Annex 14
to the Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products Submitted for the State Registration (Re-Registration) and for Expert Evaluation of Materials about Introduction of Changes to Registration Materials during the Validity Period of Registration Certificate (item 9 of section IV)

REGISTRATION FORM

for Medicinal Product Submitted for Re-Registration

Date of submission: "___" _____ 20__	№_____

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) _____ (name)
Seal	_____ (position)

Name of medicinal product	
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)	
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 (for domestic manufacturers in Ukrainian, for foreign manufacturers in Ukrainian and English):

1) Manufacturer(s) responsible for batch release	
Name of legal person or full name of physical person-entrepreneur	
Location of activity	
Country	
Tel./fax	
e-mail	

2) Official batch release for <u>Blood Products and Vaccines</u>

(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	
Location of activity	
Country	
Tel./fax	
e-mail	
Brief description of functions performed	

□ Attach a copy of manufacturing license (subitem 5.3, item 5 of this Annex).

□ Attach copy of proof of GMP compliance envisaged in subitem 5.5, item 5 of this Annex.

3.2. Approved manufacturer(s) of the active substance(s) and site(s) of manufacture

(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.

Active substance	
Name of legal person or full name of physical person-entrepreneur (manufacturer)	
Location of activity	
Country	
Tel./fax	
e-mail	

Brief description of manufacturing steps performed by manufacturing site

□ For each active substance, attach a declaration of the manufacturer's authorized person (subitem 5.6 of this Annex).

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
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), SPhU, European Pharmacopoeia, common name, scientific (chemical) name.*

Details of any overages should not be included in the composition columns but stated below

Active substance(s)

Excipient (s)

5. APPENDED DOCUMENTS

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

□ 5.2. 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.

□ 5.3. Copy of manufacturing license (if according to manufacturer's national legislation the manufacturing license is available in electronic form only (e.g. USA), the printout with reference to the appropriate official site certified by applicant's signature/stamp should be provided) or other licensing document to manufacture the applied pharmaceutical form in the manufacturer's country. Copy should be certified by stamp of the applicant/representative of the applicant in Ukraine.

□ 5.4. Copy of registration certificate in Ukraine with attachments to registration certificate.

□ 5.5. Certified copy of the document confirming the compliance of manufacture of medicinal product with GMP issued by the State Administration of Ukraine on Medicinal Products according to the MoH Ukraine Order of December 27, 2012 № 1130 "On approval of procedure for confirming compliance of manufacture of medicinal products with GMP" registered with the Ministry of Justice of Ukraine of January 21, 2013 №133/22665 (amended) or applicant's letter of guarantee to submit such document during specialized expert evaluation. Copies should be certified by stamp of the applicant (if available)/representative of the applicant in Ukraine.

□ 5.6. For each active substance, attach a declaration from the Qualified Person (QP) of each manufacturing license holder specified in application which use AS as a starting material and declaration from the QP of each of the manufacturing license holders specified in registration

form as responsible for batch release, if different. In application specify that AS manufacturer complies with good manufacturing practice for starting materials. Alternatively, such declaration may be signed by one QP on behalf of all QPs involved (provided this is clearly indicated).

(Annex 14 in wording of MoH Ukraine Order №460 as of 23.07.2015)