

# Switzerland

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## REGULATORY OVERVIEW

### 1. Please give a brief overview of the regulatory framework for medicinal products/pharmaceutical products/drugs (as they are called in your jurisdiction), including the key legislation and regulatory authorities.

Medicinal products are regulated by the Federal Law on Medicinal Products and Medical Devices (Law on Therapeutic Products) (*Heilmittelgesetz*) of 15 December 2000 (LTP). Several ordinances have been issued based on the LTP. Swiss legislation on medicinal products in many areas closely follows EC pharmaceutical regulation.

Medicinal products can (with few exceptions) only be admitted to the market by a marketing authorisation (see *Question 8*). Marketing authorisations are granted by the Swiss Agency for Therapeutic Products (*Schweizerisches Heilmittelinstitut*) (Swissmedic) (see *box*, *The regulatory authority*). There is no automatic recognition of the marketing authorisations granted in the EU (or vice versa).

The LTP and the ordinances based on it set out the conditions for the authorisations needed to manufacture, import, sell, trade and export medicinal products. The authorisations are granted by Swissmedic, or by the cantons in exceptional circumstances. The LTP also contains rules about the prescription, dispensing and advertising of medicinal products.

The Federal Health Insurance Act (*Krankenversicherungsgesetz*) 1994 (as amended) and the ordinances based on it regulate reimbursement of medicinal products by social health insurance. Reimbursement status is granted by the Swiss Federal Office of Public Health (SFOPH).

## PRICING AND STATE FUNDING

### 2. Please give a brief overview of the structure and funding of the national healthcare system.

The healthcare system reflects the federalist structure of Switzerland. Only certain areas are in the competence of the confederation. With few exceptions, health matters are traditionally in the competence of the 26 cantons. For example, most hospitals are governed and owned by the cantons, if they are not privately owned.

Important areas of the healthcare system which are in the competence of the confederation are the legislation on social health insurance (*Soziale Krankenversicherung*) and on pharmaceutical products and medical devices.

Each individual 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*), is often supplemented by optional additional private insurance (private *Zusatzversicherung*). The insurance system in principle allows a free choice of healthcare provider(s). The healthcare system is mainly financed by all of the following:

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

Insured people contribute to social health insurance through premiums to their sick fund and patient co-payments. The premiums may vary significantly between the regions and the different sick funds. The social health insurance premiums of low-income people are, in addition, subsidised by the cantons and the federal government.

### 3. In what circumstances are the prices of medicinal products regulated?

#### Non-reimbursable products

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

#### Reimbursable products

For reimbursable products, the Federal Health Insurance Act (*Krankenversicherungsgesetz*) 1994 (as amended) sets out regulations for determining the maximum price which 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 be listed in the Speciality List (SL) issued by the Swiss Federal Office of Public Health (SFOPH). The SL is published every year as a booklet and updated monthly. It is available on the internet at [www.bag.admin.ch/kv/gesetze/sl/d/index.htm](http://www.bag.admin.ch/kv/gesetze/sl/d/index.htm).

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**4. When is the cost of a medicinal product funded or reimbursed by the state? Please briefly outline the procedure and pricing for state funding or reimbursement (for example, is the reimbursement paid to the producer, pharmacist or end-user)?**

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The social health insurance covers both:

- The costs of medicinal treatment administered in the stationary environment (that is, if the patient spends at least one night in the respective institution).
- In case of ambulatory treatment, the costs of the medicinal products listed on the SL.

In the stationary environment, the sick funds from time to time agree with the hospitals a lump sum per patient and per day for the costs of treatment. The costs that are not covered by this lump sum are borne by the cantons. The costs of stationary and ambulatory treatment are, depending on the insurance system in the canton of the patient's domicile and his sick fund, directly paid for by the sick fund of the patient or reimbursed to him after he has paid the cost. In case of ambulatory treatment, the price paid or reimbursed by the sick funds is, in principle, the SL price.

Applications for a listing in the SL must be made to the SFOPH. The granting of a marketing authorisation does not mean that a pharmaceutical product is automatically reimbursed. Manufacturers and distributors can choose whether to apply for reimbursable status. However, the SFOPH can place a pharmaceutical product of great importance on the SL without prior application from the manufacturer. About two-thirds of the pharmaceutical products registered in Switzerland are listed on the SL. Whether or not a pharmaceutical product is a prescription drug does not affect reimbursement.

A medicinal product is only admitted to the SL if the applicant can show its efficacy, usefulness and economy (for example, a positive cost to benefit ratio). Development costs, treatment costs and efficacy compared to similar medicines must be taken into particular account in assessing the economy of a product. The SFOPH bases its decision on a recommendation of the Federal Commission for Medicinal Products. The relevant criteria for fixing the SL price are:

- The prices of drugs having the same indication or a similar mode of action.
- The average ex-factory price (without VAT) of the product in four other countries with similar economic structures in the pharmaceutical industry. At present, the prices in Germany, Denmark, England and The Netherlands are usually used for the comparison. Under certain circumstances, the prices in France, Italy and Austria are also used.

According to a decision of the competent appeal board, the SFOPH must apply the above two criteria in a balanced way. It cannot assess the price by using only one of the two criteria to impose a lower price.

In determining the SL price, the SFOPH 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 SFOPH considers the price to be too high, it may give an alternative price, which the applicant can accept or reject. If the applicant rejects the alternative price, a formal decision is issued by the SFOPH. The decision can be appealed.

The ex-factory price of a generic product to be listed in the SL must be at least 30% lower than the price of the original. If the price of the original product has already been reviewed two years after expiration of the patent protection or after 17 years of listing in the SL, the ex-factory price of the generic product must be at least 15% lower. The SFOPH also seeks ways to lower the prices of generic products further. Pharmacists can replace an original product with a generic product, unless the doctor expressly excludes this. The price of parallel imports must in principle be at least 15% lower than the ordinary price.

Any price increase of a reimbursed product must be approved by the SFOPH. An application for a price increase can be submitted at least two years after the listing of the product in the SL or after the last increase.

The regulations provide for several examinations at various stages, for the SFOPH to consider whether all the listing criteria are still fulfilled. The SFOPH can decide on an appropriate price decrease on the basis of these examinations.

SFOPH decisions relating to listing in the SL, particularly the prices, can be appealed first to the Federal Administrative Court and then to the Federal Supreme Court.

## MANUFACTURING

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**5. Please give an overview of the authorisation process to manufacture medicinal products. In particular:**

- **To which authority must the application be made?**
  - **What conditions must be met to obtain authorisation?**
  - **Are there specific restrictions on foreign applicants?**
  - **What are the key stages and timing?**
  - **What fee must be paid?**
  - **How long does authorisation last and what is the renewal procedure?**
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### Application

The application must be made to Swissmedic.

### Conditions

The following criteria must be satisfied to obtain authorisation (*Article 3 et seq., Ordinance on Establishment Licences of 17 October 2001*):

- The facilities of the applicant must operate a system to ensure the pharmaceutical quality of medicinal products and that the management and staff in the individual departments concerned are 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 separate from manufacture.
- Care must be exercised in the manufacturing process, meaning, in particular, manufacture according to EU Good Manufacturing Practices (GMP), especially 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.

Whether the conditions are met is checked by Swissmedic through an inspection. An inspection can also be performed any time during the term of a licence.

#### Restrictions on foreign ownership

There are no restrictions on foreign ownership.

#### Key stages and timing

The key stages in the process are application, inspection, grant of the licence and regular inspections (in principle every two years).

#### Fee

The fees for examining an application for a manufacturing licence are CHF500 (about US\$415), plus fees for the inspection (including preparing and writing a report) calculated at CHF800 (about US\$660) per inspector per half day. Inspections can take up to several days, depending on the size of the facilities, and the complexity of the products and manufacturing techniques.

#### Period of authorisation and renewals

Licences are granted for renewable terms of five years.

### 6. What powers does the regulator have to:

- **Monitor compliance with manufacturing authorisations?**
- **Impose penalties for a breach of a manufacturing authorisation?**

Swissmedic and the cantons have powers to monitor compliance with manufacturing authorisations in their respective areas, which are defined in the LTP and related ordinances. They must verify by periodic inspection that the conditions for the authorisation are

met. Swissmedic and the cantons can also, free of charge, take samples, request essential information and documents, and ask for any help necessary for this purpose. They exercise these powers.

Swissmedic and the competent authorities of the cantons can, in principle, take any administrative measure necessary to enforce the LTP, subject to the principles of proportionality and of public interest. The LTP lists certain measures that Swissmedic or the competent authorities of the cantons can take. In relation to breaches of the manufacturing licence, Swissmedic can, in particular:

- Raise objections and set an appropriate time period for re-establishment of the lawful situation.
- Suspend or revoke the licence.
- Close down the establishment.
- Seize, hold in official storage or destroy medicinal products which endanger health or which do not conform to the LTP.
- Prohibit the distribution, supply, import, export and trade in foreign countries of medicinal products, order their immediate recall from the market, or order the publication of recommendations of conduct to prevent damage.

Swissmedic publishes information about revocation decisions.

### CLINICAL TRIALS

#### 7. Please give an overview of the regulation of clinical trials. In particular:

- **Which legislation and regulatory authorities regulate clinical trials?**
- **What authorisations are required and how is authorisation obtained?**
- **What consent is required from trial subjects and how must it be obtained?**
- **What other conditions must be met before the trial can start (for example, the requirement for a sponsor and insurance cover)?**
- **What are the procedural requirements for the conduct of the trial (for example, using certain medical practices and reporting requirements)?**

#### Legislation

Clinical trials are regulated by the LTP and the Ordinance on Clinical Trials with Medicinal Products. Clinical trials with pharmaceutical products must be performed under the Guidelines on Good Clinical Practice of the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) 1996. Clinical trials with medical devices must be performed according to certain legislation such as Annexes VIII and X of Directive 93/42/EC concerning medical devices (Medical Devices Directive).

**Authorisation**

The competent ethics committee must approve the trial (see [www.swissethics.ch](http://www.swissethics.ch)). The ethics committee assesses the trial from the ethical point of view and verifies its scientific quality, taking into account local conditions. The ethics committees are appointed and supervised by the cantons. There are certain rules relating to their composition.

Swissmedic must be notified of clinical trials with pharmaceuticals before they are carried out. Swissmedic confirms receipt of the notification by telefax. If Swissmedic does not raise objections within 30 days from notification, the trial can start. Swissmedic can prohibit a trial or attach conditions to its execution if the requirements are not met. Swissmedic can carry out an inspection at any time to control the execution of a clinical trial. Clinical trials involving somatic gene therapy and clinical trials with medicinal products containing genetically modified microorganisms require authorisation from Swissmedic.

**Conditions**

The main conditions for the performance of a clinical trial are that:

- The trial subjects must give their free informed consent to their participation in the trial. The cantons of Geneva, Basel and Ticino require trial subjects to be entered on a public trial subject register.
- The trial subjects must be guaranteed full compensation for injuries suffered in the trial. This is interpreted as requiring insurance cover up to a certain amount for any damage caused by the trial, occurring both during the trial and within five years after it ends. The amount of insurance cover is determined by Swissmedic and as a rule is at least CHF10 million (about US\$8.3 million) for the whole trial and CHF1 million (about US\$830,000) for each case of personal injury.
- Swissmedic must be notified by the trial's sponsor of an interruption to the trial within 15 days, and of completion of the clinical trial within 90 days. A final report must be filed with Swissmedic within six months from an interruption or completion of the trial.

There is no obligation on Swissmedic or the producers of medicinal products to make clinical trials public. However, in 2005 the Swiss Academy of Medical Sciences, the Swiss Medical Association and the Swiss pharmaceutical industry launched initiatives to require the public registration of the performance and termination of a clinical trial. Editors of important medicinal journals are also requiring public registration before accepting study results for publication. Mandatory public registration will probably be introduced in the new Act on Clinical Research With Human Beings, which may enter into force in a couple of years.

**MARKETING****8. Please give an overview of the authorisation process to market medicinal products. In particular:**

- **To which authority must the application be made?**
- **What conditions must be met to obtain authorisation?**
- **What are the key stages and timing?**
- **What fee must be paid?**
- **How long does authorisation last and what is the renewal procedure?**

**Application**

A marketing authorisation is required for putting 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, the International Conference on Harmonisation Common Technical Document (CTD). Swissmedic accepts registration documents in the form approved by the EU. It also supports submitting data electronically. This should be discussed with the electronic data submission co-ordinator of Swissmedic on a case-by-case basis. The following documents must be included:

- Analytical, chemical, pharmaceutical, pharmacological, toxicological and clinical documents that certify the efficacy and safety of the substance.
- 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.

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 under it.

**Conditions**

The conditions for a marketing authorisation are that the product is safe and effective, and of high quality. While a high quality of manufacturing must always be guaranteed, the application is mainly assessed on the efficacy and relative safety of the drug (the ratio between benefit and risk). If a drug or process has already been approved in another country that possesses a similar system of control for drugs, the results of the examinations carried out for that purpose are considered.

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 (see *Question 5*).

### Key stages and timing

The normal registration (that is, authorisation) process takes at least six to seven months. If Swissmedic has queries or requests further information or documents, these time periods do not apply and registration can take up to one or two years. Making contact with the individuals dealing with the application at Swissmedic is quite simple. Hearings on important points can be obtained at a senior level with Swissmedic. If Swissmedic rejects an application, its decision can be appealed to the Federal Administrative Court, and finally to the Federal Supreme Court.

### Fee

The fees for an examination of an application for a marketing authorisation vary considerably, depending on the type of application. Examples of fees are:

- For a new active substance: CHF25,000 (about US\$20,700) (using the fast track method: CHF60,000 (about US\$49,720)).
- For a product with an existing registered active substance (simplified procedure): CHF7,000 (about US\$5,800) (using the fast track method: CHF35,000 (about US\$29,000)).
- For renewing an existing authorisation: CHF500 (about US\$415).

In addition, Swissmedic charges a sales fee of between CHF0.014 (about US\$0.012) and CHF5 (about US\$4.14) (depending on, among other things, the ex-factory price of the product) for each pharmaceutical product unit sold. The fee contributes to Swissmedic's market surveillance activities.

### Period of authorisation and renewals

The licence is granted for renewable terms of five years.

#### 9. Please briefly outline the abridged procedure for obtaining marketing authorisations for medicinal products. In particular:

- Which medicinal products can benefit from the abridged procedure (for example, generics)?
- What conditions must be met?
- What procedure applies and what information can the applicant rely on?

The LTP and the executing Ordinances offer a simplified procedure for certain medicinal products, including:

- Generics.
- Imports of medicinal products from a country with an equivalent authorisation system (parallel imports).
- Drugs with ingredients that have already been registered.
- Orphan drugs.

The procedure is mainly governed by the Ordinance on the Simplified Marketing Authorisation of Medicinal Products and the Marketing Authorisation of Medicinal Products by Notification of 22 June 2006.

If there is no treatment or no satisfactory treatment against a perilous or heavily disabling disease and if the medical preparation is of a high therapeutic use, a fast track procedure, which is more expensive, is available on the applicant's request and enables registration to be completed within about four months. However, if Swissmedic has queries or requests further information or documents, these time periods do not apply.

The fast track procedure must be requested at least three months before the application for the marketing authorisation is filed.

#### 10. Are foreign marketing authorisations recognised in your jurisdiction? If so, please briefly outline the recognition procedure.

For pharmaceutical products there is no procedure for the recognition of foreign marketing authorisations in Switzerland. However, the results of tests performed for obtaining the marketing authorisation in a country with equivalent medicinal product control must be taken into account in the Swiss admission proceeding. The Swiss-EU Bilateral Agreement provides for the mutual recognition of GMP inspections and batch certificates, the results of clinical trials and of conformity assessments of medical devices. Switzerland is also party to the Pharmaceutical Inspection Convention (PIC), the PER-Scheme and other international treaties and memoranda of understanding.

#### 11. What powers does the regulator have to:

- Monitor compliance with marketing authorisations?
- Impose penalties for a breach of a marketing authorisation?

Swissmedic must verify that medicinal products conform to their marketing authorisation. It can, free of charge, take samples, request essential information and documents and ask for any help if necessary for this purpose. Swissmedic has powers to monitor compliance with marketing authorisations and uses them.

Swissmedic can take administrative measures to ensure compliance with a marketing authorisation similar to those for breach of a manufacturing authorisation (*see Question 6*). If the requirements are no longer met, Swissmedic can cancel the marketing authorisation.

#### 12. Are parallel imports of medicinal products into your jurisdiction allowed? If so, please briefly outline what conditions must be met by the parallel importer. Can intellectual property rights be used to oppose parallel imports?

Under the LTP, a person or company wishing to make parallel imports can apply to Swissmedic for a marketing authorisation using the simplified procedure (*see Question 9*), but only for

medicinal products that are no longer patented (see *Question 19*). 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.

Products that are patent protected cannot be imported in parallel. Apart from the patent protection, a successful applicant for a marketing authorisation for an original product is also granted a ten-year data exclusivity protection independent of the patent. If the data exclusivity survives the patent, the parallel importer cannot base its application for a marketing authorisation on the data of the original applicant.

The ban on parallel imports of patented products is based on the LTP and a ruling of the Federal Supreme Court of 2000 (*BGE 126 III 129*). Under this ruling, only the marketing of a patented product in Switzerland exhausts the patent rights in relation to Switzerland (so-called national exhaustion). The rights are not exhausted by marketing the product in other jurisdictions. The Patent Act 1954 is being reformed (see *Question 34*).

Contrary to patents (national exhaustion), the Federal Supreme Court has based a number of decisions on the principle of international exhaustion of trade mark rights (see *Question 24*) and copyright.

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### 13. Please briefly outline the restrictions on marketing practices such as gifts or “incentive schemes” for healthcare establishments or individual medical practitioners.

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The LTP prohibits offering and accepting financial or other advantages to individual medical practitioners or healthcare establishments, except for:

- Gifts of a modest value, relevant to the professional activity of the recipient (for example, pens, calculators, prescription pads or any other article for daily professional use). According to practice, gifts are considered to be of a modest value if they are not worth more than CHF300 (about US\$250) per year and per health care professional.
- Discounts that are standard for the relevant product.
- Discounts that are justified on business administration grounds, for example volume discounts, introducing a product to a market (during a certain period) or defending a product against generics.

However, what the limits are and what exactly is meant by the above last two types of discounts is still to be determined by Swissmedic and the courts. With regard to the support of medical congresses, Swissmedic issued a publication containing detailed rules at the beginning of 2006. If a medical professional receives a discount on medicinal products which is higher than allowed, he must pass the reduction on to the patient or insurer that pays for the product.

The LTP and the Federal Health Insurance Act contain strict penalties for breaches of the ban on granting prohibited discounts. Criminal law provisions on bribery can also apply.

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### 14. Please briefly outline the restrictions on marketing medicinal products on the internet, by e-mail and by mail order.

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The LTP in principle bans the direct supply of drugs to patients by distributors (especially through mail order distribution). However, the cantons can grant exceptions through authorisations. To obtain an authorisation for mail order distribution, both of the following must be met:

- The applicant must give guarantees of:
  - proper advice to patients;
  - adequate medical monitoring of the effects of the drug;
  - compliance with all the specific safety requirements.
- The patient must supply a doctor's prescription for each drug, whether it is a prescription or non-prescription drug.

## ADVERTISING

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### 15. Please briefly outline the restrictions on advertising medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
  - What types of medicinal product cannot be advertised?
  - What restrictions apply to advertising that is allowed?
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Advertising medicinal products is governed by:

- The LTP.
- The Ordinance on Advertising for Medicinal Products.
- The Code of Conduct of the Pharmaceutical Industry in Switzerland (private Pharma Code), operated by the Swiss Society of Chemical Industries, which applies to advertising to professionals (doctors, dentists and chemists).

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 (see *Question 4*). Swissmedic supervises advertising. Both 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.

The relevant regulations contain detailed rules about advertising elements that are not allowed, particularly for public adverts. Adverts on radio and television must be submitted to Swissmedic in advance for approval. Public adverts in a printed form do not generally require prior approval. However, exceptions to this include adverts for analgesics, sedatives, sleeping tablets, laxatives and anorectics.

Swissmedic has issued a communication about internet marketing. In its communication, Swissmedic requires that access to advertising for prescription-only products must be limited to healthcare professionals by means of password protection. Journalists may also be granted password-protected access to data on such products. For non-reimbursable OTC products, Swissmedic does not restrict advertising on the internet provided it conforms with the general rules on advertising. Swissmedic also explains which links and types of domain names it considers admissible.

The Swiss Pharma Quality Association (SPQA) has set up a quality control label, certifying that the relevant web content is reliable and safe, and that it complies with the LTP and its implementing Ordinances, the Pharma Code, the Federal Law on Data Protection and the requirements of Health on the Net (HON).

## PACKAGING AND LABELLING

**16. Please briefly outline the regulation of packaging and labelling of medicinal products. In particular:**

- Which legislation applies and which regulatory authority enforces it?
- What information must the packaging and/or labelling contain?
- What other conditions must be met (for example, information being stated in the language of your jurisdiction)?

The packaging and labelling requirements are set out in detail in the Ordinance on Marketing Authorisations. There are also some relevant provisions in the Ordinance on Simplified Marketing Authorisation for Complementary and Herbal Medicinal Products. Packaging intended for a patient must contain the following information:

- Designation of the product, if necessary stating the dose.
- Contents of the individual pack.
- Name, type and quantity of the active substances.
- Name and domicile of the holder of the marketing authorisation 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.

- The child warning notice and invitation to read the packing insert/patient information.

Exceptions may be granted by Swissmedic 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. In this case however, 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. Special rules apply to packaging that contains a quantity of products for the treatment of several patients.

The holder of the marketing authorisation must provide product information for members of the medical professions. The relevant information is contained in the Swiss Compendium of Medicinal Products, a comprehensive reference work for use in Switzerland, which is available on the internet at [www.documed.ch](http://www.documed.ch).

Patients must also be provided with patient information, usually in the form of leaflets inside packaging. Information provided to both medical professionals and patients must be approved by Swissmedic. The product information must be written in the official Swiss languages of German, French and Italian.

## TRADITIONAL HERBAL MEDICINES

**17. Please briefly outline the regulation of the manufacture and marketing of traditional herbal medicinal products in your jurisdiction.**

The Ordinance on Simplified Marketing Authorisation for Complementary and Herbal Medicinal Products outlines the conditions on which complementary, herbal, homeopathic, anthroposophic and Asian medicinal products can be granted marketing authorisation in the simplified procedure or on simple mandatory notification. It closely follows Directive 2004/24/EC on traditional herbal medicinal products (Traditional Herbal Medicines Directive) and Directive 2001/83/EC on the Community code relating to medicinal products for human use. The GMP requirements for manufacturers are essentially those of PIC/S GMP Guide for Active Pharmaceutical Ingredients (PE 007-2).

## PATENTS

**18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? What are the legal criteria to obtain a patent? Which legislation applies?**

A patent can be issued for a medicinal product if there is a technical rule for the application of natural forces which can be repeated. The rule must:

- Be innovative (novelty requirement).
- Be capable of commercial application.
- Show a certain level of invention (inventive step requirement).

**19. How is a patent obtained? In particular:**

- To which authority must the application be made?
- What are the key stages and timing?
- What fee must be paid?

**The authority**

The application must be made to the Swiss Federal Institute of Intellectual Property (SFIIP) ([www.ige.ch](http://www.ige.ch)).

**Fee**

The fee for registration and examination of the application by the SFIIP is CHF700 (about US\$600). An annual fee of CHF100 (about US\$85) must be paid for the fifth and sixth year and an annual fee of CHF310 (about US\$260) must be paid for the seventh up to the twentieth year following the application date.

**Process and timing**

The application must be submitted on the official form and in one of the three national languages (German, French and Italian). The SFIIP first checks whether the application meets the formal requirements. If it does, the applicant receives confirmation of receipt. Priority for further patent applications can be claimed within one year following the application date.

About three to four years after application the SFIIP examines whether the invention is capable of commercial application. The novelty and inventive steps requirements are not checked. Accelerated examination can be requested. If the statutory requirements are met, the patent is issued, registered and published. Appeals against decisions of the SFIIP can be made to the Federal Administrative Court.

**20. How long does patent protection last? How is a patent renewed or patent protection extended?**

The patent protection is valid for 20 years from the date on which the application is submitted. The patent protection expires after 20 years and cannot be renewed. However, like in the EU, a supplementary protection certificate can be issued. This option for extending a patent specifically applies to medicinal products and is intended to take into account the period between patent registration and grant of a marketing authorisation, during which clinical trials must be carried out.

An application for a supplementary protection certificate must be submitted to the SFIIP no later than six months after the grant of the marketing authorisation. The certificate is valid from the date of expiry of the normal patent protection, for a period equal to the time between the date of the patent application and the date the marketing authorisation was granted, less five years. The certificate is valid for up to five years and the maximum period of protection from the date on which the marketing authorisation is issued is 15 years. The SFIIP fee for issuing the supplementary protection certificate is CHF2,500 (about US\$2,075). The annual fee is CHF310 (about US\$260).

**21. In what circumstances can a patent be revoked?**

The SFIIP cannot revoke a patent it has issued. Third parties can file an objection against the registration of a patent within three months from publication of the filing of the application, or can submit a nullity claim to the competent court once the patent has been issued. A patent can be annulled if any of the following apply:

- The subject matter of the patent application is not patentable.
- The invention is excluded from patentability.
- The party registering the patent is not the inventor or legal successor of the inventor.

**22. When is a patent infringed? How is a claim for patent infringement made and what remedies are available?**

The patent holder can take legal action under civil law or penal law against any person who:

- Unlawfully uses the patented invention (imitation is deemed to be use).
- Refuses to indicate to the competent authorities the origin of unlawfully manufactured products in his possession.
- Removes the patent marking from products or their packages without authorisation from the patentee or the licensee.
- Aids, abets, participates in or facilitates performance of any of these acts.

The remedies available include:

- Injunctions.
- Claims for damages.
- The party in breach paying profits it has made to the patent holder.
- Criminal proceedings.

**TRADE MARKS****23. Can a medicinal product brand be registered as a trade mark? What are the legal criteria to obtain a trade mark? Which legislation applies?**

Trade mark protection can in principle be obtained for any graphically reproducible product brand, provided that it acts to distinguish a company's goods or services from those of its competitors and is not any of the following:

- Common property.
- Descriptive.

- Misleading.
- Contrary to public policy, morality or applicable law.

International Nonproprietary Names (INN) fall within the second category. Trade mark applications are only checked for absolute grounds of refusal but not for relative grounds of refusal (prior similar rights) (see *Question 24*).

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#### 24. How is a trade mark registered? In particular:

- **To which authority must the application be made?**
- **What fee is payable?**
- **What are the key stages and timing?**

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##### The authority

The application must be made to the SFIIP.

##### Fee

The application fee is CHF550 (about US\$460) or CHF350 (about US\$290) if it is filed electronically and covers up to three product and/or service classes. There is a supplementary fee of CHF100 (about US\$85) and of CHF60 (about US\$50) if filed electronically for each additional class. The fast track procedure costs an additional CHF400 (about US\$330).

##### Process and timing

The application for a national trade mark is made on an official form. Provided it is admitted for trade mark protection, the mark is protected as from the application or priority date. As a rule, the application is examined within two to five months. A fast track method with a maximum processing time of one month is available for an additional fee. If the trade mark registration is refused, it is possible to file an argumentation against the refusal. The SFIIP's decision can be appealed. Once registered, the trade mark is published in the Swiss Official Gazette of Commerce. Publication triggers a three-month opposition deadline.

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#### 25. How long does trade mark protection last? How is a trade mark renewed?

The registration is valid for ten years from the date of application. The applicant must begin using the trade mark within five years. The registration of a trade mark can be renewed infinitely for further periods of ten years. The renewal fee is CHF700 (about US\$580) and covers up to three classes. There is a supplementary fee of CHF100 (about US\$85) for each additional class.

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#### 26. In what circumstances can a trade mark be revoked?

The owner of an earlier trade mark which is confusingly similar and covers goods and/or services of the same kind can file an opposition against the trade mark registration within three months

of the date of publication. The opposition proceedings are inexpensive and quick. The SFIIP's decision can be appealed. As long as there is no forfeiture of claim a trade mark can be attacked by way of a civil action on the basis of danger of confusion, lack of use, lacking distinctiveness and so on (see *Question 27*).

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#### 27. When is a registered trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

According to the Trademark Act a trade mark right is infringed if a third party uses any of the following:

- An identical mark for the same goods or services.
- An identical mark for similar goods or services, provided that there is a risk of confusion.
- A similar mark for the same or similar goods or services, provided that there is a risk of confusion.

Further, the Federal Act Against Unfair Competition allows legal action against whoever takes measures, which by their nature may cause confusion with the products, works, performance or the business of another. The holder of the trade mark can take legal action against infringements of the trade mark. The remedies that are available include:

- Injunctions.
- Cancellation of the mark.
- Transfer of the mark.
- Claims for damages.
- Restitution of profits.
- Publication of judgment.
- Confiscation.
- Criminal proceedings.

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#### 28. Is your jurisdiction party to international conventions on patent and trade mark protection?

Switzerland is party to the:

- European Patent Convention 1973 (EPC) and on 12 June 2006 it deposited its instruments of ratification of the EPC Revision Act, which will enter into force on 13 December 2007 at the latest.
- Patent Cooperation Treaty 1970.
- Switzerland-Liechtenstein Patent Cooperation Treaty 1978, which states that every patent granted in Switzerland is also effective in Liechtenstein.

- WIPO Madrid Agreement Concerning the International Registration of Marks 1891 (Madrid Agreement) and the WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989.
- WIPO Nice Agreement concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.

## PRODUCT LIABILITY

### 29. Please give an overview of medicinal product liability law, in particular:

- Under what laws can liability arise (for example, contract, tort or statute)?
- What is the substantive test for liability?
- Who is potentially liable for a defective product?

#### Legal provisions

There are no special rules relating to liability for pharmaceutical products. Under the Federal Act on Product Liability of 1993 (FAPL), a producer is liable if a defective product leads to the death or injury of a person, or damage to or destruction of property. In addition, standard rules of contract, tort and criminal law (about death and physical injury) may 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 method and manner used to present the product to the general public as well as the use of the product that can reasonably be expected. The subsequent launch of an improved product on the market does not in itself make an older product defective.

#### Liability

The following are deemed to be producers:

- The manufacturer of the faulty product (in whole or in part).
- 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 cannot be identified.

### 30. What are the limitation periods for bringing product liability claims?

The limitation period for claims under the FAPL 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.

## THE REGULATORY AUTHORITY

### Swiss Agency for Therapeutic Products (*Schweizerisches Heilmittelinstitut*) (Swissmedic)

**T** +41 31 322 02 11  
**F** +41 31 322 02 12  
**E** [swissmedic.ch/de/kontakt](http://swissmedic.ch/de/kontakt)  
**W** [www.swissmedic.ch](http://www.swissmedic.ch)

**Main areas of responsibility.** These are:

- Marketing authorisations and establishment licences.
- Control of advertising and monetary advantages.
- Supervision of clinical trials.
- Market surveillance.

### 31. What defences are available to product liability claims?

The producer is not liable for a defective product under the FAPL if it proves that:

- 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.
- The error was not identifiable on the basis of scientific and technological knowledge at the time the product was put into circulation (development risk).

### 32. What remedies are available to the claimant?

The remedies under the FAPL are compensation for personal damage and for damage to goods for private use.

### 33. Are class actions allowed for product liability claims? If so, are they common?

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

## REFORM

**34. Please summarise any proposals for reform and state whether they are likely to come into force and, if so, when.**

A partial revision of the LTP and its ordinances is pending. It will facilitate an adequate supply of hospitals with medicinal products that, mainly for profit reasons, are not admitted in Switzerland in the requested pharmaceutical form, concentration, dosage or indication or which are not available. On 28 February 2007 the Federal Council sent its legislative proposal to the Parliament. Where there is no equivalent alternative available, the hospital preparation will be exempt from the general marketing authorisation by Swissmedic. Further, the import of medicinal products not admitted in Switzerland by hospitals will be eased. It will also be possible to print the information on the package and the package insert of such products in one official language or in English only.

Swissmedic has changed the insurance cover requirements for the subjects of clinical trials. Exclusion of liability clauses will only be accepted as effective if the injury:

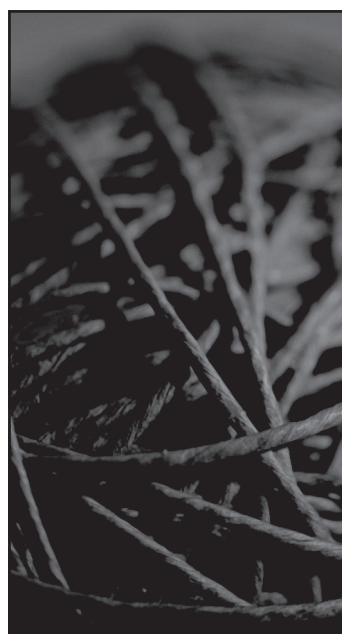
- Is caused by a medicinal product that has a marketing authorisation;
- Would also have been caused by applying a standard therapy; or
- Is caused in case of a disease which is usually lethal and for which no standard therapy is available.

Further, sponsors will be able to stipulate a franchise. These new rules apply from 1 September 2007 for object-related agreements and from 1 January 2008 for annual contracts. Various revisions of the Patents Act deal with:

- Anti-piracy, inventions in biotechnology and the implementation of the revised European Patent Convention. The revisions also provide for a broad research privilege regarding medicinal products and an exemption for activities in connection with the application for a marketing authorisation for medicinal products in Switzerland or abroad. If no referendum is filed against the revision, it will enter into force on 1 July 2008.
- Introducing a Federal Patent Court Law and a Patent Attorney Law.
- Exhaustion of patent rights (see *Question 15*).

By the end of 2007, the Federal Council, which wants to maintain national exhaustion, will present its legislative proposals regarding the second and third parts of the revision to Parliament. Parliament will discuss the proposals in 2008 and 2009.

The Federal Act on Transplantation of 8 October 2004 entered into force on 1 July 2007. This states that numerous provisions of the LTP apply by analogy to products made of human or animal organs, tissue or cells, which are standardised or which have a standardised manufacturing process. This Act resulted in some minor adaptations of the Federal Act on Product Liability.



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