Annex 1
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 Submitted for State Registration

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

Name of medicinal product	
Active substance(s)	
Pharmaceutical form, dose	
Type, size and contents of package	
Applicant	
Person authorized to act on behalf of the applicant	

I hereby ensure the validity of information contained in submitted registration materials according to the type of medicinal product and hold responsibility according to the current legislation. I agree that, if registration dossier (according to type of medicinal product) has not been submitted after the Center's receipt of the MoH letter of referral within three months, the application for state registration of this medicinal product shall be revoked.
All data have been obtained by the applicant in a legal way and do not violate the right of the third party, protected by the patent and certificate of trade mark for goods and services (subitem 4.16, item 4 of this Annex).

It is hereby confirmed that all envisaged fees will be paid according to the legislation requirements.
☐ Please attach letter of authorization for communication/signing on behalf of the applicant (subitem 4.4, item 4 of this Annex).

On behalf of the applicant	_____ (signature) _____

	(name)
Seal	_____ (position)

1. General Items of Registration Form

(In case of filling in information related to specific type of medicinal product, the list of other types of medicinal products not related to this one, shall be withdrawn).

Note. This section to be completed for any type of medicinal product, including those referred to below.

This registration form is submitted according to the following:

☐ **Medicinal product with complete dossier (stand-alone dossier)**

☐ **Medical immunobiological product**	☐ **Other medicinal product**

(registration dossier with administrative, pharmaceutical, preclinical and clinical data shall be submitted)

□ **New active substance (AS)**

Note. *AS is used for the first time.*

□ **Known active substance**

Note. *AS has been used previously.*

□ **Medicinal product with well-established medicinal use**

(the registration dossier with full administrative, pharmaceutical data and detailed scientific references should be submitted to demonstrate the efficacy and safety of active substance (section III of the Procedure)

□ **Informed consent application**

(the medicinal product possessing the same qualitative and quantitative composition in terms of AS and the same pharmaceutical form of the registered medicinal product where consent has been given by existing holder of registration certificate to use his data for registration of the applied medicinal product).

The registration dossier with complete administrative data should be submitted with consent of the holder of registration certificate for registered medicinal product to use his pharmaceutical, preclinical and clinical data)

Note. The registered medicinal product and medicinal product being the subject of this registration form can have the same or different holder(s) of registration certificate.

Registered medicinal product:

Name of medicinal product, strength, pharmaceutical form	
Holder of registration certificate	
Registration certificate №	

□ Attach informed consent from the registration certificate holder of the registered medicinal product (subitem 4.2, item 4 of this Annex).

□ **Generic medicinal product**

□ **Single component** □ **Multicomponent**

(The registration dossier with complete administrative and pharmaceutical data and appropriate preclinical and clinical data, if applicable, including equivalence to reference medicinal products (if studies have been conducted) (section III of the Procedure)) should be submitted.

Reference medicinal product:

Name of medicinal product, strength, pharmaceutical form	
Holder of registration certificate	
Date of registration	
Registration certificate №	

Medicinal product used for equivalence study (where applicable):

Name of medicinal product, strength, pharmaceutical form	
Holder of registration certificate	
Date of registration	
Registration certificate№	
Bioavailability study (code) №/EudraCT № (if available)	

Note. Section shall be filled in for each medicinal product used for equivalence study.

□ **Hybrid medicinal product**
(In cases, when medicinal product doesn't fall within the definition of generic medicinal product or when bioequivalence can not be demonstrated in bioavailability studies or in case of differences in active substance, dosage, pharmaceutical form, route of administration, etc., the mixed registration dossier with complete administrative, pharmaceutical data and appropriate preclinical and clinical data of the applicant shall be submitted (section III of the Procedure).

Reference medicinal product:

Name of medicinal product, strength, pharmaceutical form	
Holder of registration certificate	
Date of registration	
Registration certificate №	

Differences vs. reference medicinal product:
□ changes in AS;
□ change in therapeutic indication;
□ change in pharmaceutical form;
□ change in strength (quantitative change to AS);
□ change in route of administration;
□ bioequivalence cannot be demonstrated through bioavailability studies.

Medicinal product used in equivalence studies (if conducted) and/or in other studies:

Study (code) №/EudraCT № (if available)	
Name of medicinal product, strength, pharmaceutical form	
Holder of registration certificate	
Registration certificate №	

Note. Section shall be filled in for each medicinal product used for equivalence study.

□ **Similar biological medicinal product**

(the registration dossier with complete administrative and pharmaceutical data and appropriate preclinical and clinical data should be submitted (section III of the Procedure)).

Reference biological medicinal product (should be innovative):

Name of medicinal product, strength, pharmaceutical form	
Holder of registration certificate	
Date of registration	
Registration certificate №	

Differences vs. reference biological medicinal product (if any):

☐ changes in the raw material(s);

☐ changes in the manufacturing process;

☐ change in therapeutic indication;

☐ change in pharmaceutical form;

☐ change in strength (quantitative change to AS);

☐ change in route of administration(s);

☐ other _____
_____

(**Note:** An overview of the chosen reference medicinal product used throughout the comparability programme for quality, safety and efficacy studies during the development of the biosimilar, is to be included in Module 1.5.2.)

□ **Medicinal product with a fixed combination**

(registration dossier with complete administrative and pharmaceutical data shall be submitted, but preclinical and clinical data shall be submitted related to this combination only (see section III of the Procedure).

□ **Traditional use medicinal product**

□ **Herbal origin**	□ **Other medicinal product**

(Registration dossier shall be submitted as indicated in section III of the Procedure)

□ **Medicinal product from in bulk product**

☐ **Medical immunobiological product**	☐ **Other medicinal product**

(The registration dossier with complete administrative and pharmaceutical data (of manufacturer of in bulk product, supplemented by manufacturer's documentation related to stages he/she performs), preclinical and clinical data (of manufacturer of in bulk product) should be submitted (section III of the Procedure).

□ **Changes requiring new registration**
(the appropriate sections of registration dossier shall be submitted justifying the indicated changes and being sufficient for expert evaluation)

Tick the necessary (only one change shall be ticked) and specify obligatory the type of medicinal product from the stated above according to which the registration dossier is composed.

• **Changes in AS that do not result in a new AS:**
□ different salt, ester, complex/derivative (same active moiety of molecule);
□ different isomers, mixture of isomers;
□ minor change of biological substance or product of biotechnology;
□ new ligand or coupling mechanism for radiopharmaceutical medicinal product;
□ change to the extraction agents or the ratio of herbal substance/herbal preparation.

• **Change of strength, pharmaceutical form and method of administration**
□ change of bioavailability;
□ change of pharmacokinetics;
□ change or addition of a new strength/potency;
□ change or addition of new pharmaceutical form;
□ change or addition of new route of administration.

Note: the applicant must be the same as the holder of registration certificate for registered medicinal product for which changes are made.
Only one change requiring a new registration may be introduced to one registration certificate otherwise a new registration of medicinal product shall be conducted.

Medicinal product registered in Ukraine for which the appropriate changes are made

Name of medicinal product, strength, pharmaceutical form	
Holder of registration certificate	
Registration certificate №	

□ **Medicinal product of limited use (orphan product)**

Has the medicinal product been designated as medicinal product of limited use (orphan product)?
□ No □ Pending □ Yes

Date	
Registered number of medicinal products of limited use	

□ Designation as a medicinal product of limited use (orphan product) has been refused

Date	
Decision №	

□ Application for designation has been withdrawn

Date	

□ Attach a copy of decision about designation as a medicinal product of limited use (orphan product) (if any) (subitem 4.13, item 4 of this Annex).

2. REGISTRATION FORM PARTICULARS

2.1. Name and ATC code

2.1.1. N**ame of medicinal product**

2.1.2. Name of AS

Note. *Only one name should be given in the following order of priority: International Nonproprietary Name (hereinafter- INN)*, State Pharmacopeia of Ukraine (hereinafter –SPhU), European Pharmacopoeia, common name, scientific (chemical) name.*
**AS should be declared by its recommended INN, accompanied by its salt or hydrate form, if necessary.*

2.1.3. Pharmacotherapeutic group (use current ATC code)

ATC code **Group**

If no ATC code has been assigned, please indicate, if an application for ATC Code has been

made: □

□No □Yes

2.2. Strength (dose), pharmaceutical form, route of administration, container and pack sizes

2.2.1. Strength (dose) and pharmaceutical form
(use current list of standard terms of SPhU or European Pharmacopoeia)

Pharmaceutical form	
Active substance(s)	
Strength (dose)	

2.2.2. Route(s) of administration (use current list of standard terms of SPhU or European Pharmacopoeia)

2.2.3 Packaging: container/closure and administration device including description of material from which it is constructed (use current list of standard terms of SPhU or European Pharmacopoeia)

For each type of container give:

Description:

Container	Material	Closure

Administration device:

For each type of pack give:

2.2.3.1. Package size(-s).

2.2.3.2. Proposed shelf life.

2.2.3.3. Proposed shelf life (after first opening package/container).

2.2.3.4. Proposed shelf life (after reconstitution/dissolution or dilution).

2.2.3.5. Proposed storage conditions.

2.2.3.6. Proposed storage conditions after first opening package.

□ Give proposals on labeling (subitem 4.12, item 4 of this Annex).

2.2.4 The medicinal product incorporates, as an integral part, one or more medical devices (Article 1(2)(a) of Directive 93/42/EEC or Technical Regulation pertinent to medical devices approved by the Decree of the Cabinet of Ministers of Ukraine of 02 October 2013 №753) or one or more active implantable medical devices (Article 1(2)(c) of Directive 90/385/EEC or Technical Regulation pertinent to active implantable medical devices approved by the Decree of the Cabinet of Ministers of Ukraine of 02 October 2013 №755).

2.2.4.1.: Manufacturer of the device (for manufacturers outside the EEA, please add the contact person):

Contact person

Title/Position	Name

Location		
Country		
Tel./fax		
e-mail		

2.2.4.2 Device identification:

Name of the device		
Serial number or other indication necessary to delimit precisely the medical device which is an integral part of medicinal product		

2.2.4.3. CE mark:

Does the device have a CE mark?
□ No □ Yes

If yes, please add the confirmation in Module 3 of the registration dossier.

2.2.4.4.: Authorized Body

Has the Authorized Body issued a certificate for medical device?

□ No □ Yes

If yes, please add the certificate in appropriate section of Module 3 of the registration dossier.

Please indicate for each Authorized Body involved:

(For combined ATMPs, identify an Authorised Body in any case)

Name of the Authorised Body:	
Authorised Body Number:	

Contact person:

Title/Position	Name	

Location:		
Country:		
Tel./fax:		
e-mail:		

2.3. Legal status

2.3.1. Proposed dispensing category:

□ subject to medical prescription
□ not subject to medical prescription
□ in hospital only

2.3.2. For medicinal products proposed to be subject to medical prescription, the applicant shall submit its proposals related to the dispensing category of medicinal product but the MoH Ukraine shall reserve the right to define the dispensing category.

2.3.3 Supply for medicinal products not subject to medical prescription

□ supply through pharmacies only
□ supply through non-pharmacy outlets and pharmacies (if applicable)

2.3.4 Promotion for medicinal products not subject to medical prescription:

□ promotion to health care professionals only

□ promotion to the general public and health care professionals (if applicable)

2.4. Applicant (holder) of registration certificate/contact persons/companies

2.4.1. Holder of registration certificate (applicant):	
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	

2.4.2. Person/company authorised for communication on behalf of the applicant during the registration procedure in Ukraine:	
Full name of authorized person to represent the applicant	
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	

□ If different to subitem 2.4.1 of this item, attach a letter of authorisation (subitem 4.4, item 4 of this Annex).

2.4.3. Person/Company authorised for communication between the registration certificate holder and the competent authorities of Ukraine after registration if different from indicated in subitem 2.4.2 of this item**:**	
Full name of authorized person to represent the applicant	
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	

□ If different to subitem 2.4.1 of this item, attach a letter of authorisation (subitem 4.4, item 4 of this Annex).

2.4.4. Summary of the applicant pharmacovigilance system. **Qualified person of the applicant responsible for pharmacovigilance**	
Full name of qualified person of the applicant responsible for pharmacovigilance	
Location of activity	
Country	
24 H tel./fax	
e-mail	
□ Add CV of the qualified person for pharmacovigilance (subitem 4.5, item 4 of this Annex), and applicant's letter of guarantee (subitem 4.19, item 4 of this Annex). **Contact person in Ukraine of the qualified person of the applicant responsible for pharmacovigilance,** if different from the above:	
Full name of contact of the qualified person of the applicant responsible for pharmacovigilance	
Location of activity	
Country	
24 H tel./fax	
e-mail	
□ if different from the above, add CV of the contact person in Ukraine (subitem 4.5, item 4 of this Annex). **Pharmacovigilance system master file**	

Is the Pharmacovigilance system master file available? □ No □ Yes If yes:	
Master file №	
Location of legal person or address of physical person-entrepreneur (where master file is kept)	
Country	

Note: For Risk Management Plan, see module 1, section 1.8.2. of registration dossier.

2.5. Manufacturers

All manufacturing sites where manufacturing procedures take place and quality control sites mentioned in registration dossier must be consistent regarding their names, location and types of activity throughout the whole registration dossier.

2.5.1. Manufacturer(s) responsible for batch release **1) Authorised by the applicant manufacturer(s) (or importer(s)) responsible for batch release** (as indicated in instruction for medicinal use and in labeling, where applicable):	
Name of legal person or full name of physical person-entrepreneur	
Location of activity	
Country	
Tel./fax	
e-mail	
□ Attach a copy of manufacturing license (subitem 4.6, item 4 of this Annex). □ Attach a copy of proof of GMP compliance (if any) (subitem 4.7, item 4 of this Annex). **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	

Contact person responsible for handling claims for defective products

Position	Name

Location	
Country	
24 H tel./fax	
e-mail	

2.5.2. 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, immediate and other packaging manufacturing sites and importers. For each site, provide the relevant information.

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 copy of proof of GMP compliance (if any) (subitem 4.7, item 4 of this Annex).

☐ Attach a copy of manufacturing license (subitem 4.6, item 4 of this Annex).

Indicate a name of qualified person: (if not mentioned in manufacturing license)

Has the site been inspected for GMP compliance by an authorized body of Ukraine or by authorities of countries where MRA procedures apply?

☐ No ☐ Yes

If yes:

Date of last inspection of GMP	
Name of competent authority conducting inspection	
Type of inspection (pre-/post-registration/special/re-inspection)	
Category of inspected medicinal products and active substances	
Conclusion: Compliance with GMP: □ No □ Yes □ Please add for each manufacturing site the conclusion of inspecting competent authority	

2.5.3. 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. Brokers or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks (when relevant). For each site, provide the relevant information.

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

Brief description of manufacturing steps performed by manufacturing site

□ For each active substance, attach a Qualified Person declaration (subitem 4.20, item 4 of this Annex).

Has the site been inspected for GMP Compliance by an authorized body of Ukraine or by authorities of countries where MRA procedures apply?

□ No □ Yes

If yes:

Date of last inspection	

Name of competent authority conducting inspection	
Type of inspection (pre-/post-registration/special/re-inspection)	

Conclusion:

Compliance with GMP: ☐ No ☐ Yes

☐ Please add for each site of manufacture the conclusion from the competent authority, which carried out the inspection (subitem 4.6, item 4 of this Annex).

Has a Ph.Eur. Certificate of suitability (CEP) been issued for AS?

☐ No ☐ Yes

If yes:

Name of the CEP holder	
Name of legal person or full name of physical person-entrepreneur (CEP holder)	
Certificate №	
Date of last update	

☐ Attach copy of CEP (subitem 4.8, item 4 of this Annex).

Is an AS Master File to be used for this AS?

☐ No ☐ Yes

If yes:

Name of the ASMF holder	
Name of legal person or full name of physical person-entrepreneur (ASMF holder)	
Master file reference number assigned by EMA/competent authority (if available)	
Date of submission for review	
Date of last update	

☐ Attach letter of access to ASMF (subitem 4.8, item 4 of this Annex).

☐ Attach copy of commitment letter from the manufacturer of AS to inform the applicant in case of modification of the manufacturing process or specifications (subitem 4.9, item 4 of this Annex).

Has a certificate for a Vaccine Antigen Master File (VAMF) used for this product been issued or

applied for? □ No □ Yes If yes:	
Substance name	
Name of legal person or full name of physical person-entrepreneur being a certificate holder/VAMF applicant	
Reference number of application/certificate	
Date of submission (if pending)	
Date of approval or last update (if any)	
□ Attach copy of VAMF certificate (subitem 4.17, item 4 of this Annex)	

2.5.4. Contract companies used for clinical trial(s) on bioavailability and/or bioequivalence or used for the validation of blood product manufacturing processes. For each contract company, state where analytical tests are performed and where clinical data are collected and give:	
Title of the study	
Protocol code	
EudraCT № (if available)	
Name of the company	
Address of conducting activity	
Country	
Tel./fax	
e-mail	
Duty performed according to contract	

2.6. Qualitative and quantitative composition of medicinal product

2.6.1. Qualitative and quantitative composition of medicinal product (AS and excipients):

Please indicate to which quantity the composition refers (e.g. 1 capsule)
List the active substances separately from the excipients:

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

** Only one 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)

2.6.2 List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product

NONE □

Name	Function			Animal origin susceptible to TSE[4]	Other animal origin	Human origin	Ph. Eur. certificate of suitability for TSE (specify number)
	AS[1]	EX[2]	R[3]				
1.							
2.							
3.							
Etc.							

[1] AS – active substance.
[2] EX – excipient (including starting materials used in manufacture of active substance/excipient).
[3] R – reagent/culture medium (including those used in preparation of master and working cell banks).
[4] TSE – transmissible spongiform encephalopathy.

□ If a Ph. Eur. certificate of suitability for TSE or a document of veterinary control authorities of the country of origin of the raw materials concerning registered TSE cases in the country (based on results of clinical and laboratory control) is available, attach it in subitem 4.10, item 4 of this Annex.

2.6.3. Has a EU certificate for a Plasma Master File (PMF) used in this dossier been issued or applied for?

□ No □ Yes

If yes:

Plasma referring to PMF	

Function

AS[1] EX[2] R[3]

Name of the PMF Certificate Holder/ PMF Applicant Name of legal person or full name of physical person-entrepreneur being a certificate holder/PMF applicant	
Reference number of certificate/application	
Date of submission (if pending)	
Date of approval or last update (if approved)	

[1] AS - active substance;

[2] EX - excipient (incl. starting materials used in the manufacture of the active substance/excipient);

[3] R - reagent/culture medium (incl. those used in the preparation of master and working cell banks).

□ Attach copy of certificate (subitem 4.18, item 4 of this Annex).

2.6.4. Does the medicinal product contain or consist of Genetically Modified Organisms (GMO)?

□ No □ Yes

If yes, does the medicinal product comply with the established requirements?

Give the appropriate reference

□ No □Yes

3. OTHER INFORMATION

3.1. Is the medicinal product protected by patents for invention, useful model or production prototype, which are also valid in Ukraine?

□ No □Yes

If yes:

Patent number	Date of issue	Valid till	Patent holder

❑ Attach copies of patents according to subitem 4.14 item 4 of this Annex.

❑ For state registration of medicinal products based on or related to intellectual property with the patent issued according to the Ukrainian legislation the applicant shall submit a copy of patent or license to manufacture or sell the registered medicinal product. Applicants should submit a letter indicating that rights of the third party being patent-protected are not violated because of the registration of medicinal product.

3.2. Is the trade mark protected in Ukraine?

□ No □ Yes

If yes, please indicate:

Document number	Date of issue	Valid till	Holder

❑ Attach copies of documents specified in subitem 4.15, item 4 of this Annex.

3.3. Has the medicinal product been registered in manufacturing country and other countries?

□ No □ Yes

If yes:
❑ Attach copy of registration certificate (subitem 4.3, item 4 of this Annex).
❑ Indicate list of countries, where the medicinal product has been registered/re-registered.

If no:
❑ Please substantiate (subitem 4.3, item 4 of this Annex)

3.4. Has the preliminary scientific consultation pertinent to this medicinal product has been carried out in Ukraine?

□ No □ Yes

If yes, please indicate:

Date of conducting	
Reference to scientific recommendations	

Has the preliminary scientific consultation pertinent to this medicinal product has been carried out in other country?

□ No □ Yes

If yes, please indicate:

Country(ies)	
Date of conducting	
Reference to scientific recommendations	

□ Attach copy of consultation letter (subitem 4.11, item 4 of this Annex).

3.5. Is the decision taken about full or temporary prohibition of use and/or about refusal to register medicinal product in other countries?

❑ No ❑ Yes

If yes:

Country(ies)	
Reason and date of prohibition/refusal	

4. APPENDED DOCUMENTS

□ 4.1. Justification of type of medicinal product (section 1.5 Module 1) and/or Module 2 of the registration dossier, optional for applicant.

□ 4.2. Informed consent from holder of registration certificate for registered medicinal product in free form (if any).

□ 4.3. (*) Copy of document confirming registration of this medicinal product according to national legislation of applicant and/or manufacturer but if such document lacks –substantiate the reason of its lack.

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

□ 4.5. CV that should include qualification and experience of authorized body responsible for pharmacovigilance and/or contact person in Ukraine (if different).

□ 4.6. 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. This document may not be submitted with application but obligatory must be submitted when the Center recommends medicinal product for registration.

□ 4.7. 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.

□ 4.8. Letter(s) of access to Active Substance Master File(s) from its holder or copy of Ph. Eur. Certificate(s) of Suitability. Copy should be certified by stamp of the applicant (if available)/representative of the applicant in Ukraine.

□ 4.9. Copy of written obligation of the active substance manufacturer to inform applicant about any modifications of manufacturing process or specifications (in free form). Copy should be certified by stamp of the applicant (if available)/representative of the applicant in Ukraine.

□ 4.10. European Pharmacopoeia certificate of suitability for TSE or a document issued by veterinary surveillance authority of the country of origin of the raw materials concerning registered TSE cases (based on results of clinical and laboratory control) in the country (if any).

□ 4.11. Copy of consultation letter related to conducted preliminary scientific consultation pertinent to medicinal product (if any).

□ 4.12. Proposals for labeling medicinal product.

□ 4.13. Copy of decision about designation of medicinal product as a medicinal product of limited use (orphan product) (if any).

□ 4.14. Copies of patents for invention, useful model or production prototype, which are valid in Ukraine (if any).

□ 4.15. Copies of documents related to trade mark protection in Ukraine (if any).

□ 4.16. Letter which template is provided in Annex 25 of this Procedure.

□ 4.17. Copy of certificate for VAMF (if any).

□ 4.18 Copy of certificate for PMF.

□ 4.19. Letter of guarantee from the applicant about ensuring operation of adequate system to supervise safety of medicinal products at their medical use, including in Ukraine (in free form).

□ 4.20. For each active substance, attach a declaration from the Qualified Person (QP) of each of manufacturing license holders specified in the 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).

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* It shall not be provided by applicants/manufacturers being the residents and using contract-manufacturing capacities, which are outside of Ukraine.

(Annex 1 in wording of MoH Ukraine Order №460 as of 23.07.2015)