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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/swissmedic/en/home.html (> Legal matters, standards > Pharmacopoeia > Implementation dates).
The pharmacopoeia is a collection of provisions regarding the **quality of medicines**. The Ph. Eur. contains around 2,500 single monographs on active substances, pharmaceutical excipients, herbal drugs, preparations and forms of administration, around 380 general chapters and general texts and about 2,800 descriptions of reagents (version: Ph. Eur. 10.5). The Ph. Helv. contains about 100 monographs and about 50 general texts (version Ph. Helv. 11.1)
The provisions are fundamental: they **are valid for all medicinal products** placed on the market in Switzerland (Therapeutic Products Act, TPA, 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 39 European States and the EU as an organisation. The basis for this is the Council of Europe Convention for the Elaboration of a European Pharmacopoeia ("Convention", Swiss law SR 0.812.21).
Like many European states, Switzerland produces a **national pharmacopoeia** (Ph. Helv.) to supplement the Ph. Eur. This means it is also possible to define binding quality requirements for medicinal products that are of purely Swiss relevance.

Entry into force of the Pharmacopoeia

The Swissmedic Agency Council enacts an Agency Ordinance to bring the Ph. Eur. and Ph. Helv. into force (SR 812.214.11). A new addendum to the Ph. Eur. comes into force three times a year: in each case on 1 January, 1 April and 1 July. A new edition is published every three years. The Ph. Helv.is also updated regularly: a new edition is published every two to three years.

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

This European Pharmacopoeia organisation, based in Strasbourg, 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 (FDFA).

COM, the European Pharmacopoeia Commission
The COM consists of delegations from the Member States and from the EU as an organisation. It unanimously adopts all texts for the Ph. Eur., with each delegation having veto rights. The Swiss delegation is appointed by the Federal Department of Home Affairs (FDHA), has three members and three alternate members from the authorities and from industry and is led by the Head of the Pharmacopoeia Division. In addition, 28 observer states and two organisations (WHO, TFDA) also attend the COM sessions.

Ph. Eur. Groups of Experts and Working Parties
The monographs and other texts of the pharmacopoeia are drawn up by professionals in a total of around 60 international Groups of Experts and Working Parties, and are then verified in laboratories. Swiss experts from industry, the authorities, and graduate institutes hold around 100 expert mandates in these groups and therefore make a significant contribution to this work. Around 55 percent of specialist work is undertaken by Swissmedic employees. Draft monographs from the expert groups are published in Pharmeuropa Online, the official publication of the EDQM, for public consultation (https://pharmeuropa.edqm.eu/home). Further details on the elaboration of a Ph. Eur. monograph can be found at the EDQM: www.edqm.eu (European Pharmacopoeia > The Ph. Eur. work programme > Elaborations & Revisions)

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. Several experts from Switzerland – all from the authorities – collaborate in the certification programme.
The input from the certification programme supports the Ph. Eur. Groups of Experts and Working Parties in taking 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
The CD-P-PH supervises the work of the COM, and its Resolutions define the date on which the adopted monographs come into force. This date is valid for all signatory states and also for the EU. Switzerland is represented in this committee by the Swiss Federal Office of Public Health (FOPH) and Swissmedic.

Swiss Federal Department of Foreign Affairs (FDFA)
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 FDFA is consulted by Swissmedic when decisions by the COM concern topics related to foreign policy, such as the inclusion of observer states.

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 (Swiss Pharmacists' Association), GSASA (Swiss Association of Public Health Administration and Hospital Pharmacists) and SDV (Swiss Druggists Association) are represented therein, as are the cantonal pharmacists and specialists from industry, universities and Swissmedic. Based on their mandate, the Chairs of the Expert Groups are members of the SPK. The SPK is chaired by the head of the Pharmacopoeia Division.

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 support Swissmedic in drawing up opinions on the Ph. Eur. draft monographs published in Pharmeuropa Online. They also elaborate the Ph. Helv. texts. The scientific secretariat of the committees is always provided by an employee of the Pharmacopoeia Division.

Working Groups
Ad-hoc Working Groups can be set up for specific topics. This was the case, for example, with drawing up the Rules of Good Manufacturing Practice for medicinal products in small quantities ("GMP small quantities" – quality assurance regulations for manufacturing medicinal products that are exempt from authorisation and dispensed in pharmacies and drugstores to their own customers).

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 130 Swiss professionals involved in elaborating the pharmacopoeia. In this way, the principle laid down in the Therapeutic Products Act (Art. 52, para. 2) of associating interested spheres in the elaboration of the pharmacopoeia is respected.

The division's main tasks are:
- Participation in producing the Ph. Eur.
- Publication of the Ph. Helv.
- The coordination of all actors on a Swiss and European level regarding pharmacopoeia-related activities

For the Ph. Eur., this includes:
- Direct participation in Groups of Experts and Working Parties
- Formulating Swiss stances and submitting these to the EDQM and the COM
- Informal discussions with the NPAs and other delegations
- Collaboration with national pharmacopoeia secretaries of other member states
- 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 - FOBL)

For the Ph. Helv., this includes:
- Developing and updating monographs and texts in collaboration with laboratories
- Editing and publishing of the work in the official Swiss 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 1 division head, 5 scientific officers, 1 specialised writer and 2 administrative assistants
- On an organisational level, the division is part of the Licensing Sector of Swissmedic.

- For analytical laboratory work, collaboration with the Swissmedic Official Medicines Control Laboratory (OMCL) is particularly important.
- The Pharmacopoeia Division is supported in its work by the members of the Swiss and European pharmacopoeia expert groups, who provide assistance on a voluntary basis.
- It nominates and supervises the pharmacopoeia experts (total of approximately 190 expert mandates) and manages the scientific secretariat of the Swiss pharmacopoeia expert groups (organisation of meetings including minute-taking, coordination/assurance of resulting work).

5. Legal basis

- Convention for the Elaboration of a European Pharmacopoeia (SR 0.812.21)
- Protocol on the Convention for the Elaboration of a European Pharmacopoeia (SR 0.812.211)
- Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA), in particular:

  Art. 4 para. 1 let. g : Definition of the term "Pharmacopoeia“
  Art. 8 : confirmation of the fact that the requirements of the Pharmacopoeia must be met in order for medicinal products to be placed on the market in Switzerland
  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, a Federal Ordinance, SR 812.211)
- Ordinance 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
- Swiss Federal law on compendiums of Federal Law and the Federal Gazette (Publications Act, PublA, SR 170.512)

6. Publications and where to find them

- The Ph. Eur. is available as a book or as an electronic version in the original languages of the Council of Europe (English and French).
- 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).
- The electronic version (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 online free of charge in German, French and Italian (www.phhelv.ch). A print-on-demand version can be ordered for a fee from the Federal Office for Buildings and Logistics (FOBL), 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, downloaded 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 Online is a publication by the EDQM with texts and monographs of the Ph. Eur. for public consultation and contains scientific publications and information on issues related to the pharmacopoeia. Information on Pharmeuropa Online can be found at: https://pharmeuropa.edqm.eu/home

- The Work Programme of the Ph. Eur. shows monographs and texts that are in preparation and their current status: see www.edqm.eu/en/european-pharmacopoeia-work-programme-607.html.
- Additional information on the content of the Ph. Eur. and ongoing revision work can be found in the Knowledge Database of the EDQM: www.edqm.eu/en/where-find-knowledge-database.
- Other publications in specific professional journals, such as the Swissmedic Journal (www.swissmedic.ch/swissmedic/en/home.html > About us > Publications > Swissmedic Journal).

7. Additional information

Information on the pharmacopoeia from Swissmedic:

- www.swissmedic.ch/swissmedic/en/home.html > Legal matters, standards > Pharmacopoeia
- www.swissmedic.ch/arzneibuch (direct link to the German version)
- www.swissmedic.ch/pharmacopee (direct link to the French version)
- www.swissmedic.ch/farmacopea (direct link to the Italian version)
- www.swissmedic.ch/pharmacopoeia (direct link to the English version)

Information on the European Pharmacopoeia:

- www.edqm.eu

8. Contact addresses

Swissmedic Swiss Agency for Therapeutic Products Pharmacopoeia Division Hallerstrasse 7 3012 Bern	+41 (58 462 95 35 (Tel. Secretariat) pharmacopoeia@swissmedic.ch (e-mail)