

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

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 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?

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

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

4. What are the approximate fees for each authorization?

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

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

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

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

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

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

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

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

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

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

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?

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 based on 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), Ethics Committee Eastern Switzerland EKOS, Ethics Committee Ticino,*

¹The 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, not legally binding and serve information purposes only.

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** (*Konformitätsbewertungsverfahren*) 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,