

Annex 4
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 Part II)

Application

**for Re-Registration of 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**

Date of submission: “ ____ ” _____ 20__	No _____
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I declare that the quality of medicinal product, in respect of the methods of preparation and control, has been regularly updated by variation procedure to take account of technical and scientific progress.

I confirm that no changes have been made to the medicinal product particulars other than those approved by MoH.

I hereby ensure the validity and hold responsibility for information contained in submitted materials of the registration dossier. I agree that, if the materials of registration dossier have not been submitted after the Center's receipt of the MoH letter of referral within three months, the application for state re-registration of this medicinal product shall be revoked.

All envisaged fees will be paid according to the legislation requirements.

On behalf of the applicant	_____ (signature) _____ (full name)
Seal (if available)	_____ (position)
Name of medicinal product	
Name of medicinal product in the United States of America, the Swiss Confederation, Japan,	

Australia, Canada, the European Union (item 5 of this application)	
Active substance(s)	
Pharmacotherapeutic group (use the current ATC code):	
Pharmaceutical form, dose	
Type, size and contents of package	
Registration certificate №	
Applicant (holder of registration certificate)	
Manufacturer responsible for batch release	
Person authorized to act on behalf of the applicant	
Date of first registration in Ukraine	
Date of expiry of registration certificate	

1. Applicant (holder of registration certificate) (for domestic manufacturers in Ukrainian, for foreign manufacturers in Ukrainian and English):

Name of legal person or full name of physical person-entrepreneur	
Location of legal person or address of physical person-entrepreneur	
Country	
Tel./fax	
e-mail	

2. The applicant's representative (person authorised to act on behalf of the applicant):

Name of legal person or full name of physical person-entrepreneur being the applicant's representative	
Location of legal person or address of physical person-entrepreneur	
Country	
Tel./fax	
e-mail	

3. Approved manufacturers (in Ukrainian and English):

1) Manufacturer(s) responsible for batch release

Name of legal person or full name of physical person-entrepreneur	
Address of manufacturing capacities	
Country	
Tel./fax	
e-mail	

2) Official batch release for Blood Products and Vaccines

(Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release):

Name of laboratory	
Location of laboratory	
Country	
Tel./fax	
e-mail	

3.1. Approved manufacturer(s) of the medicinal product and site(s) of manufacture:

(Including manufacturing sites of any diluent/solvent presented in a separate pack/container but forming part of the medicinal product, quality control/in-process testing sites, and importers (if

applicable)).	
Name of legal person or full name of physical person-entrepreneur	
Address of manufacturing capacities	
Country	
Tel./fax	
e-mail	
Brief description of functions performed	

3.2. Approved manufacturer(s) of the active substance(s) and site(s) of manufacture <i>(All manufacturing sites involved in the manufacturing process of each source of active substance, including quality control/in-process testing sites, should be listed. For advanced therapy (biotech) medicinal products include all sites of storage of master and working cell bank and preparation of working cell banks.</i>	
Active substance	
Name of legal person or full name of physical person-entrepreneur (manufacturer)	
Address of manufacturing capacities	
Country	
Tel./fax	
e-mail	
Brief description of manufacturing steps performed by manufacturing site	

4. Qualitative and quantitative composition

Qualitative and quantitative composition of medicinal product

(AS and excipients):

Indicate to which quantity the composition refers (e.g. 1 capsule)

List the active substances separately from the excipients:

Name of AS*	Quantity	Unit	Reference/monograph
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1. 2. 3. etc.			
Name of excipient (s) 1. 2. 3. etc.	Quantity	Unit	Reference/monograph

** The name for each AS should be given in the following order of priority: INN should be named by its recommended INN, accompanied by its salt or hydrate form (if necessary), common name, scientific (chemical) name.*

Details of any overages:

Active substance(s)

Excipient (s)

5. Data about validity of registration of medicinal product by competent authority 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 on date of submitting application for re-registration

Country _____

Competent authority _____

Registration (certificate or other similar document) № _____

Date of registration «__» _____

Date of re-registration «__» _____

6. APPENDED DOCUMENTS (tick the necessary)

☐ 6.1. Letter of authorization for communication/signing documents on behalf of the applicant (registration certificate holder).

☐ 6.2. Chronological list of all variation applications submitted to MoH since the issue of registration certificate in Ukraine: a list of all approved or pending Type IA/IB and Type II variations, variations requiring a new registration, USR, giving the date of submission, date of approval (if approved) and brief description of the change in form of comparative table.

☐ 6.3. Copy of registration certificate in Ukraine with attachments to registration certificate.

☐ 6.4. Certified copy of the document confirming the compliance of manufacturing conditions of medicinal product submitted for registration with requirements to manufacture of medicinal products in Ukraine issued by central executive body which implements the state policy in quality and safety control of medicinal products or commitment letter of manufacturer responsible for batch release to produce the appropriate 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.

☐ 6.5. Copy of document confirming the validity of registration of this medicinal product by competent authority 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 or reference to information about registration of such medicinal product. Reference to this information is provided on official online-resource of competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, the European Union (pertinent to medicinal product registered through centralized procedure).