

SPECIFIC PROVISIONS

applicable to homeopathic medicinal products and their registration dossier

1. Homeopathic medicinal products which materials of registration dossier may not contain the proof of their therapeutic efficacy shall satisfy the following requirements:

medicinal products are intended for oral or external use;

no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto;

there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

2. Registration dossier may cover a series of medicinal products derived from the same homeopathic stock or stocks. The following documents shall be included with the materials of registration dossier in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the medicinal products concerned:

scientific name given in pharmacopoeia (SPhU or European Pharmacopoeia, if no - German Homeopathic Pharmacopoeia (GHP), Homeopathic Pharmacopoeia of the United States (HPUS), British Herbal Pharmacopoeia (BHP), Dr. Willmar Schwabe's Homoeopathic Pharmacopoeia) of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered;

dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic use, on the basis of an adequate bibliography;

description of manufacturing and control of each pharmaceutical form and a description of the method of dilution and potentization of medicinal product;

copy of manufacturing license (if according to manufacturer's national legislation the manufacturing license is available in electronic form only (e.g. USA), the printout with reference to the appropriate official site certified by applicant's signature/stamp should be provided) or other licensing document to manufacture the applied pharmaceutical form in the manufacturer's country;

certified copy of the document confirming the compliance of manufacture of medicinal product with GMP issued by the State Administration of Ukraine on Medicinal Products according to the MoH Ukraine Order of December 27, 2012 № 1130 "On approval of procedure for confirming compliance of manufacture of medicinal products with GMP" registered with the Ministry of Justice of Ukraine of January 21, 2013 №133/22665 (amended) or applicant's letter of guarantee to submit such document during specialized expert evaluation;

proposals for labelling;

instruction for medical use drawn up according to the requirements of Annex 20 of the Procedure if the outer packaging has insufficient information;

data concerning the stability of the medicinal product.

{Annex 7 in wording of MoH Ukraine Order №460 as of 23.07.2015}