Pharmacopoeia unit

In terms of the Act No.362/2011 Coll. on the medicinal products and medical devices the Pharmacopoeia Unit at the State Institute for Drug Control (SIDC) ensures the cooperation at the elaboration of European Pharmacopoeia and compilation of the Slovak Pharmaceutical Codex.

European Pharmacopoeia 8th edition

The European Pharmacopoeia (Ph. Eur.) defines requirements for the qualitative and quantitative composition of medicines, the tests to be carried out on medicines and on substances and materials used in their production. The monographs of the Pharmacopoeia are applicable throughout the 37 member states of the Council of Europe and the European Union.

It covers active substances, excipients and preparations of chemical, animal, human or herbal origin, homoeopathic preparations and homoeopathic stocks, antibiotics, as well as dosage forms and containers. It also includes texts on biologicals, blood and plasma derivatives, vaccines and radiopharmaceutical preparations. According to the Act No. 663/2006 Coll. (Convention on the Elaboration of a European Pharmacopoeia) the Ph. Eur. and its requirements became the official standards applicable within the Slovak Republic. These quality standards therefore have an impact on the quality of medicinal products and substances also in the Slovak Republic.

The legal framework and the mission of the European Pharmacopoeia are available at the website of the European Directorate for the Quality of Medicines and HealthCare (EDQM) https://www.edqm.eu/en/european-pharmacopoeia-background-50.html

Since January 1st 2014 the European Pharmacopoeia 8th edition is valid. The European Pharmacopoeia is being published in a 3-year cycle with thrice-yearly supplements. Users are recommended to consult the index of the most recent supplement to ensure they use the latest versions of the monographs and general chapters.

Publication Schedule:

Commission Sessions		8th Edition Supplements	Publication Schedule	Implementation Date
Session N°	Date			
–	–	8th Edition	15 July 2013	1 Jan. 2014
145	Mar. 2013	8.1	1 Oct. 2013	1 Apr. 2014
146	June 2013	8.2	1 Jan. 2014	1 July 2014
147	Nov. 2013	8.3	1 July 2014	1 Jan. 2015
148	Mar. 2014	8.4	1 Oct. 2014	1 Apr. 2015
149	June 2014	8.5	1 Jan. 2015	1 July 2015
150	Nov. 2014	8.6	1 July 2015	1 Jan. 2016
151	Mar. 2015	8.7	1 Oct. 2015	1 Apr. 2016
152	June 2015	8.8	1 Jan. 2016	1 July 2016
153	Nov. 2015	9th Edition	15 July 2016	1 Jan. 2017

Slovak Pharmaceutical Codex defines technical requirements for preparation, quality assessment, labelling, storage, prescription and dispensation of extemporaneous preparations and stock preparations and intermediate products. The first edition contains 68 monographs of medicinal products, 17 monographs of active substances and excipients, 89 monographs of herbal drugs and herbal teas. Currently the second edition is being prepared.