

Annex 2
to the Procedure for Review of Registration
Materials Pertinent to Medicinal Products
Submitted for the State Registration (Re-
Registration) and Materials about
Introduction of Changes to Registration
Materials during the Validity Period of
Registration Certificate for Medicinal
Products Registered by Competent
Authorities of the United States of America,
the Swiss Confederation, Japan, Australia,
Canada and Medicinal Products Registered
by Competent Authority of the European
Union Through Centralized Procedure (Item
1 of Part II)

LIST

of registration materials to be submitted for review with the purpose of
registration

1. Materials pertinent to methods of quality control of medicinal product (in Ukrainian).
2. Materials of registration dossier, on which basis the registration of medicinal product was conducted by appropriate competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada or competent authority of the European Union through centralized procedure and used at the territory of these countries or Member States of the European Union with the data specified about registration of medicinal product in these countries including country of registration, competent authority and date of registration confirmed by the applicant and/or its representative taking in account all changes introduced after registration of this medicinal product.

Packages of changes to this dossier approved in reference country shall be submitted as annexes following the complete content of dossier or may be submitted in dossier replacing sections in previous version. Copies of applications for introducing changes and document about their approval in reference country shall precede the package of changes.
3. Mock-up of packages for medicinal product and text of labelling for primary and secondary (if available) packaging of medicinal product according to the requirements of Annex 23 of Procedure for conducting expert evaluation.
4. Instruction for use of medicinal product stated according to the requirements of Annex 20 of the Procedure for conducting expert evaluation and Summary of product characteristics* stated according to Annex 22 of the same Procedure.
5. Document confirming payment of registration fee.
6. Certified in due order copy of document issued by the State Service of Ukraine on Medicines and Narcotics Control in established MoH order, which confirms the compliance of manufacturing conditions of submitted for

registration medicinal product with the current in Ukraine GMP requirements, or commitment letter of manufacturer to produce the appropriate medicinal product for supply in Ukraine with the same manufacturing capacities used in manufacture of medicinal products intended for use at the territory of the United States of America, the Swiss Confederation, Japan, Australia, Canada or Member States of the European Union.

7. Letter of guarantee from the applicant or applicant's representative, where he guarantees the completeness and reliability of information, which he submits in registration dossier (optional for applicant).

8. Letter from the applicant or applicant's representative, where it is stated, that the rights of third party protected by the patent or transferred by the license are not violated in view of registration of medicinal product.

*Shall be submitted, if available (at applicant's discretion).

{Annex 2 amended by MoH Ukraine Order [№ 1202 as of 02.10.2017](#)}