

Annex 3
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 4 of Part II)

CONCLUSION

**based on results of review of registration materials submitted for state registration of
medicinal product registered by competent authority**

(country)

and used at the territory of this country or Member States of the European Union

Based on results of review of registration materials submitted for state registration of medicinal
product registered by competent authority of

(country of registration, competent authority and date of registration)

and used at the territory of

(country(ies))

Name of medicinal product (in Ukrainian and English)_____

Pharmaceutical form, strength (dose)_____

Package:

primary_____

secondary_____

Applicant (registration certificate holder) (in Ukrainian) _____

Manufacturer (in Ukrainian), address of manufacturer (in Ukrainian) _____

Based on results of review of registration materials it is established:

Availability of 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):

• yes

• no

Availability of 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:

• yes

• no

Confirmation of the fact of registration of medicinal product by appropriate competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada or registration of medicinal product by competent authority of the European Union through centralized procedure and use at the territory of these countries or Member States of the European Union

☐ yes

☐ no

Availability of materials pertinent to methods of quality control of medicinal product

☐ yes

☐ no

Availability of 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 used at the territory of these countries or Member States of the European Union

☐ yes

☐ no

Availability of text of labelling for packaging of medicinal product according to the requirements established in Ukraine

☐ yes

☐ no

Availability of instruction for use of medicinal product stated according to the requirements established in Ukraine

☐ yes

☐ no

Availability of document confirming payment of registration fee

☐ yes

☐ no

Availability of certified copy of document, which confirms the compliance of manufacture of medicinal product with GMP requirements, issued by the State Service of Ukraine on Medicines and Narcotics Control according to the Procedure for confirming conditions of medicinal product manufacture with GMP requirements approved by MoH Ukraine Order as of 27 December 2012 № 1130, registered with the Ministry of Justice of Ukraine as of 21 January 2013 under № 133/22665 (amended)

☐ yes

☐ no

or

Availability of commitment letter of manufacturer responsible for batch release to produce the medicinal product for supply in Ukraine with the same manufacturing capacities used in manufacture of medicinal products intended

for use in the United States of America, the Swiss Confederation, Japan, Australia, Canada or Member States of the European Union

☐ yes

☐ no

Availability of explanation/additional data and/or information provided by the applicant in response to the Center's request that were necessary for further review of registration materials (in accordance with paragraphs two and three of item 3 of Part II of 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 ", approved by the MoH Ukraine Order of November 17, 2016 under № 1245, registered with the Ministry of Justice of Ukraine on December 14, 2016 under № 1619/29749,) and their acceptability

☐ yes ☐ no

CONCLUSION

All registration materials were submitted in full; if “no”, specify which materials the registration dossier lacks	☐ yes	☐ no
{Paragraph twenty four was excluded based on the MoH Ukraine Order № 1202 as of 02.10.2017}		
Name of manufacturer of such medicinal product, his location and address of manufacturing capacities stated in application for state registration of medicinal product comply with information on which basis this medicinal product was registered by appropriate competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada or the European Union; if “no” specify which information is inappropriate	☐ yes	☐ no

The materials reviewed, taking into account the answers to the remarks, allow to make a decision on the state registration of such a medicinal product.	☐ yes	☐ no
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{Annex 3 amended by the MoH Ukraine Order № 1202 as of 02.10.2017, № 1391 of 15.06.2020}