

Annex 1
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 II)

**Application
for the State 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 _____
Name of medicinal product	
Name of medicinal product in the United States of America, the Swiss Confederation, Japan, Australia, Canada, the European Union (item 3.3 of this application)	
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.

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

Attach letter of authorization for communication/signing documents on behalf of the applicant.

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

1. General Items of Registration Application

(In case of filling in information related to specific type of medicinal product, the list of other types of medicinal products shall be withdrawn).

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

This registration application is submitted according to the following:

Medicinal product with complete dossier (stand-alone dossier)

Medical immunobiological product	Other medicinal product
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☐ **New active substance (AS)**

Note. AS is used for the first time.

☐ **Known active substance**

Note. AS has been used previously.

☐ **Generic medicinal product**

☐ Single component	☐ Multicomponent
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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.

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**

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

☐ **Medicinal product with a fixed combination**

☐ **Changes requiring new registration**

Tick the necessary (only one change shall be ticked).

• **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.

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

Name of medicinal product, strength, pharmaceutical form	
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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	
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☐ Attach a copy of decision about designation as a medicinal product of limited use (orphan product) (if any).

2. REGISTRATION APPLICATION PARTICULARS

2.1. Name and ATC code

2.1.1. Name of medicinal product

2.1.2. Name of AS
Note. Only one name should be given in the following order of priority: INN* of pharmacopeia of country of registration, 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 submitted: ☐

☐No☐Yes**2.2. Strength (dose), pharmaceutical form, route of administration, container and pack sizes****2.2.1. Strength (dose) and pharmaceutical form**

Pharmaceutical form	
Active substance(s)	
Strength (dose)	

2.2.2. Route(s) of administration**2.2.3 Packaging: container/closure and administration device** (including description of material from which it is constructed)**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

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	Full name

Location	
Country	
Tel./fax	
e-mail	

2.2.4.2 Medical 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 appropriate sections of 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	Full 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.

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.

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 responsible for pharmacovigilance, and applicant's letter of guarantee	
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	
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	

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

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 manufacturing capacities					
Country					
Tel./fax					
e-mail					
Attach a copy of document confirming compliance of manufacture with GMP requirements (if any) and commitment letter of the manufacturer responsible for batch release to produce 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 and Member States of the European Union. 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 <table border="1"> <tr> <td>Position</td> <td>Full name</td> </tr> <tr> <td></td> <td></td> </tr> </table>		Position	Full name		
Position	Full 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	
Address of manufacturing capacities	
Country	
Tel./fax	
e-mail	
Brief description of functions performed 	
Attach copy of proof of GMP compliance (if any)	

2.5.3. 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. 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.</i>	
Active substance	
Name of legal person or full name of physical person-entrepreneur	
Address of manufacturing capacities	
Country	
Tel./fax	
e-mail	
Brief description of manufacturing steps performed by manufacturing site 	
Name of the Ph.Eur. Certificate of suitability (CEP) holder	
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)	

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

** 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, if available)
	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.

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	
	AS¹ EX² R³
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).

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

3.2. Is the trade mark protected in Ukraine?

☐ No ☐ Yes

If yes, please indicate:

Document number	Date of issue	Valid till	Holder

3.3. 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

Country _____

Name of competent authority _____

Registration (certificate) № _____

Date of registration “ ____ ” _____

Applicant may submit either:

☐ copy of certificate of pharmaceutical product (if available) or copy of document confirming registration of this medicinal product

or

☐ assessment report of medicinal product issued 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 appropriate similar document issued 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 (if available) or

☐ Information is provided by free online resource of Competent Authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, Competent Authority of the European Union and Used at the Territory of These Countries or Member States of the European Union [www. _____ \(screenshot\)](#) of appropriate web page attached)

3.4. Is the decision taken about full or temporary prohibition of use and/or about refusal to register medicinal product by Competent Authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, Competent Authority of the European Union Through Centralized Procedure Used at the Territory of These Countries or Member

States of the European Union?	
No	Yes
If yes:	
Country(ies)	
Reason and date of prohibition/refusal	

4. APPENDED DOCUMENTS (submitted to the State Expert Center of MoH of Ukraine)

☐ 4.1. Copy of document confirming 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 this medicinal product on online resource of Competent Authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada or the European Union (submitted, if available, at applicant's discretion)

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

(Annex 1 amended by the MoH Ukraine Order №1220 as of 02.10.2017, № 1391 of 15.06.2020)