Polish Pharmacopoeia

Submitted by urpl_techniczny on Fri, 01/04/2016 - 11:40

POLISH PHARMACOPOEIA

General and legal base

The Pharmacopoeias have been the official publications containing lists of basic qualitative requirements for medical products placed on the pharmaceutical market at the given territory for decades. The first collection of qualitative requirements for applied agents, considered the first Polish Pharmacopoeia (*Pharm. Regni Pol.*) was published in the Kingdom of Poland in 1817; Polish Pharmacopoeia, XIIIth edition remains currently in force.

The task of elaboration and publishing of the Polish Pharmacopoeia has been assigned to the President of the Office under Article 4, Paragraph 1, Clause 5 of the Act of 18 March, 2011, *on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products*. This provision also states that the date of entrance of the requirements specified in the Polish Pharmacopoeia into force is announced in a form of an Announcement of the President of the Office in the Public Information Bulleting.

The principles of applying of the Pharmacopoeia provisions in Poland are stipulated in Article 25 of the Pharmaceutical Law Act of 6 September, 2001. Paragraph 1 of this Article recommends the use of the European Pharmacopoeia or translation thereof into the Polish language included in the Polish Pharmacopoeia; Paragraph 2 specifies, *inter alia,* application of the Polish Pharmacopoeia requirements in the scope of monographs having no equivalents in the Ph. Eur.

Organization of Elaboration Process of the Polish Pharmacopoeia (Pharmacopoeia Department and Pharmacopoeia Commission)

Tasks associated with preparation and publication of the Polish Pharmacopoeia are carried out by Pharmacopoeia Department and Pharmacopoeia Commission with their groups of experts. The Pharmacopoeia Department participates in the elaboration and publication process of Polish Pharmacopoeia and coordinates the activity of Polish Pharmacopoeia Commission and 11 groups of experts. In a series of the meetings of the Commission and groups of experts the materials for Polish Pharmacopoeia are being verified and adopted.

The Polish Pharmacopoeia (Pharmacopoea Polonica – PhPol)

Since 2006, the Polish Pharmacopeia has been the Polish version of the

European Pharmacopoeia. The Polish Pharmacopoeia also contains a systematically extended section of national monographs for galena products, the list of doses, lists A, B and N of active substances described in the monographs. The publication system of the European Pharmacopoeia requires constant updating of the Polish Pharmacopoeia. The main volume of XIIth edition of the Polish Pharmacopoeia, which is in full accord with the European Pharmacopoeia 10.0 – 10.2, was published in November 2020; the Supplement 2021 PhPol XII based on the Supplements 10.3 – 10.5 Ph. Eur. was published in December 2021 and the Supplement 2022 PhPol XII based on the materials of the Ph. Eur. 10.6 – 10.8 was published in November 2022. The main volume of XIIIth edition of the Polish Pharmacopoeia, which is in full accord with the European Pharmacopoeia 11.0 – 11.2, was published in November 2023.

Cooperation with the European Pharmacopoeia Commission

On the 21st December 2006 Poland became a party of *the Convention on the Elaboration of a European Pharmacopoeia*. Since December 2006 Polish representatives have been taking part in the activities of the European Pharmacopoeia Commission and its groups of experts or working parties in Strasbourg.