Life Sciences Commercialisation in Switzerland: Overview

by Frank Scherrer, Marcel Boller, Claudia Keller, Dominique Roos, and Ines Holderegger, *Wenger & Vieli AG*

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

This Q&A provides a high-level overview of key practical issues, including the life sciences sector, pricing and state funding, distribution and sale, importing, advertising, patents, trade marks, competition law, and product liability.

Life Sciences Sector Overview

1. Give a brief overview of the life sciences sector in your jurisdiction.

The Swiss health care market is composed of a variety of companies in terms of size, organisation, development stage and activities. Activities include research and development (R&D), clinical trials, manufacturing, marketing, counselling, and trading in the fields of medicinal products and medical devices. In addition to the two multinational companies Novartis and Roche, which both have their headquarters in Basel, a large number of other companies, including small and medium#sized companies (SMEs), are based in different parts of Switzerland in both the medicines and the medical devices sectors. Switzerland also hosts the regional headquarters of various international groups.

M&A in Switzerland continues to benefit from its diversity of health care companies, composed of, among others:

- Young R&D-focused start-ups, which generally emerge near to the Swiss Federal Institutes of Technology in Lausanne or Zurich.
- Well-established revenue-generating SMEs located all over Switzerland that develop and manufacture drug products or medical devices.
- Subsidiaries of international groups.

In 2022, the Australian CSL group acquired the Swiss group Vifor Pharma for USD11.7 billion.

2. Give a brief overview of key life sciences funding issues in your jurisdiction.

In the Swiss investment landscape, there is usually a good understanding of the generally high risk with regard to health care start-ups. Early-stage companies are often granted financing by family offices and high-net-worth individuals. Some Swiss and foreign-based venture capital funds also invest in Swiss early-stage companies (that is, grant seed financings).

These venture capital funds typically become more active after the initial rounds of financing. Larger-size rounds (financings exceeding CHF10 million) see activity from many foreign-based as well as Swiss-based venture capital funds.

Both the regulatory framework and intellectual property law (including the rules on the transfer or licensing of patent rights, transferring marketing authorisations, or implementing co#marketing or co#promotion arrangements) leave the parties considerable flexibility to structure any transaction or collaboration according to their needs.

Pricing, Government Funding, and Reimbursement

National Health Care System

3. What is the structure of the national health care system, and how is it funded? Briefly explain how pharmaceuticals are introduced into that system.

Structure and Funding

The health care system reflects the federal structure of Switzerland. Only certain areas are controlled by the confederation, and the other areas are controlled 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 and important areas of the health care system are now legislated for and controlled by the confederation, including:

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

- Genetic testing.
- Transplantation.

Under the social health insurance legislation, individuals must be insured with a sick fund of their 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 health care provider(s). The basic insurance provides for an extensive catalogue of reimbursed treatments, medicinal products and medical devices.

Funding

The health care system is mainly financed by:

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

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

Interaction of the Life Sciences Industry with the Health Care System

There are many types of interactions between the life sciences industry and the national health care system, for example:

- The pharmaceutical and medical device industries sell their products to the health care service providers either directly or through wholesalers.
- The life sciences industry mandates or finances various research projects performed by health care institutions.
- The life sciences industry supports many educational events and projects in the health care sector.

Price Regulation and Reimbursement

4. How are the prices of medicinal products regulated? When is the cost of a medicinal product funded by the government or reimbursed? How is a pharmacist compensated for dispensing services?

Price Regulation

Non-reimbursable products. There is no price regulation of non-reimbursable products. Swissmedic does not evaluate prices when granting marketing authorisation. However, in case of price abuses by a market dominant company or illegal agreements on prices, the Competition Commission (ComCo) or the price surveillance authority can in principle intervene (see *Question 31*).

Reimbursable products. For reimbursable products, the Federal Health Insurance legislation sets out regulations for determining the maximum price that health care providers (pharmacies, drugstores, hospitals, and 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 *Federal Office of Public Health* (FOPH). In case of in-patient hospital treatment, reimbursement of medicinal products, except for certain more expensive medicinal products, is included in the flat-rate treatment fees for diagnosis related groups (DRGs) paid by the insurance companies.

For certain more expensive medicinal products, additional fees (*Zusatzentgelte*) are agreed.

Reimbursement

Depending on the applicable insurance system, the costs of ambulatory treatment, including medicinal products, are paid for by patients' sick funds either directly or by reimbursing patients after they have paid the costs upfront. The costs of in-patient treatment are paid in part (at least 55%) by the canton of residence of the insured person and in part (a maximum of 45%) by the sick fund. The costs are invoiced directly to the canton and the sick fund. The sick funds are not part of the state administration but perform governmental tasks and are supervised by the state administration.

Under the basic health insurance regime, medicinal products dispensed in ambulatory treatment are reimbursed if they are prescribed by a physician (or under certain circumstances, by a chiropractor) and listed in one of the lists drawn up for this purpose, particularly the SL. Optional additional private insurances also cover most authorised medicinal products that are not listed on the SL. The costs of medicinal products dispensed in in-patient hospital treatment are covered through the payments for DRGs paid by the sick funds and the contributions of the cantons. For certain expensive medicinal products, additional fees can be charged by hospitals within DRGs.

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

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

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

- Prices of other drugs for the treatment of the main indication of the product.

These two criteria are weighted at 50% each.

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

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

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

Currently, the ex-factory price of a generic product listed on the SL must be at least:

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

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

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

Any price increase of a reimbursed product must be approved by the FOPH. An application for a price increase can be submitted at the earliest two years after the listing of the product on the SL or after the last increase. Price increases have been in principle excluded since 2021, unless there are no alternative products and supply for Switzerland must be assured.

FOPH decisions relating to listing on 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 health care providers can charge for certain medicinal products. The SL price takes into account a distribution margin, which is different for prescription and non-prescription products.

Pharmacist Reimbursement

For prescription medicines, pharmacists can charge for certain services in addition to the SL price (including control of the prescription, information and instructions, and the keeping of a patient file). The reimbursement of these services is based on a contract between the Swiss pharmacists' association and the insurance companies, which must be approved by the Swiss government.

Distribution and Sale

5. Who is authorised to prescribe and supply medicines to patients or consumers? Who is authorised to distribute prescription medicines and over-the-counter medicines?

The sale of medicinal products to patients requires a licence. Some categories of products can only be sold by pharmacists (and, depending on the cantonal law, doctors and possibly other professionals). Other categories can also be sold by chemists. Previously, pharmacists were only allowed to dispense prescription medicines on medical prescription. As of 2019, pharmacists can also dispense medicinal products without prescription if:

- They have direct contact with the person concerned.
- They document the dispensed product.
- And either:
    - the medicinal product and indication has been designated by the Federal Council;
    - the case is justified and exceptional.

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

- The applicant must have a cantonal retailing licence.
- The applicant must operate a quality assurance system ensuring, among other things, that the:
    - patient is identified;
    - adverse interactions with other medicinal products are checked; and

    - proper advice is given to patients.

- The patient must supply a doctor's prescription with any order, whether it is a prescription or non-prescription drug.

6. How is the wholesale distribution of medicines regulated?

In Swiss law, "wholesale" means all activities relating to the paid or unpaid transfer or provision of medicinal products (including acquisition, stocking, storage, offering, advertising, supply and so on) of medicinal products to persons authorised to trade, process, dispense them or use them in a professional capacity.

Wholesale trade in medicinal products requires a licence issued by Swissmedic. The licence is subject to fulfilment of technical and operational conditions and an appropriate system of quality assurance. The licence can also be issued if the applicant already possesses a manufacturing or import licence for medicinal products. Any person engaged in the wholesale trade of medicinal products must respect the recognised principles of Good Distribution Practice (GDP), including the following requirements:

- A system to ensure the pharmaceutical quality of medicinal products is in operation, and the company management and staff in the individual departments concerned take an active part in the system.
- Each department has a sufficient number of qualified and competent staff members to enable it to achieve its quality targets.
- The tasks of all persons occupying key positions in the company are set out in job descriptions and their hierarchical positions are set out in organisational charts.
- A responsible person is available.
- The facilities are organised in an appropriate way.
- The facilities are designed, structured, maintained and modernised regularly to guarantee the safe wholesale trade of medicinal products.
- A documentation system is available that comprises the working instructions, process descriptions and protocols of the relevant wholesale procedures.
- The requirements and obligations of Articles 15 (Responsibility and Good Distribution Practice) and 16 (Documentation Obligations) of the Medicinal Products Licensing Ordinance are fulfilled.

The activities covered by the licence are described in the licence. The holder of a wholesale licence will be, among other things, authorised to sell, store and advertise medicinal products to persons authorised to trade, process, dispense them or use them in a professional capacity. A wholesale licence may, but does not always, include the market release. A separate licence is required for import, export and trade abroad.

7. Which regulatory authority supervises the distribution of medicines? What are the consequences of non-compliance with the medicine distribution laws?

Wholesale distribution is supervised by Swissmedic. Retail distribution is supervised by the cantons. Non-compliance with federal distribution laws can lead to administrative measures or criminal sanctions under Article 86*ff* of the Law on Therapeutic Products (LTP). Swissmedic can take all administrative measures necessary to enforce the provisions of the LTP, and can, among other things, suspend or revoke licences.

Supervision is performed mainly through regular inspections to check whether all the conditions for the approval requirements are met. As a rule, adverse findings must be corrected within a certain period of time. Articles 56 to 62 of the Medicinal Products Licensing Ordinance establish uniform regulations for inspections, which apply to both Swissmedic and the cantons.

Cross-Border Trade and Parallel Imports

8. What are the main requirements to import medicinal products into your jurisdiction? Are parallel imports of medicinal products into your jurisdiction allowed?

Import Requirements

Under the Law on Therapeutic Products (LTP), a licence granted by Swissmedic is required for any person who, in a professional capacity, imports ready#to#use medicines intended for distribution or dispensing in Switzerland.

Any person applying for a licence to import medicinal products must prove that:

- A system to ensure the pharmaceutical quality of medicinal products is in operation and that the company management and staff in the individual departments concerned take an active part in the system.
- Each department has a sufficient number of qualified and competent staff members to enable it to achieve its quality targets.
- The tasks of all persons occupying key positions in the company are set out in job descriptions and their hierarchical positions are set out in organisational charts.
- A responsible person is available.
- The facilities are organised in an appropriate way.

- The facilities are designed, structured, maintained and modernised regularly to guarantee the safe import of medicinal products.
- A documentation system is available that comprises the working instructions, process descriptions and protocols of the relevant import procedures.
- Processes are compliant with the GDP rules and traceability of the medicinal products is ensured.
- The manufacturer of the medicinal products to be imported has a manufacturing licence issued by a country whose GMP control system is considered by Swissmedic to be equivalent, or which states that the medicinal products are manufactured in compliance with the GMP rules valid in Switzerland.

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 where the following conditions are met:

- The product originates from a country with an authorisation system equivalent to that of Switzerland.
- The product satisfies the same requirements as products already approved in Switzerland, in particular in relation to labelling and product information.
- The parallel importer meets 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 in principle adopted the regional exhaustion of patent rights system. Patent rights are exhausted in relation to the parallel imports if the products have been put on the market by the patent owner, or with their consent, in Switzerland or the EEA.

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

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

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

Advertising

9. What is the main legislation and what are the regulatory authorities that control pharmaceutical advertising? Does the industry have a system of self-regulation based on industry codes of conduct? What are the main elements of that system?

The advertising of medicinal products is regulated by the:

- Law on Therapeutic Products.
- Ordinance on Advertising for Medicinal Products.
- 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) and applies to advertising to professionals (including doctors, dentists and chemists).

Advertising to the general public is only allowed for non-prescription drugs that are not listed on the SL. Medicinal products that are prescription-only or that are listed on the SL cannot be advertised to the public.

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

10. Is there a definition of advertising or advertisement in relation to pharmaceuticals? What kinds of activities, channels and communications meet those definitions (and are therefore subject to restrictions), and what falls outside (and is therefore permitted)?

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

There is no restriction on certain communication channels. In principle, all communication that meets these requirements is regarded as advertising (including printed and online articles, leaflets, flyers and so on).

The following does not constitute advertising and is therefore not covered by the scope of the Ordinance on Advertising for Medicinal Products:

- The packaging material and the product information.
- Sales catalogues and price lists, provided that they do not contain medical information about medicinal products.
- Information of a general nature about health or diseases, provided that it does not refer directly or indirectly to specific medicinal products.

11. Do companies have to set up internal procedures for managing and approving their advertising of pharmaceuticals?

A marketing authorisation holder must:

- Designate a person who is responsible for the advertising of the medicinal products that it places on the market. This person must have scientific, medical or other appropriate professional training or experience.
- Set up internal procedures for managing and approving the advertising.

The Pharma Code requires subscribers to set up a scientific service, including a doctor, or if suitable, a pharmacist or scientist, to be responsible for ensuring the conformity with the Pharma Code of all its promotional and information materials before these are deployed.

12. Does pharmaceutical advertising have to be approved by a regulator?

Pharmaceutical advertising to the general public for analgesics, sleeping pills, sedatives, laxatives or anorectics (in printed or in electronic media, in books, circular letters, on posters, or in software applications) must be submitted to Swissmedic for approval before publication if the medicinal product information states a potential for abuse or dependence.

Swissmedic may oblige a marketing authorisation holder that seriously or repeatedly infringes the provisions on the advertising of medicinal products to submit for a reasonable period of time all drafts of its planned advertising to Swissmedic, in the form designated by Swissmedic, for review and approval before publication.

13. Are there rules on comparative advertising that apply to pharmaceutical advertising?

Comparative advertisements are permitted if the statements are scientifically correct and are based on equivalent clinical trials or data collection that meet the requirements of Article 5(5) of the Ordinance on Advertising for Medicinal Products, which states that:

- Advertising claims must be based on and reflect the current state of scientific knowledge.
- Advertising claims can only refer to:
    - clinical trials that have been conducted and published or accepted for publication in accordance with the rules of Good Clinical Practice; and
    - data collections such as meta-analyses or practical experience reports that have been published in a scientifically recognised professional medium.
- If studies are used for comparison that are based on experiments in vitro or on animals (in the case of human medicinal products) or are not based on experiments on the target animal (in the case of veterinary medicinal products), this must be openly stated.

It is permissible to use the brand name of another company's product as part of a comparative advertisement. However, it may be misleading to refer in a comparative advertisement to a competitor's product or indication that has not (yet) been authorised.

14. Is it possible to share information about pharmaceuticals or indications that are unlicensed and is there a risk that this could be caught by advertising rules?

The advertising of unlicensed medicinal products or indications is unlawful. However, the provision of information of a general nature about health or diseases is permissible, provided it does not relate directly or indirectly to specific medicinal products. Information about new indications is therefore permissible as long as it does not relate to specific medicinal products. However, the distinction between information and advertising is not always simple in the individual case.

The regulation of the Pharma Code is somewhat more generous. The Pharma Code allows informational materials given out in response to a request at events for medicinal persons with international participation to refer to medicinal products that are not authorised in Switzerland but in other countries, or that are authorised in Switzerland under different conditions. Such information materials must be accompanied by both:

- Reference to the countries where the medicinal product is authorised, and to the fact that the medicinal product is not authorised in Switzerland or is subject to different conditions in Switzerland.
- Reference to the possible differences in registration requirements and the government-approved professional information (indications, warnings and so on) in the country or countries where the medicinal product is authorised.

In addition, pharmaceutical companies can provide factual information at satellite symposia or similar events on new medicinal products or indications, dosages, dosage forms or packaging that have not (yet) been authorised in Switzerland. It must be

pointed out at the beginning of the presentation and in an appropriate manner that Swissmedic has not yet authorised the medicinal product or the new indication, possible use, dosage, dosage form or packaging.

Where pharmaceutical companies share information with investors and financial analysts, the information content must:

- Be strictly limited to scientific, technical, organisational or financial aspects of the company's activities that are of interest to potential investors (for example, annual reports of the company, or presentation of the research activities of the company).
- Not be aimed at promoting a medicinal product.
- Only mention the name of the preparation and active ingredient and the therapeutic area or field of application in the context of a presentation of new medicinal products or medicinal products under development, active ingredients or preparations under development, as well as the future prospects and focal points in the research and development activities of the company.

It is also permissible for pharmaceutical companies to issue press releases to journalists mentioning unauthorised medicines or indications. Using the brand name in such press releases is allowed. However, the International Non-proprietary Name (INN) of the compound must be used as well. Such press releases can only be given to journalists. On the internet, such press releases must therefore be password-protected. Press releases for non-specialist media must not constitute advertising.

15. Are there particular rules or issues with the use of the internet and social media for advertising pharmaceuticals?

The only particular rule on using the internet for advertising prescription-only medicinal products is that advertising for prescription-only medicinal products on the internet (on a domain ending in .ch or addressed to the Swiss market) must be password-protected and only accessible to health care professionals. Apart from this, the general rules on advertising apply.

Swissmedic has issued various guidelines on the advertising of medicinal products on the internet. The placement of a link to a third-party website is acceptable. However, such a link cannot be used to circumvent the advertising provisions. In principle, the provider of a website bears sole responsibility for the content of its website. However, the context in which a link has been set, as well as the technical method used, can sometimes establish responsibility of the provider of a website for the content on the linked website.

For example, in the case of "framing", internet users are led to different (including third-party) websites without leaving the originally selected website. This enables the author of a website to incorporate the content of external websites into their own website. Swissmedic recommends that a warning notice should appear if the website is left by clicking on a link. The warning notice should clearly express that by clicking on the link to the website of a foreign third party the user leaves the website and that conformity with the requirements of Swiss legislation cannot be guaranteed.

There are no specific legal provisions on the use of social media by pharmaceutical companies. However, Swissmedic and the industry association scienceindustries have issued recommendations concerning social media. According to these recommendations, the use of social media channels is permissible in principle, but special attention must be paid to the prohibition on advertising prescription-only medicines to the public. In addition, where employees use personal accounts on

social media platforms such as Facebook, LinkedIn, Instagram, or YouTube, the use of "Share", "Like" or "Comment" functions may be considered to be advertising by Swissmedic.

16. What are the consequences of non-compliance with the rules on advertising pharmaceuticals? How are the rules enforced and by which authorities or organisations?

The competent authority for the surveillance of advertising for medicinal products is Swissmedic. In an administrative proceeding, which can be triggered by the market surveillance department of Swissmedic or a complaint of a competitor, the market surveillance department of Swissmedic will assess the information or promotion and, if it is unlawful, will order appropriate measures. Usually, this is a prohibition on the use of the advertising. Swissmedic may also order a recall of the advertising material or a correction letter.

If Swissmedic opens an administrative criminal investigation and concludes that the advertising regulations have been violated, it can impose a fine or monetary penalty on the natural person(s) responsible. Theoretically, a fine up to CHF50,000 can be imposed on any person who wilfully contravenes the regulations on advertising medicinal products. If the person concerned acts professionally, they are liable to a monetary penalty of up to 180 daily penalty units (Article 87(2), LTP). Daily penalty units are determined based on the personal and economic circumstances of the offender at the time of the judgment, according to income and wealth, living expenses, any family and support obligations. Daily penalty units can reach CHF3,000 as a maximum. Swissmedic only conducts a limited number of criminal administrative proceedings. Penalties are most often in the range of CHF400 to CHF5,000, but can be higher in serious cases.

In principle, anyone can report an advertising violation to Swissmedic. The notifier is not informed about further proceedings if they take place.

In the area of self-regulation, the Pharma Code Secretariat must ensure the objective and impartial supervision of pharmaceutical companies' activities and duties under the Pharma Code. Anyone can notify the Code Secretariat of circumstances that are suspected to be in breach of the Pharma Code. If the Code Secretariat considers a breach to be patent and serious, it will issue a written summons to the pharmaceutical company to discontinue and permanently desist from the conduct, and will set a short deadline for remedial measures to be undertaken and for receipt of written confirmation that this has been done. However, the Code Secretariat has no sanctioning powers. If a pharmaceutical company does not follow the Code Secretariat's summons, it can refer the case to Swissmedic.

Advertising to the Public

17. Which pharmaceuticals can and cannot be advertised to the public? What information must and must not be included in advertising of pharmaceuticals to the public?

Advertising to the general public is only allowed for non-prescription drugs that are not listed on the SL. Medicinal products that are prescription-only or that are listed on the SL cannot be advertised to the public.

Advertising to the general public must not:

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

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

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

18. Is it permitted to provide free samples to the public? Are there restrictions on special offers and other types of inducements?

The distribution of sample packages to the public as a means of advertising medicinal products is allowed under the following conditions:

- Samples for the public can only be distributed free of charge.
- Samples must be clearly visible and permanently marked as "free samples", and must comply with Swissmedic's requirements for information and texts on containers and packaging material.
- Samples of medicinal products for human use cannot contain more than one recommended daily dose.
- Samples of medicinal products of dispensing categories C and D can only be dispensed to the public by the corresponding dispensing points. They cannot be offered for self-service.

The distribution of vouchers for free samples is not permitted. However, it is permissible to refer to the availability of free samples within a pharmaceutical advertisement (for example: "Ask for a free sample at your pharmacy or drugstore").

Engagement with Patient Organisations

19. What activities are permitted (or required) in relation to engagement with patient organisations? What restrictions apply?

Co-operation with patient organisations is regulated in the Pharma Code and the Pharma Co-operation Code. These contain rules:

- Safeguarding the independence of patient organisations.
- Prohibiting the promotion of certain specific prescription-only medicinal products.
- Requiring a written agreement on aims, scope and type of support and partnership.
- Prohibiting requiring patient organisations being the sole pharmaceutical company providing financial or other support for them.
- On consultancy or service contracts with patient organisations.
- On events and hospitality in dealing with patient organisations.
- On the use of logos and documents of patient organisations.

In addition, scienceindustries has issued a recommendation in regard to the support by pharmaceutical companies for patient organisations.

Advertising to Health Care Professionals and Organisations

20. What are the definitions of a health care professional and a health care organisation? What information must be included in advertising to them?

The following are considered to be health care professionals and are therefore permissible addressees of professional advertising within their entitlement to prescribe, dispense or use medicinal products:

- Physicians, dentists, veterinarians and chiropractors.
- Pharmacists.
- Chemists.
- Other persons according to Articles 24 and 25 of the Law on Therapeutic Products (such as duly trained professionals under the supervision of a person that is entitled to dispense the prescription-only or non-prescription medicinal product).

- Persons entitled by the cantons to use medicinal products in their professional capacity under Article 52(2) of the Ordinance on Medicinal Products (such as paramedics with a federally recognised training).

Advertising to health care professionals that goes beyond the mention of the brand name and the indication must contain the following minimum content:

- Name of the preparation.
- Active ingredients with the abbreviated designation (INN or designation of the latest edition of the Pharmacopoeia, or, in their absence, other generally recognised abbreviated designations approved by Swissmedic).
- Name and address of the marketing authorisation holder.
- At least one indication or possible use, as well as the dosage and the method of use.
- Summary of the limitations of use, adverse effects, and interactions.
- Dispensing category.
- Indication that detailed further information can be obtained from the published product information.
- For veterinary medicinal products for food-producing animals, the withdrawal periods.
- Indication that the health care professionals can request from the company a complete copy of the study report and the relevant references.

Only the distinction between health care professionals and laypersons is relevant. Health care organisations are not considered to be a separate category of addressees of advertising.

Gifts and Incentives

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

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

- Gifts of a modest value that are relevant for the professional activity of the recipient (for example, prescription pads or another article for daily professional use). Gifts are considered to be of a modest value if their total value is not more than CHF300 per year per health care professional. The industry codes, which are based on the European Federation of Pharmaceutical Industries and Associations (EFPIA) codes, are more restrictive and prohibit any gifts to health care professionals other than:

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

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

These rules are further detailed by the Ordinance on Integrity and Transparency, which also came into effect on 1 January 2020.

These rules will be extended to certain medical devices determined by the Federal Council no earlier than in 2025.

Under the Health Insurance Act, if a health care service provider receives a discount on reimbursable therapeutic products, it must pass the reduction on to the patient or insurer that pays for the product. Under the revised law, it is possible to pass on only a part of the granted rebates if there is an agreement between the health care service provider and the health insurance company that allows the rebates to be retained for improving the quality of treatment. The LTP contains penalties for breaches of the ban on granting prohibited discounts, and the Federal Health Insurance Act contains penalties for not passing on discounts.

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

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

Transparency and Disclosure

22. Do pharmaceutical companies have to disclose details of transfers of value to health care professionals or health care organisations?

There is a distinction between the statutory provisions and the self-regulation rules about transparency and disclosure. Under the statutory provisions, all discounts and rebates granted on purchases of medicinal products must be:

- Shown on the receipts and invoices and in the accounts of both the selling and the purchasing persons and organisations.
- Disclosed to the FOPH on request.

These obligations apply to all discounts and rebates granted on the purchase of medicines to persons or organisations that prescribe, dispense, use or purchase medicines for this purpose.

Signatories to the Pharma Co-operation Code have additional transparency and disclosure obligations, and must disclose all pecuniary benefits they grant to health care professionals or health care organisations who have their primary practice or definitive business address or their registered office in Switzerland.

No distinction is made between public and private providers. The Pharma Co-operation Code contains rules on the exceptions to the disclosure requirement and specifications on the form, content, and timing of disclosure. Pharmaceutical companies must make the required disclosures on their corporate websites, which must be nationally and internationally accessible to the public.

23. What are the consequences of non-compliance with the rules on marketing to health care professionals?

The FOPH is the competent authority for the surveillance of monetary benefits to health care professionals.

The FOPH can take administrative measures (Article 66, LTP), such as ordering a stop to certain behaviour.

Anyone who intentionally violates the obligations regarding undue benefits can be punished with imprisonment of up to three years or a monetary penalty (Article 86(1)(h), LTP).

If the person concerned acted negligently, or in less severe cases, they can be punished with a monetary fine (Article 86(4), LTP).

In principle, such proceedings are conducted against a natural person. If a fine of up to CHF20,000 is envisaged and the investigation of the persons punishable would require investigative measures that would be disproportionate in view of the penalty imposed, the relevant natural persons may be exempted from prosecution and the pharmaceutical company may be fined in their place (*Article 7, Federal Act on Administrative Criminal Law, VStrR; Article 89, LTP*). Anyone who violates the transparency obligations regarding rebates and repayments when trading in medicinal products is subject to a fine of up to CHF50,000 (Article 87(1)(h), LTP).

In case of undue benefits, the Code Secretariat can order a company to stop a certain behaviour. If the pharmaceutical company does not follow the Code Secretariat's order, it can forward the case to the FOPH. The Code Secretariat has no sanctioning authority of its own.

Patents

Conditions for Patentability

24. Provide a brief definition of a patent, the key legal requirements to obtain it and the law that applies.

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.

Swiss patent law is codified in the Federal Patent Act and the related ordinances. The Patent Cooperation Treaty 1970 (PCT), the European Patent Convention 1973 (EPC) and related ordinances also apply to international or European patent applications.

There is an ongoing governmental project to modernise the Swiss Patent Act. Under the current law, the Swiss Federal Institute of Intellectual Property examines Swiss patent applications with respect to the application's completeness and clarity as well as the invention's technical nature and unity. There are plans to introduce the possibility for applicants to request a full examination, that is, an examination also covering the novelty and inventive step requirements. In addition, English is planned to be accepted as a language for the application proceedings, with the intention of making a Swiss patent more attractive for international applicants. The intention is also to appoint the Federal Patent Court as a new appeals authority against decisions of the Federal Institute of Intellectual Property. Currently, appeals are heard by the Federal Administrative Court.

Types of Patent Available

The Federal Patent Act allows patents for new inventions applicable in industry. However, anything that is obvious with regard to the state of the art (Article 7(2)) is not patentable as an invention.

Main Categories Excluded from Patent Protection

While elements of the human body in their natural environment are not patentable, an element of the human body is patentable as an invention if it is produced by means of a technical process, a beneficial technical effect is indicated and the novelty and inventive step requirements are fulfilled. A naturally occurring sequence or partial sequence of a gene is not patentable as such. However, sequences that are derived from a naturally occurring sequence or partial sequence of a gene can be patented as an invention if:

- They are produced by means of a technical process.
- Their function is specifically indicated.
- The novelty and inventive step requirements are fulfilled.

New processes for the production of existing products can also be protected by patent.

Inventions whose exploitation is contrary to human dignity or that disregard the integrity of living organisms or that are in any other way contrary to public policy or morality are not patentable. Article 2 of the Patent Act includes a list of inventions for which no patent can be granted, including:

- Processes for cloning human beings and the clones obtained thereby.
- Processes for forming hybrid organisms by using human germ cells, human totipotent cells or human embryonic stem cells and the entities obtained thereby.
- Processes of parthenogenesis by using human germinal material and the parthenogenetic entities obtained thereby.
- Processes for modifying the germ line genetic identity of human beings and the germ line cells obtained thereby.
- Unmodified human embryonic stem cells and stem cell lines.
- The use of human embryos for non-medical purposes.
- Processes for modifying the genetic identity of animals that are likely to cause them suffering without being justified by overriding interests worthy of protection, and animals resulting from such processes.

Also excluded from patentability are:

- Methods for treatment by surgery or therapy and diagnostic methods practised on the human or animal body.
- Plant varieties and animal varieties or essentially biological processes for the production of plants or animals. However, subject to the reservation of paragraph 1, microbiological or other technical processes and the products obtained thereby as well as inventions that concern plants or animals are patentable, provided that their application is not technically confined to a single plant or animal variety.

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

Specific Provisions for the Life Sciences Industry

Patent protection is limited by law under certain circumstances. In particular, it is possible for third parties to claim a non-exclusive licence to produce and export pharmaceuticals to a country with insufficient pharmaceutical capacity that is in need of the product for combating public health problems.

Registering a Patent

25. Which authority registers patents? Briefly outline the key stages and timing in obtaining a patent.

Patent Registration Authority

A national application must be filed with the *Swiss Federal Institute of Intellectual Property* (SFIIP). The fees are as follows:

- Application fee: CHF200
- Fee for the examination of the application: CHF500.

- Fee for an optional search by the SFIIP: CHF500
- Fee for an expedited examination: CHF200.

An annual extension fee must be paid after the end of the third year following the date of registration. The fees are CHF100 to CHF960 annually, depending on the year (CHF100 for year four, increasing up to CHF900 for year 20).

Applicants can also file a:

- European patent application with the *European Patent Office* (EPO).
- Patent Cooperation Treaty application, with the SFIIP if domiciled in Switzerland or a Swiss national, or with *WIPO*, or the EPO in some cases.

All three authorities' websites provide application guidance.

The national application must be submitted on the official form. A patent application must include:

- Information on the patent holder (name, address, and country of domicile).
- A mailing address in Switzerland or Liechtenstein if the patent holder is a foreign entity.
- The priority claim, if applicable, including the country and date of the prior application as well as the application number.
- A description of the invention.
- At least one formal patent claim.
- An abstract.
- If necessary, technical drawings. The technical documentation must be in German, French or Italian.

Process and Timing

Once the application is submitted, the SFIIP checks whether the national application meets the formal requirements and whether the application fee has been paid. If this is the case, the applicant receives confirmation of receipt.

An invention will have a priority right in accordance with Article 4 of the WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) where:

- The invention is the subject of a regular filing.
- The filing takes place in or with effect in a country that is a party to the Paris Convention.

This right can be claimed for a patent application filed in Switzerland for the same invention within 12 months from the date of the first filing. The first filing in a country that grants reciprocity to Switzerland has the same effect as the first filing in a country that is party to the Paris Convention.

The effect of the priority right is that the application cannot be prejudiced by any circumstances that have arisen since the date of the first filing.

The patent application is published (at *www.swissreg.ch*) 18 months after filing. Following publication of the patent application, any person can inspect the dossier. The Federal Council can restrict the right of inspection only if required by manufacturing or trade secrets or other overriding interests. However, third parties do not have any right to participate in the application proceedings for a Swiss national patent. Therefore, unlike before the EPO, a third party cannot prevent a patent from being granted by filing third-party observations.

About three to five 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*).

Decisions of the SFIIP can be appealed before the Federal Administrative Court.

Patent approval is not conditional on any technology transfer from the owner to a third party.

The existence of a patent dispute does not prevent review of an application for a pharmaceutical's marketing authorisation.

Length of Patent Protection

26. When does patent protection start and how long does it last? Can monopoly rights be extended by other means?

Duration

Patent protection is valid for 20 years from the date when the application is submitted. The first term of protection is three years. Annual maintenance fees are then due. Patent protection expires after 20 years and in principle 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 grant 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 or within six months from obtaining the patent if it is obtained after 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 between CHF1,060 and CHF1,560.

Together with the revision of the Law on Therapeutic Products in 2016, the Federal Patent Act and related ordinances were revised, with the revisions coming into effect on 1 January 2019. From 1 January 2019, an extension of patent protection for six months is available on application if the approved product information reflects all studies performed according to a paediatric investigation plan. The extension can be in the form of an extension of the SPC (Article 140n, Patent Act) or, if there is no SPC, in the form of a paediatric SPC (Article 140t, Patent Act).

Patent Infringement

27. What rights does a patent grant to its owner? On what grounds can a patent infringement action be brought? What are the main defences to a patent infringement action? How is a claim for patent infringement made and what remedies are available?

Rights Granted by a Patent

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

Grounds for Patent 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 decisions can be appealed to the Federal Supreme Court.

Remedies for a patent infringement include:

- Injunctions (preliminary or final).
- Declaratory judgments.

- Assignment of the patent.
- Orders 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.

Decisions of the Federal Patent Court can be appealed to the Federal Supreme Court.

Defences to a Patent Infringement Action

Research exemption. Article 9 of the Federal Patent Act sets out patent exemptions. It includes a research exemption that states that a patent does not extend to acts undertaken for research or experimental purposes to obtain knowledge about the subject-matter of the invention, including its uses. In particular, any scientific research concerning the subject-matter of the invention is permitted.

IP exhaustion. Switzerland has in principle adopted the regional exhaustion of patent rights system. Patent rights relating to parallel imports are exhausted if the products have been put on the market by the patent owner, or with their consent, in Switzerland or the EEA. See *Question 8, Parallel Imports*.

Other exemptions. Further exemptions covered by Article 9 of the Federal Patent Act include the:

- Private use exception, for acts undertaken within the private sphere for non-commercial purposes.
- Educational use exception, for the use of the invention for teaching purposes in educational institutions.

Applying for marketing authorisation for a medicinal product does not infringe a patent, as such an application is not considered to be a commercial use of the patent. This is specifically set out in Article 9(1)(c) of the Federal Patent Act, which states that the effects of the patent do not extend to acts necessary for obtaining marketing authorisation for a medicinal product in Switzerland or in countries with equivalent medicinal product control.

The revision of the Federal Patent Act that came into effect on 1 January 2019 provides additional exemptions for:

- Actions in the context of a medical activity that relate to an individual person or animal and concern medicinal products, in particular, the prescription, supply or use of medicinal products by persons legally entitled to do so.
- The direct individual preparation of medicinal products by pharmacies in execution of a medical prescription as well as actions concerning medicinal products prepared in this way.

International IP Treaties

28. Is your jurisdiction party to international treaties that facilitate the recognition of foreign IPRs in your jurisdiction?

General

Switzerland is a party to the:

- Paris Convention.
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).
- Lugano Convention on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial matters 1988.
- Geneva Act of the Lisbon Agreement (entered into force with respect to Switzerland, on December 1, 2021).

Patents

Switzerland is a party to the *Patent Cooperation Treaty 1970 (PCT)*.

Trade Marks

Switzerland is a party to the:

- WIPO Madrid Agreement Concerning the International Registration of Marks 1891 (Madrid Agreement).
- WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol).
- WIPO Trademark Law Treaty 1994.
- Nice Agreement concerning the International Classification of Goods and Services 1957.
- Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks 1973.

Trade Marks

Legal Requirements to Obtain a Trade Mark

29. Provide a brief definition of a trade mark, the key legal requirements to obtain it, and the law that applies.

The trade mark legislation includes the Federal Law on the Protection of Trademarks and Indications of Source of 28 August 1992, and the related Ordinance of 23 December 1992.

A trade mark must be a graphically reproducible sign that is distinctive (capable of distinguishing a person's or enterprise's goods or services from those of another) with no absolute grounds for refusal.

Trade mark rights are enforceable from their date of registration application, or their seniority date, provided they are registered. Trade marks used abroad and that 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.

Medicinal brands can generally be registered and are examined independently by the SFIIP (for trade mark registration) and by Swissmedic (for marketing 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 of a specific shape as a trade mark can also be refused if the shape constitutes the nature of the goods or is technically necessary for the goods or their packaging.

Registering a Trade Mark

30. Which authority registers trade marks? Briefly outline the key stages and timing to obtain a registered trade mark.

Trade Mark Registration Authority

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.

Swissmedic does not review proposed trade marks in the trade mark registration proceedings. Proposed product names are reviewed by Swissmedic as part of the marketing authorisation proceeding.

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 from the application date. The application is examined generally within either:

- Four to six months after payment of the application fees.
- Six working days after its filing, if both the:
    - electronic application is clearly registrable;
    - 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 for the first examination (registration or provisional refusal) and of two months for each further step in the application process 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. Third parties cannot participate in the application process and therefore cannot challenge the trade mark when it is still in the application stage.

Where a trade mark is duly filed first in another member state of the Paris Convention or with effect in such a member state, the applicant or successor in title can claim the date of the first filing for the filing of the same trade mark in Switzerland, provided the filing in Switzerland takes place within six months of the date of the first filing. The first filing in a state that grants reciprocity to Switzerland has the same effect as the first filing in a member state of the Paris Convention.

In addition, any person who exhibits goods or services bearing a trade mark at an official or officially recognised exhibition under the Convention Relating to International Exhibitions in a Member State of the Paris Convention 1928, can claim the opening date of the exhibition for filing the application, provided that the trade mark is filed within six months of this date.

Any person who claims priority under the Paris Convention or an exhibition priority must file a declaration of priority with the SFIIP. The SFIIP may require the submission of a priority document.

Competition Law Issues

Competition Authorities and Legislation

31. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector.

Competition Law and Main Provisions

The relevant legislation in the field of competition law is the:

- Federal Act on Cartels and other Restraints of Competition 1995 (Cartel Act).
- Ordinance on the Control of Concentrations of Undertakings 1996 (Merger Control Ordinance).
- Ordinance on Sanctions imposed for Unlawful Restraints of Competition 2004 (Cartel Act Sanctions Ordinance).

Competition Authority

The competent administrative authority for the enforcement of Swiss competition law is ComCo. ComCo acts on its own accord or on receiving a complaint.

ComCo can impose fines of up to 10% of the turnover of the last three business years of the undertaking concerned in cases of:

- Unlawful agreements among competitors on prices, territories or quantities.
- Unlawful vertical agreements on absolute territorial protection or resale price fixing.
- Abuse of a dominant position.

Other unlawful agreements and behaviours can be declared illegal and prohibited. Since 1 January 2022, the abuse of relative market power is also illegal, although this is not subject to the sanctions regime. Abuse of relative market power will also exist if a product that is offered for sale in Switzerland and abroad cannot be procured abroad at the local market price and conditions.

Private parties can also sue other parties in civil courts. Any person hindered by an unlawful restraint of competition from entering or competing in a market is entitled to request the elimination of or desistance from the hindrance, damages and satisfaction and/or surrender of unlawfully earned profits, in accordance with the provisions on agency without authority.

Although the pharmaceutical sector is to a wide extent excluded from the scope of application of the Cartel Act due to the price regulation of reimbursed medicinal products, there have been a number of investigations, including the following:

- In 2000, ComCo found that the market regulations established by the Sanphar association infringed the Cartel Act. The market regulations provided for, among other things, rebate band widths for manufacturers and wholesalers, and margins for pharmacies and self-dispensing doctors. The Sanphar association was dissolved soon after this decision.
- In 2000 ComCo found that a price fixing cartel regarding vitamins was illegal.

- In 2006, in a preliminary investigation, ComCo assessed whether the price for the pharmaceutical Thalidomid Pharmion was abusively high. In a prima facie analysis ComCo concluded that there were no indications of abusive pricing. ComCo specifically mentioned that the question would become moot once the product's price had been reviewed by the FOPH and accepted for reimbursement.
- In 2009, ComCo held that price recommendations for retail prices of the drugs Viagra, Cialis, and Levitra amounted to unlawful resale price maintenance. The prices of these drugs were not subject to governmental price control. The reasons for the decision were, among others, that the recommendations were followed by more than 80% of pharmacies and that the retail prices were entered into a very widely used IT system. The three companies in question were fined with a total of over CHF5 million. The Swiss Federal Court finally in 2021 decided that the price recommendations in this case were unlawful.
- In 2015, ComCo issued a final report on a preliminary investigation regarding Alloga, the biggest pre-wholesaler in Switzerland in connection with the allegation that it had abused its dominant position by threatening Amedis-UE (a wholesaler belonging to a competing group) to stop delivery if it did not agree to provide substantial securities. ComCo found indications for a market dominant position of the pre-wholesaler and for abusive behaviour, but did not open an in-depth investigation because the pre-wholesaler agreed in a settlement to change its practice.
- In 2016, ComCo imposed a sanction of CHF4.5 million on the health software and information vendor HCI Solutions for alleged abuse of a dominant market position regarding the publication of medicinal product information. This sanction is still under judicial review.
- ComCo has been conducting a preliminary investigation regarding the distribution of pharmaceutical products in Switzerland since September 2010. Apart from a final report of 11 May 2015 on a partial aspect of the preliminary investigation (regarding allegations of abuse of market dominance against Alloga, the biggest pre-wholesaler in Switzerland) no findings have yet become known.
- In September 2022, ComCo conducted a dawn raid at Novartis' headquarters in Basel for alleged abuse of patent rights (blocking patents).

Besides these cases, many mergers of pharmaceutical companies have undergone Swiss merger control.

32. Has pharmaceutical competition case law in your jurisdiction focused on any key areas?

In a long-lasting case, ComCo has focused on resale price recommendations in the area of off-list medicinal products (products that are not subject to price control by the Federal Office of Public Health). Otherwise, there has been no particular focus on specific key areas.

Commercial Contracts and Competition Law

33. Briefly outline the competition issues that can arise in relation to commercial contracts and other business arrangements relating to medicinal products.

Under the Cartel Act, agreements fixing prices or quantities and agreements allocating geographical markets or customer groups between effective or potential competitors are considered to be "hard core" cartels and are subject to a direct sanction regime.

Vertical agreements stipulating minimum or fixed resale prices, or the prohibition of passive sales to territories other than the allocated territory, are also subject to the direct sanction regime. To be lawful, these types of restraints in distribution or licence agreements, and other types of restraints notably affecting competition, must be justified by economic efficiency grounds. There is little guidance in case law and literature defining the situations in which such restraints can be justified.

The abuse of a dominant market position can be directly sanctioned. Discrimination among licensees or customers may constitute an abusive practice if the unequal treatment cannot be justified by legitimate business reasons.

Licensing Approvals and Formalities

34. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved by a government or regulatory body? Are there any formalities or other requirements to make the licence enforceable?

There is no requirement for licences and royalties to a foreign licensor to be approved by a government or regulatory body. There are no patent-specific restrictions placed on licensing or transferring patents to foreign parties or for inventions funded by public investment. However, general trading restrictions (such as sanctions and embargos) and contractual restrictions may apply. In addition, in May 2022, the Federal Council opened a consultation on investment control legislation.

Product Liability

Regulators

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

Swissmedic is the competent authority for the surveillance of the safety of medicinal products. For this purpose, it collects pharmacovigilance notifications, analyses them and takes appropriate measures. Swissmedic and the cantons can require necessary information, documents and support. If required and appropriate, Swissmedic can order administrative measures to prevent health risks. Such measures may include changes to the product information, warning letters or product recalls. Most often, the measures are agreed between the company concerned and Swissmedic.

Despite such measures, the manufacturer of a defective product may still be liable based on the Federal Act on Product Liability of 1993 (Product Liability Act) and general tort and contract law where a defective product has caused damage (see *Question 36*).

Medicinal Product Liability Law

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

Legal Provisions

There are no special rules relating to product liability for pharmaceutical products. Under the Product Liability Act, which is based on the Product Liability Directive (*85/374/EEC*), 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 the circumstances. Special consideration must be given to the:

- Ratio between benefit and risk.
- Method and manner used to present the product (product information).
- Reasonably expected use of the product.
- Point in time the product was placed on the market.

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

In 2015, the Federal Supreme Court decided a prominent case regarding the contraceptive Yasmin. The plaintiff claimed that she had suffered a pulmonary embolism because of Yasmin and that the drug was a defective product, as the patient leaflet did not contain sufficient information on the risks of the active substance. The Federal Supreme Court based its decision on the general legal rules on product liability. The court ruled that only the expectations of the health care professional were relevant to the question of whether a prescription drug product offered the safety that could justifiably be expected, as the patient lacked the necessary expertise. The fact that drugs could have undesirable side-effects did not render them defective if the product

information for health care professionals contained corresponding information. The lack of information in the patient leaflet of Yasmin was not relevant and the court ruled that the marketing authorisation holder was not liable in this case.

However, on 26 November 2021 the High Court of the Canton of Berne decided differently about a medical device (hip implant), finding that the expectations of the patient were relevant alongside the knowledge of the health care professional.

Liable Parties

37. Who is potentially liable for defective medicinal products?

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

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

Defences

38. What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

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. However, there is otherwise no regulatory compliance defence.
- The error was not identifiable based on scientific and technological knowledge at the time the product was put into circulation (development risk).
- It produced base material or part of the product only and the defect was caused by the construction of the product in which the base material or part was incorporated, or by the instruction given by the producer of that product.

Product Liability Claims

39. How can a product liability claim be brought?

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

Limitation Periods

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

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

Class Actions

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

Remedies

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

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

Contributor Profiles

Frank Scherrer

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

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

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

Languages. German, English, French

Marcel Boller

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

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

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

Languages. German, English, French, Italian

Claudia Keller

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

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

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

Languages. German, English

Dominique Roos

Wenger Vieli AG
T +41 58 958 58 58
F +41 58 958 59 59
E *d.roos@wengervieli.ch*
W *www.wengervieli.ch*

Professional qualifications. MLaw, University of Zurich, Switzerland, 2015; admitted to the Bar in Switzerland, 2018

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

Languages. German, English, Spanish

Ines Holderegger

Wenger Vieli AG
T +41 58 958 58 58
F +41 58 958 59 59
E *i.holderegger@wengervieli.ch*
W *www.wengervieli.ch*

Professional qualifications. MLaw, University of Lucerne, Switzerland, 2017; admitted to the Bar in Switzerland, 2020

Areas of practice. Pharmaceutical and health law; life sciences; commercial and contract law; advertising law; data protection law; intellectual property law.

Languages. German, English

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