The Pharma Legal Handbook

Switzerland

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

Switzerland

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Switzerland. It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Wenger Plattner, a leading law firm law firm in Switzerland, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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01

REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

Swiss Agency for Therapeutic Products (Schweizerisches Heilmittelinstitut [Swissmedic]):
The Swiss Agency for Therapeutic Products (hereinafter: **Swissmedic**) is the competent authority for various **authorizations and licenses** in the field of medicinal products and medical devices (e.g. marketing authorizations; manufacturing licenses; licenses for exporting, importing and distributing; authorizations for clinical trials). It is an institution under public law with its own legal personality located in Berne and was founded in 2002. Swissmedic is furthermore responsible for **market surveillance** in the area of therapeutic products and has also numerous competences in relation to **law enforcement**. It should be mentioned that Swissmedic may even **adopt legislation**, such as the Ordinance on simplified authorisation and marketing authorisation on the basis of a notification of medicinal products *(Verordnung des Schweizerischen Heilmittelinstituts* über die vereinfachte Zulassung von Arzneimitteln und die Zulassung von Arzneimitteln im Meldeverfahren *vom 22. Juni 2006 [VAZV; SR 812.212.23])*. Consequently, Swissmedic has an almost comprehensive competence with regard to medicinal products and medical devices.

Federal Office of Public Health (FOPH) (Bundesamt für Gesundheit [BAG]):
The Federal Office of Public Health (hereinafter: **FOPH**) in Berne plays a key role especially in the **legislative procedures** in all sectors of the public health law (e.g draft legislations and ordinances). It is responsible for the coordination of the health policy and the supervision of the compulsory health insurance. While Swissmedic is competent for various authorizations and licenses in the field of medicinal products and medical devices, the FOPH mainly deals with questions concerning **pricing and reimbursement of medicinal products** within the framework of the Federal Act on Health Insurance *(Bundesgesetz über die Krankenversicherung vom 18. März 1994 [KVG; SR 832.10])*.

Ethics committees (Ethikkommissionen):
There are 7 ethics committees in Switzerland, each of which is responsible for a specific canton or region *(Ethics Committee northwest/central Switzerland EKNZ, Cantonal Ethics Committee Bern, Ethics Committee Geneva (CCER),*

[1]The terminology used below is based on the English translation of the legal texts by the Swiss Federal Chancellery. English versions of the law are, contrary to the official German, French and Italian versions, legally not binding and serve information purposes only.

Ethics Committee Eastern Switzerland EKOS, *Ethics Committee Ticino,* Cantonal Commission on Ethics in Human Research CER-VD, *Ethics Committee Zurich)*. For conducting a **research project** (e.g. concerning medicinal products), an authorization from the responsible ethics committee is required (in addition to Swissmedic's authorization).

Conformity Assessment Bodies (Konformitätsbewertungsstellen):
Medical devices do not require any marketing authorization by Swissmedic. However, a **conformity assessment procedure** (*Konformiätsbewertungsverfahren*) is required for certain types of medical devices.

These procedures are carried out by private conformity assessment bodies (*Konformitätsbewertungsstellen*). They are approved and monitored by Swissmedic. Since the Swiss medical device law is currently undergoing a total revision and the draft of the new **Medical Devices Ordinance** is not yet final, no further details can be provided at this moment. However, the main elements of the new law are set out in **Chapter 7**.

Cantonal authorities:
In addition, there are also authorities in each canton responsible e.g. for certain types of inspections or the granting of professional licences for doctors. As these authorities are not of great importance below, they are not listed.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

1. The regulatory framework for the authorization of medicinal products and biologicals

The legal framework for the authorization of medicinal products and biologicals is regulated by the **Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act)** (hereinafter: **TPA**) *(Bundesgesetz über Arzneimittel und Medizinprodukte vom 15. Dezember 2000 [Heilmittelgesetz, HMG; SR 812.21])*. According to the TPA, **medicinal products** means products of chemical or biological origin which are intended to have or are presented as having a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps; blood and blood products are also considered to be medicinal products (art. 4 para. 1 lit. a TPA). In addition, there are numerous **ordinances** governing the details (e.g. the *Ordinance on Medicinal Products* and the *Ordinance on Licensing in the Medicinal Products Sector*).

The TPA is divided into 8 chapters: General Provisions; Medicinal Products; Medical Devices; Common Provisions on Medicinal Products and Medical Devices; Swiss Agency for Therapeutic Products; Enforcement; Administrative Procedure and Rights of Appeal; Criminal Provisions; Final Provisions.

2. The regulatory framework for the authorization of medical devices

Same as medicinal products, medical devices are also regulated by the TPA. The Swiss legislator thus implements – contrary to other countries – both, medicinal products and medical devices, in one law. **Medical devices**

means products, including instruments, apparatus, in vitro diagnostics, software and other goods or substances which are intended to have, or are presented as having, a medical use and whose principal effect is not obtained with a medicinal product (art. 4 para. 1 lit. b TPA). Medical devices are additionally regulated, among others, by the **Medical Devices Ordinance** *(Medizinprodukteverordnung vom 17. Oktober 2001 [MepV; SR 812.213])*. Since the Swiss medical device law is currently undergoing a total revision and the draft of the new **Medical Devices Ordinance** is not yet final, no further details can be provided at this moment. However, the main elements of the new law are set out in **Chapter 7**.

The main difference, which will also apply under the new law, is that medical devices (contrary to medicinal products) **do not require marketing authorization** by Swissmedic before being placed on the market.

3. The regulatory framework of pricing and reimbursement of medicinal products, biologicals and medicinal devices

These aspects are outlined in **questions 12 and 13**.

3. What are the steps to obtaining authorization to develop, test, and market a product?

The following overview is intended to cover two main aspects: First the authorization for clinical trials and second the marketing authorization. Any previous steps (such as pre-clinical trials and clinical trials with animals) are not outlined below.

1. Authorization for clinical trials

Clinical trials of therapeutic products require prior authorization from Swissmedic (art. 54 para. 1 TPA). Swissmedic verifies whether the **medicinal products** meet the requirements of Good Manufacturing Practice and of medicinal product safety or whether the **medical devices** meet the requirements specified in art. 45 TPA (i.e. the medical device does not endanger the health of the user or a third party when used in accordance with its intended use), the product risks are duly considered in the clinical trial, and the product data is in line with current scientific knowledge and correctly indicated in the protocol (art. 54 para. 4 TPA).

Art. 54a TPA provides the obligation to develop a **paediatric investigation plan**: For each medicinal product, a paediatric investigation plan shall be drawn up with a view to its marketing authorization which sets out the requirements for the development of the medicinal product in paediatrics and which must be submitted to Swissmedic.

For clinical trials of therapeutic products in humans, the **Human Research Act** (hereinafter: **HRA**) *(Bundesgesetz* über die Forschung am Menschen *vom 30. September 2011 [Humanforschungsgesetz, HFG; SR 810.30])* applies in addition to the provisions of the TPA (art. 53 TPA). For conducting a research project, an authorization from the responsible **ethics committee** is required (art. 45 para. 1 lit. a HRA). The authorization is granted if the **ethical, legal and scientific requirements** of the HRA are met. This includes, for example, general

requirements for research involving persons (such as protection of participants, information and consent), liability and coverage or additional requirements for research involving particularly vulnerable persons (art. 45 para. 2 HRA).

2. Marketing authorization

Ready-to-use medicinal products can be placed on the market only if they are authorized by Swissmedic (art. 9 para. 1 TPA). Any person or organization applying for a marketing authorization must prove that the medicinal products with indications or procedures are of **high quality**, **safe** and **effective** (art. 10 para. 1 lit. a TPA). **High quality** means that the medicinal product must meet certain conditions; anyone applying for marketing authorization has to show that the medicinal product complies with the requirements of the **pharmacopeia** and the applicable **GMP-Standards**. In order to prove that a medicinal product is **safe and effective**, clinical trials have to be conducted.

It is the general purpose of the TPA to protect the human (as well as the animal) health and to guarantee that only high quality, safe and effective therapeutic products are placed on the market (art. 1 para. 1 TPA). Swissmedic shall grant a marketing authorization if the conditions are fulfilled and may attach conditions and requirements to the authorization (art. 16 para. 1 TPA).

Swiss legislation provides **different marketing authorization procedures**, as outlined in their main aspects below (see also chapter 3):

· "Ordinary" authorization procedure:

Ready-to-use medicinal products may be placed on the market only if authorized by Swissmedic (art. 9 para. 1 TPA). The requirements for the application for a marketing authorization according to the "ordinary" authorization procedure are regulated in art. 11 TPA. This provision mainly concerns medicinal products with **new active substances**. The ordinary authorization procedure is the longest compared to the other procedures.

· Simplified authorization procedure:

For the authorization of certain categories of medicinal products and where this is compatible with the **quality, safety and efficacy requirements**, among others, a simplified authorization procedure is provided (art. 14 TPA). It applies, for instance, in the following cases: medicinal products made with **known active substances**; medicinal products whose **active substances are used in a medicinal product** which, when the application was submitted, has been authorized as a medicinal product for at least 10 years in at least one **EU or EFTA country** and which is comparable in terms of indications, dosage and method of administration; **non-prescription medicinal products with indications** which, when the application was submitted, have been proven to have been used medically for at least 30 years, and for at least 15 years in EU and EFTA countries.

· Marketing authorization on the basis of a notification:

Complementary medicines without indications and **medicinal products** for which, due to their **low risk potential**, a simplified marketing

authorization proves to be disproportionate, among others, may be placed on the market on the basis of a notification (art. 15 TPA). An "ordinary" or simplified marketing authorization procedure is not necessary in such case.

Medical devices, one the other hand, are not subject to a marketing authorization (see also chapter 3).

4. What are the approximate fees for each authorization?

Swissmedic's fees are regulated in an **ordinance** adopted by Swissmedic itself *(Verordnung des Schweizerischen Heilmittelinstituts über seine Gebühren vom vom 14. September 2018 [GebV-Swissmedic; SR 812.214.5])*. The fee for the authorisation of a medicinal product with a new active substance is 80 000 Swiss francs. The fee for the authorisation of a clinical trial is 5000 Swiss francs.

Swissmedic is mainly **financed by means of fees**, which are regulated individually and transparently in **Annex 1 and 2** to the ordinance mentioned above. This is just one aspect ensuring Swissmedic's **independency from politics and other federal institutions** such as the Federal Department of Home Affairs or the FOPH. Swissmedic decides without external influences and there is no "superior" authority that could influence a decision. Needless to say, Swissmedic's **decisions** (e.g. decision of non-approval of a medicinal product) may be appealed to the Federal Administrative Court.

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/ registrations renewed?

The first marketing authorisation of a medicinal product is valid for a limited period. According to art. 16 TPA, the marketing authorisation is issued for the first time for a period of **five years**. Swissmedic shall order a shorter period of authorisation if the authorisations are limited in accordance with art. 9a TPA (so-called **Temporary authorisation**) or this is necessary for the protection of health. The authorisation of medicinal products on the basis of a notification shall be valid for an **unlimited period**.

The renewal of the marketing authorisation is regulated in art. 16b TPA. According to this provision, a marketing authorisation shall be renewed upon application if the authorisation requirements continue to be met. As a rule, renewed authorisations are valid for an **unlimited period**. Swissmedic may, however, limit them in particular cases.

The detailed procedures are set out in the **Ordinance on Medicinal Products** *(Verordnung über die Arzneimittel vom 21. September 2018 [Arzneimittelverordnung, VAM; SR 812.212.21])*.

In this context, it should be emphasised that the TPA provides a special provision for **revocation and transfer of the authorisation**. For example, Swissmedic may revoke the authorisation for a medicinal product if it is not actually placed on the market within three years of the granting of the authorisation or if it is no longer actually on the market during a period of three successive years after it has been placed on the market (art. 16a para. 1 TPA). The purpose of this **sunset clause** is to ensure that medicinal products are effectively available on the market.

Since **medical devices** are not authorized by Swissmedic, the question of the duration of approval does not arise. Decisions and certificates taken or issued by conformity assessment bodies are valid for a period of five years. On application, the certificates may be extended for a maximum of five years at a time (art. 12 para. 1 Medical Devices Ordinance *[Medizinprodukteverordnung vom 17. Oktober 2001, MepV; SR 812.213]*). Since the Swiss medical device law is currently undergoing a total revision and the draft of the new **Medical Devices Ordinance** is not yet final, no further details can be provided at this moment. However, the main elements of the new law are set out in **Chapter 7**.

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

The main elements of the authorization process for brand-name products are outlined in **question 3**. Requirements for approval of generic products are less stringent than for original or brand-name products.

To begin with, **original preparation** means a medicinal product that is authorised by Swissmedic as the first product with a **specific active substance**, including all dosage forms authorised at the same time or later (art. 4 para. 1 lit. a^{sexies} TPA). **Generic medicinal product** means a medicinal product authorised by Swissmedic which is essentially the same as an original preparation and which is interchangeable with the original preparation due to its identical active substances and its dosage form and dosage (art. 4 para. 1 lit. a^{septies} TPA).

The **documentation** (e.g. documentation about preclinical and clinical trials) relating to a medicinal product containing at least one new active substance and authorised in an "ordinary" authorization procedure shall be **protected for a period of ten years** (art. 11a TPA). This so-called **"Document protection in general"** must be distinguished from patent protection under the **Federal Act on Patents for Inventions (Patents Act, PatA)** *(Bundesgesetz über die Erfindungspatente vom 25. Juni 1954 [Patentgesetz, PatG; SR 232.14])*.

The authorization process of generic products is regulated in art. 12 TPA **(Authorisation of essentially similar medicinal products)**. The **application** for a marketing authorization for a medicinal product which is essentially the same as a medicinal product whose documents are protected **may be based on the results of the pharmacological, toxicological and clinical tests** if the **holder of the marketing authorization** for the medicinal product with document protection provides written **permission or** the **protection period** for the relevant documents has **expired**.

This means that generic products manufacturers have to wait until the protection period for the relevant documents has expired (unless the brand-name products manufacturer gives his written permission before). After this period, the documents from the "ordinary" authorization procedure can be used for the authorization procedure for the generic product. The manufacturer of the generic product therefore does not have to conduct any new (and expensive) clinical trials.

With regard to this procedure, there are **no differences** for local manufacturers versus foreign-owned manufacturers. However, any person or organization

applying for a marketing authorization must have a registered address, registered office or a branch office in Switzerland.

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

Combination products are not regulated in the TPA and there is no official Swissmedic practice.

However, these kinds of products exist on the Swiss market, which means they are authorized by Swissmedic. The "**Guidance document Formal requirements HMV4"** (*cf. https://www.swissmedic.ch/swissmedic/en/home/kpa/homeopathic-anthroposophic-medicines/information/anpassung_wl_formale_anforderungen.html, last visited on 31 March 2021*) contains technical information concerning the application form for medicinal products with a medical device component. Since the legal situation is inconclusive, it is recommended to seek legal assistance.

8. How is compliance with regulations monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

Market surveillance and inspection procedures are also regulated in the TPA. Swissmedic and the other authorities entrusted with the implementation of the TPA (e.g. the FOPH) monitor, within the limits of their competences, whether the **manufacturing, distribution, dispensing and presentation of therapeutic products** are in accordance with the TPA. They verify by means of periodic inspection that the conditions for the licenses are still fulfilled (art. 58 para. 1 TPA). Swissmedic verifies the therapeutic products placed on the market. The Agency further verifies that medicinal products comply with the granted marketing authorization and that medical devices satisfy the legal requirements (art. 58 para. 2 TPA). Swissmedic is responsible for monitoring the safety of therapeutic products. To this effect, it in particular collects the notifications referred to in art. 59 TPA (**mandatory notification, notification system and the right to notify**), evaluates them, and takes the necessary administrative measures. Any person manufacturing or distributing ready-to-use therapeutic products must put in place a **system of notification** (art. 59 para. 1 TPA).

Even if Switzerland's regulations are not identical to those of the U.S. Food and Drug Administration and the European Medicines Agency, they are nevertheless comparable.

9. What is the potential range of penalties for noncompliance?

The revision of the TPA, of 1 January 2019, included stricter **penal provisions** than the previous version of the law. Art. 86 to 90c TPA regulate the criminal provisions in detail. Only an overview is given below:

First, the law distinguishes between **Felonies and misdemeanours** (art. 86 TPA) on the one hand, and **Other Offences** (art. 87 TPA) on the other hand. Any person who wilfully commits a **felony or a misdemeanour** (e.g. placing on the market, using, prescribing, importing or exporting, or trading in a foreign country medicinal products without the required marketing authorisation or licence) shall be liable to a **custodial sentence** not exceeding three years or to a **monetary penalty** (art. 86 para. 1 TPA). A custodial sentence

not exceeding **ten years**, which may be combined with a monetary penalty, shall be imposed on any person who knows or must assume that the violation specifically **endangers human health** or achieves a high turnover or makes substantial profits through commercial activity (art. 86 para. 2 TPA).

Any person who wilfully commits **others felonies** (e.g. manufacturing, placing on the market, importing or exporting, or trading in a foreign country therapeutic products or excipients which do not conform to the requirements stated in the pharmacopoeia) shall be liable to a **fine** not exceeding 50 000 Swiss francs (art. 87 para. 1 TPA).

Prosecutions at federal level are conducted by Swissmedic and the FOPH. Swissmedic may order **covert surveillance measures** (e.g. **observations or undercover enquiries**) pursuant to the Swiss Criminal Procedure Code *(Schweizerische Strafprozessordnung vom 5. Oktober 2007 [Strafprozessordnung, StPO; SR 312.0])*.

In addition, the **Swiss Penal Code** (e.g. if someone gets injured by a therapeutic product or in case of corporate criminal liability) and other private and public law provisions may also be applicable.

10. Is there a national healthcare system? If so, how is it administered and funded?

Basic health insurance is mainly regulated by two federal laws: The **Federal Act on Health Insurance** (hereinafter: **HIA**) *(Bundesgesetz über die Krankenversicherung vom 18. März 1994 [KVG; SR 832.10])* and the **Federal Act on the Supervision of Health Insurance** (hereinafter: **SHIA**) *(Bundesgesetz betreffend die Aufsicht über die soziale Krankenversicherung vom 26. September 2014 [Krankenversicherungsaufsichtsgesetz, KVAG; SR 832.12])*.

Every person domiciled in Switzerland is **obliged to conclude basic health insurance** within three months of moving to Switzerland or from the birth of a child (art. 3 para. 1 HIA). The insurer can be freely chosen (art. 4 HIA), there is **no "single public health insurance"** (Öffentliche Einheitskrankenkasse).

Any person who offers basic health insurance is obliged to seek for an authorization from the **FOPH**. At the moment, there are **57 authorised insurance companies** on the Swiss market offering basic health insurance (*cf. https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-versicherer-aufsicht/verzeichnisse-krankenundrueckversicherer.html, last visited on 31 March 2021*). Insurers are legal entities (organized according to private or public law) which do not pursue a profit-making purpose; they offer basic health insurance (art. 2 para. 1 SHIA). They must treat all persons equally, regardless of age or state of health. For example, **no insurer can refuse to insure a seriously ill person**. There is a legal obligation to conclude a contract which each person (*Kontrahierungszwang*). Furthermore, it makes no difference which insurance is chosen when it comes to **insurance benefits**. Each insurer is **obliged** to reimburse the costs of treatment, medication etc. mentioned in the HIA and the applicable ordinances. However, there are **qualitative differences**, such as in terms of customer service or the duration of the reimbursement process. If someone does not conclude a basic health insurance timely, cantonal authorities are allowed to

allocate such person to one of the insurers (art. 6 para. 2 HIA). It can therefore be concluded that **every resident in Switzerland has basic health insurance**.

The **tariffs/premiums** (*Krankenkassenprämien*) for the basic health insurance have to be approved annually by the FOPH (art. 16 SHIA). Unlike in other countries, the health insurance premium does not depend on **wages**. A person with a very high income must pay the same premium as a person living on the edge of the subsistence level. Persons, who do not have sufficient financial means, can request a **premium reduction** (art. 65 HIA). A certain amount is then paid by the canton to the insurer.

However, insurance premiums **vary between the insurers and the cantons**. The premium also depends on the **deductible**, which can be freely chosen by the insured **(the higher the deductible, the lower the premium)**.

The Swiss healthcare system is, as outlined above, regulated by federal laws and ordinances. Nevertheless, the **cantons** are responsible for the **provision and funding** of healthcare. This will be illustrated by the example of a hospital: The majority of hospitals is controlled or owned by cantons and municipalities. **Cantons co-finance the public hospitals together with the health insurers.** Consequently, the canton has to pay at least 55% of the cost of inpatient hospitalisation (art. 49a para. 2ter HIA); the other 45% are covered by the insurer.

11. How does the government (or public) healthcare system function with private sector healthcare?

The main principles of **public health insurance** are outlined in question 10. In contrast to basic health insurance, there is **no obligation** for a person to conclude a private health insurance that provides additional benefits (e.g. a private room during a hospital stay). Insurance companies offering basic health insurance usually offer private health insurance products too. One of the main differences between these two forms is that private health insurances are governed by the **Federal Act on Insurance Contracts** *(Bundesgesetz über den Versicherungsvertrag vom 2. April 1908 [Versicherungsvertragsgesetz, VVG; SR 221.229.1])*. In private healthcare sector, the **Swiss Financial Market Supervisory Authority** (*Eidgenössische Finanzmarktaufsicht FINMA*) approves the tariffs/premiums. However, private health insurers can choose whether or not to conclude an insurance contract with a person, which means that persons can be refused due to their age or health condition. Consequently, **discrimination** that is prohibited within the scope of the HIA is permitted and practised within the scope of the Federal Act on Insurance Contracts. In contrast to the supervisory function of the FOPH over the public health insurance sector, the supervision of the private insurance sector is exercised by the FINMA. Most insurers offer both, basic and private health insurances.

12. Are prices of drugs and devices regulated and, if so, how?

As outlined in **question 3**, ready-to-use medicinal products may be placed on the market only if authorized by Swissmedic (art. 9 para. 1 TPA). This authorization does not cover pricing and reimbursement. The competent authority for pricing (and reimbursement) is the **FOPH.**

A medicinal product can only be **reimbursed** by the health insurance if it is listed by the FOPH on the so-called "specialty list" *(Spezialitätenliste)* (art. 52 para. 1 lit. b HIA). First, an application for a medicinal product to be listed on the specialty list has to be filed with the FOPH. In order to be listed, the Swissmedic approved medicinal product must satisfy the criteria of **effectiveness, functionality and economic efficiency** (art. 65 para. 1 and 3 of the **Ordinance on Health Insurance** [hereinafter: **OHI**] *[Verordnung über die Krankenversicherung vom 27. Juni 1995, KVV; SR 832.102]*).

In order to assess the **effectiveness criterion**, the same documents are used as those submitted to Swissmedic for marketing authorisation. However, the FOPH may require further documentation (art. 32 **Ordinance on the Benefits of the Mandatory Health Insurance** [hereinafter: **OBHI**] *[Verordnung des EDI über Leistungen in der obligatorischen Krankenpflegeversicherung vom 29. September 1995; Krankenpflege-Leistungsverordnung, KLV; SR 832.112.31]*). With regard to the **functionality of a medicinal product**, the FOPH analyses its impact, composition and possible side effects (art. 33 OBHI). The **economic efficiency** of a medicinal product is evaluated by using a combination of different concepts:

First, the FOPH compares the price of the medicinal product with the average price of the same medicinal product in the reference countries Germany, Denmark, Great Britain, the Netherlands, France, Austria, Belgium, Finland and Sweden (*Auslandspreisvergleich*) (*cf. https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Mitteilungen-zur-Spezialitaetenliste.html, last visited on 31 March 2021*). **Second**, the FOPH compares the price of the medicinal product with the price of other medicinal products in Switzerland used to treat the same disease (*therapeutischer Quervergleich*). Both results will be evaluated **equally** (art. 65b OHI; art. 34a et seqq. OBHI). The FOPH has a large discretion in the composition of the reference drugs. The calculation process is illustrated by the following example: the average price in the reference countries is **100 Swiss francs**; the average price for other medicinal products in Switzerland used to treat the same disease is **150 Swiss francs**; as a result, the price for the new medicinal product is set at **125 Swiss francs** ([100+150] / 2).

However, the price determined by these criteria is not yet definitive. The FOPH takes into account costs for **research and development** (unless the original product is a successor product that does not bring any therapeutic progress). In case of **significant therapeutic progress**, a so-called **innovation supplement** *(Innovationszuschlag)* is granted for a maximum of 15 years (art. 65b para. 6 and 7 OHI).

Medicinal products do not remain on the speciality list indefinitely. A **re-evaluation** of the 3 criteria takes place every 3 years. In consequence, the FOPH may order a **reduction** of the price (art. 65d OHI).

Medical Devices, on the other hand, are not listed on the speciality list. There is a separate list for medical devices (among others) used by patients, the so-called **Mittel- und Gegenständeliste (MiGel)**. However, this list does not apply to all medical devices.

13. How are the drugs and devices used by patients paid for? What roles do public and private payers play?

The main principles of pricing are outlined in **question 12**. A medicinal product can only be **reimbursed** by the health insurance if it is listed by the FOPH on the so-called "specialty list" *(Spezialitätenliste)*. In order to be listed, the Swissmedic approved medicinal product must satisfy the criteria of **effectiveness, functionality and economic efficiency** (art. 65 para. 1 and 3 OHI).

Consequently, medicinal products **not listed** on the "specialty list" have to be paid for exclusively by the patients themselves. If several equivalent medicinal products exist, doctors usually prescribe listed ones. If a medicinal product is not reimbursed by the health insurance, doctors must inform their patients of this fact before prescribing the medicinal product. It can therefore be essential for a pharmaceutical company that their medicinal product is listed.

In order to be reimbursed by the health insurance, **medical devices** have to be listed, for example, on the so-called **Mittel- und Gegenständeliste (MiGel)**.

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

Medicinal products are classified into categories according to whether or not they are subject to **prescription** (art. 23 para. 1 TPA). Swissmedic categorizes each medicinal product for which it has granted a marketing authorization. It takes into account the professional competence of the professional groups entitled to dispense medicinal products (art. 23a para. 1 TPA).

Medicinal products in categories **A** and **B** are subject to a **prescription**, category **D** medicinal products require **professional advice** in advance (e.g. the consultation of a pharmacist) (*"Abgabe nach Fachberatung")* and category **E** medicinal products can be sold **over the counter** (e.g. in supermarkets). Category **C was abolished** on 1 January 2019.

The following persons are entitled to **dispense prescription-only** (categories A and B) **medicinal products** (art. 24 para. 1 TPA):

Pharmacists, on presentation of a **doctor's prescription**. They may **dispense medicinal products without a doctor's prescription** if they have direct contact with the person concerned, if they document the product dispensed, and if the medicinal products and indications have been designated by the Federal Council *(e.g. medicinal products for the continuation of a permanent medication)* **or** if the case is justified and exceptional.

All other **medical professionals** in accordance with the provisions on so-called **pro-pharmacy** *("Selbstdispensation")* and taking account of art. 1 para. 3 lit. c TPA.

All **duly trained professionals**, under the supervision of a person specified in lit. a) and b).

The following persons are entitled to **dispense non-prescription** (categories D and E) **medicinal products** (art. 25 para. 1 TPA):

a) **Persons** entitled to dispense prescription medicinal products.

b) **Druggists** holding a federal diploma.

c) All other **duly trained persons**, within the limits of their right to dispense medicinal products.

d) All **duly trained professionals**, under the supervision of persons referred to in lit. a) and b).

Any person dispensing medicinal products must have a **cantonal license** (art. 30 para. 1 TPA). The requirements are regulated in the cantonal health laws and ordinances.

Cantonal law also regulates the question of whether doctors are allowed to dispense medicinal products themselves *("Selbstdispensation")*. In **Basel-Stadt**, for example, only pharmacies are allowed to dispense medicinal products. To give another example, in **Zurich**, doctors are allowed to run a **"private pharmacy"** in their medical office, which means they can not only prescribe medicinal products, but also dispense them directly to their patients.

Dispensers are **never compensated in any way by manufacturers** if they prescribe or dispense a certain medicinal product (which would be highly illegal). This guarantees **absolute independence** in the choice of the medicinal product. Doctors *(if allowed to dispense)* and pharmacists are either **compensated directly by their patients** (after a consultation or treatment) or by the **patients' health insurance**. The health insurance reimburses the costs for medicinal products only if they are listed on the "specialty list" *(Spezialitätenliste)*.

These provisions do not apply to **medical devices**. For the protection of health, the Federal Council may, for certain medical devices: adopt provision that such medical devices can only be dispensed upon a medical prescription; lay down the necessary technical and operational conditions or a mandatory notification for their dispensing and use; attach to the dispensing of products the condition that the devices concerned must be traceable between their manufacture and their use and vice versa (art. 48 para. 1 TPA). Since the Swiss medical device law is currently undergoing a total revision and the draft of the new **Medical Devices Ordinance** is not yet final, no further details can be provided at the moment. However, the main elements of the new law are set out in **Chapter 7**.

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

The recognized **rules of pharmaceutical and medical sciences** must be respected when **prescribing**, dispensing and using medicinal products, and the principles of the corresponding therapy approach must be respected when prescribing, dispensing and using complementary medicines without indications. A medicinal product may only be prescribed if the state of **health of the consumer or patient is known** (art. 26 para. 1 and 2 TPA).

Failure to comply with this obligation may be penalised: Any person who wilfully dispenses medicinal products contrary to the due diligence requirements stipulated in art. 26 TPA shall be liable to a **custodial sentence** not exceeding three years or to a **monetary penalty** (art. 86 para. 1 lit. a TPA). It is important to emphasize that this provision applies regardless of whether a person has been endangered or injured or not. A custodial sentence not exceeding **ten years**, which may be combined with a monetary penalty, shall be imposed on any person who knows or must assume that the violation specifically **endangers human health** or achieves a high turnover or makes substantial profits through commercial activity (art. 86 para. 2 TPA).

It is therefore essential for a doctor or pharmacist to be aware of the patient's state of health before dispensing a medicinal product. To give one example, the **Swiss Association of Cantonal Pharmacists** *(Kantonsapothekervereinigung)* has issued a document **"Rules of Good Dispensing Practice for Therapeutic Products"** (cf. "*Regeln der Guten Abgabepraxis für Heilmittel*" *vom 14. September 2009, http://www.kantonsapotheker.ch [last visited on 31 March 2021]*) addressed primarily to pharmacists and doctors. In Switzerland, doctors and pharmacists are basically fully aware of these strict rules, which serve to protect the health of patients. It is widely accepted that many medicinal products cannot simply be bought "over the counter" like in other countries. The involvement of doctors and pharmacists in the course of dispensing helps to avoid **medication errors** and to actively **inform patients** about potential risks and side effects.

Art. 26 TPA also applies to **medical devices** (art. 48 para. 2 TPA). Since the Swiss medical device law is currently undergoing a total revision and the draft of the new **Medical Devices Ordinance** is not yet final, no further details can be provided at the moment. However, the main elements of the new law are set out in **Chapter 7**.

02

PRECLINICAL AND CLINICAL TRIAL REQUIREMENTS

16. Are clinical trials required to be conducted locally as a condition (stated or implicit) for marketing approval?

17. How are clinical trials funded?

18. What are the requirements for preclinical and clinical trial protocols? Who must approve the protocols?

19. What are the requirements for consent by participants in clinical trials?

20. May participants in clinical trials be compensated?

21. How are participants in clinical trials protected and indemnified against any harm that arises as a result of participation in the trial?

02 PRECLINICAL AND CLINICAL TRIAL REQUIREMENTS

16. Are clinical trials required to be conducted locally as a condition (stated or implicit) for marketing approval?

No, clinical trials do not have to be conducted locally as a condition for marketing approval.

17. How are clinical trials funded?

Clinical trials are funded by a sponsor. **Sponsor** means a person or institution headquartered or represented in Switzerland that takes responsibility for organising a clinical trial, and in particular for the initiation, management and **financing of the trial** in Switzerland (art. 2 lit. c **Clinical Trials Ordinance** [hereinafter: **ClinO**; *Verordnung über klinische Versuche in der Humanforschung vom 20. September 2013, KlinV; SR 810.305]*). The responsible ethics committee shall review the financing of the clinical trial and the agreements between the sponsor, third parties and the investigator concerning the allocation of tasks, remuneration and publication (art. 25 lit. i ClinO). Other organizations may also support a clinical trial financially. All sources have to be disclosed to the responsible ethics committee which has to approve the financing.

18. What are the requirements for preclinical and clinical trial protocols? Who must approve the protocols?

The ClinO differs between several categories of trials which are subject to different requirements. The application documents to be submitted to the responsible ethics committee for the procedure for clinical trials are listed in Annex 3 of the ClinO. The **Swiss Ethics Committees** offer on their website useful templates for all documents including protocols. Study protocols must include, for example, a declaration of interest, rules concerning the storage of biological material and health related data etc. (*cf. https://swissethics.ch/en/templates [last visited on 31 March 2021]*). Protocols must be approved by the responsible ethics committee.

19. What are the requirements for consent by participants in clinical trials?

Art. 16 **Human Research Act** (hereinafter: **HRA**; *Bundesgesetz über die Forschung am Menschen vom 30. September 2011; Humanforschungsgesetz, HFG; SR 810.30*) regulates the conditions for the so-called **"Informed Consent"**: Persons may only be involved in a research project if they have given their informed consent. **Consent must be given in writing**; the Federal Council may specify exemptions (para. 1).

The **persons concerned must receive comprehensible oral and written information** on: a) the nature, purpose and duration of, and procedure for, the research project; b) the foreseeable risks and burdens; c) the expected benefits of the research project, in particular for themselves or for other people; d) the measures taken to protect the personal data collected; e) their rights (para. 2).

Before a decision on consent is made by the persons concerned, they must be allowed an appropriate **period for reflection** (para. 3).

The Federal Council may specify further elements of the information to be provided (para. 4). These additional provisions are set out in the **ClinO**.

In addition to art. 16, there are two other provisions in the HRA: The first deals with **consent to further use for research** (art. 17) and the second with **incomplete information** (art. 18). These provisions are not further specified here.

The responsible ethics committee verifies the patient informed consent as part of the authorization procedure, in one of the official languages German, French or Italian. The sponsor or the project lead is responsible for the accurate translation.

The Swiss Ethics Committees offer on their website useful templates for patient informed consent, *cf. https://swissethics.ch/en/templates (last visited on 31 March 2021).*

20. May participants in clinical trials be compensated?

Art. 14 HRA regulates the non-remunerative participation and distinguishes between two types of research projects (para. 1): **No person** may receive payment or any other non-cash advantage for participation in a **research project with an expected direct benefit**. This means a research project whose **results can be expected to improve the health of the participants** (art. 3 lit. d HRA). **On the other hand**, participation in a **research project with no expected direct benefit** may be appropriately remunerated.

The law does not further specify what "appropriately remunerated" means. However, the responsible **ethics committee** shall review the protocol with regard to the appropriateness of the remuneration for participants (art. 25 lit. d sec. 7 ClinO).

Furthermore, no person may demand or accept payment or any other non-cash advantage from another in return for the latter's participation in a research project (para. 2).

21. How are participants in clinical trials protected and indemnified against any harm that arises as a result of participation in the trial?

The HRA contains special provisions for **liability and coverage**. Art. 19 regulates the liability: Any person who carries out a research project involving persons shall be liable for damage suffered by them in connection with the project. The Federal Council may specify exemptions from liability (para. 1). Compensation claims become time-barred three years after the injured party has become aware of the damage and of the liable party, but no later than ten years after the completion of the research project. The Federal Council may specify a longer limitation period for particular research areas (para. 2). The provisions of the Code of Obligations on tort are otherwise applicable; in the exercise of official duties, the Government Liability Act, or cantonal government liability law, is applicable (para. 3).

According to art. 20, which regulates the **coverage**, liability must be appropriately covered through insurance or in some other manner. The Federal Government and its public-law institutions and corporations are exempt from the liability coverage requirements (para. 1). The Federal Council may specify further elements (para. 2 and 3).

03

MARKETING, MANUFACTURING, PACKAGING & LABELING, ADVERTISING

22. What is the authorization process for the marketing of new drugs, biologics, medical devices, over-the-counter medications, and other medicinal products?

23. What is the authorization process for the marketing of generic versions of these products?

24. What are the typical fees for marketing approval?

25. What is the period of authorization and the renewal process?

26. What are the requirements, if any, for post-approval pharmacovigilance?

27. Are foreign marketing authorizations recognized?

28. Is parallel import of medicines or devices allowed?

29. What are the restrictions on marketing practices such as gifts, sponsorships, consultancy agreements, travel and entertainment, or other incentives for healthcare organizations and individual medical practitioners?

30. How is the manufacturing of medicines and devices regulated and by which agencies?

31. Are local manufacturing requirements compatible with Good Manufacturing Practices (GMPs) as defined by the US Food & Drug Administration (US FDA) and/or the European Medicines Agency (EMA)?

32. What is the inspection regime for manufacturing facilities?

33. Are manufacturing facilities open for inspection by foreign inspectors or third-party inspectors as authorized by the FDA/EMA?

34. What are the requirements for storage, packaging, and handling of medicines and devices and their constituent components?

35. What information must be included in medicine and device labeling?

36. What additional information may be included in labeling and packaging?

37. What items may not be included in labeling and packaging?

38. What are the restrictions and requirements for the marketing and advertising of medicines and devices?

39. Where can medicines and devices be sold or delivered? Can medicines and devices be sold or delivered via post?

40. What are the restrictions and requirements for electronic marketing and advertising via email, by internet, social media, and other channels?

41. May medicines and devices be advertised or sold directly to consumers?

42. How is compliance monitored?

43. What are the potential penalties for noncompliance?

03 MARKETING, MANUFACTURING, PACKAGING AND LABELING, ADVERTISING

22. What is the authorization process for the marketing of new drugs, biologics, medical devices, over-the-counter medications, and other medicinal products?

Medicinal products

According to the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act; TPA) medicinal products are considered as products of chemical or biological origin which are intended to have and are presented as having a medicinal effect on the human or animal organism. The distribution of medicinal products in Switzerland requires a market authorisation by the competent authority, irrespective of whether the medicinal product requires a prescription or can be sold over the counter. The competent authority for granting such marketing authorisation is the Swiss Agency for Therapeutical Products (Swissmedic). Swissmedic assesses whether the conditions for granting marketing authorisation, i.e. high quality, safety and efficacy of the medicinal product, are fulfilled. Companies or persons applying for a marketing authorisation must have their domicile, registered office or a branch office in Switzerland. Marketing authorisation is granted through the ordinary, the fast-track or the simplified procedure (see for details below). Moreover, certain medicinal products may be placed on the market following a notification to Swissmedic (e.g. homeopathic and anthroposophical products). Lastly, medicinal products for life-threatening or debilitating diseases may be granted a temporary marketing authorisation by way of a simplified procedure under certain circumstances.

Ordinary procedure

The ordinary procedure is initiated with the submission of the required information and documents to Swissmedic. The required documents are listed in the Ordinance on the Requirements for Marketing Authorisation of Medicinal Products and relating guidelines. In particular, Swissmedic provides a "Directory Overview of documents to be submitted". In correspondence with the conditions for granting marketing authorisation, the complete documentation must prove the high quality, safety and efficacy of the medicinal product. Swissmedic requires using standard forms and the common technical document format (CTD) of the International Conference on Harmonisation for the application. In the interest of an efficient processing, Swissmedic recommends submitting data electronically.

The ordinary procedure takes at least one year. Swissmedic issued a guideline, in which it describes the timetable for authorisation procedures and the time limits targeted by Swissmedic in connection with submitted authorisation applications. For the ordinary procedure such targeted time limits are 30 days for the formal control, 120 days for the first evaluation phase and establishment of the list of questions, 90 days for the second evaluation process and preliminary decision and 90 days for the decision. These

time limits are only considered as guidelines. If Swissmedic requires further information or documents the authorisation process can be prolonged.

Fast-track procedures

Upon request of the applicant, a fast-track procedure is available provided that the following conditions are cumulatively met: (i) the medicinal product promises prevention against, or treatment for, a severe, disabling or life-threatening disease; (ii) treatment using currently authorised medicinal products is either unavailable or unsatisfactory and (iii) the new medicinal product is expected to be of high therapeutic value. Application for a fast-track procedure must be made at least three months before the application for the marketing authorisation in order to allow Swissmedic to approve the procedure and to plan resources in advance. This procedure enables to obtain marketing authorisation within four to five months after the submission of the application for the marketing authorisation.

Similar to the fast-track procedure, Swissmedic offers a procedure with prior notification. This procedure is available upon request of the applicant and for medicinal products containing a new active substance, medicinal products with a known active substance that cannot be authorised via the simplified procedure or for an additional indication. It enables to obtain marketing authorisation within a timeframe that is 20% shorter than the ordinary procedure. However, the applicant must accept a substantive increase of the fees.

Simplified procedure

A simplified procedure is available for certain categories of medicinal products such as medicinal products with active substances that have already been authorised, medicinal products from a country with an equivalent marketing authorisation system and complimentary medicines. The procedure is governed by the Ordinance on the Simplified Marketing Authorisation of Medicinal Products and Authorisation by Way of Notification and the corresponding guidelines of Swissmedic.

Medical Devices

The distribution of medical device, including diagnostics, in Switzerland requires the respective manufacturer or importer to complete the applicable conformity assessment procedure. This also applies to medical devices that are provided for free, rented or used directly on patients. Mandatory notification obligations apply for manufacturers and importers from a non-treaty country (Switzerland has concluded treaties with EU Member States, EFTA States and Turkey) and for devitalised human tissue.

23. What is the authorization process for the marketing of generic versions of these products?

Generic versions of medicinal products require a separate and independent market authorisation as the market authorisation is personal and refers to a specific product. For the marketing authorisation of generic products, the simplified authorisation procedure is available. The application may refer to

the pharmacological, toxicological and clinical tests of one or more reference products that are currently or previously authorised by Swissmedic provided that the applicant for the original medicinal product issues a written permission or the protection period of the original product has expired. This protection period is typically granted for the documents relating to an original medicinal product containing at least one new active substance and lasts 10 years. It must be distinguished from the protection derived from a patent.

24. What are the typical fees for marketing approval?

The fees for marketing approval depend on the applicable authorisation procedure and are governed by the Ordinance on Fees levied by the Swiss Agency for Therapeutic Products. In general, the following fees apply:

- Fees for authorisation of medicinal products with a new active substance: CHF 80'000 for the ordinary authorisation procedure or CHF 120'000 (plus CHF 5'000 for the request) if the fast-track authorisation procedure is used.
- Fees for authorisation of medicinal products with an existing and authorised active substance: CHF 15'000-30'000 depending on whether the product is with or without innovation.
- Fees for renewing an existing authorisation: CHF 500.

25. What is the period of authorization and the renewal process?

The first marketing authorisation is valid for a period of five years and can be renewed if the conditions for authorisation are still fulfilled. Applications for renewal of authorisation can be submitted at earliest one year and no later than six months before the authorisation expires. The renewed authorisation is generally valid for an unlimited time period. However, Swissmedic may limit the validity on a case-by-case basis. Moreover, Swissmedic may review the authorisation at any time and adapt to changing circumstances or revoke the authorisation.

26. What are the requirements, if any, for post-approval pharmacovigilance?

Holders of marketing authorisation must establish a pharmacovigilance system and have various notification and reporting obligations to Swissmedic. In particular, holders of marketing authorisation for a medicinal product with a new active substance must submit a periodic safety update report in the following four years after the authorisation.

With regard to medical devices, a company distributing medical devices in Switzerland must introduce and maintain a post-market surveillance system for the collection and analysis of the experiences with the medical devices.

27. Are foreign marketing authorizations recognized?

There is no automatic recognition of foreign marketing authorisations. If a medicinal product has already been authorised in a country with a comparable control system for medicinal products, Swissmedic will, upon request of the applicant, take into account the results of the assessments performed by the foreign authority during the authorisation procedure. The following

countries are recognised by Swissmedic as having comparable control systems for medicinal products: Australia, EU, EEA and EFTA Member States, Japan, Canada, New Zealand, Singapore, USA.

28. Are parallel imports of medicines or devices allowed?

Parallel imports of medicinal products or medical devices into Switzerland cannot be restricted under trademark law as for such parallel imports the principle of international exhaustion applies. With regard to patent law, the principle of regional exhaustion applies in Switzerland, i.e. a product placed in an EEA state by the patent owner can be imported into Switzerland from the EEA without consent of the patent owner. However, for medicines the principle of national exhaustion still applies, if the price of the concerned medicinal product is determined by public authorities in Switzerland or the country of origin. In this case, the consent of the patent owner is required for the parallel import of the product into Switzerland.

Parallel imports of medicinal products must obtain a marketing authorisation, for which the simplified procedure is available. Swissmedic does not consider possible patent claims in the authorisation procedure. Patent owners have to submit such claims to the civil courts.

29. What are the restrictions on marketing practices such as gifts, sponsorships, consultancy agreements, travel and entertainment, or other incentives for healthcare organizations and individual medical practitioners?

The TPA has been revised with regard to incentives for healthcare organisations and individual medical practitioners and the new provisions entered into force on 1 January 2020. Together with the revised TPA the Ordinance on Integrity and Transparency in the Context of Therapeutic Products entered into force governing financial incentives in connection with medicinal products in detail.

As under the previous law, it is prohibited to offer, request, grant or accept undue financial benefits in connection with prescription-only medicinal products. However, the following benefits are not considered as undue financial benefits and thus, as an exception, are permissible:

- Benefits of modest value and related to the medical practice. According to the Ordinance, a benefit is considered to be of modest value if the total value does not exceed CHF 300 per year and per person.
- Support contributions for research, further education and training, provided that certain criteria are met. The relevant criteria can be found in the Ordinance.
- Compensation for equivalent considerations, in particular for such services in connection with orders and deliveries of therapeutic products.

Price discounts or rebates granted on the purchase of therapeutic products provided that they have no influence on the choice of treatment.

Moreover, healthcare service providers must pass on price discounts and refunds granted to them to the patient and/or insurer. Lastly, criminal provisions with regard to bribery as well as the Federal Act against Unfair Competition may also apply.

30. How is the manufacturing of medicines and devices regulated and by which agencies?

The manufacturing of medicinal products requires an establishment licence. The requirements for such a licence are set out in detail in the Ordinance on Authorisations in the Field of Medicinal Products. Swissmedic issues this licence if the requirements are fulfilled and on the basis of a successful inspection. The establishment licence is limited to a specific field of activity, i.e. a licence for manufacturing does not automatically cover activities of import, export, trade etc. For such activities an additional authorisation is required.

With regard to medical devices no licences are required for the manufacturing of such products. Switzerland follows the EU system of compliance assessment and certification based on bilateral agreements (see for the bilateral agreements question 22).

31. Are local manufacturing requirements compatible with Good Manufacturing Practices (GMPs) as defined by the US Food & Drug Administration (US FDA) and/or the European Medicines Agency (EMA)?

Establishment licence holders, who manufacture medicinal products, must comply with the rules of Good Manufacturing Practices (GMP). Switzerland follows the EU GMP as set out in Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of Good Manufacturing Practice in respect of medicinal products for human use and investigational medicinal products for human use.

32. What is the inspection regime for manufacturing facilities?

Swissmedic inspects the manufacturing facilities on a periodically basis in order to review the fulfilment of all requirements for retaining the licence. The inspection interval depends on the type of activity. In addition, Swissmedic may order inspections at any time.

33. Are manufacturing facilities open for inspection by foreign inspectors or third-party inspectors as authorized by the FDA/EMA?

Upon prior notification to Swissmedic, foreign authorities are entitled to inspect establishments in Switzerland, which operate in the therapeutic sector, provided that:

- the inspection has the sole purpose of verifying compliance with the regulations on therapeutic products;
- the result of the inspection is used solely in administrative proceedings in connection with the enforcement of regulations on therapeutic products;
- the concerned establishment consents to the inspection; and
- the foreign authority informs Swissmedic of the result by providing it with the inspection report in an official Swiss language or in English. A copy of the report shall be delivered to Swissmedic within 10 days after issuing the report by the foreign authority.

The notification must be submitted to Swissmedic at latest 30 days prior to the planned beginning of the inspection. Swissmedic may accompany the foreign authority during the inspection.

34. What are the requirements for storage, packaging, and handling of medicines and devices and their constituent components?

The competence to regulate and monitor wholesale and retail trade is divided between the Federal Government and the Cantons. For wholesale trade the Federal Government follows the Good Distribution Practice (GDP) of the EU, which describes the minimum standard that a wholesale distributor must meet to ensure that the quality and integrity of medicines is maintained throughout the supply chain (this includes storage, packaging and handling). With regard to retail trade each canton is responsible to regulate the storage, packaging and handling of medicines.

35. What information must be included in medicine and device labeling?

The labelling of medicinal products is governed by the Ordinance on the Requirements for Marketing Authorisation of Medicinal Products and the corresponding guideline of Swissmedic. The following information must be included, amongst others, in the packaging of medicines intended for the patient:

- Name of the medicinal product, if necessary, stating the dosage and galenic form.
- Composition of the medicinal product.
- Marketing authorisation holder.
- Batch number.
- Essential medical instructions for using the product.
- Expiry date.
- Storage instructions.
- Marketing authorisation number.
- Child warning notice as well as note to read the package leaflet.

Swissmedic may grant exceptions for certain information, if, for technical reasons, it is not possible to include all the required information on the packaging. Such Exceptions are available for the information regarding the composition of the medicinal product, the marketing authorisation holder, the medical instructions, the storage instructions, the marketing authorisation number and the child warning notice.

For the labelling on packaging of medical devices, Swiss law refers to EU law, in particular to Directive 93/42/EEC concerning medical devices, which defines the minimum content required.

36. What additional information may be included in labeling and packaging?

In principle, information and texts on the packaging of medicinal products are restricted to the legally required information (see question 35). Other information, texts or illustrations are only permitted, if a direct connection with the use of the medicinal product can be established, the inclusion of such information is important for providing health information and the information is not misleading.

37. What items may not be included in labeling and packaging?

As stated in the previous question, information on packaging of medicinal products is, in principle, limited to the legally required information. Other information may be included under certain conditions. As a consequence, medicinal products advertising on the packaging is not permitted. Moreover, the appearance of a medicinal product should not lead to any trivialisation or confusion with a consumer product such as food or drink. Lastly, some specific information may not be included in labelling and packaging such as constituents that are not contained in the medicinal product.

38. What are the restrictions and requirements for the marketing and advertising of medicines and devices?

Promotion and advertising of medicinal products and medical devices is governed by the TPA, the Ordinance on the Advertisement of Medicinal Products as well as the Medical Devices Ordinance. In addition, the Federal Act against Unfair Competition applies as well.

In general, advertisement of medicinal products and medical devices must not:

- be misleading, 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.

Advertising aimed at healthcare professional is allowed for any medicinal product authorised for marketing in Switzerland. Such advertisement has to be recognisable as advertisement and separated from editorial contributions. In addition, advertisement is only allowed for the authorised indications and use of the medicinal product. Advertising aimed at healthcare professionals is also allowed for any medical devices. Any misleading statements concerning the medical devices' efficacy and performance are prohibited.

Advertising aimed at the general public is restricted with regard to both medicinal products and medical devices. Public advertising for medicinal products is only allowed for over-the-counter products. In contrast, no public advertising is allowed for:

- Prescription-only medicinal products.
- Medicinal products containing narcotic or psychotropic substances.
- Medicinal products that may not be used without the intervention of a doctor for the necessary diagnosis, prescription or treatment.
- Pharmaceuticals that are frequently misused or are likely to lead to addiction or dependence.
- Medicinal products with a recommended dosage of more than 0.5g of pure alcohol with regard to advertising in radio and television.

Public advertising for medical devices is prohibited for medical devices that:

- may be dispensed on medical prescription only;
- are placed on the market for exclusive use by professionals.

Advertising in print and electronic media as well as on radio, television and cinema have to be submitted to Swissmedic for approval prior to publication if the following two conditions are met:

- the medicinal product concerned belongs the group of analgesics, sleep-inducing medication, sedatives, laxatives, and anorectics (appetite suppressants);
- the medicinal product concerned has a potential for misuse or addiction according to the product information.

39. Where can medicines and devices be sold or delivered? Can medicines and devices be sold or delivered via post?

Medicinal products are differentiated between two categories of drugs: prescription-only and over-the-counter medicinal products. These two categories are further divided into four sub-categories (categories A, B, D and E). Swissmedic classifies the products during the authorisation process.

In principle, medicinal products can only be sold by a person or institution, which holds a license to dispense such products. Depending on the category of the concerned medicinal product, some professionals may dispense the product and some not. Pharmacists are allowed to dispense subscription-only medicinal products on doctor's prescription. They may dispense such products without a doctor's prescription, if they have direct contact with the person concerned and document the product dispensed and if either the medicinal product and indication has been designated by the Federal council or the case at hand is exceptional and the dispense can be justified. Over-the-counter medicinal products may be sold by druggists as well.

The LTP prohibits, in principle, mail order delivery of medicinal products. This applies to all form of orders, which are made from distance (i.e. e-mail, internet or in writing). However, the cantons my grant on an exceptional basis authorisations to operate a mail delivery service of medicinal products. In order to obtain such authorisation, the following conditions must be fulfilled:

- the applicant must own a cantonal retailing license;
- the applicant must have a quality assurance system in place, which ensures amongst others the identification of the patient, a check of adverse interactions with other medicinal products and proper advice to patients;
- the patient provides a doctor's prescription for the concerned medicinal product;
- a sufficient medical supervision by a doctor is ensured.

The dispensing of medical devices is regulated according to their intended purpose and to the information provided by the first mover on the Swiss market. Hence, a mail delivery service for medical devices is not in principle prohibited. A prescription for medical devices is only necessary if the device concerned could endanger human health even when used correctly or it contains medicinal products for which a prescription is mandatory. Such medical devices may only be dispensed if the sales point can guarantee that professional advice is available, which limits the possibility to introduction of a mail service delivery.

40. What are the restrictions and requirements for electronic marketing and advertising via email, by internet, social media, and other channels?

As described in question 38, certain restrictions apply with regard to advertising on radio, television and cinema. For advertising on the internet, Swissmedic has issued specific guidelines, which clarify certain aspects of such advertising (e.g. use of domain names, hyperlinks and sufficient distinction between promotional and informative aspects). Access to advertising for prescription-only medicinal products, which may only target healthcare professionals, must be limited using a password protection.

41. May medicines and devices be advertised or sold directly to consumers?

With regard to advertising, please refer to question 38. With regard to sale, please refer to question 39.

42. How is compliance monitored?

Swissmedic and the cantons are entrusted with the implementation of the TPA and monitor whether the manufacture, distribution, dispensing and presentation of medicines and devices are in accordance with the law. The specific monitoring competences of Swissmedic and the cantons are outlined in the TPA. Monitoring is carried out by periodic inspections of the authorisation holders and notification obligations as well as notification rights.

43. What are the potential penalties for noncompliance?

In general, Swissmedic and the competent cantonal authorities can take all administrative measures necessary to enforce the TPA. Administrative measures of the competent authorities are subject to the principles of proportionality and public interest. The TPA lists possible measures. In particular, the competent authorities are allowed to:

- Raise objections and set an appropriate time period for restoring the state of law.
- Suspend or revoke licences and marketing authorisations.
- Close down establishments.
- Prohibit the distribution, dispensing, import, export and foreign trade from Switzerland of therapeutic products, order their immediate recall from the market, or order the publication of recommendations of conduct to prevent damage.

Moreover, the competent authorities may also impose criminal sanctions, i.e. custodial sentence up to three years or fines up to CHF 50'000.

04

TRADITIONAL MEDICINES AND OVER-THE-COUNTER PRODUCTS

44. What are the regulatory requirements for traditional, herbal, complementary, or alternative medicines and devices?

45. Can these traditional, herbal, complementary, or alternative products be advertised directly to the public?

46. What health, advertising, and marketing claims may be made for traditional, herbal, complementary, or alternative products?

47. What are the regulatory requirements for over-the-counter (non-prescription) medications?

48. Are there any limitations on locations or channels through which OTC products may be sold?

49. What health, advertising, and marketing claims may be made for OTC products?

50. Can OTC products be marketed or advertised directly to the public?

51. What is the mechanism by which a prescription-only product can be converted to an OTC product?

52. What are the requirements for the importation of either traditional medicines or OTC products?

04 TRADICTIONAL MEDICINES AND OVER-THE-COUNTER PRODUCTS

44. What are the regulatory requirements for traditional, herbal, complementary, or alternative medicines and devices?

The distribution of alternative medicinal products such as traditional, herbal or complementary medicines requires a marketing authorisation. Such authorisation is always required for medicinal products, irrespective of whether it concerns prescription-only or over-the-counter products. Marketing authorisation for complementary and herbal medicines as well as other alternative medicines is governed by the TPA and the Ordinance on Simplified Marketing Authorisation of Complementary and Herbal Medicinal Products. In general, complementary and herbal medicines benefit from the simplified procedure as described in chapter 3 or an authorisation by way of notification. The choice of the right authorisation procedure depends on the composition of the medicinal product concerned and its intended use. Swissmedic provides guidelines, which assist in identifying the right procedure. The same applies to Asian medicinal products, for which Swissmedic also issued specific guidelines.

The TPA allows for certain medicinal product to be authorised by way of notification. This authorisation procedure is open for:

- complementary medicines without indications and with their active substances listed for specific therapy approaches.
- other medicinal products with a low risk potential, for which a simplified marketing authorisation would be disproportionate. In particular, individual teas, cough and throat lozenges and pastilles can be authorised in connection with a notification.

The regulation of medical devices in Switzerland follows the compliance assessment and certification based on bilateral agreements. Manufacturer and importer have to complete the applicable conformity assessment procedure before distributing the devices in the Swiss market.

45. Can these traditional, herbal, complementary, or alternative products be advertised directly to the public?

Swiss law classifies medicinal products into two categories, i.e. prescription-only and over-the-counter products. Accordingly, the applicable advertising regulation depends on whether a complementary medicinal product requires a prescription or not. For prescription-only medicinal products advertising aimed at the general public is prohibited, whereas advertising for over-the-counter medicines is permitted. Irrespective of the category, the advertisement is not permitted for:

- medicinal products containing narcotic or psychotropic substances.
- medicinal products that may not be used without the intervention of a doctor for the necessary diagnosis, prescription or treatment.

- pharmaceuticals that are frequently misused or are likely to lead to addiction or dependence.

46. What health, advertising, and marketing claims may be made for traditional, herbal, complementary, or alternative products?

Advertising of complementary medicines aimed at healthcare professionals must be based on scientifically recognised specialist media or recognised monographs of complementary medicine. Advertising statements in this regard must contain a reference to the respective therapy direction.

For advertising aimed at the general public, the Ordinance on the Advertisement of Medicinal Products outlines, which claims may be made in connection with a certain medicinal product. These requirements are applicable to all medicinal products for which public advertising is permissible. The Ordinance requires all information in the public advertising to be in accordance with the product information approved by Swissmedic. In particular, only indications or possible applications approved by Swissmedic may be advertised. For medicinal products without package leaflets, the approved text on the packaging applies. The latter applies in particular to medicinal products that are authorised without specific indication or possible application. In this case, the approved text on the packaging limits at the same time the scope of the advertisement. It is prohibited to circumvent this restriction by enclosing flyers, brochures etc. which inform about possible applications.

47. What are the regulatory requirements for over-the-counter (non-prescription) medications?

The distribution of over-the-counter medicinal products requires a marketing authorisation from Swissmedic. The applicable procedure depends on the composition of the concerned product. Compared to prescription-only products, over-the-counter products are subject to different regulations with regard to advertising (please refer to question 46) and dispensation (please refer to question 48).

48. Are there any limitations on locations or channels through which OTC products may be sold?

The following persons are entitled to distribute over-the-counter products:

- Everyone that is entitled to distribute prescription-only products, i.e. pharmacists and doctors.
- Druggist holding a federal diploma.
- All duly trained professionals within the limits of their right to dispense medicinal products provided that they are supervised either by a pharmacist, a doctor or a druggist. Persons, who hold an education in complementary medicine that is recognised by the Federal Government, may distribute certain over-the-counter products.

As described in chapter 3, the LTP prohibits, in principle, mail order delivery of medicinal products. This applies to all form of orders, which are made from distance (i.e. e-mail, internet or in writing). However, the cantons my grant on an exceptional basis authorisations to operate a mail delivery service of medicinal products.

49. What health, advertising, and marketing claims may be made for OTC products?

Please refer to question 46.

50. Can OTC products be marketed or advertised directly to the public?

Please refer to question 45.

51. What is the mechanism by which a prescription-only product can be converted to an OTC product?

Medicinal products are categorised into the four categories A, B, D and E with A and B encompassing prescription-only products and D and E encompassing over-the-counter products. Swissmedic categorises the medicinal products during the authorisation process and reviews the categorisation periodically. The holder of the marketing authorisation can request a conversion of the categorisation. The procedure is governed by the Ordinance on Medicinal Products and the corresponding guidelines of Swissmedic. Request for conversion of the categorisation based on adaptions of the medicinal product must be notified in advance to Swissmedic in order to seek approval from Swissmedic.

52. What are the requirements for the importation of either traditional medicines or OTC products?

The importation of traditional medicines or over-the-counter products follows the general regulation for importation of medicinal products. Importation of medicinal products requires an import licence granted by Swissmedic. Medicinal products may be imported into Switzerland if a marketing authorisation has been obtained for such products. Imports of non-authorised medicinal products will be blocked by the Custom authorities. The Federal Council may permit the importing of non-authorised medicinal products if they have been prescribed by a health care professional and are imported in small quantities for private use. It may also allow the importing of small quantities of medicinal products for which no alternative and equivalent medicinal product has been authorised to be imported.

05

PRODUCT LIABILITY

53. What types of liability are recognized in your jurisdiction?

54. How do these types of liabilities apply to the manufacturers of medicines and devices?

55. Does potential liability extend to the manufacturer only or could claims extend to corporate executives, employees, and representatives?

56. How can a liability claim be brought?

57. What defenses are available?

05 PRODUCT LIABILITY

53. What types of liability are recognized in your jurisdiction?

Swiss law generally distinguishes between two types of liability: contractual and non-contractual. Contractual liability is governed by the section about **breach of contract** in the Swiss Code of Obligations (CO; Art. 97 et seqq.).

Non-contractual liability is regulated on the one hand by the **general tort law** provisions of the CO (Art. 41 et seqq.) and on the other hand by provisions of special legislation.

In this latter regard, the most important special legislation to mention is the Swiss **product liability law** (PLL) which was enacted in 1993, based on the European Council Directive 85/374/EEC of 25 June 1985. This Swiss act sets out a liability for products which have caused **physical injury to the body or the property** of a person.

Generally, the liability extends to the **compensation for the damage occurred**. Additionally, according to the general tort law provisions, the aggrieved party is entitled to **compensation for personal suffering**. According to the prevailing opinion, such compensation could be claimed under the product liability law as well. However, the sums which Swiss courts award under this heading are insignificant.

Liability for **bodily injury cannot be (contractually) excluded** beforehand. This rule is explicitly mentioned in the product liability law (Art. 8 PLL), but it is recognized as well for the other two legal grounds for liability, the contractual one and the one under general tort law.

The **prerequisites** under which liability is established differ from one type to another:

1. The contractual liability requires a **contractual relationship** between the party at fault and the injured party. In case of a **sales contract**, the seller will be automatically liable (**strict liability**) for any **direct damage** which the delivery of the defect product has caused (Art. 208 para 2 CO). For any further, i.e. **indirect damage**, the seller will be liable only if he can be held culpable (**fault-based liability**) for the defect of the product (Art. 208 para 3 CO). The delineation between direct and indirect damage has always been and remains very delicate. In its newer case law, the Swiss Federal Court has at least clarified that the fact alone that a damage only occurred when a product had been used according to the normal or agreed usage, does not render the damage an indirect one (Swiss Federal Court decision 133 II 257).

2. The **tort-based** liability requires first of all that the action of the tortfeasor which caused the damage was unlawful. However, when a bodily harm or damage to physical property occurred, unlawfulness is automatically assumed. The second prerequisite is that the tortfeasor's behavior was

culpable (**fault-based liability**). Culpable behavior means that the tortfeasor acted (at least) **negligently**, that is, in defiance of his general duty of care.

3. Under the **product liability law,** the **manufacturer** of a **defect product** is liable for the **injury or dead of a person** or for the damage or destruction of personally used property which this product has caused (Art. 1 PLL). Once the above requirements are fulfilled, the liability is triggered automatically and does not depend on any fault of the manufacturer (**strict liability**). (For the specific requirements of the product liability law, see question 54; for the potential defenses available under this law, see question no. 57.)

54. How do these types of liabilities apply to the manufacturers of medicines and devices?

If a medicine or a medical device has caused harm, the liability has to be examined under the three legal bases for liability introduced in question 53 above. In theory, these **three legal grounds** for liability **coexist**, that is, a three-fold liability could be established in one single case.

However, in cases in which a pharmaceutical product has caused physical harm to an end user (patient), both **contractual liability and liability based on general tort** law will **hardly** ever be **relevant** in the relationship between the manufacturer of the pharmaceutics and the patient: Contractual liability requires the existence of a contractual relationship, which is regularly not present, as pharmaceutical products are usually not sold from the manufacturer directly to the patient. Likewise, it will be difficult to prove a manufacturer's culpable behavior, which would be necessary to hold him liable under general tort law.

On the other hand, the liability under the product liability law is "broader" as it does not require either of these two prerequisites (contract or fault). Therefore, in cases in which the **product liability law** is applicable, an examination of the other legal grounds for liability is usually redundant. For this reason, the rest of this chapter will now focus on the product liability law and disregard the contractual and the tort law liability.

Unlike certain other jurisdictions, Switzerland has (with few exceptions, e.g. during the stage of clinical trials, see in this regard chapter 2 question 21) **not enacted any special legislation with regard to product liability for medicines and medical devices**. Therefore, the liability for therapeutics will be examined under the general provisions of the product liability law.

The **specific requirements** of this law are as follows:

The **bodily damage** has to be brought about by a **defect product**. According to the legal definition of the law, the notion "**product**" is very broad. It encompasses every movable or part of a movable (Art. 3 PLL). Due to this wide application, nearly all medicine, even such that for example contain nano-materials or nano-particles, as well as all medical devices, will qualify as products within the meaning of the law.

Naturally, the core of every product liability is the notion of the **defectiveness** of the product - and at the same time the definition of this term is the most delicate one. Under the Swiss product liability law, a product is defect,

if it does **not provide for the security which one can legitimately expect (from it) in consideration of all circumstances** (Art. 4 para 1 PLL).

In order for the definition to be as **comprehensive** as possible, the law ties in with the **legitimate security expectations** of the product and does not consider the type of the product or the type the defect. Nevertheless, the legal doctrine and courts often use the following three categories in order to classify the defect in a given case: the defect can typically be either in **construction**, in **fabrication** or in **instruction**.

These categories are also used when categorizing the defect in a pharmaceutical product. For example, the manufacturer of a pharmaceutical has to **inform** about its risks and side effects. Insufficient information can be a defect in instruction.

With the comprehensiveness of the definition comes along its **vagueness**. For example is it not completely clear **whose** legitimate security expectations have to be satisfied. The law speaks only of the security "one" can expect. The prevailing opinion is that the benchmark is the **public at large**, which includes a **third person** who is not necessarily the end user of the product.

With regard to **medicines which are only available on prescription**, the Swiss Federal Court has a few years ago adopted in a controversial decision the American "learned intermediary doctrine" (Swiss Federal Court decisions 4A_365/2014 and 4A_371/2014). According to this decision, medicines which are only available on prescription have to meet the **expectations of the physician** and not the ones of the patient. Therefore, when determining whether or not the hazard note of the manufacturer was complete enough, the decisive factor is the information which the manufacturer provides to the physician (the learned intermediary), rather than the package insert of the medicine which is available to the patient.

When **determining** the legitimate security expectation, the law stipulates that one has to account for **all circumstances**. The statute enumerates - not conclusively - certain circumstances which particularly have to be considered (Art. 4 para 1 PLL):

a) The way in which the product was introduced to the public;
b) The usage with which one can reasonably expect;
c) The point in time at which it was put on the market.

When applying the "legitimate security expectations"-test to **therapeutic products**, several points have to be emphasized:

Firstly, it has to be remembered that therapeutic products are - per definition - not flawless as **side effects** can never be entirely precluded. Therefore, the legitimate security expectations of therapeutic products are **never absolute**. Rather, such security expectations are reduced from the outset and they have to be put in relation to the **severity of the medical condition** for which the product is used and to the **chances of recovery it promises**.

Secondly, the fact that therapeutic products may contain side effects and the security expectations one has on them is reflected in the **procedure by which they are put on the market**: To be sure, in Switzerland medicines

and medical devices undergo a rigid authorization procedure and conformity assessment, respectively, before being put on the market. However, these tests base on a **risk-benefit ratio** and not on absolute certainty or safety. Generally, if this ratio is positive (i.e. the benefits outweighs the risk), the authorization or the conformity will be granted.

According to the case law of the Swiss Federal Court, the fact that a medicine was authorized to be placed on the market provides not more than a mere **indication** that it is fulfils the security expectations which are placed in it. However, its **market authorization does not preclude the existence of a defect** in the product (Swiss Federal Court decisions 4A_365/2014 and 4A_371/2014).

On the other hand, it has to be considered that some defects cannot be discovered in clinical tests with a limited number of study participants and they will only appear once the product is released on the market. If, however, in such a situation, the defect can be qualified as a development risk, the manufacturer will be released from liability (see below question 57).

Thirdly, medicine products can at best reflect the latest state of scientific knowledge and nothing more advanced can be reasonably expected. Certainly, this is true for any product and thus the statute itself clarifies in a general manner that a product shall not be deemed defective only because a better product was put on the market later (Art. 4 para 2 PLL).

If the defectiveness of a product is established (and provided that no defense is available, see question 57), the liability hits the **manufacturer**. According to the definition of the law, manufacturer is the person who has produced the end product as well as the persons(s) which have produced any part of it (Art. 2 para 1 a. PLL). Moreover, any person who impersonates the manufacturer by putting his own name or brand on the product as well as the importer are regarded as manufacturer under the law and are hence liable (Art. 2 para 1 b. and c. PLL).

55. Does potential liability extend to the manufacturer only or could claims extend to corporate executives, employees, and representatives?

According to the product liability law, the liability extends to the manufacturer only (for the persons who fall under this definition, see above question 54). A **personal liability** of the corporate executives, employees and representatives is **excluded**.

Under tort law, a liability of the corporate executives, employees and representatives is theoretically conceivable, though. Such personal liability, however, could only occur if a culpable conduct of the person involved could be established. This will only very rarely be the case.

56. How can a liability claim be brought?

Swiss law knows **no special procedural rules** for liability claims, rather the general procedural rules, especially the Swiss Civil Procedure Code (CPC), will apply for these types of claims. Therefore, a liability claim for therapeutic products, regardless of whether the liability is based on contract law, general

tort law or specific product liability, has to be brought against the liable party in a **normal civil claim**.

The aggrieved party can choose out of **four places of jurisdiction**: At his own domicile, at the seat of the injuring party (the manufacturer), at the place where the damaging act occurred or where it had its effect (Art. 36 CPC).

The claimant has to **prove** all the prerequisites of his claim. Under the product liability law, he has particularly to prove the defectiveness of the product. The fact that in practice this prove is often hard to show, doesn't result in a reversal of evidence to the disadvantage of the manufacturer (Swiss Federal Court decision 133 III 81).

The provisions about **prescription period** in the product liability law provide that claims have to be brought within **3 years** from the moment that the claimant had or should have had knowledge of the damage, the defect and the identity of the manufacturer (Art. 9 PLL) and in any case within 10 years from the date when the product was first placed on the market (Art. 10 PLL).

57. What defences are available?

The product liability law allows for several defenses, a few of which could be of particular interest in the context of liability claims against manufacturer of pharmaceutical products.

1. The manufacturer is **not liable** if he proves that the **defect could not be detected according to the state of scientific knowledge** at the time when the product was placed on the market (Art. 5 para 1 e. PLL).

This defense bases on the principle that a manufacturer should not be liable for **development risks**. Naturally, this defense is not a carte blanche for manufacturers not to exercise adequate care when developing pharmaceuticals.

According to the Swiss Federal Court, the **state of scientific knowledge** is to be assessed according to **objective criteria**, not according to the level of knowledge of a single manufacturer. However, only **accessible** knowledge and such that has been **recognized** by the concerned scientific community has to be considered. Isolated opinions don't have to be taken into account, at least with regard to products which *do not* pose a specifically high danger for the population (Swiss Federal Court decision 137 III 226). Conversely, this last statement of the Swiss Federal Court has been interpreted by some scholars that regarding pharmaceutics - which generally *can* pose an increased danger to humans - **minority opinions** in the scientific community ***do* have to be considered** by the manufacturer, who will otherwise not be able to use the "development risk"-defense.

2. Another defense is that the manufacturer is not liable if the defect stems from the fact that the product complies with mandatory state regulations (Art. 5 para 1 d. PLL). However, this - at first glance promising looking - defense can in fact hardly ever be available to a manufacturer of a pharmaceutic product. As aforementioned (question 54 above), the fact that a medicine received market authorization or that a medical device received conformity, does not preclude that the product is defective.

3. The last defense to mention is that the manufacturer is not liable if he did not put the pharmaceutic product on the market (Art. 5 para 1 a. PLL). With regard to pharmaceutical products, this defense has as well only a limited scope. E.g. during the phase of clinical tests, this defense will indeed relief the manufacturer from liability under the product liability law. However, during this phase, he is liable according to the rules of special legislation anyway (see chapter 2 question 21).

06

PATENTS AND TRADEMARKS

58. What are the basic requirements to obtain patent and trademark protection?

59. What agencies or bodies regulate patents and trademarks?

60. What products, substances, and processes can be protected by patents or trademarks and what types cannot be protected?

61. How can patents and trademarks be revoked?

62. Are foreign patents and trademarks recognized and, if so, under what circumstances?

63. Are there any non-patent/trademark barriers to competition to protect medicines or devices?

64. Are there restrictions on the types of medicines or devices that can be granted patent and trademark protection?

65. Must a patent or trademark license agreement with a foreign licensor be approved or accepted by any government or regulatory body?

06 PATENTS AND TRADEMARKS

58. What are the basic requirements to obtain patent and trademark protection?

The general principals of patents and trademarks are regulated in *the Federal Act on the Protection of Trade Marks and Indications of Source (**TmPA**;* SR 232.11*)* as well as in *the Federal Act on Patents for Inventions (**PatA**;* SR 231.14*)* and the **corresponding regulations** (SR 232.111 and SR 232.141).

A. Patents

Patents may be obtained on the basis of a national or European application or via the designation of Switzerland (directly or through the European application) pursuant to *the Patent Cooperation Treaty (PCT; SR 0.232.141.1)*.

Patent law protects inventions. A patent grants the owner the right to prohibit all others from commercially using the protected invention. Patents for technical inventions are granted only for ***new* inventions** which are susceptible of ***industrial application*** and which do not result in an obvious way from the state of the art (an ***inventive step*** is required) and which are sufficiently disclosed.

The invention as such merely gives rise to expectancy, the so-called *"right to the grant of a patent"* (art. 3 PatA). Although this includes the legitimation to file a patent application and the right to be named as the inventor, it does **not grant any claims** to protection under patent law. Exclusivity claims in particular can only be enforced on the basis of the granted patent. In order to obtain patent protection, a patent needs to be registered with the *Swiss Federal Institute of Intellectual Property (IPI)*. The patent is granted by registration in the patent register. Until then, there is no exclusive right and the inventor is not entitled to bring any action against any infringing party.

Upon filing a patent application, the IPI will first conduct a **formal examination** and then proceed to the validation of the technical elements of the invention upon receipt of the examination fee. Unlike the European Patent Office, the IPI does not examine whether the invention is new or whether it results in an obvious way from the state of the art. However, it is examined whether an invention within the meaning of the Patent Act exists at all, whether it is legally disclosed and whether the structure of the technical documents meets the legal requirements. The IPI therefore recommends **carrying out a patent search**. Consequently, the applicant is under no obligation to disclose prior art. The publication is published at the latest 18 months following the application or the earlier designated priority date. The patents are granted on the basis of mere examination of formal aspects (see below) and the term of protection is **20 years** from the filing date (art. 14 PatA).

***Supplementary Protection Certificates** (SPC)* can be obtained for **medicinal products** and plant protection products. The IPI grants a SPC upon request if, at the time of the application a product (active substance or combination of active substances), a process for its manufacture or a possible use is protected

by a patent and insofar as a marketing authorization under pharmaceutical law exists in Switzerland. The certificate protects all uses of a product as a medicinal product or plant protection product that were granted before the patent expired and are protected by the patent. It **grants the same rights** as the patent and is also subject to the same restrictions. This extends the protection for an authorised product - i.e. an active ingredient or composition of matter - **by up to 5 years**, starting from the time when the patent protection expires after the maximum protection period (20 years). In this way, the SPC partially compensates for the loss of time in the use of the patent (art. 140*a* et seq. PatA). The application for a certificate must be submitted to the IPI within six months of the first authorization to place the product on the Swiss market as a medicinal product, or six months after the grant of the patent if it was granted later than the authorization under pharmaceutical law. As part of the revision of *the Therapeutic Products Act (TPA)* the legislator created the possibility of a six months SPC extension for pediatric pharmaceuticals. The pediatric extension is either possible by extending an already granted SPC, or through a new pediatric SPC.

B. Trademarks

A trademark is a protected sign that **distinguishes the goods or services** of one company from those of other companies (art. 1 TmPA). That distinguishing function is intended to individualize the goods and services designated so that consumers can distinguish a product once valued from the quantity of goods and services offered by other company.

Trademark law is based on the so-called ***registration principle***, according to which the trademark is not created until it is entered in the trademark register (art. 5 TmPA). Meaning that trademark protection can be obtained through **national registration or designation** of Switzerland via the Madrid System (see further question 62). The minimum requirements for a trademark, in order to be registered are:

i) The sign does not infringe on other's rights (e.g. older trademarks);
ii) the sign needs to be distinctive;
iii) the sign must not be descriptive;
iv) the sign does not go against public order or public morality.

A trademark right belongs to the person or company who first files the trademark. A trademark is **valid for 10 years** from the date of filing the application and may be renewed indefinitely for subsequent periods of 10 years each (if an application for renewal is submitted and the fees are paid; art. 10 TmPA).

59. What agencies or bodies regulate patents and trademarks?

As mentioned under question 58, the **IPI** (https://www.ige.ch/en.html) is the first point of contact for its customers concerning industrial IP rights, meaning trademarks, patents and designs in Switzerland.

The IPI is also the designated office for dealing with international patent applications claiming patent protection in Switzerland pursuant to the PCT.

Applicants domiciled in Switzerland may also file **European patent applications** with the IPI, with the exception of divisional applications. Further the IPI is the designated office for international trademark applications under the Madrid Agreement (and Protocol) on the basis of a Swiss trademark, as mentioned in question 62.

60. What products, substances, and processes can be protected by patents or trademarks and what types cannot be protected?

A. Patents

As mentioned under question 58, for an invention to be patentable, it must be of a technical character and entail a physical interaction with the environment. Furthermore, the invention must be executable and reproducible in industrial application.

The PatA excludes certain inventions from patentability, partly for **moral and ethical reasons**, partly because they are **not to be monopolized** by a patent (art. 2 PatA). The following are excluded from patenting:

i) methods for diagnostic, therapeutic or surgical procedures practiced on the human or animal body. Though substances and compositions solely intended for medical use or for use in the manufacture of means to a medical end (a "Swiss-type claim", also available for second and further medical indications) are patentable even if the underlying substances and composition form part of the prior art;

ii) the human body as such, at all stages of its formation and development, including the embryo (an element of the human body is, however, patentable if it is produced by means of a technical process and a beneficial technical effect is indicated);

iii) naturally occurring gene sequences or partial sequences (however, technically produced derivatives of gene sequences may be patented if their function is specifically indicated);

iv) 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, such as the process for cloning human beings, processes for modifying the germ line genetic identity of human beings or the creation of other organisms by using human genetic material as well as the use of human embryos for non-medical purposes;

v) essentially biological processes for the production if animal breeds and plant varieties as well as certain biotechnological inventions, however, in the event that biological material is directly obtained by a patent manufacturing process, the effects of the patent also extend to the propagated material and products in which the biological material in incorporated.

B. Trademarks

As already mentioned, a trademark is a sign that distinguishes the goods or services of one company from those of other companies. Trademark protection is available not only for words and devices but also for sounds, holograms and three-dimensional objects, as well as combinations of such elements with each other or with colors.

The **absolute grounds for exclusion** are that certain signs may not be protected as trademarks (art. 2 TmPA; **avoidance of false monopolization**). Excluded from trademark protection are:

i) signs that belong to the public domain, except where they have become established as a trademark through use for the goods or services for which they are being claimed.
ii) signs contrary to public policy, morality or applicable law;
iii) shapes that constitute the essence of the claimed goods and shapes of the claimed goods or their packaging that are technically necessary;
iv) signs that are misleading.

Whether a sign satisfies the condition of one of those absolute grounds for exclusion must, in principle, be decided on the basis of the **overall impression**. The IPI, following the case law of the Federal Supreme Court, tends to be strict with signs lacking distinctiveness or showing deceptive contents or misleading indications of origin.

In Switzerland there is no protection of signs not registered as trademarks. An exception is made for any use relevant under *the Federal Act against Unfair Competition (UCA; SR 241)* or if a sign is considered a *"notorious trademark"*, because the mark is known to the Swiss public for any reasons whatsoever, for example, intensive promotion or celebrity association.

61. How can patents and trademarks be revoked?

A. Patents

Once granted, the patent may be **opposed** by third parties within a time limit of nine months of the publication of the entry in the Patent Register (art. 59*c* PatA). The notice of opposition must be filed in a written reasoned statement. Opposition may only be filed on the grounds of non-patentability essentially for reasons of public policy or morality (i.e. the human body, a naturally occurring sequence or partial sequence of a gene, or inventions that are contrary to the public policy or morality, see question 60). Hence, the requirements of novelty or non-obviousness can only be scrutinized by the Federal Patent Court in nullity or infringement proceedings by virtue of a counterclaim or objection. If the IPI finds in favor of the opposition in its entirety or in part, it may revoke the patent or maintain it as amended. The decision regarding an opposition is subject to appeal to the Federal Administrative Court.

B. Trademarks

The proprietor of an earlier trademark may file an **opposition** to a registration on the basis of **relative grounds for refusal, such as the similarity to an earlier trademark** (art. 31 TmPA). The opposition must be submitted in writing to the IPI with a statement of reasons within three months of publication of the registration. The opposition fee must also be paid within this time limit. If the opposition is justified, the registration shall be revoked in whole or in part; if this is not the case, the opposition shall be rejected.

Furthermore, a trademark is protected if it is **used** in relation to the goods or services for which it is claimed. Where the holder has not used the trademark

in relation to the goods or services for which it is claimed for an uninterrupted period of five years following the expiry of the opposition period with no opposition having been filed or upon conclusion of opposition proceedings, he may no longer assert his right to the trademark, unless there are proper reasons for non-use (art. 12 TmPA). If use of the trademark is commenced or resumed after more than five years, the right to the trademark is restored with effect from the original priority date, unless non-use of the trademark has been invoked prior to its commencement or resumption of use. Any person who invokes non-use of a trademark is required to substantiate his claim; evidence of use is required to be provided by the proprietor of the trademark. Since January 2017, it is possible to file a **request for the cancellation** of a trademark in case of non-use with the IPI and not only by means of civil action.

62. Are foreign patents and trademarks recognized and, if so, under what circumstances?

A. Patents

The patent gives its owner the right to prohibit others from commercially using the invention. The scope of protection of the Swiss part of a European patent or a Swiss patent is **limited to the territory of Switzerland and Liechtenstein** in accordance with the principle of territoriality (according to a special treaty, the protection of patents granted for Switzerland also extends to the Principality of Liechtenstein). Therefore, only the act of use carried out in Switzerland is illegal. However, it is not necessary for the infringer to be active in Switzerland himself. It is sufficient if his activities have an economic effect in the territory of Switzerland.

B. Trademarks

The trademark right gives the proprietor the exclusive right to use and dispose of the trademark to identify the goods or services for which it is claimed. This right is limited to the **territory in which the trademark is registered**, meaning that a trademark needs to be registered in Switzerland in order to obtain such exclusivity in Switzerland.

The international registration of trademarks is regulated by *the Madrid Agreement Concerning the International Registration of Marks (MMA; SR 0.232.112.3)* as well as *the Madrid Protocol (MMP; SR 0.232.112.4)*, these treaties are administered *by the International Bureau of the World Intellectual Property Organization (WIPO)* in Geneva. The MMA enables a trademark owner who has registered a trademark in his home country (national basic registration) to apply for an international registration at WIPO. In this case, the trademark will be registered for all the contracting states designated by the applicant unless these states expressly refuse within 12 months. Switzerland is a member of these treaties.

63. Are there any non-patent/ trademark barriers to competition to protect medicines or devices?

The Federal Act on Medicinal Products and Medical Devices (TPA; SR 812.21) applies to the handling of therapeutic products (medicinal products and medical devices), particularly in their manufacture and placing on the market;

narcotics, in so far as they are used as therapeutic products as well as therapeutic treatments, such as gene therapy, in so far as they directly relate to therapeutic products. *Swissmedic (Swiss Agency for Therapeutic Products)* is the Swiss authority responsible for the authorization and supervision of such therapeutic and medicinal products.

The UCA is aimed at all participants in the competition. The aim is to express the equivalence of the interests of business, consumers and the general public. In principle, a cumulative applicability of the Act in relation to intellectual property rights is to be assumed. Meaning that **if a patent or trademark registration is waived, the protection of secrets under unfair competition law shall remain**. The Act regulates general unfair practice; there are no special barriers to competition related to medicines or devices.

64. Are there restrictions on the types of medicines or devices that can be granted patent and trademark protection?

Generally, there are **no additional or specific restrictions** in the context of medicines or devices, other than the above-mentioned restrictions related to patent or trademark law (see question 60). However, the TPA protects human and animal health by guaranteeing that only high quality, safe and effective therapeutic products are placed on the market. The TPA further regulates the principles for placing products on the market and the authorization procedure (as mentioned above in question 63).

65. Must a patent or trademark license agreement with a foreign licensor be approved or accepted by any government or regulatory body?

Generally, there are **no formalities** required for a patent or trademark license, neither for a Swiss licensor, nor for a foreign licensor. However, as with any legal transaction, written form is recommended, especially for evidence reasons and in order to avoid possible interpretation disputes. Further the registration in the patent or trademark registered brings some advantages.

A. Patents

According to the PatA license agreements of third parties not recorded in the patent register are **invalid** against persons who have acquired in **good faith** the rights to the patent (art. 34 PatA). This means that the registration of the license agreement in the patent register is not a constitutive requirement for the establishment of the license. In the internal relationship between licensor and licensee, the entry in the register therefore only has declaratory effect. In external relations, the entry in the register strengthens the legal position of the licensee vis-à-vis an acquirer of rights to the patent who must allow the licensee to use the patent in accordance with the license agreement.

B. Trademarks

According to the TmPA a license agreement can be entered in the trademark register at the request of one of the parties. It then becomes **binding** on any rights to the trademark subsequently acquired. The entry in the register has **no direct effect** between the parties (art. 18 TmPA). A license agreement is valid even if the license is not registered in the trademark register.

07

REGULATORY REFORMS

66. Are there proposals for reform or significant change to the healthcare system?

67. When are they likely to come into force?

07 REGULATORY REFORMS

66. Are there proposals for reform or significant change to the healthcare system?

The revised **Therapeutic Products Act (TPA)** entered into force on 1 January 2019. Current **therapeutic products legislation projects** are listed on the website of the Federal Office of Public Health (hereinafter: **FOPH**) (*cf.* https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/heilmittel/aktuelle-rechtsetzungsprojekte.html, *last visited on 31 March 2021*). Current legislation projects in the area of **health insurance** are also listed on the website of the FOPH (*cf.* https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-revisionsprojekte.html, *last visited on 31 March 2021*). The following overview is intended to provide basic information concerning five major legislation projects.

1. Ordinary revision of the TPA

After several years of discussion, the revised TPA entered into force on 1 January 2019 (some dispositions entered into force earlier).

One of the main aims was to **facilitate market access** for certain medical categories by creating new and simpler access opportunities (e.g. new authorization procedures for medicinal products approved in an EU or EFTA country) and to simplify self-medication by modifying the allocation of medicinal products to different supply categories (*cf.* chapter 1, questions 3 and 14).

A second aim was to improve **drug safety** in general: The market supervision was modernised and tightened up (e.g. introduction of the pharmacovigilance plan, application of Good Vigilance Practice, increased scope and more detailed definition of reporting obligations). The safety of medicinal products used in paediatrics was also improved: A new **register for off-label dosage recommendations** for the medicinal products used in paediatrics was created (*cf.* https://swisspeddose.ch/, *last visited on 31 March 2021*) and new obligations and incentives for the pharmaceutical industry to promote the development of paediatric medicinal products were established. Minimum requirements for the prescription of medicinal products were defined as well.

The last of the three main aims was to **increase transparency**. For instance, the **assessment reports** for human medicinal products with new active ingredients on which the authorization decisions are based (so-called SwissPAR) and the **summary report** of the results of clinical trials are now published by Swissmedic.

2. Total revision of MPLO and Falsified Medicines Directive:

The totally revised **Ordinance on Licensing in the Medicinal Products Sector (MPLO)** *(Verordnung über die Bewilligungen im Arzneimittelbereich vom 14. November 2018 [Arzneimittel-Bewilligungsverordnung; AMBV; SR*

812.212.1]) entered into force on 1 January 2019. One of the main aims of this total revision is to improve the safety of medicinal products.

The modifications will improve, among others, medicine control and traceability in the distribution chain. **Intermediaries** now face greater responsibility in the medicines market. Another new aspect concerns **experimental medicines**: They can now be administrated for a limited period in certain cases. This first part entered into force on 1 January 2019.

A second step is the implementation of new safety features: An **unique identifier** will make it possible to verify that medicinal products are authentic. An **anti-tampering device** is intended to detect whether packages have been opened. The new **art. 17a TPA** concerning the voluntary placing of safety features to medicinal product packaging as well as the detailed provisions that are regulated in a separate ordinance are **not yet in force**. As of today, it is not apparent when these planned revisions will enter into force.

3. Therapeutic products: integrity, transparency and discounts:

The new **Ordinance on Integrity and Transparency in the Context of Therapeutic Products (OITTP)** *(Verordnung über die Integrität und Transparenz im Heilmittelbereich vom 10. April 2019 [VITH; SR 812.214.31]*) entered into force on 1 January 2020. It was adopted on the basis of the new art. 55 and 56 TPA. At the same time, art. 33 TPA (Promises and acceptance of material benefits) was abolished.

Art. 55 TPA **(Integrity)** regulates, in general, that the choice of treatment must not be influenced by financial incentives. Doctors have to choose a treatment exclusively under scientific and objective criteria. This provision applies to the prescription, supply and use of **prescription medicinal products**. However, the Federal Council (*Bundesrat*) may extend the scope to **other categories** of therapeutic products. Gifts with a maximum value of **300 Swiss francs per year** that are **relevant to the medical or pharmaceutical practice** are allowed. Contributions for research, education and training are allowed under certain circumstances as well.

Second, the new regulation is stricter concerning **discounts and bonuses**. Art. 56 TPA **(Duty of transparency)** stipulates that all price discounts and refunds granted on **therapeutic products** (which means medicinal products and medical devices) must be reported and disclosed to the FOPH upon request. The provision shall apply to both, **purchase and sale** of therapeutic products. Therapeutic products with a **low risk potential** are excluded from the scope of art. 56 (e.g. Class I medical devices).

The responsible authority for the enforcement is the **FOPH**. It can order administrative measures and conduct administrative penalty proceedings.

4. Total revision of medical devices legislation:

One of the most controversial legislative projects in the field of therapeutic products is the total revision of the **Medical Devices Ordinance (MedDO)** *(Medizinprodukteverordnung vom 17. Oktober 2001 [MepV; SR 812.213])*. The main purpose of this total revision is to harmonise Swiss medical device law

with the EU's new **medical devices regulation (EU-MDR)** and **In-vitro medical devices regulation (EU-IVDR).**

The medical device industry plays an important economic role in Switzerland and generates more than 70 percent of their sales through exports, half of which go to the EU. This corresponds to approximately **4 percent of all Swiss exports** (export volume 10.6 billion Swiss francs) and a share of **2.2 percent of the Swiss gross domestic product** (*cf. Bundesamt für Gesundheit BAG, Totalrevision der Medizinprodukteverordnung und Verordnung über klinische Versuche mit Medizinprodukten (neue Medizinprodukte-Regulierung), Erläuternder Bericht, 14 May* 2019, page 7, *https://www.bag.admin.ch/bag/de/home/medizin-und-forschung/heilmittel/aktuelle-rechtsetzungsprojekte/revision-med-prod-verord-mepv.html, last visited on 31 March 2021*). Considering the great economic importance, the question arises as to why the revision was controversially discussed in Switzerland. First of all, the new MedDO, same as the EU-MDR and EU-IVDR, will bring fundamental change to all actors on the market. There are now numerous obligations not only for manufacturers, but also for traders. However, the most controversial point with regard to Switzerland was the unique adoption of EU law by the Swiss parliament. On the one hand, the MedDO refers directly to the EU-MDR in numerous dispositions. On the other hand, both, **implementing and delegated acts** adopted by the European Commission automatically enter into force for Switzerland too.

In addition to the total revision of the MedDO, further amendments to medical devices legislation have been planned and/or adopted. In order to create the necessary legal basis for the implementation law, namely the totally revised MedBO, the new ordinance on clinical trials with medical devices (*Verordnung über klinische Versuche mit Miedzinproduktenand [KlinV-Mep; SR 810.306])* the EU-IVDR implementation ordinance, the TPA as well as the Human Research Act (HRA) (*Humanforschungsgesetz, [HFG; SR 810.30])* will also be partially revised. Originally, the amendments to the TPA and HRA, as well as the ordinances, were to have entered into force on 26 May 2020. In connection with the COVID-19 pandemic, the European Commission announced on 25 March 2020, that the full applicability of the EU-MDR would be postponed by one year. The most important provisions, which concern, among other things, the requirements for market launch, market surveillance or the new requirements for clinical trials, will enter into force on 26 May 2021. The exemptions for the placing on the market and putting into service of medical devices that have not undergone a conformity assessment procedure have already been put into force on 1 August 2020. The EU-IVDR provisions will be included in a separate regulation and will enter into force on 26 May 2022.

The situation is even more complex: In addition to the harmonization of mentioned medical device legislation updates to the **Mutual Recognition Agreement (MRA)** need to be negotiated by the **Switzerland-EU** Joint Committee in order to introduce mutual obligations for Switzerland and the EU at international treaty level. (cf. https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/heilmittel/aktuelle-rechtsetzungsprojekte/revision-med-prod-verord-mepv.html, last visited on 31 March 2021).

5. Revision of the HIA: regulatory measures to contain costs:

Swiss health insurance law is often partially revised several times a year. However, these revisions usually do not result in major system changes, but small changes that are just as important, especially when it comes to so-called "cost-saving measures". Switzerland has one of the **most expensive healthcare systems**.

As a consequence, cost-saving measures have been the subject of constant political discussion for years. Almost all sides (politicians, hospitals, doctors, insurers, patients etc.) agree that health care costs are too high. There is **consensus** that **savings must be made**, but there is **no consensus** on **how** these savings can be achieved.

In August 2019, the Federal Council adopted the first of several packages of so-called **"cost containment measures – package 1"** *(Massnahmen zur Kostendämpfung – Paket 1).* This package must now be discussed in Parliament.

The content of this first proposal is highly technical, complicated and controversial. Only one example is given below: The Federal Council proposes the introduction of a so-called **"reference price system for medicinal products"** (*Referenzpreissystem für Arzneimittel*). To begin with, **generics are more than twice as expensive** in Switzerland as in the nine European reference countries considered by the FOPH for pricing purposes. The FOPH shall determine the maximum amount insurers have to pay for **patent-expired medicinal products and generic products with the same active ingredient**. If a more expensive drug is sold, the **insured** must pay the difference to the reference price. With the introduction of a reference price system, savings of 310-480 million Swiss francs could be realized (*cf. Bundesamt für Gesundheit BAG, Faktenblatt Referenzpreissystem bei Arzneimitteln vom 21. August 2019, https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-revisionsprojekte/kvg-revision-massnahmen-zur-kostendaempfung-Paket-1.html, last visited on 31 March 2021*). It is currently impossible to predict **when, how and whether** these provisions will enter into force.

In addition to the cost containment measures – package 1 the Federal Council (*Bundesrat*) deiced on 19 August 2020 to open the consultation procedure on the "**cost containment measures – package 2**", which lasted until 19 November 2020.

The content of the second package of measures is no less technical and complicated than the first package. The focus of the second package is on improving the overall management of the health care system. Central to this is the introduction of a **targetsetting**, which is to define cost targets for the development of costs in the compulsory health care insurance as well as measures to correct any possible target overruns (*cf. Bundesamt für Gesundheit BAG, Faktenblatt Zielvorgabe vom 19. August 2020, https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-revisionsprojekte/kvg-aenderung-massnahmen-zur-kostendaempfung-paket-2.html, last visited on 31 March 2021*). The proposed targetsetting is intended to help exploit the existing efficiency potential in the healthcare system. Efficiency

potential exists if a certain state of health through medical treatment can also be achieved at lower healthcare costs. Furthermore, the competencies of the federal government with regard to the remuneration of medical services are to be strengthened so that these can be provided more cost-effectively in the future. This includes a regulation for the **agreement of pricing models and any reimbursements** as well as an associated **exemption from access to official documents**. In addition, the legal basis will be created for a differentiated examination of **effectiveness, expediency and economic efficiency** (*WZW-Kritierien*) as well as for the **assessment of the most cost-effective reimbursement** possible for analyses, medicines as well as means and objects.

The second package aims to strengthen the effect of package 1, i.e. to contain the development of costs in the compulsory health care insurance to a medically justifiable level and in this way to limit the increase in premiums paid by the insured. The measures are directed at all players and are intended to make them consistently responsible. The savings potential of package 2 is estimated at over one billion Swiss francs. As with Package 1, it is currently impossible to predict **when, how, and whether** these provisions will enter into force, particularly because the consultation procedure did not end until 19 November 2020.

67. When are they likely to come into force?

This aspect is already outlined in **question 66**.

08

CANNABINOID DRUGS, MEDICINAL CANNABIS AND OPIOID DRUGS

68. Are Cannabinoid Drugs authorized in your country?

69. What are the regulatory authorities with jurisdiction over Cannabinoid Drugs?

70. Is there a specific regulatory framework for the authorization pricing, and reimbursement of Cannabinoid Drugs?

71. Which are the Cannabinoid Drugs that have received market approval to date?

72. Who can prescribe Cannabinoid Drugs?

73. Is there a list of doctors authorized to prescribe Cannabinoid Drugs?

74. What approvals or notifications are required to prescribe Cannabinoid Drugs?

75. Which organizations are authorized to sell/distribute Cannabinoid Drugs available?

76. Is there a list of retailers/ distributors authorized to sell Cannabinoid Drugs?

77. Are there proposals for reform or significant change to the regulation of Cannabinoid Drugs?

78. When are they likely to come into force?

79. Is Medicinal Cannabis authorized in the country?

80. What are the regulatory authorities with jurisdiction over Medicinal Cannabis?

81. What is the regulatory framework for the authorization, pricing, and reimbursement of Medicinal Cannabis?

82. How is the production and import of Medicinal Cannabis regulated and by which agencies/authorities?

83. What approval or notifications are necessary to produce or import Medicinal Cannabis?

84. What is the regulatory framework for the marketing and distribution of Medicinal Cannabis?

85. How can patients obtain Medicinal Cannabis?

86. Who can prescribe Medicinal Cannabis?

87. Is there a list of doctors authorized to prescribe Medicinal Cannabis?

88. What approvals or notifications are required to prescribe Medicinal Cannabis?

89. Where is Medicinal Cannabis available?

90. Is there a list of retailers authorized to sell Medicinal Cannabis?

91. Are there proposals for reform or significant change to the regulation of Medicinal Cannabis?

92. Are Opioid Drugs authorized in your country?

93. What are the regulatory authorities with jurisdiction over Opioid Drugs?

94. Is there a specific regulatory framework for the authorization, pricing, and reimbursement of Opioid Drugs?

95. Which are the Opioid Drugs that have received market approval to date?

96. Who can prescribe Opioid Drugs?

97. Is there a list of doctors authorized to prescribe Opioid Drugs?

98. What approvals or notifications are required to prescribe Opioid Drugs?

99. Which organizations are authorized to sell/distribute Opioid Drugs available?

100. Is there a list of retailers/ distributors authorized to sell Opioid Drugs?

101. Are there proposals for reform or significant change to the regulation of Opioid Drugs?

102. When are they likely to come into force?

08 CANNABINOID DRUGS, MEDICINAL CANNABIS AND OPIOID DRUGS

CANNABINOID DRUGS

68. Are Cannabinoid Drugs authorized in your country?

In principle, the cultivation, introduction, production and placing on the market of narcotics containing an effective concentration of Cannabinoid Drugs are not permitted (art. 8 para. 1 lit. d of the Narcotics Act (NarcA) (*Bundesgesetz über die Betäubungsmittel und die psychotropen Stoffe vom 3. Oktober 1951 [Betäubungsmittelgesetz; BetmG; SR 821.121]*). However, the Federal Office of Public Health (FOPH) may, upon request, grant exemption permits for the cultivation, importation, production, and marketing of Cannabinoid Drugs if it is for restricted medical use, for scientific research or for drug development and not prohibited by an international agreement (art. 8 para. 5 NarcA).

The mentioned prohibition mainly concerns products with the active substance THC, which have a total THC content of at least 1.0 %. If a product contains a THC content of less than 1.0 %, it no longer falls under the Narcotics Act, but under the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act) (TPA) *(Bundesgesetz über Arzneimittel und Medizinprodukte vom 15. Dezember 2000 [Heilmittelgesetz, HMG; SR 812.21]).*

69. What are the regulatory authorities with jurisdiction over Cannabinoid Drugs?

The regulatory authorities over Cannabinoid Drugs are the FOPH as well as the Swiss Agency for Therapeutic Products (Swissmedic). The FOPH plays a key role especially in the legislative procedures in all sectors of the public health law. The competence of the FOPH lies primarily in the approval of applications for exemption and the enforcement of the NarcA. Swissmedic is the competent authority for authorizations and licenses in the field of Cannabinoid Drugs (e.g. licences for importing, exporting and distributing). Swissmedic is therefore responsible for regulating the approval of Cannabinoid Drugs and CBD-containing products that are to be marketed as medicinal products in Switzerland under the TPA. The regulatory competence over the narcotics directory ordinance lies in the responsibility of the FDHA. The latter supplements the lists at the request of Swissmedic, which submits a request if a supplement to the lists appears appropriate due to international developments or new hazards.

70. Is there a specific regulatory framework for the authorization pricing, and reimbursement of Cannabinoid Drugs?

1. The regulatory framework for the authorization of Cannabinoid Drugs

The legal framework for the authorization of Cannabinoid Drugs is regulated by the NarcA, because Cannabinoid Drugs are prohibited narcotics in the meaning of the NarcA (art. 8 para. 1 lit. d NarcA). The NarcA

regulates the availability of Cannabinoid Drugs for medical and scientific purposes in particular. The NarcA is supplemented by the Narcotics Control Ordinance *(Betäubungsmittelkontrollverordnung vom 25 May 2011 [BetmKV; SR 812.121.1])* and the Narcotics Directory Ordinance of the FDHA (Verordnung des EDI über die Verzeichnisse der Betäubungsmittel, psychotropen Stoffe, Vorläuferstoffe und Hilfschemikalien vom 30 May 2011 *2011 [BetmVV-EDI; SR 812.121.11])*. The former regulates the licensing and control of Cannabinoid Drugs as well as the import, export and transit of Cannabinoid Drugs. The latter mainly contains lists of the various narcotics, including Cannabinoid Drugs and categorizes them. Cannabinoid Drugs used as therapeutic substances are not subject to the provisions of the NarcA, but are subject to those of the TPA, insofar as the TPA contains no rule or a less stringer rule (art. 1b NarcA).

2. The regulatory framework for the pricing and reimbursement of Cannabinoid Drugs

Treatment with cannabis medicines is currently not covered by the compulsory health insurance (OKP) (this also applies to the approved Sativex®; cf. question 71). The reason for this is in particular due to the unclear scientific evidence regarding the efficacy and cost-effectiveness of cannabis medicines. Reimbursement of cannabis medicines by the health insurance is made exceptionally in individual cases after consultation with the medical officer. The proposed amendment to the law (*cf.* question 77) does not provide for adjusting the current requirements for reimbursement via the OKP.

71. Which are the Cannabinoid Drugs that have received market approval to date?

Currently, Sativex® is the only cannabis medicine approved for use in Switzerland. It can be prescribed by doctors without an exceptional authorization from the FOPH, but only in the case of spasticity in multiple sclerosis.

72. Who can prescribe Cannabinoid Drugs?

Cannabinoid Drugs can only be prescribed by a doctor licensed to practice in Switzerland on the basis of an exceptional authorization issued by the FOPH. To prescribe authorized Cannabinoid Drugs an exemption permit is not required (see question 71).

73. Is there a list of doctors authorized to prescribe Cannabinoid Drugs?

There is no specific list of authorized doctors, as all licensed doctors in Switzerland can prescribe Cannabinoid Drugs. Doctors authorized to practice are listed in the Medical Professional Register (MedReg), which is a binding list of all medical professionals who are authorized by a cantonal authority to obtain Cannabinoid Drugs. The register can be accessed at the following link: https://www.medregbm.admin.ch/Betrieb/Search (*last visited on 31 March 2021).*

74. What approvals or notifications are required to prescribe Cannabinoid Drugs?

The use of Cannabinoid Drugs in the sense of art. 8 para. 5 NarcA is only a matter of concrete individual cases in which a limited medical use is justified. For a prescription in these cases, the following requirements must be met:

- incurable chronic disease
- suffering can be alleviated by taking Cannabinoid Drugs that are basically prohibited
- therapy and treatment options are exhausted
- dispensing Cannabinoid Drugs, which are prohibited per se, can avoid inpatient treatment

In addition to the written request, which must be submitted by the treating doctor, a written declaration by the patient is also required, in which he or she agrees to the application (art. 28 para. 2 lit. d of the Narcotics Addiction Ordinance) *(Verordnung über Betäubungsmittelsucht und andere suchtbedingte Störungen [Betäubungsmittelsuchtverordnung; BetmSV; SR 812.121.6])*. Exemption permits are only issued to doctors authorized to practice in Switzerland for the treatment of patients who are Swiss residents. The control of these specifications is the responsibility of the FOPH (art. 29 of the Narcotics Addiction Ordinance). After approval of the application by the FOPH, the patient can be prescribed the cannabis-containing medicine tailored to his or her personal needs, the so-called extemporaneous preparations.

As already mentioned in question 72 there is currently only one Cannabinoid Drug, who can be prescribed without an exceptional authorization from the FOPH and without fulfilling the just mentioned requirements.

75. Which organizations are authorized to sell/distribute Cannabinoid Drugs available?

Anyone who wants to sell or distribute Cannabinoid Drugs in Switzerland needs an exemption permit from the FOPH if the cannabinoids do not serve as an active ingredient for a medicinal product authorized by Swissmedic. The exemption can be granted if there is no international agreement to the contrary and the Cannabinoid Drugs are used for scientific research, drug development or restricted medical use (art. 8 para. 5 NarcA, art. 28 of the Narcotics Addiction Ordinance and art. 8 of the Narcotics Control Ordinance).

76. Is there a list of retailers/distributors authorized to sell Cannabinoid Drugs?

No, there is no list of authorized retailers or distributors to sell Cannabinoid Drugs.

77. Are there proposals for reform or significant change to the regulation of Cannabinoid Drugs?

As already alluded in question 68, Cannabinoid Drugs are considered a prohibited narcotic and are subject to a comprehensive traffic ban in Switzerland. This means that cannabis may not be cultivated, produced, imported or distributed. Currently, the medical use of Cannabinoid Drugs is therefore only possible to a limited extent and with an exceptional permit from the FOPH.

The demand for Cannabinoid Drugs treatments has surged in recent years, with nearly 3,000 exemptions granted in 2019 alone. The exception permit

process is burdensome, delays treatment and no longer fits the exceptional nature. Therefore, the Federal Council proposes to revise the NarcA. The aim of the revision of the law is to better exploit the potential of cannabis as a medicine and to simplify access to Cannabinoid Drugs for those affected.

To achieve this goal, the ban on the circulation of Cannabinoid Drugs for medicinal purposes is to be lifted, which means that treatment with medicinal cannabis products will no longer require an exceptional authorization from the FOPH. In the future, only the treating doctor will decide on the treatment with medicinal cannabis products. Furthermore, the cultivation, processing, production and trade of medicinal cannabis will be subject to Swissmedic's authorization control system, as it is the case with other narcotics used for medical purposes. And lastly, the commercial export of cannabis for medical purposes is to be newly permitted to create economic perspectives for domestic cultivators of cannabis. There will be no change in the reimbursement of cannabis medicines, which is why treatment will only be reimbursed by the mandatory health insurance in exceptional cases. However, the FOPH is examining whether there is also a need for action about the question of reimbursement.

78. When are they likely to come into force?

The Federal Council referred the dispatch on the amendment of the law to parliament on 24 June 2020. Whether, how and when the changes will come into force is not clear at this time.

MEDICINAL CANNABIS

79. Is Medicinal Cannabis authorized in the country?

In principle, the cultivation, introduction, production and placing on the market of narcotics containing an effective concentration of Cannabinoid Drugs are not permitted (art. 8 para. 1 lit. d NarcA). However, the FOPH may, upon request, grant exemption permits for the cultivation, importation, production and marketing of Medicinal Cannabis if it is for restricted medical use, for scientific research or for drug development and not prohibited by an international agreement (art. 8 para. 5 NarcA).

The mentioned prohibition mainly concerns products with the active substance THC, which have a total THC content of at least 1.0%. If a product contains a THC content of less than 1.0 %, it no longer falls under the NarcA, but under the TPA and is classified as a CBD-containing product. CBD-containing products with a medicinal purpose are considered medicinal products according to Art. 4 lit. a TPA and according to Art. 9 para. 1 TPA, may not be placed on the market without authorization by Swissmedic.

80. What are the regulatory authorities with jurisdiction over Medicinal Cannabis?

The regulatory authorities over Medicinal Cannabis are the FOPH as well as Swissmedic. The competence of the FOPH lies primarily in the approval of applications for exemption and the enforcement of the NarcA. Swissmedic, for its part, is responsible for regulating the approval of Medicinal Cannabis with less than 1 % of THC content and CBD-containing products that are to be marketed as medicinal products in Switzerland.

81. What is the regulatory framework for the authorization, pricing, and reimbursement of Medicinal Cannabis?

1. The regulatory framework for the authorization of Medicinal Cannabis

The legal framework for the authorization of Cannabinoid Drugs with more than 1 % THC content is regulated by the NarcA, because Cannabinoid Drugs are prohibited narcotics in the meaning of the NarcA (art. 8 para. 1 lit. d NarcA). The NarcA regulates the availability of Cannabinoid Drugs for medical and scientific purposes in particular. The NarcA is supplemented by the **Narcotics Control Ordinance and the Narcotics Directory Ordinance of the FDHA**. The former regulates the licensing and control of Cannabinoid Drugs as well as the import, export and transit of Cannabinoid Drugs. The latter mainly contains the lists of the various narcotics, including Cannabinoid Drugs, and categorizes them. Cannabinoid Drugs used as therapeutic substances are not subject to the provisions of the NarcA, but are subject to those of the TPA, insofar as the TPA contains no rule or a less stringer rule (art. 1b NarcA). The regulatory framework for CBD-containing products with a medical purpose is the TPA.

2. The regulatory framework for the pricing and reimbursement of Medicinal Cannabis

Treatment with cannabis medicines is currently not covered by compulsory health insurance (OKP) (this also applies to the approved Sativex®; cf. question 71). The reason for this is in particular the unclear scientific evidence regarding the efficacy and cost-effectiveness of cannabis medicines. Reimbursement of cannabis medicines by the health insurance is made exceptionally in individual cases after consultation with the medical officer. The proposed amendment to the law (*cf.* question 80) does not provide for adjusting the current requirements for reimbursement via the OKP.

82. How is the production and import of Medicinal Cannabis regulated and by which agencies/authorities?

For the production and placing on the market of Medicinal Cannabis, an exceptional authorization from the FOPH is required (art. 8 para. 5 NarcA), provided that these substances do not serve as an active ingredient for a medicinal product authorized by Swissmedic (art. 8 para. 7 NarcA). By "producing" are all operations meant from extraction, production, preparation, treatment or processing, purification, conversion, to packaging, storage, and delivery of the final product, as well as quality controls and release (art. 2 lit. c of the Narcotics Control Ordinance).

In addition, the import of medicinal cannabis requires an exceptional authorization from the FOPH in any case (art. 8 para. 5 NarcA). Based on a

corresponding exceptional authorization, Swissmedic can issue the additionally required import and export authorization for the Medicinal Cannabis.

83. What approval or notifications are necessary to produce or import Medicinal Cannabis?

Individuals or companies wishing to import Medicinal cannabis into Switzerland must submit an application to Swissmedic for an import permit (art. 24 para. 1 of the Narcotics Control Ordinance). Swissmedic grants this authorization provided that an exemption permit has been issued by the FOPH in accordance with art. 8 para. 5 NarcA. The authorization is issued for a single import. If an import of medicinal cannabis takes place, the holder of the import licence must notify Swissmedic in writing about the receipt of the medicinal cannabis within a maximum period of ten working days (art. 30 para. 1 oft the Control of Narcotic Drugs Ordinance).

A permit is furthermore required to produce Medicinal Cannabis. A cultivation permit is granted to anyone who holds an operating license or acts on behalf of a holder of an operating license by Swissmedic (art. 14 para. 1 of the Narcotics Control Ordinance). The producer of Medicinal Cannabis must then provide proof of a system to protect the medicinal cannabis from theft (art. 14 para. 2 of the Narcotics Control Ordinance). The application for a cultivation permit must contain information on the person of the applicant, the type of activity and the location of cultivation and storage. Furthermore, a current excerpt from the commercial register, an excerpt from the criminal register and professional diplomas must be submitted with the application (art. 15 of the Narcotics Control Ordinance). It must be noted that the transfer of the produced Medicinal Cannabis is only allowed for authorized persons, such as persons or companies with an exemption permit from the FOPH or medical professionals authorized to handle Medicinal Cannabis (*cf.* art. 16 of the Narcotics Control Ordinance).

84. What is the regulatory framework for the marketing and distribution of Medicinal Cannabis?

Regarding the marketing of medicinal cannabis, there is no specific regulatory framework in Switzerland, as medicinal cannabis is only distributed by doctors, who do not have to or should not undertake any marketing measures.

The distribution of medicinal cannabis is regulated by the laws and ordinances listed in question 81.

85. How can patients obtain Medicinal Cannabis?

If it is a cannabis medicine, patients can obtain this from a doctor directly or from a pharmacy via a prescription. Patients who are entitled to the medical use of a cannabis product that is prohibited in principle on the basis of an exceptional authorization from the FOPH can obtain this directly from the prescribing doctor.

86. Who can prescribe Medicinal Cannabis?

Only a doctor may prescribe Medicinal Cannabis. Besides, the application for an exemption for the medical use of cannabis can only be submitted by a doctor.

87. Is there a list of doctors authorized to prescribe Medicinal Cannabis?

The Medical Professional Register (MedReg) is a binding list of all medical professionals who are authorized by a cantonal authority to obtain narcotics, including the prescription of Medicinal Cannabis. The register can be accessed at the following link: https://www.medregbm.admin.ch/Betrieb/Search (*last visited on 31 March 2021).*

88. What approvals or notifications are required to prescribe Medicinal Cannabis?

The use of Medicinal Cannabis in the sense of Art. 8 para. 5 NarcA is only a matter of concrete individual cases in which a limited medical use is justified. For a prescription in these cases, the following requirements must be met:

- incurable chronic disease
- suffering can be alleviated by taking Cannabinoid Drugs that are basically prohibited
- therapy and treatment options are exhausted
- dispensing Cannabinoid Drugs, which are prohibited per se, can avoid inpatient treatment

In addition to the written request, which must be submitted by the treating doctor, a written declaration by the patient is as well required, in which he or she agrees to the application (art. 28 para. 2 lit. d of the Narcotics Addiction Ordinance). Exemption permits are only issued to doctors authorized to practice in Switzerland for the treatment of patients who are Swiss residents. The control of these specifications is the responsibility of the FOPH (art. 29 of the Narcotics Addiction Ordinance). After approval of the application by the FOPH, the patient can be prescribed the cannabis-containing medicine tailored to his or her personal needs, the so-called extemporaneous preparations.

89. Where is Medicinal Cannabis available?

Medicinal cannabis can be obtained either through an authorized doctor or through a pharmacy that receives a prescription issued by a doctor. The number of pharmacies in Switzerland that can offer and distribute medicinal cannabis is limited. Currently, only the Bahnhofapotheke in Langnau and the Hänseler AG in Herisau are authorized to sell.

90. Is there a list of retailers authorized to sell Medicinal Cannabis?

No, there is no list of retailers authorized to sell Medicinal Cannabis. This is because the prescription for Medicinal Cannabis or the issuance of a prescription for a cannabis-containing drug in Switzerland can only be made by doctors. The production of medicines containing cannabis is carried out by a pharmacy, but only based on a prescription from a doctor.

91. Are there proposals for reform or significant change to the regulation of Medicinal Cannabis?

As already alluded in question 79, cannabis is considered a prohibited narcotic and is subject to a comprehensive traffic ban in Switzerland. This means that cannabis may not be cultivated, produced, imported or distributed. Currently, the medical use of cannabis is therefore only possible to a limited extent and with an exceptional permit from the FOPH.

The demand for cannabis treatments has surged in recent years, with nearly 3,000 exemptions granted in 2019 alone. The exception permit process is burdensome, delays treatment and no longer fits the exceptional nature. Therefore, the Federal Council proposes to revise the NarcA. The aim of the revision of the law is to better exploit the potential of cannabis as a medicine and to simplify access to cannabis medicines for those affected.

To achieve this goal, the ban on the circulation of cannabis for medicinal purposes is to be lifted, which means that treatment with medicinal cannabis products will no longer require an exceptional authorization from the FOPH. In the future, only the treating doctor will decide on the treatment with medicinal cannabis products. Furthermore, the cultivation, processing, production and trade of medicinal cannabis will be subject to Swissmedic's authorization control system, as it is the case with other narcotics used for medical purposes. And lastly, the commercial export of cannabis for medical purposes is to be newly permitted to create economic perspectives for domestic cultivators of cannabis. There will be no change in the reimbursement of cannabis medicines, which is why treatment will only be reimbursed by the mandatory health insurance in exceptional cases. However, the FOPH is examining whether there is also a need for action about the question of reimbursement.

The Federal Council referred the dispatch on the amendment of the law to parliament on 24 June 2020. Whether, how and when the changes will come into force is not clear at this time. It should be noted that there will be no change for cannabis for non-medical purposes: It remains prohibited.

OPIOID DRUGS

92. Are Opioid Drugs authorized in your country?

Yes, Opioid Drugs are authorized in Switzerland.

93. What are the regulatory authorities with jurisdiction over Opioid Drugs?

The regulatory authorities over Opioid Drugs are the FOPH as well as Swissmedic. The competence of the FOPH lies primarily in the enforcement of the NarcA. Swissmedic, for its part, is responsible for regulating the approval of Opioid Drugs and Opioid-containing products that are to be marketed as medicinal products in Switzerland under the TPA. The regulatory competence over the Narcotics Directory Ordinance is the responsibility of the FDHA. The latter supplements the lists at the request of Swissmedic, which submits a request if a supplement to the lists appears appropriate due to international developments or new hazards.

94. Is there a specific regulatory framework for the authorization, pricing, and reimbursement of Opioid Drugs?

1. The regulatory framework for the authorization of Opioid Drugs

The legal framework for the authorization of Opioid Drugs is regulated by the TPA, insofar as they are used as therapeutic products (art. 2 para. 1 lit. b TPA). If they are not used as therapeutic products, the regulatory framework is the NarcA since Opioid Drugs can be narcotics (*cf.* art. 2 lit. a NarcA). In addition, there are numerous ordinances governing the details (e.g. the Ordinance on Medicinal Products and the Ordinance on Licensing the Medicinal Products Sector).

2. The regulatory framework for the pricing and reimbursement of Opiod Drugs

The pricing and reimbursement are governed by the general principles. The following remarks therefore correspond to those already made in chapter 01 under question 12. A medicinal product can only be reimbursed by the health insurance if it is listed by the FOPH on the so-called "specialty list" (*Spezialitätenliste*) (art. 52 para. 1 lit. b HIA). First, an application for a medicinal product to be listed on the specialty list has to be filed with the FOPH. In order to be listed, the Swissmedic approved medicinal product must satisfy the criteria of effectiveness, functionality and economic efficiency (art. 65 para. 1 and 3 of the Ordinance on Health Insurance [hereinafter: OHI] [Verordnung über die Krankenversicherung vom 27. Juni 1995, KVV; SR 832.102]). In order to assess the effectiveness criterion, the same documents are used as those submitted to Swissmedic for marketing authorization. However, the FOPH may require further documentation (art. 32 Ordinance on the Benefits of the Mandatory Health Insurance [hereinafter: OBHI] [Verordnung des EDI vom 29. September 1995 über Leistungen in der obligatorischen Krankenpflegeversicherung; Krankenpflege-Leistungsverordnung, KLV; SR 832.112.31]). With regard to the functionality of a medicinal product, the FOPH analyses its impact, composition and possible side effects (art. 33 OBHI). The economic efficiency of a medicinal product is evaluated by using a combination of different concepts:

First, the FOPH compares the price of the medicinal product with the average price of the same medicinal product in the reference countries Germany, Denmark, Great Britain, the Netherlands, France, Austria, Belgium, Finland and Sweden (Auslandspreisvergleich) (*cf.* *https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Mitteilungen-zur-Spezialitaetenliste.html, last visited on 31 March 2021*). Second, the FOPH compares the price of the medicinal product with the price of other medicinal products in Switzerland used to treat the same disease (therapeutischer Quervergleich). Both results will be evaluated equally (art. 65b OHI; art. 34a et seqq. OBHI). The FOPH has a large discretion in the composition of the reference drugs. The calculation process is illustrated by the following example: the average price in the reference countries is 100 Swiss francs; the average price for other medicinal products in Switzerland used to treat the same disease is 150 Swiss francs; as a result, the price for the new medicinal product is set at 125 Swiss francs ([100+150] / 2).

However, the price determined by these criteria is not yet definitive. The FOPH takes into account costs for research and development (unless the original product is a successor product that does not bring any therapeutic progress). In case of significant therapeutic progress, a so-called innovation supplement (Innovationszuschlag) is granted for a maximum of 15 years (art. 65b para. 6 and 7 OHI).

95. Which are the Opioid Drugs that have received market approval to date?

The Narcotics Directory Ordinance lists all controlled substances in Annexes 1 to 8. The controlled substances are divided into different dispensing categories. Based on these lists, Swissmedic maintains a list of authorized narcotic medicinal products for human use, which also includes Opioid Drugs. The list is updated on an ongoing basis but is not exhaustive or binding. Only the lists in the Narcotics Ordinance are binding for the assessment of approved Opioid Drugs.

The list can be accessed under section 4.1 on the Swissmedic website using the following link: https://www.swissmedic.ch/swissmedic/de/home/services/listen_neu.html#944532819 (*last visited 31 March 2021)*

96. Who can prescribe Opioid Drugs?

Opiod Drugs may only be prescribed by doctors, who have a professional license. When prescribing, dispensing and using medicinal products, the recognized rules of medical and pharmaceutical science must be observed by the doctor (art. 26 para. 1 TPA).

97. Is there a list of doctors authorized to prescribe Opioid Drugs?

The Medical Professional Register (MedReg) is a binding list of all medical professionals who are authorized by a cantonal authority to obtain Opioid Drugs. The register can be accessed at the following link: https://www.medregbm.admin.ch/Betrieb/Search (*last visited on 31 March 2021).*

98. What approvals or notifications are required to prescribe Opioid Drugs?

First of all, the prescribing doctor needs to be registered in the MedReg, to provide proof of the license to practice the profession. When prescribing and dispensing Opioid Drugs, the accepted rules of medical and pharmaceutical science must be followed by the doctor and a drug may only be prescribed if the health condition of the user is known (art. 26 TPA). Further, the prescription of Opioid Drugs must always be made with a prescription issued by a doctor, which he examined him- or herself (art. 46 of the Narcotics Control Ordinance).

The prescription, dispensing and administration of narcotics for substitution treatment requires a permit from the competent canton and for heroin-assisted treatment an additional permit from the federal government (art. 3a NarcA, section 2 and 3 of the Narcotics Addiction Ordinance).

99. Which organizations are authorized to sell/distribute Opioid Drugs available?

Organizations that manufacture or broker Opioid Drugs in Switzerland (manufacturing, wholesale, import and export) require an operating license (art. 4 para. 1 NarcA, art. 11 para. 1 of the Narcotics Control Ordinance). Likewise, pharmacies that carry out more than nine brokering of medicines require an operating license (art. 11 para. 4 of the Narcotics Control Ordinance). An operating license is issued by Swissmedic for individuals and companies and by the cantonal authorities for pharmacies, hospitals and scientific institutions (art. 5 para. 1 of the Narcotics Control Ordinance). The period of validity is five years. An operating license is granted if the applicant person or company meets the following criteria:

- entry in the Commercial Register
- the controlled substances are protected from theft
- designation of a person for the compliance with the narcotics legislation. The responsible person must be a medical professional or a person with a university degree in natural sciences.

In Switzerland, primarily pharmacists are authorized to sell Opioid Drugs. In principle, they may only dispense Opioid Drugs on the basis of a doctor's prescription, unless there is a justified exceptional case, or the Federal Council has provided for the dispensing of the drug by pharmacists. Furthermore, doctors are also authorized to dispense Opioid Drugs under the provisions on self-dispensation and trained specialists under the supervision of a pharmacist or a doctor. Self-dispensing by doctors is not regulated by federal law but is assessed according to the health law of the respective canton.

100. Is there a list of retailers/distributors authorized to sell Opioid Drugs?

Yes, there is a list of companies or individuals that have an operating license to handle controlled drugs, such as Opioid Drugs according to list a in Annex 2 of the Narcotics Directory Ordinance from the FDHA. The list can be accessed under section 4.3 on the Swissmedic website using the following link: https://www.swissmedic.ch/swissmedic/de/home/services/listen_neu.html#944532819 (*last visited 31 March 2021)*

101. Are there proposals for reform or significant change to the regulation of Opioid Drugs?

Currently, there are no planned reforms or efforts for significant change in the regulation of Opioid Drugs. However, due to the high potential for dependence and the significant increase in consumption in the recent years, especially of Opioid painkillers, the consumption of Opioid Drugs is being closely monitored by the authorities.

102. When are they likely to come into force?

See question 101.

09

ORPHAN DRUGS AND RARE DISEASES

103. What is the definition of Rare Diseases in your country?

104. Does the designation of 'Orphan Drug' exist in your country? (Does it correspond with the definition of Rare Diseases?)

105. What is the regulatory framework for the authorization of an Orphan Drug? (Is this regulatory framework based on Rare Disease status or can it alternatively be based on Orphan Drug foreign status?)

106. Does your country have provisions for relaxed clinical trial/scientific evidence requirements in respect of Orphan Drugs as compared to other drugs?

107. Is there an expedited pathway for Orphan Drugs?

108. Are foreign marketing authorizations recognized in your jurisdiction for Orphan Drugs? If yes, marketing authorizations from which countries are recognized?

109. Can Orphan Drugs be reimbursed? If so, is there a specific reimbursement procedure for Orphan Drugs?

110. How are the prices of Orphan Drugs regulated?

111. In case of reference price based on a basket of countries, what countries are included?

112. Have there been any significant legal/judicial developments in relation to Orphan Drugs in your country?

113. Are there proposals for reform or significant change to the regulation of Orphan Drugs? If yes, when are they likely to come into force?

09 ORPHAN DRUGS AND RARE DISEASES

103. What is the definition of Rare Diseases in your country?

A disease is deemed to be rare if it affects no more than five out of every 10,000 people.

104. Does the designation of 'Orphan Drug' exist in your country? (Does it correspond with the definition of Rare Diseases?)

Yes it does. However, the fact that a rare disease affects only a small number of people means that there is little specialist knowledge available. For this reason, it frequently takes years or even decades for the condition to be diagnosed correctly. It is often hard to find what treatments and forms of care are available. The few recognised therapies that exist are often limited to combating the symptoms. The causes of most rare diseases are not yet clear. Consequently, there is still no hope of a cure for the large majority of these rare conditions.

105. What is the regulatory framework for the authorization of an Orphan Drug? (Is this regulatory framework based on Rare Disease status or can it alternatively be based on Orphan Drug foreign status?)

In Switzerland, the designation of 'Orphan Drug' is granted to a medical product for human use upon application if the applicant proves that the medical product meets the criteria of Art. 4 paragraph 1 letter a[decies] of the Therapeutic Products Act (TPA), namely that the medical product serves to detect, prevent or treat a life-threatening or chronically disabling disease that affects no more than five out of 10,000 persons in Switzerland at the time the application is submitted or its active substance has been granted the status of an important orphan medicinal product by another country with comparable drug control. Furthermore, Art. 14 TPA provides for a simplified authorisation procedure for important medicinal products for rare diseases (Orphan Drug). The implementing provisions have been incorporated into the ordinance of the Swiss Agency for Therapeutic Products on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (TPLO). A distinction is made in the ordinance between recognition of the status as an important medicinal product for rare diseases (Art. 4 – 7 TPLO) and the authorisation of a medicinal product that has been granted Orphan Drug Status by Swissmedic (Art. 24 – 26 TPLO).

106. Does your country have provisions for relaxed clinical trial/scientific evidence requirements in respect of Orphan Drugs as compared to other drugs?

No. However, the EU created a legal foundation in 1999 in the form of Regulation (EC) No 141/2000. It foresees various measures to promote the recognition and visibility of rare diseases and reinforces collaboration and coordination at EU level. The legal foundation supports the creation of European reference networks and promotes the networking of specialist centres and experts in different countries. It has also created incentives for more research into rare diseases. Moreover, rare diseases are one of the priorities within the EU Framework Programme for Research and Innovation.

107. Is there an expedited pathway for Orphan Drugs?

There is a simplified authorisation procedure for Orphan Drugs in Switzerland (see question 105). Therefore, Switzerland knows an expedited pathway for Orphan Drugs in matters of authorisation.

108. Are foreign marketing authorizations recognized in your jurisdiction for Orphan Drugs? If yes, marketing authorizations from which countries are recognized?

Yes, foreign marketing authorizations for Orphan Drugs are recognized in Switzerland. If a drug or process is already approved in another country with comparable drug control, the results of the tests conducted for it are taken into account (Art. 13 TPA). A list of countries which are recognized does not exist, rather there must be an individual examination in each case if the foreign authorizations of a drug can be recognized in Switzerland. The key element here is whether the foreign country has a comparable drug control.

109. Can Orphan Drugs be reimbursed? If so, is there a specific reimbursement procedure for Orphan Drugs?

Orphan drugs are reimbursed either in accordance with the list of pharmaceutical specialities or in accordance with Art. 71b Health Insurance Ordinance (HIO) under the same conditions as for off-label use. Consequently, the medicine must be used to treat a life-threatening disease, and this must be compatible with the objective of protecting health. In addition, use of the medicine must be expected to lead to major therapeutic progress, and there must be no other comparable medicine available. These conditions state that the cost of medicinal products, that are not on the list of pharmaceutical specialities and used outside the registered indications, will also be reimbursed. However, this is only the case if the disease may have a fatal outcome or lead to severe or chronic problems for the insured person, and there are no therapeutic alternatives.

110. How are the prices of Orphan Drugs regulated?

In Switzerland, as in most other countries, the authorities determine the prices of medicines and review them at regular intervals. The prices of medicines reimbursed by the statutory health insurance providers are controlled by the Federal Office of Public Health (FOPH). In order to determine the price of a medicinal product, the FOPH first considers the cost of therapy with products authorised to treat the same disease. This process is known as internal reference pricing (IRP). It then compares the prices of products in other countries (known as external reference pricing, or ERP) in line with the recommendations of the Federal Medicines Commission (FMC). For external reference pricing, prices are compared with those in countries with a pharmaceutical industry economically comparable to that of Switzerland's.

Health insurance providers only reimburse the cost of a medicine prescribed by a doctor under the provisions of statutory health insurance if the FOPH has included it in the list of pharmaceutical specialities (LS). The medicine is examined for safety, efficacy and quality before the FOPH can include it in the LS. The authority responsible for this review is Swissmedic, the Swiss Agency for Therapeutic Products. Before a medicine can be included in the LS, Swissmedic considers not only whether it is effective and appropriate in

the context of social health insurance, but also whether it is cost-effective (known as a WZW assessment, from the German words for effectiveness, appropriateness and cost-effectiveness). The decision on inclusion is taken by the FOPH at the recommendation of the FMC. If medicines no longer fulfill the WZW criteria, their prices are adjusted, their use is restricted or, in certain cases, the FOPH removes them from the LS.

111. In case of reference price based on a basket of countries, what countries are included?

There is no basket of countries on which the reference price can be based on in Switzerland. However, for external reference pricing, prices are compared with those in countries with a pharmaceutical industry economically comparable to that of Switzerland's.

112. Have there been any significant legal/judicial developments in relation to Orphan Drugs in your country?

No, there are no significant legal/judicial developments in relation to Orphan Drugs at the moment.

113. Are there proposals for reform or significant change to the regulation of Orphan Drugs? If yes, when are they likely to come into force?

There have been two important postulates (Nr. 10.4055 and Nr. 11.4025) from the Swiss Federal Assembly concerning Orphan Drugs:

- With the postulate 10.4055 "National strategy for improving the health situation of people with rare diseases", the Federal Council is mandated to develop, in collaboration with organizations, specialists and the cantons a national strategy for rare diseases. The aim is to ensure that patients with rare diseases receive the same level of medical care throughout Switzerland. This includes timely diagnosis, appropriate treatment, and equal access to effective, evidence-based to effective, evidence-based therapies and medicines. The postulate was passed on March 18, 2011.
- With the postulate 11.4025 "Hardship Commission Health" the Federal Council is instructed to examine whether a Hardship Commission could be set up for the health sector, analogous to the Hardship Commission in the migration sector. Specifically, this Hardship Commission Health should cover cases in which it is disputed whether the insurance company should cover the expensive treatment of rare diseases. This postulate was passed on December 23rd, 2011.

Considering these two postulates, the Swiss Federal Council drafted a report regarding the legal basis and financial framework to ensure care in the field of rare diseases in February 2021. The report outlines the specific challenges faced by rare diseases and orphan drugs.

10

LOCALIZATION

114. Are there any rules or regulations requiring and/or encouraging localization in your country? What is the legal framework defining these localization rules and policies?

115. Have there been any recent significant changes involving localization rules? If yes, when did they take place and what did they involve?

116. Is the process of obtaining a marketing authorization impacted by localization policies in your country? If yes, how so (what are the incentives received or the requirements)?

117. Is the pricing process for pharmaceutical products impacted by localization policies in your country? If yes, how so (what are the incentives received or the requirements)?

118. Is the reimbursement of pharmaceutical products impacted by localization policies in your country? If yes, how so (what are the incentives received or the requirements)?

119. Is the access to public or public tenders of pharmaceutical products impacted by localization policies in your country? If yes, how so (what are the incentives received or the requirements)?

120. Are import tariffs, importation and/or exportation permits, trade and/or taxation of pharmaceutical products impacted by localization policies in your country? If yes, how so?

121. Are there any other incentives or advantages offered by the current local localization rules in your country? If yes, what are they?

122. Are there discussions about the possibility of implementing localization policies in your country? If yes, what are the proposed reforms and when should they come into place?

10 LOCALIZATION

114. Are there any rules or regulations requiring and/or encouraging localization in your country? What is the legal framework defining these localization rules and policies?	No, there are none. Since Switzerland is one of the most important pharmaceutical research hubs in the world alongside the USA and its reputation extends well beyond Europe, it is not necessary to encourage localization. Accounting for a direct share of 5.4 percent of gross domestic product (GDP), the pharma industry is one of the most important sectors of the private economy in Switzerland. In 2017, the research-based pharmaceutical companies invested more than 6.5 billion Swiss Francs in research and development (R&D) in Switzerland, a figure that is almost twice the volume of the turnover achieved in Switzerland. Every Swiss Franc transferred from the Swiss healthcare system to the pharmaceutical industry is reinvested almost twice over in Switzerland. Some 46,800 employees generate 36 billion Swiss Francs in value added every year. A total of 254,100 jobs depend on the success of the pharmaceutical industry. With a 38% share of Swiss goods exports, the pharmaceutical industry is by far the most important export sector in Switzerland. The export revenues of around 88 billion Swiss Francs come mainly from European countries. However, the strongest growth in demand in recent years has come from North America and Asia. Due to the strong position of the Swiss pharmaceutical industry in the world market there are currently no rules or regulations requiring or encouraging localization in Switzerland.
115. Have there been any recent significant changes involving localization rules? If yes, when did they take place and what did they involve?	No, there are no localization rules in Switzerland (see question 114).
116. Is the process of obtaining a marketing authorization impacted by localization policies in your country? If yes, how so (what are the incentives received or the requirements)?	No, there are no localization policies in Switzerland (see question 114).
117. Is the pricing process for pharmaceutical products impacted by localization policies in your country? If yes, how so (what are the incentives received or the requirements)?	No, there are no localization policies in Switzerland (see question 114).

118. Is the reimbursement of pharmaceutical products impacted by localization policies in your country? If yes, how so (what are the incentives received or the requirements)?	No, there are no localization policies in Switzerland (see question 114).
119. Is the access to public or public tenders of pharmaceutical products impacted by localization policies in your country? If yes, how so (what are the incentives received or the requirements)?	No, there are no localization policies in Switzerland (see question 114).
120. Are import tariffs, importation and/or exportation permits, trade and/or taxation of pharmaceutical products impacted by localization policies in your country? If yes, how so?	No, there are no localization policies in Switzerland (see question 114).
121. Are there any other incentives or advantages offered by the current local localization rules in your country? If yes, what are they?	No, there are no localization rules in Switzerland (see question 114).
122. Are there discussions about the possibility of implementing localization policies in your country? If yes, what are the proposed reforms and when should they come into place?	No, since Switzerland is one of the most important pharmaceutical industries in the world alongside the USA and its reputation extends well beyond Europe, it is not necessary to encourage localization at this moment. However, growing tension within the relationship with the EU is leading to legal uncertainty. Switzerland needs to consolidate its bilateral relationship with the EU in the long term. The legal uncertainty is to a certain extent home-grown. Against the background of rising healthcare costs, calls to limit entrepreneurial freedom are bound to get louder. Therefore, it is even more important for the industry to send the right signals regarding the environment, social affairs and company management in the future.

11

BIOSIMILARS AND BIOLOGICS

123. Are biosimilar medicines considered the same as generic medicines in your country?

124. Are all biologic medicines, including biosimilar medicines, patentable in your country?

125. Is there a specific regulatory framework for the marketing authorization of biosimilar medicines in your country? If yes, what is the regulatory framework for the authorization of biosimilar medicines?

126. What kind of data package is needed to obtain approval for a biosimilar drug? Is this any different to the requirements for the original Biologics drug?

127. What are the requirements for the choice of the reference comparator product?

128. Can the comparator product be sourced from another regulatory jurisdiction? If yes, what are the data needed to support this approach?

129. How are the prices of biosimilar medicines regulated? Is this any different from the requirements for the original Biologics drug?

130. What is the reimbursement policy for biosimilar medicine? Is this any different from the requirements for the original Biologic drug?

131. Does biosimilar competition impact the reimbursement policy of the originator reference products?

132. What is the legal framework for biosimilar medicines prescribing (clinical decision maker) and dispensing (pharmacy level, hospital or retail)? Is this any different to the requirements for the original Biologics drug?

133. Is the system considering physician-led switching and/or pharmacy-level substitution (without involvement of the clinical decision maker)?

134. What are the post - authorisation requirements (including pharmacovigilance, risk management plans, post-approval studies) for biosimilar medicines? Is this any different to the requirements for the original Biologics drug?

135. Are there specific policies and requirements for labelling biosimilar medicines in the event of second medical use patents? Is this any different from the requirements for the original Biologic drug?

136. Have there been any significant legal/ judicial developments in relation to biosimilars in your country? (Including but not limited to IP, procurement, competition, misleading information campaign, access to reference comparator product)

137. Are there proposals for reform or significant change to the legal, regulatory, procurement of biosimilars? If yes, when are they likely to come into force?

11 BIOSIMILARS AND BIOLOGICS

123. Are biosimilar medicines considered the same as generic medicines in your country?

No, compared to generics with chemically synthesized active ingredients, the production of biosimilars is much more complex, and further requirements must be met for their approval.

124. Are all biologic medicines, including biosimilar medicines, patentable in your country?

Under current law, no initial notification protection (patent) is granted for biosimilars. Upon receipt of an application for authorisation of a biosimilar, Swissmedic examines a possibly ongoing first filing protection for the reference product according to Article 12 Remedies Act (HMG). If the initial notification protection has not yet expired at the time of receipt of the application, or if there is no corresponding consent from the marketing authorisation holder of the reference product, Swissmedic will not proceed with the biosimilar application. Indications, new routes of administration, new dosage forms or new dosages for reference products that are still protected may not be applied for in the case of a biosimilar. As a matter of practice, Swissmedic does not act on such applications.

125. Is there a specific regulatory framework for the marketing authorization of biosimilar medicines in your country?
If yes, what is the regulatory framework for the authorization of biosimilar medicines?

For the approval of a biosimilar, manufacturers must prove that the biosimilar is sufficiently similar to a "*reference preparation in terms of structure, pharmaceutical quality, biological activity, efficacy, safety and immunogenicity to exclude relevant clinical differences with sufficient certainty*". These characteristics of a biosimilar must be documented by its manufacturer through physicochemical and biological characterization of the biosimilar, as well as through comprehensive preclinical and clinical studies ("*comprehensive comparability exercise*").

If the approval criteria are met, the manufacturer receives approval for the drug. The sales method and the professional and patient information are determined and approved by Swissmedic.

126. What kind of data package is needed to obtain approval for a biosimilar drug?
Is this any different to the requirements for the original Biologics drug?

The data requirements for approval differ between reference products and biosimilars, as the approval procedure for biosimilars does not aim to provide renewed evidence of the efficacy and safety of the active substance. Rather, the process aims to demonstrate biosimilarity to the reference product.

For this purpose, comprehensive analytical, non-clinical and clinical comparability studies to the reference product and solid data on pharmaceutical quality are required. These comparability studies represent the cornerstone of biosimilar development and approval. The aim of these comparative studies

is to exclude potential product-related differences that could affect pharmacokinetics and dynamics, efficacy or safety.

127. What are the requirements for the choice of the reference comparator product?

In principle, manufacturers are free to decide for which indications and dosage recommendations of the reference product an authorization of the biosimilar is applied for. If the comparability of the reference product and biosimilar in terms of efficacy and safety has been documented for at least one sensitive indication and dosage, the comparability of the active substances can also be "extrapolated" to other indications. In this context, in the case of complex mechanisms of action and multiple target receptors, additional comparative analyses may be necessary in isolated cases, particularly for immunogenicity. Which indications or dosage recommendations are permissible for the biosimilar by extrapolation from the reference product is decided by Swissmedic on a case-by-case basis.

128. Can the comparator product be sourced from another regulatory jurisdiction? If yes, what are the data needed to support this approach?

No, there has never been a corresponding approved reference product in Switzerland, thus, no biosimilar approval is possible in this respect.

129. How are the prices of biosimilar medicines regulated? Is this any different from the requirements for the original Biologics drug?

In contrast to original products, whose cost-effectiveness is determined based on the APV and TQV, the cost-effectiveness test for biosimilars is based on a price gap rule compared to the reference product.

The FAP of the biosimilar is determined upon new inclusion in the SL in such a way that a price gap of at least 25 percent is maintained compared to the reference product. Only then are biosimilars considered economical. Every three years, the Federal Office of Public Health (FOPH) reviews the price of the reference product. In this context, the price of the biosimilar is also adjusted. The biosimilar is economic if the price difference to the reference product is at least 10%.

Moreover, the price of a biosimilar is at least 25% below the price of the reference product at market launch.

130. What is the reimbursement policy for biosimilar medicine? Is this any different from the requirements for the original Biologic drug?

An obligation to reimburse medicinal products by the compulsory health care insurance (OKP) exists only for medicinal products and indications that are on the SL of the Confederation. The Federal Office of Public Health (FOPH) decides on the inclusion of the drug in the SL (the SL is a conclusive positive list that is binding for insurers) and its reimbursed definitive price, in the case of new innovative drugs with the inclusion of the recommendation of the Federal Drug Commission. Medicinal products and indications that are not on the SL can be reimbursed in individual cases according to Art. 71a-c of the Ordinance on Health Insurance (KVV) if "*the use of the medicinal product*

is expected to have a major therapeutic benefit against a disease that may be fatal for the insured person or result in severe and chronic health impairments, and no other effective and approved treatment method is available due to a lack of therapeutic alternatives". In addition, reimbursement is possible in individual cases if the use of the drug is an indispensable prerequisite for the performance of another service covered by the OKP and this is clearly the primary objective. The health insurer determines the amount of reimbursement after consultation with the marketing authorization holder.

Consequently, the reimbursement policy for biosimilar medicine does not differ to the requirements for the original drug.

131. Does biosimilar competition impact the reimbursement policy of the originator reference products?

No, since reimbursement policy for biosimilar medicine does not differ to the requirements for the original drug (see question 130).

132. What is the legal framework for biosimilar medicines prescribing (clinical decision maker) and dispensing (pharmacy level, hospital or retail)? Is this any different to the requirements for the original Biologics drug?

The legal framework for biosimilar medicine prescribing does not differ to the requirements for the original drug. However, intra-organizational guidelines and policies in hospitals can influence prescribing behaviour for biosimilar products. There are only a few hospitals which have clear guidelines or statements from the hospital management on the use of biosimilars. Most hospitals in Switzerland do not currently have any guidelines from the management on the use of biosimilars. In Switzerland, the format of the medical indication dominates, i.e. the prescribing physicians decide on the therapy and not cost specifications by the management.

133. Is the system considering physician-led switching and/ or pharmacy-level substitution (without involvement of the clinical decision maker)?

In Switzerland, the automatic substitution of biologics (physician-led switching and/or pharmacy-level substitution) is not allowed as the substitution paragraph in the Health Insurance Act refers only to chemical drugs and generics (Art. 52a HIA).

134. What are the post - authorisation requirements (including pharmacovigilance, risk management plans, post-approval studies) for biosimilar medicines? Is this any different to the requirements for the original Biologics drug?

Regulatory documents must be continuously updated, and the use of a drug must be constantly monitored. The pharmaceutical company has a duty to notify the competent authorities of all changes that affect the granted marketing authorization. Depending on the scope of the changes, they may have to be approved by the authorities. Simple changes that only require notification are, for example, administrative changes at the manufacturer or minor changes in the manufacturing process. Changes to the dose, the dosage form or the form of application, for example, require approval. Any change to the summary of product characteristics also requires approval. Furthermore, the pharmaceutical company is obliged to collect and evaluate information on adverse drug reactions even after marketing authorization has been granted. Reports must

be submitted to the regulatory authority at specified intervals and in the case of serious, unexpected cases of adverse drug reactions also within short deadlines. Continuous monitoring is so important as it is not possible to detect rare or very rare side effects in clinical trials with only a few thousand patients.

Consequently, the post-authorisation requirement for biosimilars do not differ to the requirements for the original biologics drug.

135. Are there specific policies and requirements for labelling biosimilar medicines in the event of second medical use patents? Is this any different from the requirements for the original Biologic drug?

In general, the information on the drug package serves to ensure that a drug is recognized as such as unmistakably as possible. Every medicine package must, therefore, be provided with prescribed information. This includes the brand name of the drug and its active ingredient as well as some important information on safety and proper storage. Each package also contains a patient information leaflet in the three (out of four) national languages. It provides information on the purpose, correct use and symptoms of any undesirable effects of the drug.

Moreover, the product information for a biosimilar is not an exact copy of that for the original biologics drug. However, all appropriate sections of the product information text for the biosimilar must be identical to the corresponding sections of the product information for the original biologics drug. Since a biosimilar does not need to have all the indications of the original biologics drug, the information for healthcare professionals may differ in the "Indications / usage" section, for example.

136. Have there been any significant legal/judicial developments in relation to biosimilars in your country? (Including but not limited to IP, procurement, competition, misleading information campaign, access to reference comparator product)

Switzerland ratified its first legislations concerning biosimilars in 2008. Since then a few new regulations have been ratified. However, there are no significant legal/judicial developments in relation to biosimilars from the past year.

137. Are there proposals for reform or significant change to the legal, regulatory, procurement of biosimilars? If yes, when are they likely to come into force?

Under the current Swiss Patent Act (PatA), a Supplementary Protection Certificate (SPC) grants the same rights as the corresponding basic patent and is subject to the same restrictions. A SPC, thus, protects all types of commercial use of the protected medicinal product, including manufacturing, storage, offering, market placement, import, export and transit. However, these do not include the manufacture of generics or biosimilars for export purposes or the stockpiling of generics or biosimilars for market entry in Switzerland immediately after expiry of the SPC. In other words: Under applicable law, no SPC manufacturing waiver is available to Swiss generic/biosimilars manufacturers.

Initiated by the parliamentary request «SPC-Waiver: Switzerland also needs a solution to maintain the competitiveness of the generics industry»

of 12 June, the Federal Council expressed its opinion for the first time on 17 July 2019 on the introduction of an SPC Manufacturing Waiver in Switzerland. The Federal Council announced that it would analyse the advantages and disadvantages of introducing a manufacturing waiver for Switzerland and then decide on the next steps. As the competent authority, the Federal Department of Justice and Police and in particular the Swiss Federal Institute of Intellectual Property are responsible for this matter. In principle, the Federal Council will endeavour to bring the Swiss regulations on SPC into line with European law. In view of the vastly controversial discussions in the EU that preceded the introduction of the SPC Manufacturing Waiver, the Federal Council may be inclined to wait for the first experiences with the SPC Manufacturing Waiver in the EU and, based thereon, to decide on its possible implementation. The parliamentary procedure for the legislative amendment required to introduce the SPC Manufacturing Waiver will also take some time.

DIRECTORY OF LOCAL INSTITUTIONS

The following list of local institutions is not exhaustive. In particular, a list of cantonal authorities is not provided.

- Swiss Agency for Therapeutic Products (Schweizerisches Heilmittelinstitut [Swissmedic])
- Federal Department of Home Affairs (Eidgenössisches Departement des Innern [EDI])
- Federal Office of Public Health (FOPH) (Bundesamt für Gesundheit [BAG])
- Ethics committees (Ethikkommissionen): Ethics Committee northwest/central Switzerland EKNZ, Ethics Committee Bern, Ethics Committee Geneva, Ethikkommission Ostschweiz EKOS, Ethics Committee Ticino, Ethics Committee Vaud, Ethics Committee Zurich
- Swiss Financial Market Supervisory Authority (Eidgenössische Finanzmarktaufsicht [FINMA])
- Swiss Federal Institute of Intellectual Property (Eidgenössisches Institut für Geistiges Eigentum [IGE])

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