Switzerland

Frank Scherrer and Gabriela Taugwalder
Wenger & Vieli AG

REGULATORY OVERVIEW

1. What is the regulatory framework for the authorisation, pricing and reimbursement of drugs, biologicals and devices (as they are termed in your jurisdiction)?

Legislation

Medicinal products and medical devices 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 EU pharmaceutical regulation in many areas.

Medicinal products can only be admitted to the market (with some exceptions) by a marketing authorisation (see Question 8). There is no automatic recognition of marketing authorisations granted in the EU. However, marketing authorisations in countries with a comparable marketing authorisation system such as the EU or the US are taken into account.

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

Medical devices do not require a marketing authorisation. In the field of medical devices Switzerland has essentially transposed EU regulations, mainly into the Ordinance on Medical Devices (Medizinprodukteverordnung). The CE mark allows the free movement of medical devices within the European Economic Area (EEA) and Switzerland.

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

Regulatory authorities

Marketing authorisations are granted by the Swiss Agency for Therapeutic Products (Schweizerisches Heilmittelinstitut) (Swissmedic) (see box, The regulatory authorities). Authorisations to manufacture, import, sell, trade and export medicinal products are granted by Swissmedic, or in certain exceptional circumstances by the cantons. Reimbursement status for medicinal products is granted by the Swiss Federal Office of Public Health (SFOPH). The SFOPH decides on the maximum price for reimbursed medicinal products.

Biotechnology and combination products

Certain special rules and guidelines exist for the marketing authorisation of biotechnology and combination products as well as for the reimbursement of combination products.

PRICING AND STATE FUNDING

2. What is the structure of the national healthcare system, and how is it funded?

Structure

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

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

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

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

Funding

The healthcare system is mainly financed by:

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

3. How are the prices of medicinal products regulated?

Non-reimbursable products

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

Reimbursable products

For reimbursable products, the Federal Health Insurance legislation sets out regulations for determining the maximum price that healthcare providers (that is, pharmacies, drug stores, hospitals and self-dispensing doctors) can charge for reimbursable products. For a pharmaceutical product to be reimbursed within the framework of the social health insurance system, it must generally be within the lists drawn up for this purpose, particularly the Speciality List (SL) issued by the SFOPH (see www.bag.admin.ch/kv/gesetze/sl/d/index.htm).

4. When is the cost of a medicinal product funded by the state or reimbursed to the patient? How is the pharmacist compensated for his dispensing services?

Depending on the insurance system in the canton of the patient’s domicile, the costs of ambulatory treatment are directly paid for by the sick fund of the patient or reimbursed to him after he has paid the cost. The costs of stationary treatment are directly paid for by the sick funds. The sick funds are not part of the state administration. 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 most 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 average ex-factory price (without VAT) of the product in other countries. Since 1 October 2009, the prices in Germany, Denmark, UK, The Netherlands, France and Austria are used for the comparison. The SFOPH can also use other countries for the comparison.
- The prices of drugs that have the same indication or a similar mode of action.
- The SFOPH sets the reference price. If an application for a price increase is filed or a new indication becomes available or if a new mode of action becomes available, the SFOPH adds or deducts the innovation premium. The innovation premium can be granted. In determining the SL price, the SFOPH adds a distribution margin to the ex-factory price. If the SFOPH considers the price to be too high, it can give the applicant an alternative price, which the applicant can accept or reject. If the applicant finally rejects the price proposed by the SFOPH, a formal decision is issued by the SFOPH. The decision can be appealed.

Fulfilment of the admission conditions 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 of the review. There is also a review of the admission conditions:

- Immediately after expiration of patent protection.
- If an application for a price increase is filed or a new indication is authorised by Swissmedic for a medicinal product whose listing in the SL is not subject to a limitation.

The following rules apply for generic products listed in the SL:

- The ex-factory price of the generic product must be at least 60% lower than the price of the original, if the Swiss market volume of the original (including its co-marketing products) exceeded CHF25 million per year on average during the four years before patent expiry. (As at 1 November 2011, US$1 was about CHF0.94.)
- The ex-factory price of the generic product must be at least 50% lower, if the market volume of the original (including its co-marketing products) was between CHF16 million and CHF25 million on average during the 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 on average during the four years before patent expiry.
- The ex-factory price of the generic product must be at least 20% lower, if the market volume of the original (including its co-marketing products) was between CHF4 million and CHF8 million on average during the four years before patent expiry.
- The ex-factory price of the generic product must be at least 10% lower, if the market volume of the original (including its co-marketing products) did not exceed CHF4 million on average during the four years before patent expiry.
The ex-factory price of parallel imports must generally be at least 15% lower than the ordinary ex-factory price, unless the product is already on the generic price level.

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

The SL sets out the maximum price that the pharmacist can charge for certain medicinal products. The SL price takes into account a distribution margin which is different for prescription and non-prescription products. There is no maximum price for pharmaceutical products which are not listed in the SL. In relation to prescription medicines, pharmacists can charge for certain services in addition to the distribution margin (including control of the prescription, information and instructions, and the keeping of a patient file). The reimbursement of these services is based on a contract between the Swiss pharmacists’ association and the insurances that must be approved by the Swiss government.

**MANUFACTURING**

5. What is the authorisation process for manufacturing medicinal products?

**Application**

The application must in principle be made to Swissmedic. Hospital pharmacies and other establishments holding a retailing licence may have to apply to the canton.

**Conditions**

The following criteria must be satisfied to obtain authorisation from Swissmedic (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 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), particularly as set out in Directive 2003/94/EC on good manufacturing practice for medicinal products).
- The work of all persons occupying key positions in the company must be set out in job descriptions and their positions in the hierarchy shown in organisation charts.

The fulfilment of conditions is inspected by Swissmedic. An inspection can also be performed any time during a licence term.

**Restrictions on foreign applicants**

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

**Key stages and timing**

The key stages in the process are:

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

**Fee**

The fees for examining an application for a manufacturing licence are CHF500, plus fees for the inspection (including preparing and writing a report) calculated at CHF800 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 in relation to manufacturing authorisations?

**Monitoring compliance**

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, without incurring costs, take samples, request essential information and documents, and ask for any necessary help.

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

- Raise objections and set an appropriate time period for re-establishment of the lawful situation.
- Suspend or revoke the licence (this decision will be published by Swissmedic).
Close down the establishment.

Seize, hold in official storage or destroy medicinal products which endanger health or which do not conform to the LTP.

Prohibit the distribution, supply, import, export and trade in foreign countries of medicinal products, order their immediate recall from the market, or order the publication of recommendations of conduct to prevent damage.

Imposing penalties
Apart from administrative measures (see above, Monitoring compliance), Swissmedic and the competent cantonal courts can also impose criminal sanctions.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities
Clinical trials are regulated by:

- The LTP.
- The Ordinance on Clinical Trials with Medicinal Products.
- Legislation such as Annexes VIII and X of Directive 93/42/EC concerning medical devices (Medical Devices Directive), if they involve medical devices.

The competent ethics committee must approve the trial (see www.swissethics.ch) and it must be notified to Swissmedic.

Authorisations
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 microorganisms require authorisation from Swissmedic. For certain trials, reports from other authorities or commissions are necessary.

Consent
Trial subjects must give their free informed consent to participation in the trial. Clause 4.8 of ICH-GCP applies. The complete information given to the trial subjects and the way the informed consent is obtained must be reviewed by the competent ethics committee.

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

- The trial project and documentation must be set up according to the applicable rules.
- The competent ethics committee has approved the trial.
- Swissmedic has not objected or has approved the trial.
- Trial subjects must be guaranteed full compensation for injuries suffered in the trial. This requires 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. Swissmedic determines the amount of insurance cover, which is generally at least CHF10 million for the whole trial and CHF1 million for each case of personal injury.

Procedural requirements
Procedural requirements are set out in the Ordinance on Clinical Trials with Medicinal Products and the ICH-GCP.

For example, the trial sponsor must notify Swissmedic of an interruption to the trial within 15 days, and the trial’s completion within 90 days. A final report must be filed with Swissmedic within six months of the trial’s interruption or completion.

Swissmedic or the producers of medicinal products are not obliged to make clinical trials public. The new law on research involving humans, which was approved by parliament on 30 September 2011 and is scheduled to take effect in summer 2013, provides for mandatory public registration of authorised clinical trials (with certain exceptions).

MARKETING

Authorisation and abridged procedure

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

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

- Analytical, chemical, pharmaceutical, pharmacological, toxicological and clinical documents that certify the efficacy and safety of the product.
- Drafts of the product information to be provided to professionals and patients.
- Packaging design.
- Samples of the medicinal product, active and auxiliary agents, intermediate and by-products, if requested by Swissmedic.
The required documents are listed in detail in the Ordinance on the Requirements for the Marketing Authorisation of Medicinal Products and its Annexes of 9 November 2001 (Ordinance on Marketing Authorisations) and guidelines issued by Swissmedic.

Authorisation conditions
The conditions for a marketing authorisation are that the product is safe and effective, and of high quality. While high quality manufacturing must always be guaranteed, the application is mainly assessed on the drug's efficacy and relative safety (the ratio between benefit and risk). If a drug or process has already been approved in another country that possesses a similar system of control for drugs, those examination results are considered (see Question 10). Swissmedic does not examine whether there is patent protection.

A marketing authorisation can only be granted to a person or company having its domicile, registered office or branch office in Switzerland. The applicant must also have a manufacturing, import or wholesale licence (see Question 5).

Other conditions
A medicinal product must be placed on the market after three years of marketing authorisation.

Marketing authorisation is revoked if the product is not marketed for three years or more (with some exceptions).

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: 120 days.
- Advance notice of the decision: 90 days.
- Decision: 90 days.

If Swissmedic has queries or requests further information or documents, these internal time periods are stopped and the authorisation process can take longer. Swissmedic individuals dealing with the application can be contacted. 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, including:

- CHF25,000 for a new active substance and CHF60,000 using the fast track method.
- CHF7,000 for a product with an existing registered active substance (simplified procedure) and CHF35,000 using the fast track method.
- CHF500 for renewing an existing authorisation.

In addition, Swissmedic charges a sales fee of between CHF0.014 and CHF5 (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
Marketing authorisation is granted for renewable terms of five years. The marketing authorisation holder must submit a renewal application with supporting information at least six months before the expiry date.

Post-marketing commitments and pharmacovigilance obligations
Marketing authorisation holders for medicinal products with a new active substance must submit periodic safety update reports (PSURs) (in principle, annually) to Swissmedic, within five years from authorisation, and in certain other situations. Additional guidance is given by Swissmedic publications and the ICH efficacy guidelines.

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

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

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

- So far unknown adverse events if product safety measures or further investigations for such measures are necessary.
- Accumulation of known or so far unknown adverse events, including serious abuse and serious intoxications.
- Quality defects if batches are affected that were put on the Swiss market.

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

9. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

Simplified procedure
The LTP and related ordinances offer simplified procedures 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 or a hospital internal radiopharmaceutical establishment for the needs of the hospital.

Complementary and herbal medicinal products.

Drugs containing certain allergens.

The procedure is mainly regulated by the:

- Ordinance on Simplified Marketing Authorisation of Complementary and Herbal Medicinal Products of 22 June 2006.
- Ordinance on Simplified Marketing Authorisation of Medicinal Products containing Allergens of 11 December 2009.

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 benefit.

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 marketing authorisation application is filed.

10. Are foreign marketing authorisations recognised in your jurisdiction?

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

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

11. What powers does the regulator have in relation to marketing authorisations?

Monitoring compliance

Swissmedic must verify that medicinal products conform to their marketing authorisation. It can, without incurring costs, take samples, request essential information and documents, and ask for any help. Swissmedic can also 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 (see Question 6, Imposing penalties). If the requirements are no longer met, Swissmedic can cancel the marketing authorisation.

Imposing penalties

If the marketing authorisation is breached, penalties can apply.

Parallel imports

12. Are parallel imports of medicinal products into your jurisdiction allowed?

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

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

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

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

As an exception to the principle of regional exhaustion, the patent owner’s consent is requested if the product price is government fixed in Switzerland and/or in the country where the product has been put into circulation.

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

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

The LTP prohibits the offer and acceptance of 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 per year per healthcare professional.

- Discounts with a direct effect on the product price, which are standard in the relevant field or discounts that are justified on business administration grounds, including the following:
  - volume discounts;
  - introducing a product to a market (during a certain period);
  - defending a product against generics.

- The exact meaning of the last two types of discount has not yet been determined in case law.

In early 2006, Swissmedic issued a publication containing detailed rules on physicians' participation in medical congresses sponsored by the industry.

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 may also apply. There is little case law in this area. In case of compliance with the LTP, the rules of the respective organisations and the principle of transparency, these provisions have hardly any impact.

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

14. What are the restrictions on marketing medicinal products on the internet, by e-mail and by mail order?

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

- The applicant must own a cantonal retailing licence.
- The applicant must give guarantees of:
  - proper advice to patients;
  - adequate medical monitoring of the effects of the drug; and
  - 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.

The advertising rules apply to advertising of drugs through the internet and e-mail (see Question 15).

ADVERTISING

15. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

The advertising of medicinal products is regulated 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 (Pharma Code), which:
  - is operated by scienceindustries (the Swiss professional association of the chemical, pharma and biotech industries);
  - applies to advertising to professionals (including doctors, dentists and chemists).

Swissmedic supervises advertising and enforces the advertising rules using governmental powers. In practice, the Secretariat of the Pharma Code supervises and enforces the advertising provisions of the Pharma Code in relation to advertising to professionals. If a company does not comply with or refuses to follow the ruling of the Pharma Code Secretariat, then the Pharma Code Secretariat will, if it considers the violation of the Pharma Code to be a possible health risk, transmit the affair to Swissmedic for evaluation and further procedures.

Restrictions

Advertising to professionals is allowed for all medicinal products registered in Switzerland. Advertising to the general public is only allowed for non-prescription drugs which are not listed on the SL (see Question 4).

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.

Ads on radio, television and in the cinema concerning some categories of OTC products must be submitted to Swissmedic in
advance for approval. Public adverts in a printed form do not generally require prior approval. However, exceptions include some adverts for analgesics, sedatives, sleeping tablets, laxatives and anorectics.

Internet advertising
Swissmedic issued a communication in 2006 about internet advertising. In its communication, Swissmedic requires access to advertising for prescription-only medicinal products to be limited to healthcare professionals through 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 Federal Supreme Court. This requirement should also be observed for advertising of reimbursable products.

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

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

The Swiss Health Quality Association (SHQA) has set up an industry supported quality control label “SHQA seal of internet confidence”. This certifies that a website complies with the LTP, relevant ordinances, the Pharma Code, the Federal Law on Data Protection and the Prerequisites of the certification mark of the Health on the Net Foundation.

PACKAGING AND LABELLING

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

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

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

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

Information requirements
Packaging intended for the patient must generally 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 marketing authorisation holder as recorded in the Commercial Registry.
- Batch number.
- Necessary medical instructions for using the product.
- The calendar expiry date (not coded), storage instructions, and if needed, the time within which the product must be used after it is opened.
- The marketing authorisation number.
- The child warning notice and invitation to read the packaging leaflet/patient information.

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

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

The marketing authorisation holder must provide product information for members of the medical profession. The relevant information for most pharmaceutical products is published in the Swiss Compendium of Medicinal Products, which is available online (at www.kompendium.ch or http://swissmedinfo.oddb.org). A recent decision of the Federal Administrative Court held that Swissmedic does not have a sufficient legal basis for obliging marketing authorisation holders to use these two directories. Therefore, Swissmedic now only recommends publication in these two directories. Swissmedic is planning to set up a directory on its own website.

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.

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

TRADITIONAL MEDICINES

17. Outline the regulation of the manufacture and marketing of alternative or complementary medicinal products.

The manufacture and marketing of these 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 under which complementary, herbal, homeopathic, anthroposophic and Asian medicinal products can be granted marketing authorisation, using the simplified procedure or 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 are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation
A patent is a registered proprietary right to an invention that is a new solution to a technological problem. Products and processes can be patented if the invention is:
- Novel (that is, not already part of the prior art).
- Not obvious to a person skilled in the art.
- Suitable for industrial application (commercially applicable, suitable for execution and reproducible).
- Not legally excluded from protection.

A patent gives its owner protection from another person commercially using his invention without permission.


Scope of protection
The Federal Patent Act was revised in 2007 to, among other things, provide rules for the patentability of biotechnological inventions, which are compatible with 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 at its various stages of development, and parts of it, in its natural environment.
- The sequence (or part) of a gene existing in nature.
- Methods of surgical or therapeutic treatment and diagnosis applied to humans or animals.
- Plant or animal varieties or essentially biological processes for the production of plants or animals.
- Inventions, the implementation of which are contrary to the dignity of humans or creatures, public order or morality (such as procedures for cloning humans).

A detailed list of exemptions is set out in Article 1a, 1b and 2 of the Federal Patent Act.

19. How is a patent obtained?

Application and guidance
A national application must be filed with the Swiss Federal Institute of Intellectual Property (SFIIP) (www.ige.ch/en.html). The application fee is CHF200 and the fee for the examination of the application by the SFIIP is CHF500. The fees for an optional

search by the SFIIP are CHF500 and CHF200 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 annually for years five and six.
- CHF200 annually for years seven and eight.
- CHF310 for year nine and onwards.

Applicants can also file a:
- Patent Cooperation Treaty application with the SFIIP if domiciled in Switzerland or a Swiss national, or with WIPO (www.wipo.int) or in some cases with the EPO.

All three websites provide application guidance.

Process and timing
The national application must be submitted on the official form. A patent application includes:
- A description of the invention.
- At least one formal patent claim.
- An abstract.
- If necessary, technical drawings. The technical documenta-


tion must be in German, French or Italian.

Once the application is submitted, the SFIIP checks whether the invention is capable of industrial 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 (at www.swissreg.ch) 18 months after filing.

About three to four years after application, the SFIIP examines whether the invention is capable of industrial 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 (at www.swissreg.ch). Appeals against decisions of the SFIIP can be made to the Federal Administrative Court.

Deposit system
Switzerland does not operate a patent deposit system. Applications are examined by the SFIIP to see whether some of the substantive conditions for patentability are met before a patent is registered (see above, Process and timing).

20. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal
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 (see below, Extending protection).
Extending protection

Similarly to the EU, a supplementary protection certificate (SPC) can be issued. The option for extending a patent specifically applies to medicinal products and is intended to take into account the period between patent registration and granting of marketing authorisation, during which clinical trials must be carried out.

An application for an SPC 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 SPC is CHF2,500. The annual fee is CHF310.

21. How can a patent be revoked?

Third parties have nine months from publication of the patent registration to oppose the patent registration with the SFIIP, on the grounds that its subject-matter is excluded from the scope of protection (see Question 18). Further grounds of opposition are available in relation to European patents, such as:

- Lack of novelty, inventive step or industrial application.
- The patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- The subject-matter of the patent extends beyond the content of the application as filed.

Third parties can also submit a nullity claim to the Federal Patent Court, after registration, on the grounds that:

- The subject-matter of the patent is not patentable.
- The invention is not disclosed in the patent specification in such a way that a person skilled in the art could perform it.
- The subject-matter of the patent extends beyond the content of the application as filed.
- The registered owner is not the inventor or his legal successor and has not acquired the right to the patent under another title.

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

Conditions for infringement

The patent holder can take legal action under civil law or criminal 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 the above acts.

Claim and remedies

On 1 January 2012 the Federal Patent Court became active. This court replaced the 26 cantonal jurisdictions in patent matters. Its sentences can be appealed to the Federal Supreme Court.

Remedies for a patent infringement include:

- Injunctions (preliminary or final).
- Declaratory judgment.
- Assignment of the patent.
- Order to disclose the origin and quantity of the objects in the defendant’s possession and to disclose the addressees and the extent of any transfer to commercial recipients.
- Rendering of accounts.
- Damages, redress or surrender of profits.
- Publication of the judgment.
- Destruction of infringing goods and their removal from the market.
- Criminal sanctions.
- Assistance from the customs authorities.

23. Are there non-patent barriers to competition to protect medicinal products?

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

Data exclusivity is granted for three years for data filed in support of an authorisation for a new:

- Indication for an original preparation.
- Way of administering an original preparation.
- Galenic form of an original preparation.
- Dosage of an original preparation.

If the new indication, way of administration, galenic form or dosage leads to a significant therapeutic improvement, the marketing authorisation holder can apply for five years of protection.

TRADE MARKS

24. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

A trade mark must be a graphically reproducible sign which is distinctive, that is, capable of distinguishing a person or enterprise’s goods or services from those of another, provided no absolute grounds for refusal are given.
Trade mark rights are enforceable from their date of application or their seniority date, provided they will be registered. Trade marks used abroad, and which are well-known in Switzerland within the meaning of Article 6 bis of the Paris Convention ("notorious marks"), enjoy the same protection as a registered mark.


Scope of protection
Medicinal brands can generally be registered and are examined independently by the SFIIP (trade mark registration) and by Swissmedic (market authorisation).

However, registration can be refused if the mark:
- lacks distinctiveness (for example, international non-proprietary names).
- is misleading.
- is contrary to public order, morality or applicable law.

Registration can also be refused if the shape constitutes the nature of the goods, or the shape of the goods or of their packaging is technically necessary.

25. How is a trade mark registered?

Application and guidance
The SFIIP registers trade marks (www.ige.ch/en.html). Guidance is available on its website.

The application fee for a national application is CHF550 and covers up to three product/service classes. There is a supplementary fee of CHF100 for each additional class.

International trade mark registrations are also protected in Switzerland if they have a Swiss designation (see Question 30, Trade marks).

Process and timing
An 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. The application is examined generally within either:
- three to six months after 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 of CHF400. If trade mark registration is refused, it is possible to file an opposition 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 period.

26. How long does trade mark protection typically last?

Duration and renewal
The registration is valid for ten years from the date of application.

The registration of a trade mark can be renewed indefinitely for further ten-year periods. The renewal fee for a national trade mark is CHF550.

Extending protection
There are no other ways to extend a registered trade mark.

27. How can a trade mark be revoked?

If the trade mark is not being used for a continual period of five years without important reasons, it becomes vulnerable to cancellation. Third parties can file a cancellation action for non-use with the competent court.

Third parties can also file a nullity court action if they believe that the mark should not have been registered due to absolute grounds of refusal, or because it has become generic.

A collective trade mark or guarantee mark is cancelled if either:
- the regulations do not satisfy or no longer satisfy the legal requirements, and the owner does not remedy this within the deadline set by the court.
- the owner tolerates repeated use that infringes essential provisions of the regulations and does not remedy this within the deadline set by the court.

Finally, the Swiss designation of an international registration is revoked following a successful central attack on the foreign basic registration.

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

Conditions
A trade mark is infringed if both:
- the earlier (senior) trade mark is identical or confusingly similar to the later (junior) sign (mark, company name or domain name).
- the senior trade mark claims protection for goods and/or services which are identical or of the same kind as the goods and/or service for which the junior sign is registered or used in the course of trade.

Other grounds of infringement include using a guarantee or collective mark in a manner contrary to the applicable regulations.

Claim and remedies
The owner of the senior trade mark can file an opposition with the SFIIP against the registration of the junior trade mark, within three months of the date on which the junior trade mark is published.
Opposition proceedings are inexpensive and quick. The SFIIIP’s decision can be appealed to the Federal Administrative Court.

As long as there is no forfeiture of claim, a civil or criminal action can be filed in court against a trade mark infringer.

Remedies for trade mark infringement include:
- Injunctions (preliminary or final).
- Declaratory judgment.
- Assignment of the trade mark.
- Order to disclose the origin and quantity of the objects in the defendant’s possession and to disclose the addressees and the extent of any transfer to commercial recipients.
- Rendering of accounts.
- Damages, redress or surrender of profits.
- Publication of the judgment.
- Destruction of infringing goods and their removal from the market.
- Criminal sanctions.
- Assistance from the customs authorities.

Patent and trade mark licensing

29. Does a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body?

There is generally no such requirement.

Patent and trade mark conventions

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

Patents
Switzerland is party to the following conventions on patents:
- TRIPS.
- PCT.
- Switzerland-Liechtenstein Patent Cooperation Treaty of 1978, which states that every patent granted in Switzerland is also effective in Liechtenstein.

Trade marks
Switzerland is party to the following conventions on trade marks:
- Paris Convention.
- TRIPS.
- 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 (Madrid Protocol).
- Nice Agreement concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.

PRODUCT LIABILITY

31. Outline the scope of medicinal product liability law.

Legal provisions
There are no special rules relating to liability for pharmaceutical products. Under the Federal Act on Product Liability 1993 (Product Liability Act), which is based on Directive 85/374/EEC on liability for defective products, a producer is liable if a defective product leads to the death or injury of a person, or damage to, or destruction of, property for private use. In addition, standard rules of contract, tort and criminal law (concerning death and physical injury) can apply if a product is defective.

Substantive test
A product is deemed to be defective if, at the time it is marketed, it does not offer the safety that can justifiably be expected of it, taking into account all circumstances. Special consideration must be given to the:
- Ratio between benefit and risk.
- Method and manner used to present the product to the general public.
- 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 (in whole or in part) of the defective product.
- Any person who applies its name or trade mark to the product.
32. How can a product liability claim be brought?

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

**Class actions**
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.

**Foreign claimants**
A claimant does not need to be a resident of, or have used the product in, Switzerland to be able to bring a claim against a Swiss producer. Claims against a Swiss producer can be brought where it is domiciled.

Swiss courts can also have jurisdiction if the damage occurred in Switzerland.

Furthermore, claims are governed at the option of the injured party by:
- The law of the state in which the person committing the tort has his place of business or, in the absence of a place of business, his place of habitual residence.
- The law of the state in which the product was purchased, unless the person committing the tort proves that the product was marketed in that state without his consent.

If a claim heard in a Swiss court is governed by foreign product liability law, no awards can be made that exceed those which would have been awarded for the same damage under Swiss law.

33. What defences are available to product liability claims?

The producer is not liable for a defective product under the Product Liability Act if it proves any of the following:
- It did not market the product.
- The product was not defective when it was put into circulation.
- It did not manufacture the product for a business purpose or within the framework of its professional activity.
- The defect is attributable to compliance with binding, official regulations.
- The error was not identifiable on the basis of scientific and technological knowledge at the time the product was put into circulation (development risk).

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

The remedies under the FAPL are compensation for personal damages and for damages to goods for private use. Punitive damages are not awarded in Switzerland.

**REFORM**

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

A reform of the LTP (see Question 1) is being prepared by the Federal Council covering several areas of the law. It aims to facilitate the marketing authorisation process, to improve safety and transparency of product information and clarify certain disputed provisions. The reform is scheduled to be submitted to parliament in 2012.

A new federal law on research involving humans was adopted by parliament on 30 September 2011 and is scheduled to enter into force in summer 2013. It will introduce federal regulation of all research involving humans (including research with medicinal products).

On 30 September 2011 parliament decided to change the Federal Health Insurance Act in relation to managed care insurance models and the amounts of patient co-payment. However, it is not yet clear if these amendments will come into effect because the revision will be put to a referendum.
The protection of the Switzerland indication of source and the Swiss national cross will be strengthened. The draft revision of the Trade Mark Act contains more precise regulations relating to the geographical source of a product or service. It defines the criteria for natural products, processed natural products, industrial goods and services to be labelled as Swiss. The draft revision of the Federal Act on the Protection of Coats of Arms and Other Public Insignia allows, for the first time, the Swiss cross to be used on Swiss products. The Swiss cross is currently only permitted for Swiss services. The Swiss Coat of Arms will remain principally reserved for the state. The draft revisions have not yet been debated in Parliament and it is still unclear when the revisions will enter into force.

FRANK SCHERRER
Wenger & Vieli AG
+41 58 958 58 58
+41 58 958 59 59
f.scherrer@wengervieli.ch
www.wengervieli.ch

Qualified. Switzerland, 1996
Areas of practice. Pharmaceutical and health law; contract law; unfair competition and cartel law; advertising law; product liability law.
Recent transactions
- Advising and representing pharmaceutical companies on a regular basis regarding marketing authorisation and reimbursement, contracts, advertising, sponsoring and gifts, and clinical trials and data protection.
- Represented a pharmaceutical company in 2011 in one of the rare successful appeals to the Swiss Federal Court in the area of drug reimbursement.
- Advising and representing pharmaceutical companies in disputes concerning contracts, product liability and unfair competition.
- Advising pharmaceutical companies concerning outsourcing.
- Advising a pharmaceutical company concerning post-merger integration.
- Advising pharmaceutical companies on the Act on the Principle of Government Publicity.

GABRIELA TAUGWALDER
Wenger & Vieli AG
+41 58 958 58 58
+41 58 958 59 59
g.taugwalder@wengervieli.ch
www.wengervieli.ch

Qualified. Switzerland, 1993
Areas of practice. Pharmaceutical and health law; intellectual property law; the law governing names; unfair competition law; advertising law (with a focus on pharmaceuticals, medical devices, cosmetics and food).
Recent transactions
- Effecting the legal review for the advertising and PR material of a multinational pharmaceutical company concerning Switzerland.
- Advising pharmaceutical clients concerning:
  - advertising, sponsoring and gifts;
  - their IP strategy and filing, and prosecuting their trade marks;
  - agreements including licensing agreements, service agreements and clinical research agreements;
  - data protection.
- Advising and representing pharmaceutical clients in:
  - disputes regarding unfair competition, trade marks, copyright and advertising;
  - name and domain name disputes.