

Annex 8
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 11 of Part III)

CONCLUSION

on results of review of materials about introduction of changes to registration materials

Based on review of **materials about introduction of changes to registration materials** for
medicinal product registered by competent authority of

_____ (country)
and used at the territory of _____
(country(ies))

Name of medicinal product _____

Pharmaceutical form, strength (dose) _____

Packaging:

primary _____

secondary _____

**Applicant (holder of registration
certificate)** _____

Manufacturer _____

Brief description of changes _____

Results of review of materials about introduction of changes to registration materials:

Confirmation of approval of changes by appropriate competent authority

☐ provided

☐ not provided

or

Letter of confirmation from the applicant that changes to registration materials are not subject to
approval by the appropriate competent authority

☐ provided

☐ not provided

The appropriate sections of materials of registration dossier, where changes have been
introduced (if available)

☐ provided

☐ not provided

Materials pertinent to updated methods of quality control of medicinal product (if necessary)

☐ provided

☐ not provided

Updated text of labeling of package of medicinal product with labeling according to the established requirements in Ukraine (if necessary)

☐ provided

☐ not provided

Updated instruction for use of medicinal product, stated according to the established requirements in Ukraine (if necessary)

☐ provided

☐ not provided

Availability of document confirming payment of registration fee (if necessary)

☐ yes

☐ no

CONCLUSION

All materials are provided in full: if “no” specify which materials registration dossier lacks	☐ yes	☐ no

{Annex 8 amended by MoH Ukraine Order № 1391 of 15.06.2020}