

Polish Pharmacopoeia

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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, Xth 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* (Journal of Laws of 2011, No. 82, item 451 as amended). 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 Bulletin.

The principles of applying of the Pharmacopoeia provisions in Poland are stipulated in Article 25 of the Pharmaceutical Law Act of 6 September, 2001 (Journal of Laws of 2008, No. 45, item 271 as amended). 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, which consists of 3 pharmacists and 1 biotechnologist, 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 Pharmacopoeia 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 Xth edition of the Polish Pharmacopoeia, which is in full accord with the European Pharmacopoeia 8.0 - 8.2, was published in November 2014; the Supplement 2015 PhPol X based on the Supplements 8.3 - 8.5 Ph. Eur. was published in December 2015. The Supplement 2016 PhPol X based on the materials of the Ph. Eur. 8.6 - 8.8 will be published in November 2016.

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

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