Life Sciences Regulation in Switzerland: Overview

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Country Q&A | Law stated as at 01-May-2023 | Switzerland

A Q&A guide to life sciences regulation in Switzerland.

This Q&A provides a high-level overview of key practical issues, including life sciences clinical trials, manufacturing, marketing, abridged procedure, pharmacovigilance, data privacy, packaging and labelling, biological medicines, medical devices, health care IT, combination products, borderlines, and natural health products.

Pharmaceuticals

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 of 2000 (*Heilmittelgesetz*) (Law on Therapeutic Products) (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 and the Federal Act on Research involving Human Beings of 2011 (Human Research Act) and related ordinances.

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

Placing medicinal products on the market requires a marketing authorisation (with some limited exceptions, see *Question 6*). There is no automatic recognition of marketing authorisations granted in the EU or in other countries. However, marketing authorisations in countries with a comparable marketing authorisation system, such as in the EU or the US, are taken into account.

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

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

Reimbursement status for medicinal products is granted by the *Swiss Federal Office of Public Health* (*Bundesamt für Gesundheit*) (FOPH). 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*), which must be led by a pharmacist entitled to dispense prescription-only medicinal products.
- Drugstores (*Drogerie*), which can only sell non-prescription medicinal products.

The cantons also have competences concerning the supervision of the manufacturing, handling, prescription and dispensing of medicinal products and medical devices. For example, they can check the handling of medicinal products and can verify the ingredients of medicinal products.

Definition of Medicinal Product

The term "medicinal products" means products of chemical or biological origin that are intended or claimed to have a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps. Blood and blood products are also considered to be medicinal products.

Clinical Trials

2. Outline the regulation of clinical trials.

Legislation and Regulatory Authorities

Clinical trials are mainly regulated by the:

- Law on Therapeutic Products.
- Human Research Act and related ordinances.
- Medical Devices Ordinance
- Ordinance on Clinical Trials with Medical Devices.
- Ordinance on Clinical Trials with the Exception of Clinical Trials with Medical Devices.
- Applicable EU provisions including:
    - Regulation 2017/745 on medical devices (Medical Devices Regulation);
    - Regulation (EU) 746/2017 on in vitro diagnostic medical devices (In Vitro Diagonostic Medical Devices Regulation).
- Data Protection Act.
- 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) Helsinki Declaration: Ethical Principles for Medical Research Involving Human Subjects, Brazil 2013.

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.

Authorisations

In principle, clinical trials with therapeutic products must be authorised by Swissmedic and the competent ethics committee. However, 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 will:

- Assess the trial from an ethical point of view.
- Examine compliance with legal requirements.
- Verify the trial's scientific quality, taking into account local conditions.

- Act to ensure the safety of the trial subjects.

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.

Trial applications must 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. If the committee requests additional documents, this time limit is suspended until the complete information has been received. In case of multi-centre trials, the leading ethics committee issues its decision within 45 days. Authorisation will be granted if the trial complies with ethical, legal and scientific requirements.

For pharmaceuticals, Swissmedic examines whether the product used in the trial complies with the requirements of Good Manufacturing Practice (GMP) and with safety requirements. For medical devices, Swissmedic examines whether the risks associated with a medical device are taken into account in the clinical trial and whether the information on the medical device corresponds to the state of scientific knowledge and is correctly represented in the trial protocol.

The trial file must 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 to the Ordinance on Clinical Trials with the Exception of Clinical Trials with Medical Devices. Swissmedic does not process incomplete files. Receipt of the application is confirmed within seven days for pharmaceuticals and ten days for medical devices. The applicant will be informed of any formal flaws in the file. Swissmedic issues its decision within 30 days of receipt of the complete application for pharmaceuticals and within 45 days for medical devices. This time limit can be extended for another 30 days or 45 days if the pharmaceutical or the medical device is applied to human beings for the first time 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 must be approved by Swissmedic and the ethics committee before 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 other 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 Human Research Act and the Swissethics templates set out the necessary content for the consent forms. The competent ethics committee will review the completeness of information given to the trial subjects and the way informed consent is obtained.

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 required insurance cover is generally at least:

- CHF10 million for the whole trial.
- CHF1 million for each case of personal injury.
- 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 no security may even be necessary. Swissethics has issued a template for the general terms and conditions of insurance for clinical trials.

Procedural Requirements

Procedural requirements are set out in the:

- Ordinance on Clinical Trials with the Exception of Clinical Trials with Medical Devices.
- Ordinance on Clinical Trials with Medical Devices.
- ICH-GCP.

If serious adverse events occur in participating subjects during the conduct of the clinical trial, the investigator must document the events 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. For trials for which Swissmedic's approval was not necessary, the notification must made to the competent ethics committee. If the 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.

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. The final ASR submission must cover the Last Patient Last Visit (LPLV) in Switzerland.

After submission of the final ASR (covering the LPLV), there is no need for further ASR submissions as the information on safety will be in the clinical study report. The clinical study report can cover a single trial or several trials with the same medicinal product. If so, the individual trials must be clearly identifiable.

Manufacturing and Distribution

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

Application

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

Wholesale distribution 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.

Conditions

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

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

- The applicant's facilities 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 GMP, in particular 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.

Wholesale licence. The conditions that must be satisfied to obtain a wholesale licence are comparable to those for the manufacturing licence (Article 11 et seq, Medicinal Products Licensing Ordinance). 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.

GMP and GDP certifications 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 and GDP.

Restrictions on Foreign Applicants

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

Fees

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 CHF200. Each attachment to a certificate costs CHF100. The fees are listed in the Ordinance of Swissmedic on Fees.

Authorisations, Variations, and Renewals

Licences granted under the revised provisions of the Law on Therapeutic Products (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 can commercially import medicinal products but cannot export medicinal products without an export licence. An application must be made to extend the scope of the licence.

Swissmedic can withdraw the licence if the conditions for its grant are no longer fulfilled, 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.
- 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. Under the LTP, for breaches of a 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 that endanger health or 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 or the competent cantonal courts can also impose criminal sanctions including:

- A custodial sentence of up to three years or a fine 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, if the person concerned:
    - knew or had to assume that the violation specifically endangered human health;
    - achieved a high turnover or made substantial profits through commercial activity.

A person who is found to be in breach through negligence is liable to a monetary penalty of up to 180 daily penalty units. Daily penalty units are determined based on the personal and economic circumstances of the person concerned, and range up to CHF3,000. The maximum penalty is therefore 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 obtain access to all documents relevant to the proceedings, including without the consent of the licensee, for example, by means of a house search.

Marketing

Authorisation Procedure

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

Application

Marketing authorisation is required to place pharmaceutical products on the market, for both prescription-only and over-the-counter (OTC) products (except in certain limited circumstances, see *Question 6*). The application must be made to Swissmedic using standard forms, and for new active substances, using the International Conference on Harmonisation Common Technical Document. Swissmedic accepts registration documents in the form approved by the EU. It also supports the submission of data electronically. The following documents must be included with the application:

- 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, its active and auxiliary agents, and 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.
- A paediatric investigation plan.

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

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 with its domicile or a 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 the manufacturing, import or wholesale of medicinal products including release

to the market. The marketing authorisation does not cover activities such as storing, transporting, distributing, selling and advertising medicinal products.

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 to the application and to answer Swissmedic's preliminary statement and list of questions. 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.

In a simplified procedure, Swissmedic can 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 9*).

Fee

The fees related to marketing authorisations for medicinal products 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, and include:

- 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.

Swissmedic also charges an annual supervisory fee. The fee is based on the ex-factory price of the medicinal products and transplant products authorised in Switzerland, and amounts to 0.65% of the turnover at ex-factory price. The fee contributes to covering Swissmedic's costs related to:

- Market surveillance activities.
- Preparation and development of standards.
- Public notifications.
- Measures against abuse and incorrect use of medicinal products.

Authorisations, Variations, and Renewals

The authorisation is granted initially for five years. Swissmedic will grant 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. However, Swissmedic can 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 but subject to approval. The transferee must submit a written application for the transfer to Swissmedic at least three months before the planned transfer date.

Protection of Confidential Information

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

Exceptions

5. Are there additional or alternative regulations for special types of medicines or medicines intended for particular types of patients or diseases?

The Law on Therapeutic Products provides for the following special approval procedures:

- A simplified authorisation procedure for certain categories of medicinal products, including:
    - medicinal products with known active substances;
    - complementary and herbal medicines;

- important medicinal products for rare diseases.

See *Question 9*.

- Under certain conditions, the applicant can apply to Swissmedic for a fast-track authorisation procedure for a medicinal product for human use or for a variation of such a product (see *Question 9*).
- In case of life-threatening or debilitating diseases, Swissmedic can temporarily authorise a medicinal product in a simplified procedure (see *Question 9*).
- Special categories of medicinal products can be placed on the market following notification to Swissmedic only. This applies to:
  - complementary medicines without indications, the active substances of which are included in lists for specific therapy approaches;
  - other medicinal products or groups of medicinal products for which, due to their low risk potential, a simplified marketing authorisation proves to be disproportionate.
- For medicinal products and procedures authorised in a foreign country having equivalent medicinal product control, the results of tests carried out for this purpose can be taken into account.
- Co-marketing medicinal products (medicinal products that can rely on the marketing authorisation documents of an already authorised medicinal product (basic product) with the written authorisation of the marketing authorisation holder) can be authorised by Swissmedic on mere notification.

6. Can products be marketed without a marketing authorisation in certain circumstances?

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 a public or hospital pharmacy 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 which are intended for dispensing to its own customers.
- Medicinal products for clinical trials.
- Medicinal products that 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 Law on Therapeutic Products of 18 March 2016 came into force. These 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.
- Medicinal products that are manufactured with certain active substances listed under Annex 5 of the Covid-19 Ordinance 3 for the treatment of COVID-19 patients, provided an application for authorisation of a medicinal product containing one of these active substances has been filed. These can be placed on the market without authorisation pending Swissmedic's decision on authorisation.

Monitoring Compliance and Penalties

7. What powers does the regulator have to monitor compliance with marketing authorisations and impose penalties for a breach?

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 necessary assistance.

Swissmedic can take administrative measures to ensure compliance with a marketing authorisation similar to those for breach of a manufacturing licence (see *Question 3, Monitoring Compliance and Imposing Penalties*). If the requirements are no longer met, Swissmedic can cancel the marketing authorisation.

Penalties may apply if the marketing authorisation is breached. However, Swissmedic does not impose specific licence conditions for breaches of a marketing authorisation. Particular individuals or entities cannot be barred from receiving a marketing authorisation if they fulfil the legal requirements.

Data and Marketing Exclusivity Protections

8. What exclusivity does a marketing authorisation holder benefit from?

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), WTO Agreement on Trade-Related Aspects of Intellectual Property Rights). In line with this principle, the Law on Therapeutic Products provides for ten years of regulatory data protection exclusivity for original preparations.

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

- Indication.
- Method of administration.
- Galenic form.
- Dosage.

For new indications, Swissmedic may grant ten 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 a paediatric investigation plan, Swissmedic may grant data protection of ten years on request.

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

If the marketing authorisation holder does not waive data protection, the granting of a marketing authorisation for an essentially identical medicinal product will be permissible at the earliest immediately after expiry of the period of protection for the medicinal product with document protection. A corresponding application for marketing authorisation can be submitted at the earliest two years before the end of the term of protection.

Abridged Procedure for Marketing Authorisation

9. Outline the abridged procedure for marketing authorisation.

Simplified Authorisation Procedure

The Law on Therapeutic Products 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 that 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 that 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.

These ordinances specify the conditions the products and the application must meet and which documents must be submitted. For medicinal products containing active substances that have already been authorised, in certain circumstances it is possible for applicants to rely on product data already authorised by Swissmedic and/or on prior literature. The documents that must be submitted with the application are mainly specified 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 (with a 50% fee increase). 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, this 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 marketing authorisation application can then be submitted no earlier than two months and no later than six months thereafter.

Temporary Authorisation

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

- This is compatible with the protection of health.
- The 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 will be 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.

Pharmacovigilance and Other Commitments

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?

Pharmacovigilance System

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 for four years from authorisation and in certain other situations. Additional guidance is given by Swissmedic publications and the International Council for Harmonisation 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 already authorised new active substances.

The manufacturer or the marketing authorisation holder must maintain a pharmacovigilance system and must notify Swissmedic if any of the following risks relating to pharmaceutical products are observed in Switzerland:

- Serious adverse events.
- Previously unknown adverse events.
- Any accumulation of known or previously unknown adverse events, including serious abuse and serious intoxications.
- Quality defects.
- Unusual distribution restrictions.

The following risks observed abroad must be notified to Swissmedic:

- Previously 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.
- Any accumulation of known or previously unknown adverse events, including serious abuse and serious intoxications.
- Quality defects, where affected batches 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 that it discovers in connection with its activities or with one of its products or its components.

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

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

Other Commitments

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

Foreign Marketing Authorisations

11.Are foreign marketing authorisations recognised in your jurisdiction?

There is no procedure for the automatic recognition of foreign marketing authorisations in Switzerland, and an independent application for marketing authorisation must be made to Swissmedic. However, results of tests performed for obtaining marketing authorisation in a country with equivalent medicinal product controls must be taken into account in Swiss authorisation proceedings. 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 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.

Data Privacy

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

Under Article 3 of the Data Protection Act (DPA), health data is considered sensitive personal data. In addition, a collection of data that permits an assessment of essential characteristics of the personality of a natural person is considered to be a "personality profile" under Article 3 of the 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).
- In the absence of legislation ensuring adequate protection, personal data can only be transferred abroad if, for example, sufficient guarantees (in particular contractual guarantees) ensure adequate protection abroad or the data subjects have individually consented (Article 6, DPA).

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

- The 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 subjects have given their individual consent, or have made their data generally accessible and have not expressly prohibited its processing.

(Article 17, DPA.)

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

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

Various laws relevant for pharmaceuticals contain additional specific regulations touching on data processing, such as the:

- Law on Therapeutic Products.
- Ordinance on Pharmaceuticals.
- Human Research Act.
- 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 *General Data Protection Regulation ((EU) 2016/679*) (GDPR)). The revision will come into effect on 1 September 2023.

Packaging, Labelling, and Tracking

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

Legislation and Regulatory Authority

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.

Information Requirements

Packaging intended for the patient must contain, among other things, 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 necessary, 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 certain exceptions to these requirements if it is not possible to mention all the details on the container for technical reasons. However, it is then compulsory to sell the container in external packaging (such as a folded box) that 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 such as 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*.

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.

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

Serialisation

Marketing authorisation holders have a general obligation to ensure the traceability of their products, and can voluntarily add safety features in Switzerland in line with the Medicrime Convention (see above, *Information requirements*).

Other Conditions

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

Biological Medicines

14. What is the definition of biological medicines in your jurisdiction? Are there any additional or alternative regulations that apply specifically to them?

Definition of Biological Medicines

Biological medicines are defined as medicinal products containing an active substance of biological origin derived from microorganisms, organs or tissues of plant or animal origin, cells or fluids of human or animal origin, including blood or plasma, or biotechnological cell substrates, whether the latter are recombinant or otherwise produced, including primary cells.

Biotechnological medicines are defined as biological medicinal products in which the active ingredient is obtained from cells cultivated in cell banks and recombinant technologies or processes are used.

Regulation of Biological Medicines

Biologicals are treated as a sub-category of pharmaceuticals.

Biotechnological products cannot be authorised in a simplified marketing authorisation procedure.

Additional authorisation requirements apply for medicinal products containing genetically modified organisms (GMOs). Swissmedic assesses products containing GMOs in accordance with the:

- Law on Therapeutic Products.
- Gene Technology Act.
- Ordinance on the Handling of Organisms in the Environment.

Product information and labelling must indicate that the product contains GMOs. 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.

Products containing GMOs are also generally excluded from the simplified marketing authorisation procedures.

Medical Devices

Legislation and Regulatory Authorities

15. What are the main legislation and regulatory authorities for medical devices in your jurisdiction?

Medical devices are regulated by the:

- Law on Therapeutic Products.
- Medical Devices Ordinance.

In general, the marketing of medical devices is not subject to a marketing authorisation. Instead, the person placing the device on the market must ensure that it does not endanger the health of the user, the consumer, the patient or a third party, and that any claims regarding its performance or effectiveness are provable.

In addition, the device must comply with the fundamental requirements according to internationally harmonised standards of the European Committee for Standardization and the ISO. Such conformity must be assessed and documented either with a self#declaration or by a notified body recognised by Swissmedic.

Swissmedic is the competent authority for the surveillance of medical devices in Switzerland.

The EU rules on market access apply in principle to medical devices. Under the regulations in effect until 21 May 2021, the Swiss-EU mutual recognition agreement on conformity assessments gave Switzerland access to the European single market for medical devices on an equal partnership basis. Since the mutual recognition agreement has not been updated, Switzerland is now considered a third country. However, Switzerland has established measures designed to limit the negative consequences of this development, particularly the inability of the Swiss authorities to access the European database for medical devices (Eudamed 3) and the lack of co-operation in market monitoring. These measures include, for example:

- Requirements to appoint an authorised Swiss representative.
- Requirements to register economic operators with Swissmedic.
- Requirements to report serious incidents to Swissmedic.
- The recognition of EU certificates of conformity in Switzerland.

Manufacturers of medical devices or their authorised representatives and importers must register the information required by part A of Annex VI to the EU Medical Device Regulation with Swissmedic.

Medical Devices Definition

16. What is the definition of a medical device (or equivalent) in your jurisdiction?

Medical devices are instruments, apparatus, appliances, software, implants, reagents, materials or other articles that:

- Are intended by their manufacturer to be used for human beings.
- Do not achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in their function by such means.
- Serve to fulfil one or more of the following specific medical purposes either alone or in combination:
    - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
    - diagnosis, monitoring, treatment, alleviation of, or compensation for, injuries or disabilities;
    - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;
    - providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

Classification of Medical Devices

17. Briefly outline any classification system and the main classifications of regulated medical devices.

Medical devices are classified into the categories in-vitro medical devices and ordinary medical devices. Ordinary medical devices are classified into the classes I, IIa, IIb, and III based on the rules of the EU Medical Devices Regulation (see *Question 18*). It is the responsibility of the manufacturers to correctly classify their devices. The requirement to consult a notified body and the provisions relating to the conformity assessment differ depending on the classification of the medical device (see *Question 18*).

Requirements to Manufacture and Market Medical Devices

18. What are the requirements to manufacture and market medical devices?

A medical device manufacturer must undertake an assessment of the conformity of the device with general safety and performance requirements before placing it on the market or putting it into service. The manufacturer drafts a declaration of conformity stating that the legal requirements are fulfilled and accepts responsibility for ensuring that the device complies with the legal requirements.

Products are classified into classes I, IIa, IIb, and III, taking into account their intended purpose and the associated risks:

- For risk class I, the conformity assessment procedure can be carried out by the manufacturer.
- For risk class II and higher, the assessment must be carried out by a notified body.

Manufacturers of medical devices of all risk classes must prepare technical documentation to show compliance with the safety and performance criteria according to the essential requirements.

The EU rules on market access apply in principle to medical devices. However, Switzerland's mutual recognition agreement with the EU on conformity assessments has not been updated (see *Question 15*).

19. Are there exceptions to the requirements (for example, for clinical studies, special individual patient use, custom devices, and compassionate use)?

In some specific circumstances, a medical device can be placed on the market and put into service even though the relevant conformity assessment procedure has not been carried out. In such cases, Swissmedic, may grant an exceptional authorisation if the use of the medical device is in the interests of public health or patient safety or health.

In addition, individual devices that have not undergone the relevant conformity assessment procedure may be placed on the market and used without authorisation from Swissmedic provided:

- The use serves to avert life-threatening conditions or to resolve the permanent impairment of a body function.
- No conforming device is available for this specific intended purpose.
- They are used exclusively by health care professionals on individual persons.
- The health care professional using the device has informed the individual concerned about the non-conformity of the medical device and the related risks.
- The individual concerned has consented to the use of the device.

20. Are there fewer or different requirements for medical devices that have already been licensed or approved in another jurisdiction?

The Swiss regulation on medical devices is generally in line with the provisions of the EU Medical Devices Regulation.

Medical devices that are marketable in the EU also in principle fulfil the requirements of Swiss law. The only deviations are that the authorised Swiss representative must be indicated on the label and that the product description may have to be in the three official languages of Switzerland.

21. What are the main requirements to import medical devices from or export medical devices to other jurisdictions?

Under the regulations in effect until 21 May 2021, the Swiss-EU mutual recognition agreement on conformity assessments gave Switzerland access to the European single market for medical devices on an equal partnership basis. However, since the mutual recognition agreement has not been updated, Switzerland is now considered a third country (see *Question 15*).

Therefore, Swiss companies must expect to face more demanding requirements when seeking to export medical devices to the EU, for example the requirement to appoint an authorised representative and, depending on the risk class of the device, to present a certificate issued by one of the notified bodies featured in the New Approach Notified and Designated Organisations (NANDO) information system.

Medical devices that are marketable in the EU in principle also fulfil the requirements of Swiss law. The only deviations are that the authorised Swiss representative must be indicated on the label and that the product description may have to be in the three official languages of Switzerland.

There is no recognition for medical devices that are certified according to a non-EU regulatory system. For these medical devices, a conformity assessment procedure according to Swiss law must be carried out before importation.

Health Care IT

22. Is there any specific regulation of medical software, health care IT, or e-health products (such as mobile health apps)?

There is no specific regulation of medical software, health care IT, or e-health products as such but software and mobile health apps or platforms can qualify as medical devices if certain criteria are met. If software qualifies as a medical device, the following regulations apply:

- Therapeutic Products Act.
- Medical Devices Ordinance.
- In vitro Diagnostic Medical Devices Ordinance.

- Human Research Act.
- Ordinance on Clinical Trials with Medical Devices.
- Data Protection Act.

Under Article 3 of the Medical Devices Ordinance, Article 3 of the In vitro Diagnostic Medical Devices Ordinance and applicable guidelines, software will qualify as a medical device if both:

- The software has a medical purpose for the benefit of an individual person (and not only for the benefit of a population). A list of medical purposes is set out in the definitions of medical devices and in vitro diagnostic medical devices in Article 3 of the Medical Devices Ordinance and Article 3 of the In vitro Diagnostic Medical Devices Ordinance respectively.
- The data processing of the software is not restricted to the following functions:
    - storage;
    - archiving;
    - communication (flow of information from a source to a recipient);
    - simple search;
    - lossless compression (compression allowing exact reconstruction of the original data).

Relevant factors include the intended purpose described in the instructions for use as well as promotional materials and the information displayed about the specific device in the user interface.

Medical device software that is not used for in vitro diagnosis is classified according to Article 15 of the Medical Devices Ordinance. Medical device software used for in vitro diagnosis is classified according to Article 14 of the In vitro Diagnostic Medical Devices Ordinance. Medical device classification is based on the potential risks associated with the use of the products in humans.

The classification determines the conformity assessment procedure and whether the involvement of a notified body is required for the placement of the software on the market in Switzerland.

Combination Products and Borderlines

23. Does your jurisdiction recognise combination products? Are there any additional or alternative regulations that apply specifically to them?

Types of Combination Products

Swissmedic recognises combination products as medicinal products with a medical device component. A classic example is a pre-filled syringe. While the syringe, the "application container", is a medical device, the contents of the syringe, for example a vaccine, is a medicinal product. There are two types of combination products:

- **Integral combination products.** In an integral combination product, the medicinal product component is manufactured with the medical device component as a linked unit intended exclusively for use in that specific combination.
- **Non-integral combination products.** In a non-integral combination product, the medical device component is enclosed or available separately (for example, a cough syrup bottle containing the syrup and a measuring cup).

Regulation of Combination Products

The legal framework for medicinal products/medical devices applies generally to the commercialisation of combination products.

Combinations between medicinal products and medical devices must be evaluated as to which sub-product fulfils the main (not merely supporting) function.

If the product is a combination that when placed on the market or put into service contains a medicinal product as an integral part in addition to the medical device, and the medicinal product fulfils a primary function, the overall product is treated as a medicinal product and is subject to the medicinal product regulations of the Law on Therapeutic Products (LTP). For the medical device part, the essential safety and performance requirements under the Medical Devices Ordinance apply.

The same regulations apply for non-separable integral combinations of a medicinal product and a device intended to administer a medicinal product that are intended solely for use in this combination and are not reusable. In this situation, the overall product qualifies as a medicinal product and is subject to the medicinal product regulations of the LTP, while the medical device part falls under the safety and performance requirements of the Medical Devices Ordinance. If the main function lies with the medical device part, the full Medical Devices Ordinance applies.

Borderlines

24.What product type determinations are relevant and are there specific mechanisms for determining which regulatory regime applies to a borderline product?

The classification of products on the borderline of two product categories is always a case-by-case consideration. The products must be considered in their entirety (involving consideration of both the intended use and composition). There are no specific statutory rules on borderline products in Switzerland. However, the competent authorities, including the Federal Food Safety and Veterinary Office (FSVO) and Swissmedic, have published guidelines to simplify the classification between therapeutic products and foodstuffs.

In distinguishing medicinal products and medical devices, Swissmedic can be expected to follow the guidance document *Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices* issued by the Medical Device Coordination Group.

Natural Health Products

25. Is there a separate regulatory regime for natural health products (or equivalent) (for example, traditional medicines, homeopathic medicines, supplements, vitamins, and minerals)?

There is no specific regulatory regime for natural health products. Either the product qualifies as a medicinal product, in which case the Law on Therapeutic Products (LTP) applies, or it qualifies as a foodstuff, in which case the Act on Foodstuffs and Utility Articles (Foodstuffs Act) applies.

The LTP provides for certain specific regulations for medicinal products of natural origin such as herbal medicines. Medicinal products with an authorised indication that exclusively contain one or more herbal substances or herbal preparations and which are not classified as complementary medicines are regulated in the Ordinance on Complementary and Herbal Medicinal Products.

The provisions in the Foodstuffs Act, the Food and Commodities Ordinance and the corresponding implementing provisions of the Federal Department of Home Affairs (FDHA) must be observed with regard to foodstuffs. The FDHA, among other things, regulates the:

- Hygienic requirements for food and its manufacturing.
- Requirements for the persons handling foodstuffs.
- Hygienic requirements for the rooms in which food is handled, as well as for the equipment and fittings of these rooms.

Products qualifying as foodstuffs can be marketed without a marketing authorisation. However, a licensing or notification requirement applies for certain products (see *Question 27*).

26. Which authorities regulate the manufacture and marketing of natural health products?

If a natural health product qualifies as medicinal product, Swissmedic is the competent authority.

The federal government is responsible enforcement of the Foodstuffs Act and food control at the border (for import, export and transit of products). The cantonal authorities enforce the Foodstuffs Act and ensure foodstuffs control within Switzerland, except where the federal government is competent. Exceptions to cantonal competence include for example:

- Recommendations of the federal authorities on the procedures for sampling and examination of foodstuffs.
- Public warnings by the federal authorities in the event of risk to the population in several cantons.

27. What notifications, registrations, approvals, and licences are required to manufacture and market natural health products?

If a natural health product qualifies as medicinal product, the specific regulations of the Law on Therapeutic Products (LTP) and its ordinances for medicinal products of natural origin apply in relation to licences and marketing authorisation. Natural health products that qualify as foodstuffs do not require marketing authorisation. In general, there are no licensing or notification requirements to place foodstuffs on the market. However, the following are subject to licensing:

- Novel foods.
- Foodstuffs produced from genetically modified organisms.
- Foodstuffs from animals that have been administered unlicensed medicinal products in clinical trials.
- Foodstuffs that are advertised as having special nutritional-physiological or other physiological effects.

Certain foodstuffs intended for people with special nutritional requirements due to health reasons are subject to notification.

There is no list of approved foodstuffs.

Any person who manufactures, handles, stores, transports, places on the market, imports, exports, or carries in transit foodstuffs or utility articles must self-supervise to ensure that the statutory requirements are complied with.

Only safe foodstuffs can be placed on the market. Foodstuffs are deemed to be unsafe if it must be assumed that they are harmful to health or unsuitable for human consumption.

The following must be considered when deciding whether a foodstuff is safe:

- Its normal conditions of use at all production, processing and distribution levels.
- Its normal conditions of use by consumers.
- The information given or otherwise made generally available to consumers on avoiding certain effects of a specific foodstuff or specific category of foodstuff that may be harmful to health.

Manufacturing

The LTP applies to the manufacture of medicinal products.

The Ordinance on Hygiene in the Handling of Foodstuffs in particular must be observed with regard to the production of foodstuffs.

Marketing

The LTP and Ordinance on Advertising for Medicinal products apply to the marketing of medicinal products.

All information relating to foodstuffs, consumer articles and cosmetics must be true. The presentation, labelling and packaging of such products and their advertising must not mislead consumers. In regard to health claims, foodstuffs can only be advertised with certain specific defined claims. The approved health claims are listed in the Ordinance concerning Food Information. Claims that are not already listed must be approved by the FSVO to be used.

28. Are there fewer or different requirements for natural health products that have already been licensed or approved in another jurisdiction?

For natural health products that qualify as medicinal products, see *Question 11*.

Natural health products qualifying as foodstuffs that have been used for human consumption to a significant degree in Switzerland or in an EU member state before 15 May 1997 do not qualify as novel foods and can therefore generally be put on the market without licensing.

Novel foods that can be marketed in the EU can also be marketed in Switzerland without a licence (except foodstuffs containing genetically modified organisms).

29. Is it possible to sell natural health products to or buy natural health products from other jurisdictions?

In principle, it is possible to import or export natural health products that are categorised as foodstuffs. However, there may be exceptions if the foodstuffs do not comply with national legislation. For medicinal products, this is generally not possible due to the marketing authorisation requirement. However, there may be exceptions for certain types of imports (such as for personal use).

Recent Developments and Reform Proposals

30. Have there been any significant recent developments or proposals for reform?

Several revisions of health insurance legislation with the aim of cost containment have recently been enacted or are currently in progress. For example, the obligation of health care service providers to send patients a copy of each invoice entered into force on 1 January 2022. Others are still in the consultation phase. One such revision relates to the provisions governing the reimbursement of medicinal products in individual cases (even if they are not included in the Speciality List issued by the Federal Office of Public Health or are not authorised by Swissmedic) as well as the pricing rules of medicinal products on the Speciality List. Entry into force may take place on 1 January 2024.

The Medical Device Ordinance was completely revised as of 26 May 2021 and adapted to the new EU law. In addition, the provisions of the EU In Vitro Diagnostic Medical Devices Regulation were transferred to a new Swiss Ordinance on In Vitro Diagnostics, and specific provisions connected with in vitro diagnostics were adapted in the Ordinance on Clinical Trials with Medical Devices. These provisions entered into force on 26 May 2022, thereby completing the revision of Swiss medical devices legislation. However, to maintain the mutual facilitation of market access and to ensure joint enforcement with the EU, the mutual recognition agreement would also have had to be adapted before 21 May 2021 (or 22 May 2022). As the mutual recognition agreement has not yet been amended, essential trade facilitations between the EU and Switzerland have ceased to exist (see *Question 15*).

On 15 June 2018, the Law on Human Genetic Testing was revised and modernised. The revision came into effect on 1 December 2022.

The Swiss Data Protection Act has been revised with the intention of aligning Swiss data protection law with the GDPR. The revision comes into effect on 1 September 2023.

The Federal Council intends to simplify the rules on mail order sales of non-prescription drugs, and plans to submit a draft amendment to the Law on Therapeutic Products to the parliament. The aim is to create a framework that enables the dispensing of medicines regardless of the classification as prescription-only or OTC, the distribution channel (pharmacy or drugstore) or the communication technology used.

A further development is that requests for access to documents based on the Federal Act on Public Access are becoming more frequent.

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