

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 follows EC pharmaceutical regulation in many areas.

Medicinal products can only be admitted (with few exceptions) 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 authorities*). There is currently no automatic recognition of marketing authorisations granted in the EU (or vice versa).

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

The Federal Health Insurance Act (*Krankenversicherungsgesetz*) 1994 (as amended) and related ordinances 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 some exceptions, health matters have traditionally been in the competence of the 26 cantons. For example, almost all non-private hospitals are governed and owned by the cantons.

The competences of the confederation have grown in recent years. Important areas of the healthcare system, which are now under the competence of the confederation, are legislation on:

- Social health insurance (*Soziale Krankenversicherung*).
- Academic professions in the healthcare sector.
- Pharmaceutical products and medical devices.
- Narcotics.
- Certain areas of research.
- Reproductive medicine.
- Transplantation.

Legislation on social health insurance provides that 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*), can be 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 different regions and sick funds. The social health insurance premiums of people of low-income 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 prices when granting marketing authorisation. However, if there is price abuse or there are illegal agreements on prices, the Competition Commission or the price surveillance authority can intervene.

Reimbursable products

For reimbursable products, the Federal Health Insurance Act (*Krankenversicherungsgesetz*) 1994 (as amended) sets out regulations for determining the maximum price that healthcare providers (that is, pharmacies, drug stores, hospitals and

self-dispensing doctors) can charge for reimbursable products. For a pharmaceutical product to be reimbursed within the framework of the social health insurance system, it must in principle be listed in one of the lists drawn up for this purpose, particularly the Speciality List (SL) issued by the Swiss Federal Office of Public Health (SFOPH). The SL is available at www.bag.admin.ch/kv/gesetze/sl/d/index.htm.

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)?

Primarily depending on the insurance system in the canton of the patient's domicile, the costs of stationary and ambulatory treatment are either directly paid for by the sick fund of the patient or reimbursed to him after he has paid the cost. Under the basic health insurance regime, medicinal products are reimbursed if they are prescribed by a physician (or, under certain circumstances, by a chiropractor) and listed in one of the lists drawn up for this purpose, particularly the SL (see Question 3, *Reimbursable products*). Optional additional private insurances also cover authorised medicinal products that are not listed in the SL.

Applications for a listing in the SL must be made to the SFOPH. The granting of marketing authorisation does not mean that a pharmaceutical product is automatically reimbursed. The holder of the marketing authorisation can choose whether to apply for reimbursable status. However, the SFOPH can place a pharmaceutical product of great importance on the SL without prior application from the marketing authorisation holder. About 40% of pharmaceutical products registered in Switzerland are listed on the SL. Whether 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. The SFOPH bases its decision on a recommendation of the Federal Commission for Medicinal Products. The following are the criteria for fixing the SL price:

- The prices of drugs that have the same indication or a similar mode of action.
- The average ex-factory price (without VAT) of the product in other countries. Since 1 October 2009, the prices in Germany, Denmark, England, The Netherlands, France and Austria are used for the comparison.

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

If the pharmaceutical product constitutes a therapeutic advancement, an innovation premium can be granted. 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.

Fulfilment of the conditions for admission is reviewed every three years for all pharmaceutical products listed in the SL. If the review shows that the price is too high, the price is decreased with effect from 1 November in the year in which the review takes place. There is also a review of the conditions for admission immediately after expiration of the patent protection.

In relation to generic products listed in the SL the following rules apply:

- The ex-factory price of the generic product must be at least 50% lower than the price of the original, if the market volume of the original (including its co-marketing products) exceeded CHF16 million (about US\$15.5 million) on average during the last four years before patent expiry.
- The ex-factory price of the generic product must be at least 40% lower, if the market volume of the original (including its co-marketing products) was between CHF8 million and CHF16 million (about US\$7.8 and US\$15.5 million) on average during the last four years before patent expiry.
- The ex-factory price of the generic product must be at least 20% lower, if the original and its co-marketing products have had a market volume not exceeding CHF8 million (about US\$7.8 million) on average during the last four years before patent expiry.

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

Any price increase of a reimbursed product must be approved by the 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.

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

MANUFACTURING

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?

Application

With some exceptions, 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 (in particular, manufacture must be according to EU Good Manufacturing Practices (GMP), especially as set out in Directive 2003/94/EC on good manufacturing practice for medicinal products (GMP Directive)).
- 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.
- Regular inspections (in principle every two years).

Fee

The fees for examining an application for a manufacturing licence are CHF500 (about US\$480), plus fees for the inspection (including preparing and writing a report) calculated at CHF800 (about US\$770) 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 conditions for 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.

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. For 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 (this decision will be published by Swissmedic).
- Close down the establishment.
- Seize, hold in official storage or destroy medicinal products which endanger health or which do not conform to the LTP.
- Prohibit the distribution, supply, import, export and trade in foreign countries of medicinal products, order their immediate recall from the market, or order the publication of recommendations of conduct to prevent damage.

For breach of the manufacturing authorisation, penalties may apply.

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). The ethics committee assesses the trial from an 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 or in certain cases a longer period of time, the trial can start. Swissmedic can prohibit a trial or attach conditions to its execution if 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 micro-organisms require authorisation from Swissmedic. For certain trials reports from other authorities or commissions are necessary.

Conditions

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

- Trial subjects must give their free informed consent to participation in the trial.
- 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\$9.7 million) for the whole trial and CHF1 million (about US\$966,410) 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.

Swissmedic or the producers of medicinal products are not obliged to make clinical trials public. In 2005 the Swiss Academy of Medical Sciences, the Swiss Medical Association and the Swiss pharmaceutical industry launched initiatives to require public registration of the performance and termination of a clinical trial. Editors of important medicinal journals also require public registration before accepting study results for publication. The draft for a new Act on Clinical Research with Human Beings, which has been submitted to parliament in October 2009, also foresees mandatory public registration of authorised clinical trials (with certain exceptions).

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

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 Common Technical Document (CTD) of the International Conference on Harmonisation. Swissmedic accepts registration documents in the form approved by the EU. It also supports submitting data electronically. 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 (*see Question 10*).

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 authorisation process takes at least about one year. Swissmedic's targeted internal time periods are:

- Formal control: 30 days.

- Examination and establishment of the list of questions: an additional 120 days.
- Advance notice of the decision: 90 days.
- Decision: 90 days (in total 330 days).

If Swissmedic has queries or requests further information or documents, these internal targeted time periods are stopped and the authorisation process can take longer. Making contact with individuals dealing with the application at Swissmedic is possible. Hearings on important points can under certain conditions be obtained 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:

- CHF25,000 (about US\$24,160) for a new active substance and CHF60,000 (about US\$57,980) using the fast track method.
- CHF7,000 (about US\$6,760) for a product with an existing registered active substance (simplified procedure) and CHF35,000 (about US\$33,820) using the fast track method.
- CHF500 (about US\$480) for renewing an existing authorisation.

In addition, Swissmedic charges a sales fee of between CHF0.014 (about US\$0.013) and CHF5 (about US\$4.8) (depending on, among other things, the ex-factory price of the product) for each pharmaceutical product unit sold. The fee contributes to Swissmedic market surveillance activities.

Period of authorisation and renewals

The marketing authorisation 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?

Simplified procedure. The LTP and related ordinances offer a simplified procedure for the marketing authorisation of certain medicinal products, including:

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

- Drugs which are manufactured in a hospital pharmacy for the needs of the hospital.

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.

Fast track procedure. The fast track procedure is more expensive. It is available on the applicant's request and enables registration to be completed within about four months if both:

- There is no treatment or no satisfactory treatment against a perilous or heavily disabling disease.
- The medical preparation is of a high therapeutic use.

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 automatic recognition of foreign marketing authorisations in Switzerland. However, results of tests performed for obtaining marketing authorisation in a country with equivalent medicinal product control must be taken into account in Swiss admission proceedings. However, an independent application for marketing authorisation must be made to Swissmedic. In November 2008, Swissmedic issued a guideline which provides that a marketing authorisation obtained through the centralised procedure is extensively taken into account in the Swiss marketing authorisation procedure. However, it is unclear to what extent Swissmedic makes its own scientific evaluation of the application.

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.

Swissmedic can take administrative measures to ensure compliance with a marketing authorisation similar to those for breach of a manufacturing authorisation. If the requirements are no longer met, Swissmedic can cancel the marketing authorisation. In the case of breach of the marketing authorisation, penalties may apply.

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 marketing authorisation using the simplified procedure. The following conditions must be met:

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

On 1 July 2009 the following came into effect:

- A revision of the Federal Law on Patents.
- A revision of the provision of the LTP regarding marketing authorisation based on a simplified procedure for parallel imported products.

For applications filed after 1 July 2009, the admission procedure no longer considers whether the medicinal products are still patented. The patent owners must monitor the publication of the marketing authorisations and defend their patent rights through a civil action.

From 1 July 2009 Switzerland has adopted the regional exhaustion of patent rights system (that is, patent rights are exhausted if products have been put on the market by the patent owner, or with his consent, in Switzerland or the EEA). This rule is subject to the exception that the patent owner's consent is still requested if the product price is government fixed in Switzerland or in the country where the product has been put into circulation.

A patent that is of subordinate importance to the functional properties of the product cannot be used to hinder parallel imports even if the product has been put on the market by the patent owner, or with his consent, outside the EEA. Switzerland recognises the principle of international exhaustion in relation to trademarks.

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

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 their total value is not more than CHF300 (about US\$290) per year and per healthcare professional.
- Discounts which are standard in the relevant field.

- 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 last two types of discount is still to be determined by Swissmedic and the courts. For participation of physicians in medical congresses, Swissmedic issued a publication containing detailed rules at the beginning of 2006.

If a medical professional receives a discount on medicinal products, 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 penalties for breaches of the ban on granting prohibited discounts or not passing on discounts received.

Penal provisions on bribery of the Swiss Criminal Law and the Federal Act against Unfair Competition can also apply.

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

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

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.
- Ordinance on Advertising for Medicinal Products.
- Paragraph 6, Article 65 of the Ordinance on Health Insurance.
- Federal Act against Unfair Competition.
- 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 8).

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 in relation to 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 issued a communication in 2006 about internet marketing. In its communication, Swissmedic requires that access to advertising for prescription-only medicinal products must be limited to healthcare professionals by means of password protection. In a decision of 24 April 2009, the Federal Administrative Court confirmed that this requirement is lawful. This has not been appealed to the Swiss Federal Court. This requirement should also be observed for advertising for reimbursable products. Swissmedic requires that advertising for OTC products on the internet conforms to the general rules on advertising. Swissmedic also explains which links and types of domain names it considers admissible. Swissmedic now expects the industry to comply with the communication on internet marketing from 1 January 2010.

An industry supported initiative has been launched by the Swiss Health Quality Association to set up a quality control label, certifying that a website complies with the LTP, the Pharma Code and the Federal Law on Data Protection.

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 the 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.

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

Special rules apply to packaging that contains a quantity of products for the treatment of several patients.

The marketing authorisation holder must provide product information for members of the medical profession. The relevant information is published 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.

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. 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 manufacture and marketing of such products is regulated in the Ordinance on Simplified Marketing Authorisation for Complementary and Herbal Medicinal Products of 22 June 2006. This Ordinance 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 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 (Code for Human Medicines Directive).

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).

The Federal Law on Patents for Inventions of 25 June 1954 (Law on Patents) and related Ordinance of 19 October 1977 apply. The Law on Patents was revised in 2007 to, among other things, provide rules for the patentability of biotechnological inventions, which are compatible with the Directive 98/44/EC on the legal protection of biotechnological inventions (Biotech Directive). New processes for the production of existing products can also be protected by patent.

The following cannot be patented:

- The human body and surgical procedures, therapy and diagnosis applied on the human body.
- Mere discoveries of something already in existence (such as naturally existing gene sequences).

19. How is a patent obtained? In particular:

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

The authority

The application must be made to the Swiss Federal Institute of Intellectual Property (SFIIP).

Fee

The fee for registration and examination of the application by the SFIIP is CHF700 (about US\$680). The fees for an optional search are CHF500 (about US\$480) and CHF200 (about US\$190) for an expedited examination. An annual extension fee must be paid after the end of the fifth year following the date of registration. The fees are:

- CHF100 (about US\$97) annually for years five and six.
- CHF200 annually for years seven and eight.
- CHF310 (about US\$300) for year nine and onwards.

Process and timing

The application must be submitted on the official form. A patent application includes a description of the invention, at least one formal patent claim and relevant drawings. The technical docu-

mentation must be in German, French or Italian. The patent application is published at www.swissreg.ch 18 months after filing, and the patent is published on its granting at the same address.

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 when the application is submitted. The first term of protection is five years. Annual maintenance fees are due after then.

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 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 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 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\$2,420). The annual fee is CHF310 (about US\$300).

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 not disclosed in the patent specification in such a way that a person skilled in the art could carry it out.
- The invention is excluded from patentability.
- Where the subject matter of the patent goes beyond the content of the version of the patent application that determined the filing date.
- The party registering the patent is not the inventor or legal successor of the inventor and had not acquired the right to the patent under any other title.

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 and volume of unlawfully manufactured products or of products that have been unlawfully put in circulation 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.

Further, the patent holder can request assistance from the customs authorities. The customs authorities can withhold suspicious goods, including goods on transfer through Switzerland, to enable the patent holder to obtain precautionary measures.

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 non-proprietary 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).

The Federal Law on the Protection of Trademarks and Indications of Source of 28 August 1992 and the related Ordinance of 23 December 1992 apply.

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?

The authority

The application must be made to the SFIIP.

Fee

The application fee is CHF550 (about US\$530) or CHF350 (about US\$340) if it is filed electronically and covers up to three product classes. There is a supplementary fee of CHF100 (about US\$97) or CHF60 (about US\$58) in the case of an electronic application for each additional class. From 1 January 2010 there will be no price reductions for electronic applications. The fast track procedure costs an additional CHF400 (about US\$390).

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 date. As a rule, the application is examined within either:

- Three to four months after the payment of the application fees.
- Ten working days after its filing, if both:
 - the electronic application is clearly registrable;
 - the list of goods and services only covers those contained in the SFIIP's electronic database of accepted goods and services (preponed examination).

A fast track method with a maximum processing time of one month is available for all kinds of applications for an additional fee. If the trade mark registration is refused, it is possible to file a protest against the refusal. The SFIIP's decision can be appealed. Once registered, the trade mark is published on www.swissreg.ch. Publication triggers a three-month opposition deadline.

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 CHF550 (about US\$530).

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

The owner of an earlier trade mark can file an opposition against the trade mark registration within three months of the date of publication if both:

- The earlier trade mark is identical or confusingly similar to the newly registered trade mark.
- The trade marks cover identical goods and/or services, or goods and/or services of the same kind.

Opposition proceedings are inexpensive and quick. The SFIIP's decision can be appealed to the Federal Administrative Court.

As long as there is no forfeiture of claim a trade mark can be challenged by way of a civil action on the basis of danger of confusion, lack of use and so on.

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

The 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.

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.

Further, the trade mark holder can request assistance from the customs authorities. The customs authorities can withhold suspicious goods, including goods in transit through Switzerland, to enable the trade mark owner to obtain precautionary measures.

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

Patents

- Paris Convention for the Protection of Industrial Property 1883/1979.
- European Patent Convention 1973 (EPC) the revised version of which entered into force on 13 December 2007.
- Language Agreement (London Agreement), which entered into force on 1 May 2008.
- Patent Cooperation Treaty 1970.
- Switzerland-Liechtenstein Patent Cooperation Treaty of 1978, which states that every patent granted in Switzerland is also effective in Liechtenstein.

Trade marks

- Paris Convention for the Protection of Industrial Property 1883/1979.

THE REGULATORY AUTHORITIES

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

T +41 31 322 02 11
F +41 31 322 02 12
E see www.swissmedic.ch/de/kontakt
W www.swissmedic.ch

Main areas of responsibility. Swissmedic's main areas of responsibility are:

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

Swiss Federal Institute of Intellectual Property (SFIIP)

T +41 31 377 77 77
F +41 31 377 77 78
E info@ipi.ch
W www.ige.ch

Main areas of responsibility. SFIIP controls applications for patents, designs and trade marks.

- Trademark Law Treaty 1994.
- 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.
- Nice Agreement concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.
- Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks 1973/1985.
- Singapore Treaty on the Law of Trademarks 2006 (entered into force on 16 March 2009).

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 for private use. 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 be reasonably 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.

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 damages and for damages 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 revision of the Law on Therapeutic Products is planned to come into force in summer 2010. It provides that specific types of medicinal products manufactured by hospitals or pharmacies no longer require marketing authorisation under certain conditions.

The revision also provides for a sunset clause (that is, a marketing authorisation will be revoked if the medicinal product is not placed on the market within three years after the marketing authorisation is granted, or if the medicinal product placed on the market is no longer actually present on the market for three consecutive years).

Changes in the ordinances also relate to medical devices (incorporation of the Medical Devices Revision Directive (Directive 2007/47/EC amending Directives 90/385/EEC, 93/42/EEC and 98/8/EC) and the facilitated marketing authorisation process for medicinal products that have been authorised under the EC centralised procedure).

A second revision of the LTP (*see Question 1*) is being prepared by the Federal Council. It will cover several areas of the law. Two important aims are to facilitate the marketing authorisation process and to clarify certain disputed provisions.

A revision of the Federal Health Insurance Act, providing for an obligation to prescribe the cheaper medicinal product of two equally suitable medicinal products, is currently being discussed in parliament.

In relation to patents, a new Federal Patent Court Act and a Patent Attorney Act will assure effective and high quality legal advice and judicature. Parliament accepted these acts in the final vote of 20 March 2009. No petitions for a referendum were filed before the 9 July 2009 deadline.

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