Be inaccurate or unethical.
- Incite an excessive, abusive or inappropriate use of medicinal products.
- Refer to off-label use or products not authorised for marketing in Switzerland.

The relevant regulations contain detailed rules about advertising elements that are not allowed, particularly in relation to public adverts.

Public adverts for analgesics, sedatives, sleeping tablets, laxatives and anorectics must be submitted to Swissmedic in advance for approval if a potential risk of abuse or addiction is mentioned in the product information of the medicinal product in question.

Internet advertising

Access to advertising for prescription-only medicinal products must be limited to healthcare professionals through password protection. This requirement should also be observed for advertising of reimbursable products.

Swissmedic requires the advertising for over-the-counter (OTC) products on the internet to conform to the general advertising rules. Swissmedic also explains which links and types of domain names it considers admissible. In 2009, Swissmedic published a communication concerning information about the marketing authorisation holder in advertising to the general public. In this communication, it outlines the:

- Kind of information that must be supplied about the marketing authorisation holder (for example, fax and phone numbers, e-mail addresses, logos, slogans and websites).
- Conditions to be followed so that advertising does not constitute an unlawful invitation to the public to contact the marketing authorisation holder.

Swissmedic considers advertising in social media unlawful if the user can like, comment and/or forward the advert. The Pharma Code Secretariat has issued recommendations on how to deal with digital channels, especially with regard to social media.

DATA PRIVACY

17. Do privacy and data protection laws impact on pharmaceutical regulation in your jurisdiction?

Under Article 3 let. c of the Swiss Data Protection Act (DPA), data on health is considered sensitive personal data. Further, a collection of data that permits an assessment of essential characteristics of the personality of a natural person is considered a personality profile under Article 3 let. d DPA.

Both sensitive personal data and personality profiles are subject to specific protective measures under the DPA. For example:

- Consent must be given expressly in the case of processing of sensitive personal data or personality profiles (*Article 4, DPA*).
- There is a duty for individuals and private entities to notify data collections to the Swiss Data Protection Officer (DPO) and a duty to provide information on the collection of sensitive personal data and personality profiles (*Article 14, DPA*).
- According to Article 6 of the DPA, in the absence of legislation ensuring adequate protection, personal data can only be transferred abroad if, for example, sufficient guarantees, in particular by contract, ensure adequate protection abroad or if the data subjects have consented in individual cases.

Federal bodies can only process sensitive personal data and personality profiles if a formal enactment expressly provides for it or if, by way of exception any of the following applies (*Article 17, DPA*):

- Such processing is essential for a task clearly defined in a formal act.
- The Federal Council authorises processing in an individual case because the rights of the data subject are not endangered.
- The data subject has given his consent in an individual case or made his data generally accessible and has not expressly prohibited its processing.

Hospitals are mostly subject to cantonal data protection laws, some of which are stricter or contain more precise rules than federal data protection law.

The above principles must be complied with also in the context of clinical trials, pharmacovigilance, adverse event reporting and processing of sensitive patient data.

Various laws relevant for pharmaceuticals contain additional specific regulations touching on data processing, like the Law on Therapeutic Products (LTP), the Ordinance on Pharmaceuticals, the Human Research Act or the Health Insurance Act.

On 23 September 2020, the Federal legislator decided on a revision of the DPA with the intention of aligning Swiss data protection law with the Regulation (EU) 679/2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation (GDPR)). Currently, the revision of the ordinances depending on the DPA is being prepared. The revision will come into effect in 2022.

PACKAGING, LABELLING AND TRACKING

18. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

The packaging and labelling requirements are set out in detail in the Ordinance on Marketing Authorisations. There are also some relevant provisions in various other ordinances such as the:

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

Swissmedic has published guidelines and explanatory notes on the product information and patient information.

In connection with the ratification of the Medicrime Convention, the Swiss Parliament, to improve the protection of patients and to combat counterfeit medicines, also decided to include a new provision in the LTP (new Article 17a) on the application of safety features to pharmaceutical packaging (similar to the safety features required by the Medicrime Convention). Switzerland intends to make it optional to add and verify safety features, although this is mandatory in the EU. Article 17a of the LTP and the implementing provisions are not yet in force.

Information requirements

Packaging intended for the patient must among others contain the following information:

- Designation of the product, if necessary, stating the dosage and galenic form.
- Contents of the individual pack.
- Name, type and quantity of the active substances.
- Name and domicile of the marketing authorisation holder as recorded in the Commercial Registry.
- Batch number.
- Necessary medical instructions for using the product.

- The calendar expiry date (not coded), storage instructions, and if needed, the time within which the product must be used after it is opened.
- The marketing authorisation number with package code.
- The child warning notice and invitation to read the packaging leaflet/patient information.

Swissmedic can grant exceptions for bullet points three, four, six, seven, eight and nine above if, for technical reasons, it is not possible to mention all the details on the container. However, in this case it is compulsory to sell the container in external packaging (such as a folded box), which contains all the information listed above. If the container is sold in such external packaging, there is no need to mention the marketing authorisation number on the (internal) container.

If there is a risk of confusion that could lead to severe consequences, Swissmedic can order appropriate measures like the use of "tall man letters".

Special rules apply to packaging that contains a quantity of products for the treatment of several patients and to packaging used for free product samples.

The marketing authorisation holder must provide product information for members of the medical profession. The product information is published in the online directory (*www.swissmedicinfo.ch*).

Patients must also be provided with patient information, usually in the form of leaflets inside packaging. Information provided to medical professionals and patients must be approved by Swissmedic.

Serialisation

Marketing authorisation holders have a general obligation to ensure the traceability of their products. As mentioned above under *Information requirements*, they can voluntarily add the safety features according to the Medicrime Convention in Switzerland on their medicinal products.

Other conditions

The product information must be written in the official Swiss languages of German, French and Italian.

PRODUCT SAFETY, QUALITY AND LIABILITY

19. Outline the key regulators and their powers in relation to medicinal product safety.

Swissmedic is competent for the surveillance of the safety of medicinal products. For this purpose, it collects pharmacovigilance notifications, analyses them and takes appropriate measures. Swissmedic and the Cantons are entitled to require necessary information, documents and support. If required and appropriate, Swissmedic can order administrative measures. Measures include adaptations of the product information of a medicinal product, warning letters or product recalls. Most often, the measures are agreed between the company concerned and Swissmedic.

These measures prevent health risks and thereby reduce the potential for product liability. Despite such measures, the manufacturer of a defective product may still be liable based on the Federal Act on Product Liability of 1993 (Product Liability Act) or general tort and contract law in case a defective product has caused damage (*see Question 21*).

20. Are there any mandatory requirements relating to medicinal product safety?

The safety of medicinal products is one of the three basic conditions for marketing authorisation. For the pharmacovigilance and quality defect notification requirements, see *Question 10*.

The law requires that all information on adverse events and quality defects that needs to be notified to Swissmedic must be collected by the marketing authorisation holder or the manufacturer and must be evaluated without delay, and that the necessary measures for risk reduction must be taken. An important means are letters to healthcare professionals (Direct Healthcare Professional Communications (DHPC)) describing safety signals. DHPC are also published on the website of Swissmedic. The marketing authorisation holder or the manufacturer has to appoint a responsible person for pharmacovigilance.

21. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.

Legal provisions

There are no special rules relating to product liability for pharmaceutical products. Under the Product Liability Act, which is based on Directive 85/374/EEC on liability for defective products, a producer is liable if a defective product leads to the death or injury of a person, or damage to, or destruction of, property for private use. In addition, standard rules of contract, tort and criminal law (concerning death and physical injury) can apply if a product is defective.

Substantive test

A product is deemed to be defective if, at the time it is marketed, it does not offer the safety that can justifiably be expected of it, taking into account all circumstances. Special consideration must be given to the:

- Ratio between benefit and risk.
- Method and manner used to present the product (product information).
- Use of the product that can be reasonably expected.
- Point in time the product was placed on the market.

The subsequent launch of an improved product on the market does not in itself make an older product defective.

In 2015 the Federal Supreme Court decided a rather prominent case regarding the contraceptive Yasmin. The plaintiff claimed that she had suffered a pulmonary embolism because of Yasmin and that the drug was a defective product, as the patient leaflet did not contain sufficient information on the risks of the active substance. The Federal Supreme Court based its decision on the general legal rules on product liability. The court ruled that in case of prescription drugs for the question whether the product offers the safety that can justifiably be expected, only the expectations of the healthcare professional are relevant as the patient lacks the necessary expertise. The fact that drugs may have undesirable side-effects does not render them defective, if the product information for healthcare professionals contains corresponding information. According to the Federal Supreme Court, the (limited) information in the patient leaflet was not relevant. The court ruled that the marketing authorisation holder was not liable in this case.

22. Who is potentially liable for defective medicinal products?

Under the Product Liability Act, the producer is liable for a defective medicinal product. The following are deemed to be producers:

- The manufacturer (in whole or in part) of the defective product.
- Any person who applies its name or trade mark to the product.
- Any person who imports the product for commercial distribution.
- The person who supplied the product, if the producer in the sense of the above three bullet points cannot be identified.
- If several persons are liable to pay compensation for the damage caused by a defective product, they are jointly and severally liable. Liability is allocated between those liable according to the principle of fault-contract-causal liability. The persons who are primarily liable are the ones who committed a fault.

23. What defences are available to product liability claims?

The producer is not liable for a defective product under the Product Liability Act if it proves any of the following:

- It did not market the product.
- The product was not defective when it was put into circulation.
- It did not manufacture the product for a business purpose or within the framework of its professional activity.
- The defect is attributable to compliance with binding, official regulations. Apart from that, there is generally no regulatory compliance defence.
- The error was not identifiable on the basis of scientific and technological knowledge at the time the product was put into circulation (development risk).
- It produced base material or part of the product only and the defect was caused by the construction of the product, in which the base material or part was incorporated, or by the instruction given by the producer of that product.

24. How can a product liability claim be brought?

A product liability claim is a civil law claim that needs to be brought in front of the competent civil court.

Limitation periods

The limitation period for claims under the Product Liability Act is three years from the date on which the injured party learns of the damage, liability and identity of the liable party. A claim is barred after ten years from the date on which the product was put into circulation.

As from 1 January 2020, the limitation period for claims under general tort law will also be three years from the date on which the injured party learns of the damage and identity of the liable party. In any event, claims for bodily harm become time barred after 20 years from the date on which the damaging act or omission occurred or stopped.

Class actions

Class actions are not possible in Switzerland. Several claimants can ask that their respective claims be joined and the proceedings conducted together, but the claims remain separate from each other and are judged separately.

25. What remedies are available to the claimant? Are punitive or exemplary damages allowed for product liability claims?

The remedies under the Product Liability Act are compensation for personal damages and for damages to goods for private use. Based on tort law, additionally financial compensation for severe pain and suffering is possible. Punitive or exemplary damages are not awarded in Switzerland.

LOCAL ESTABLISHMENT, REPRESENTATION AND RESIDENCY REQUIREMENTS

26. What local requirements apply to businesses and individuals (such as the person responsible for releasing a product onto the market) acting within or in relation to the jurisdiction?

The marketing authorisation holder must hold an establishment licence for manufacturing, import or wholesale with authority to release batches for the Swiss market. For the conditions for obtaining such license, see *Question 8*. The marketing authorisation holder must be established in Switzerland, that is, have its registered office or at least a branch office in Switzerland.

The holder of an establishment licence must have a sufficiently qualified Responsible Person (RP). The RP decides on the release of a product batch and issues a batch certificate confirming that the batch in question conforms to the composition, manufacturing procedure, specifications and quality requirements.

The RP is responsible for the direct technical supervision of the marketing authorisation holder and is expected to be regularly present at the facilities where the activities take place to overview the organisation and all activities to ensure compliance with the legal requirements at any time.

The RP must have sufficient decision power to take any action which is necessary to ensure compliance with legal requirements.

According to Swissmedic, a direct supervision implies that the RP must live within reasonable distance of the site. As a guide, the RP should live within two hours' travelling time from the site. In emergencies, the RP must be able to reach the site at any time. The RP can reside in a neighbouring country (in a region close to the Swiss border).

REFORM

27. Are there proposals for reform and when are they likely to come into force?

A major revision of the law on medical devices was decided by the authorities, adapting Swiss law to the EU's Medical Device Regulation and In Vitro Diagnostic Regulation. This revision is planned to enter into effect on 26 May 2021 respectively 2022 for in-vitro diagnostics. A revision of the MRA on the recognition of conformity assessments with the EU is also being negotiated.

In 2022, the provisions of the Law on Therapeutic Products on financial benefits will be extended to certain medical devices.

Parliament decided a revision of the Act on Human Genetic Testing (AHGT) in June 2018. It is intended to adapt the AHGT to recent developments in genetic testing. The scope of its provisions are more clearly drawn and it will provide rules for genetic testing for non-medical reasons. The revision is expected to enter into force in 2021.

In addition, a revision of the DPA was decided by the Swiss parliament. The revision will adapt the DPA to developments in society and technology, in particular improve transparency of data processing and increase self-determination of data subjects about their data. Further, the DPA will be aligned to the EU GDPR, with the main purpose of maintaining the EU adequacy decision. For Switzerland to be able to retain the existing declaration of adequacy, it must have a level of protection comparable to that of the EU.

In its ongoing efforts to protect patients against counterfeit medicines, and in addition to the legislative changes related to the ratification of the Medicrime Convention, on 29 September 2017, parliament made provision in the LTP (new Article 17a) for safety features to be added to medicinal product packaging (analogous to the features provided by EU Directive 2011/62/EU on falsified medicines (Falsified Medicines Directive). These safety features fall into two categories. The first makes it possible to verify that medicines are authentic and to identify individual boxes (unique identifier) and the second to detect whether packages have been opened (anti-tampering device). This is a preventive measure intended to prevent counterfeit medicines from entering the legal supply chain. Switzerland intends to make it optional to add and verify safety features, unlike in the EU where it is mandatory. Article 17a of the LTP is not yet in force. Currently, the implementing provisions relating to it are being drafted.

Due to the revision of the LTA, the entry into force of the Ordinance on Integrity and Transparency in the Therapeutic Products Sector and the Code Consolidation of the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Swiss Pharma Code and the Swiss Pharma Cooperation Code also had to undergo a revision. The revised Codes will enter into force on 1 January 2021.

Practical Law Contributor profiles

Frank Scherrer

Wenger & Vieli AG
T +41 58 958 58 58
F +41 58 958 59 59
E f.scherrer@wengervieli.ch
W www.wengervieli.ch

Professional qualifications. Licence en droit, University of Neuchâtel, Switzerland, 1991; LL.M. in European Legal Studies, University of Exeter, UK, 1993; Dr.iur., University of Zurich, Switzerland, 1996; admitted to the Bar in Switzerland, 1999

Areas of practice. Pharmaceutical and health law; contract law; unfair competition and cartel law; advertising law; product liability law.

Recent transactions

- Advising and representing pharmaceutical companies on a regular basis regarding marketing authorisation and reimbursement, contracts, advertising, sponsoring and gifts, clinical trials and data protection.
- Representing pharmaceutical companies in appeal proceedings regarding price decreases and revisions of marketing authorisations.
- Advising and representing pharmaceutical companies in disputes concerning contracts, product liability and unfair competition.
- Advising pharmaceutical companies concerning outsourcing.

Languages. German, English, French

Andrea Schütz

Wenger & Vieli AG
T +41 58 958 58 58
F +41 58 958 59 59
E a.schuetz@wengervieli.ch
W www.wengervieli.ch

Professional qualifications. Lic.iur., University of Fribourg, Switzerland, 2003; admitted to the Bar in Switzerland, 2008; Dr. iur., University of Zurich, Switzerland, 2011; LL.M. Health and Medical Law, University of Melbourne, 2014; CAS Forensics, University of Lucerne, Switzerland, 2016

Areas of practice. Pharmaceutical and health law; life sciences; data protection law; product liability law; unfair competition and cartel law; employment law.

Recent transactions

- Advising pharmaceutical companies on a regular basis regarding contracts, advertising, sponsoring and gifts, and data protection.
- Performing the legal review for the advertising and PR material of a multinational pharmaceutical company concerning Switzerland.
- Advising and representing pharmaceutical companies in legal proceedings concerning product liability.
- Advising and representing pharmaceutical companies in appeal proceedings regarding price decreases and revisions of marketing authorisations.

Languages. German, English

Claudia Keller

Wenger & Vieli AG
T +41 58 958 58 58
F +41 58 958 59 59
E c.keller@wengervieli.ch
W www.wengervieli.ch

Professional qualifications. Lic.iur., University of Basel, Switzerland, 2001; LL.M. at University of Hastings, College of the Law, San Francisco, 2004, admitted to the Bar in Switzerland, 2006; CAS Brand Management (HSLU) 2007; Social Media Management (Somexcloud), 2011; Data Protection CIPP/E & CIP/M certification, iapp, 2018

Areas of practice. Intellectual property law; advertising law; media law; life sciences; data protection law; product safety and liability law; unfair competition.

Recent transactions

- Advising companies on a regular basis regarding intellectual property law, in particular trademark and copyright law including licensing contracts, advertising.
- Advising companies on advertising regulation and data protection, in particular in relation to the interplay between Swiss data protection law and the European Data Protection Regulation (GDPR).
- Advising and representing companies in legal proceedings concerning product safety and product safety compliance.

Languages. German, English

Marcel Boller

Wenger & Vieli AG
T +41 58 958 58 58
F +41 58 958 59 59
E m.boller@wengervieli.ch
W www.wengervieli.ch

Professional qualifications. Lic.iur., University of Zurich, Switzerland, 2010; Dr.iur. University of Zurich, Switzerland, 2016; admitted to the Bar in Switzerland, 2018

Areas of practice. Pharmaceutical and health law; life sciences; product liability law; corporate and commercial law; information technology and data protection law; intellectual property law; unfair competition law; litigation.

Recent transactions

- Advising pharmaceutical companies and manufacturers of medical devises regarding contracts, co-operation with other stakeholders in the health sector, clinical trials and data protection on a regular basis.
- Advising and representing pharmaceutical and other companies in legal proceedings concerning product liability.
- Advising and representing pharmaceutical companies in appeal proceedings regarding price decreases and revisions of marketing authorisations.

Languages. German, English, French, Italian