1. The pharmacopoeia - the compendium of medicines

In Switzerland, the pharmacopoeia consists of the European Pharmacopoeia (Ph. Eur.) and the Swiss Pharmacopoeia (Ph. Helv.). The currently valid versions are available at www.swissmedic.ch/pharmacopoeia (Implementation dates - information access).

The pharmacopoeia is a collection of provisions regarding the quality of medicines. The Ph. Eur. contains over 2,000 single monographs on active substances and pharmaceutical excipients, forms of administration, medicinal plants, vaccines, blood products and homeopathic preparations. The Ph. Helv. contains 110 monographs and about 110 general texts (state Ph. Helv. 11.1).

The provisions are fundamental: they are valid for all medicinal products placed on the market in Switzerland (Law on Therapeutic Products, HMG, Art. 8). They are also international: The Ph. Eur. is elaborated under the aegis of the Council of Europe and comes into force simultaneously in the 37 European States, including the EU as an organisation, that have signed the Council of Europe Convention for the Elaboration of a European Pharmacopoeia ("Convention", Swiss law SR 0.812.21).

Like many European states, Switzerland elaborates a national pharmacopoeia (Ph. Helv.) to complete the Ph. Eur. This makes it possible to introduce, flexibly and rapidly, quality requirements that are important for Switzerland.

Entry into force of the Pharmacopoeia

The Swissmedic Agency Council enacts an Agency Ordinance to bring the Ph. Eur. and Ph. Helv. into force (see for example SR 812.214.11). A new addendum to the Ph. Eur. comes into force three times a year: on 1 January, 1 April and 1 July. The Agency Council is bound by the Convention to respect these three dates. The Ph. Helv. and its supplements normally come into force once a year, in the country's three official languages; the Agency Ordinance is thus modified and updated three times a year.

Because of the EU and World Trade Organization (WTO) notification procedure (technical obstacles to trade), the Pharmacopoeia division notifies the State Secretariat for the Economy (SECO) of new texts included in the Ph. Helv.

2. International integration

The following entities are involved in ensuring that the Convention for the Elaboration of the Ph. Eur. is applied:

EDQM, European Directorate for the Quality of Medicines & HealthCare
- The European Pharmacopoeia organisation in Strasbourg. It is the scientific secretariat, laboratory and administrative centre for the Ph. Eur.
- Financing for the EDQM as a sub-organisation of the Council of Europe partially comes from the signatory states. For Switzerland, attributing the relevant budget falls within the mandate of the Swiss Federal Department of Foreign Affairs (EDA).

EPC, the European Pharmacopoeia Commission
The EPC consists of delegations from the Member States and from the EU as an organisation. It unanimously adopts all texts for the Ph. Eur., whereby each delegation has veto rights. The Swiss delegation has three members and three alternate members from the authorities and from industry.
delegation is appointed by the Federal Department of Home Affairs (EDI). In addition, 24 observer states and the WHO also attend the EPC sessions.

**Ph. Eur. Expert Groups**

The monographs and other texts of the pharmacopoeia are drawn up by professionals in around 20 international Expert Groups and more than 40 Working Groups, and are then verified in laboratories. 73 Swiss experts from industry, the authorities, and graduate institutes work in 94 of these groups, and around 25 percent of them are Swissmedic employees. Draft monographs from the Expert Groups are published in PHARMEUROPA, the official publication of the EDQM, for public consultation (Pharmeuropa Online). Further details on the elaboration of a Ph. Eur. monograph can be found at the EDQM at the following link: Elaborations and Revisions of the European Pharmacopoeia - EDQM

**Certification of Suitability**

Manufacturers of pharmaceutical products can request the EDQM to issue a “Certificate of Suitability”. This confirms that a monograph in the Ph. Eur. enables an adequate control of the quality of a substance from a specific source. This certificate makes the authorisation procedure simpler: for example because it is no longer necessary to validate the analysis methods. 6 representatives from Switzerland - all from the authorities - collaborate within the framework of the certification programme.

The input from this body permits the Expert Groups to take both the latest status of science and technology and pharmaceutical practice into account when revising and drawing up a monograph.

**EDQM Experts Steering Committee on Pharmaceuticals and Pharmaceutical Care**

This Committee supervises the work of the EPC, and its Resolutions define the date on which the adopted monographs come into force. This date is valid for all 37 signatory states. Switzerland is represented by an employee of the Swiss Federal Office of Public Health and a Swissmedic employee.

**Swiss Federal Department of Foreign Affairs (EDA)**

- Is responsible for attributing the Swiss contribution to the budget of the European Pharmacopoeia Organisation
- Switzerland's permanent representation at the Council of Europe in Strasbourg provides support for the Swiss delegation at the Ph. Eur. with regard to political issues.
- The Political Affairs Division I of the EDA is consulted by Swissmedic when decisions by the EPC concern topics related to foreign policy, such as the participation of observer states at the EPC sessions.

3. Entities involved in the Swiss pharmacopoeia

**The Swiss Pharmacopoeia Commission (SPK)**

The Commission advises Swissmedic regarding the elaboration of the Ph. Helv. and provides support to the Pharmacopoeia division when establishing standards. It is a key link between the various types of users and ensures that pharmaceutical practice is taken into account. The professional associations pharmaSuisse and GSASA (Swiss Society of Public Health Administration and Hospital Pharmacists) are represented therein, as are the Cantonal pharmacists and specialists from industry, graduate institutions, and Swissmedic. The various language regions are also taken into account when the Agency Council appoints the around 14 members The SPK is chaired by the head of the Pharmacopoeia division. Specific ad-hoc working groups are set up for specific topics (e.g. good manufacturing practice - GMP: see below).

**Expert Committees**

The pharmacopoeia essentially covers five specific fields: biological products, chemistry, galenic forms, phytochemistry and complementary medicinal products. An Expert Committee is appointed by the Director of Swissmedic for each field, consisting of 10-15 experts who contribute their valuable, external knowledge of the field and their practical experience. The committees' work is devoted to the extent of around 75 percent to the Ph. Eur. and around 25 percent to the Ph. Helv. They take a stance on the draft monographs of the Ph. Eur. in PHARMEUROPA and elaborate the Ph. Helv. texts. The scientific secretariat of the committees is always provided by an employee of the Pharmacopoeia division.
Good Manufacturing Practices for medicines produced in small quantities ("GMP rules")
The rules in the Ph. Helv are applicable wherever medicinal products are manufactured in small quantities and, by virtue of Article 9, paragraph 2 of the Law on Therapeutic Products (HMG), are not subject to authorisation: for example in dispensaries, hospital pharmacies and drugstores.

4. The Pharmacopoeia division - the hub of the Swiss pharmacopoeia organisation

The Pharmacopoeia division is the National Pharmacopoeia Authority (NPA) and coordinates the network of around 120 Swiss professionals involved in elaborating the pharmacopoeia. See the overview on the subject at: (The Pharmacopoeia Network in Switzerland). In this way, the principle laid down in the Law on Therapeutic Products (Art. 52, para. 2) of associating interested spheres in the elaboration of the pharmacopoeia is respected.

The division’s main tasks are:
- Participation in the elaboration of the Ph. Eur.
- Publication of the Ph. Helv.
- The coordination of all actors on a Swiss and European level regarding pharmacopoeia-related activities (see Ordinance on the pharmacopoeia, RS 812.211, art. 2, para. 2).

For the Ph. Eur., this includes:
- Stances on the part of the Swiss delegation (scientific and political)
- NPA stances (scientific stances on draft texts for the Ph. Eur.)
- Informal discussions with other delegations
- Collaboration with national pharmacopoeia secretaries
- Editorial conference: collaboration with Germany and Austria for the translation of the Ph. Eur (English/French -> German; in accordance with the law relating to publications)
- Ensuring the availability of the Ph. Eur. in Switzerland (German and French) (Collaboration with the Federal Office for Buildings and Logistics - BBL)

For the Ph. Helv., this includes:
- Developing monographs and texts in collaboration with laboratories
- Revision, drafting and publishing of texts in the official languages (German, French, Italian)

At all levels, this includes:
- Early involvement of interested circles, and active networking with domestic and foreign partners
- Support for the experts (scientific and organisational)
- Providing information for professionals and details of specific issues related to the pharmacopoeia

Organisational aspects:
- Swissmedic's Pharmacopoeia division consists of 8 scientific officers, 1 specialised writer and 1 administrative assistant.
- For analytical laboratory work, collaboration with the Swissmedic Official Medicines Control Laboratory (OMCL) is particularly important.
- Collaboration with the around 183 expert mandates related to the Ph. Eur./Ph. Helv. is ensured by contracts and appointments to the Expert Groups and Expert Committees
- Additional know-how is brought in for specific topics by means of mandates attributed to external laboratories.
- On an organisational level, the Swissmedic Pharmacopoeia division is part of the Authorisation Sector.
5. Legal basis

- Convention of 22.7.1964 for the Elaboration of a European Pharmacopoeia (SR 0.812.21)
- Protocol of 16.11.1989 on the Convention for the Elaboration of a European Pharmacopoeia (SR 0.812.211)
- Federal Act of 15.12.2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA)
  - Art. 4, para.1 g): Definition of the term "Pharmacopoeia"
  - Art. 8: confirmation of the fact that the requirements of the Pharmacopoeia must be met in order for products to be placed on the market
- Art. 52: The Agency's responsibility for enacting and elaborating the pharmacopoeia, Confirmation of the principle of involving interested circles, note regarding international conventions on the pharmacopoeia, Stipulation by the Federal Council regarding the languages of publication
- Ordinance on the Pharmacopoeia (PhaV) of 17.10.2001; a Federal Ordinance, SR 812.211
- Ordinance of 9.11.2001 of the Swiss Agency for Therapeutic Products regarding the enactment of the pharmacopoeia and the recognition of pharmacopoeias (SR 812.214.11): to bring into force the currently valid version of the pharmacopoeia

6. Publications and where to find them

- The Ph. Eur. is available as a book, as a USB Stick or online in the original languages of the Council of Europe.
  - The French edition, in book form, has been adopted by Switzerland. The Ph. Eur. is translated jointly into German by Germany, Austria and Switzerland. The French and German editions, in book form, and the German version as a DVD can be ordered from the Federal Office for Buildings and Logistics, BBL, Publications Dept., 3003 Bern (www.bundespublikationen.admin.ch).
  - Online access, the USB Stick (in English and French) and the book in English can be ordered from the European Pharmacopoeia Organisation: https://www.edqm.eu/store
- The Ph. Helv. is available as a book with a online access in German, French and Italian, from the Federal Office for Buildings and Logistics (BBL), Publications Dept., 3003 Bern (www.bundespublikationen.admin.ch). The online version contains the texts in all three language versions, in pdf format. It can be consulted and printed out. In addition, the online version contains the reference spectra of the Ph. Helv., the manufacturing protocol and packaging protocol of Chapter 21.1, Explanations regarding the Rules of Good Manufacturing Practice for Medicines Produced in Small Quantities as a form to be completed electronically, saved and printed as well as illustrations of HPTLC chromatograms.
- "PHARMEUROPA. The European Pharmacopoeia Forum", a publication by the EDQM with texts and monographs of the Ph. Eur. for public consultation and scientific publications on issues related to the pharmacopoeia. Information on PHARMEUROPA can be found at Pharmeuropa Online.
- Other publications in specific professional journals, such as the Swissmedic Journal (www.swissmedic.ch -> Documentation-> Swissmedic Journal)
7. Additional information

Information on the pharmacopoeia from Swissmedic:

- [www.swissmedic.ch](http://www.swissmedic.ch) -> About us -> Legal matters -> Pharmacopoeia
- [www.swissmedic.ch/pharmacopoeia](http://www.swissmedic.ch/pharmacopoeia) (direct link)
- [www.swissmedic.ch/azneibuch](http://www.swissmedic.ch/azneibuch) (direct link to the German version)
- [www.swissmedic.ch/pharmacopee](http://www.swissmedic.ch/pharmacopee) (direct link to the French version)
- [www.swissmedic.ch/farmacopea](http://www.swissmedic.ch/farmacopea) (direct link to the Italian version)

European Pharmacopoeia: [www.edqm.eu](http://www.edqm.eu)

8. Contact addresses

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