Annex 3
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 1 of section IV)

REGISTRATION FORM

for Medicinal Product Produced According to the Approved Specification

Which is Submitted for State Registration

Date of submission "___" _____ 20___	№ _____

1**. Name of medicinal product** _____
_____

2. **Pharmaceutical form, strength (dose)** _____
_____
_____

3. **Pack:**
primary_____,
secondary _____

4. Applicant (holder of registration certificate) (for domestic applicant – in Ukrainian, for foreign applicant – 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_____
_____
Tel./fax _____
e-mail _____
Head _____
_____

4.1. Applicant representative (person authorized to act on behalf of the applicant) (in Ukrainian):

Name of authorized person of applicant representative _____
_____
_____

Name of legal person or full name of physical person-entrepreneur_____

_____

Location of legal person or address of physical person-entrepreneur_____
_____
_____
_____

Tel./fax_____
e-mail _____

4.2. Qualified person of the applicant responsible for pharmacovigilance and/or contact person in Ukraine of the qualified person of the applicant responsible for pharmacovigilance (**in Ukrainian**):

Name_____

_____

Name of legal person or full name of physical person-entrepreneur (of the applicant)_____

_____

Location of legal person or address of physical person-entrepreneur (of the applicant)_____
_____
_____
_____
_____

24H tel./fax_____

e-mail _____

5. Manufacturer(s) (for domestic manufacturers – in Ukrainian, for foreign manufacturers – in Ukrainian and English).

5.1. Manufacturer(s) of medicinal product

Name of legal person or full name of physical person-entrepreneur_____
_____
_____

Location of conducting activity_____
_____
_____

Tel./fax _____
e-mail _____

Head _____

_____

Medicinal product is manufactured (tick the necessary):

- ☐ Completely by the indicated manufacturer;
- ☐ Partially by the indicated manufacturer;
- ☐ Completely by another manufacturer.

5.2. Manufacturer(s) of active substance(s)

Active substance _____

_____

Name of legal person or full name of physical person-entrepreneur (of the manufacturer)_____

_____

_____

Location of conducting activity _____

_____

_____

Tel./fax_____

e-mail _____

Head _____

_____

6. Qualitative and quantitative composition of medicinal product (active substances and excipients).

List the active substances separately from the excipients.

Name of substance *	Quantity per unit of pharmaceutical form**	Reference/ monograph

_____

* Only one name 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.

** In units of weight or biological units per unit of pharmaceutical form: dragee, tablets, suppositories, ampoules, vials; in % or mg/ml, mg/g: ointments, creams, solutions, indivisible powders, collections.

7. Pharmacotherapeutic group

_____

_____

8. ATC code or suggestions to it _____

9. Proposed shelf-life _____

10. Proposed storage conditions _____

_____

11. Proposed dispensing category:

□ not subject to medical prescription

□ in hospital only

I hereby ensure the validity and hold responsibility for the information contained in the submitted materials of registration dossier.

I agree that, if materials of registration dossier have not been submitted within three months after the Center's receipt of the MoH letter of referral, the application for state registration of this medicinal product shall be revoked.

It is hereby confirmed that all envisaged fees will be paid according to the legislation requirements.

On behalf of the applicant	_____ (signature) _____ (name)
Seal	_____ (position)

APPENDED DOCUMENTS

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

□ 2. 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 the applicant's signature/stamp (if available) 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 (if available)/representative of the applicant in Ukraine. This document may not be submitted with registration form but obligatory must be submitted when the Center recommends the medicinal product for registration.

3. 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. Conclusions on other inspections conducted should be provided, if necessary. Copies should be certified by stamp of the applicant (if available)/representative of the applicant in Ukraine.

{Annex 3 in wording of MoH Ukraine Order №460 as of 23.07.2015}