

Annex 6

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 III)

LIST

of materials about introduction of changes to registration materials submitted for review

1. In case of change:

which when introduced to appropriate registration dossier in the United States of America, the Swiss Confederation, Japan, Australia, Canada or the European Union (pertinent to medicinal product registered through the centralized procedure) requires a special confirming document issued by appropriate competent authority according to legislation of appropriate country, or

which when introduced to appropriate registration dossier in the United States of America, the Swiss Confederation, Japan, Australia, Canada or the European Union (pertinent to medicinal product registered through centralized procedure) does not require a special confirming document issued by appropriate competent authority according to legislation of appropriate country,

the applicant submits to the Center the following documents:

package of changes with appropriate sections of materials of registration dossier where changes have been introduced in the United States of America, the Swiss Confederation, Japan, Australia, Canada or the European Union (pertinent to medicinal product registered through centralized procedure);

updated materials pertinent to methods of quality control of medicinal product (if available);

updated text of labelling stated according to the requirements of Annex 23 of the Procedure for conducting expert evaluation (if required);

updated instruction for use of medicinal product stated according to the requirements of Annex 20 of the Procedure for conducting expert evaluation*, and updated Summary of product characteristics* stated according to the requirements of Annex 22 of the Procedure for conducting expert evaluation.

2. In addition to documents stated in item 1, in case of change, which when introduced to appropriate registration dossier in the United States of America, the Swiss Confederation, Japan, Australia, Canada or the European Union (pertinent to medicinal product registered through centralized procedure) requires a special confirming document issued by appropriate competent authority according to legislation of appropriate country, the applicant submits to the Center a copy of document confirming introduction of appropriate changes to registration dossier in the United States of America, the Swiss Confederation, Japan, Australia, Canada or the European Union (pertinent to medicinal product registered through centralized procedure)*, if there is no such document the applicant gives reference for the Center to information about introduction of such changes on web-site of appropriate competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada or the European Union.

3. In addition to documents stated in item 1, in case of change, which when introduced to appropriate registration dossier in the United States of America, the Swiss Confederation, Japan, Australia, Canada or the European Union (pertinent to medicinal product registered through the centralized procedure) does not require a special confirming document issued by appropriate competent authority according to legislation of appropriate country, the applicant submits to the Center a letter of confirmation that changes to registration materials do not require approval of competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada or the European Union (pertinent to medicinal product registered through the centralized procedure).

4. If changes caused by requirements of legislation in Ukraine and when applicant is changed, the applicant shall submit documents envisaged by Procedure for conducting expert evaluation for appropriate type of change.

5. If change relates to correction of technical error, the applicant shall submit to the Center a letter of request of optional form specifying the error and substantiating its correction.

*Submitted (if available) at applicant's discretion.

{Annex 6 amended by the MoH Ukraine Order [№ 1202 as of 02.10.2017](#), amended by the MoH Ukraine Order [№ 1391 of 15.06.2020](#)}