

Annex 5
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)

Application

**for introducing changes to registration materials pertinent to medicinal product registered by
competent authorities of the United States of America, the Swiss Confederation, Japan,
Australia, Canada and medicinal product registered by competent authority of the European
Union through centralized procedure and used at the territory of these countries or Member
States of the European Union**

Submitted on ____, _____ 20____	No _____
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I hereby declare that:

there are no other changes than those identified in this application (except for those addressed in other applications submitted in parallel);

all conditions for the change(s) to registration materials pertinent to medicinal product registered by competent authorities of the United States of America, the Swiss Confederation, Japan, Australia, Canada and medicinal product registered by competent authority of the European Union through centralized procedure and used at the territory of these countries or Member States of the European Union are fulfilled (if applicable);

the required documents for the change(s) to registration materials pertinent to medicinal product registered by competent authorities of the United States of America, the Swiss Confederation, Japan, Australia, Canada and medicinal product registered by competent authority of the European Union through centralized procedure and used at the territory of these countries or Member States of the European Union have been submitted.

Changes will be implemented (tick where appropriate):

From the next manufacturing run/next printing,

Date _____

All fees will be paid in accordance with the requirements of the current legislation.

I guarantee the reliability of information contained in the registration materials submitted.

Main signature _____ _____ (full name)	_____ (position) « ____ » _____ 20 ____
Second signature (if applicable) _____ _____ (full name)	_____ (position) « ____ » _____ 20 ____

Type of variations (tick appropriate)

According to EU classification

Type IA_{IN}

Type IA

Type IB

Type II

safety

urgent safety restriction

quality

other

Name of medicinal product	
Active substance(s)	
Pharmaceutical form, dose	
Type, size and contents of package	
Registration certificate №	
Applicant	

Manufacturer responsible for batch release	
Person authorized to act on behalf of applicant	

Notes:

Attach copy of the application about introduction of changes, which has been submitted to competent authority of reference country, certified by the signature of the authorised person of the applicant.

{Annex 5 in wording of the MoH Ukraine Order № 1202 as of 02.10.2017, amended by the MoH Ukraine Order № 1391 of 15.06.2020 }