Annex 2
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 Homeopathic Medicinal Product Submitted for State Registration

Date of submission:

“___” _____ 20__ №_____

Name of medicinal product	
Homeopathic stock(s) and potency(ies):	
Pharmaceutical form	
Type, size and contents of package	
Applicant	
Person authorized to act on behalf of the applicant	

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.

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 4.14, item 4 of this Annex).

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

☐ Find attached 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

Note. This section to be completed for any type of medicinal product, including changes requiring new registration.

This registration form shall be submitted according to:

□ **Registration**

○ Annex 7 of the Procedure

○ General registration procedure (tick the necessary)

□ medicinal product with complete dossier

□ generic medicinal product

□ medicinal product with well-established medical use

□ medicinal product with fixed combination

□ informed consent

Annex 7 of the Procedure

Parts of registration dossier	**Available in dossier (tick the necessary)**
Module 1	□
Manufacturing license	□
Labelling of immediate and outer packaging (if available), draft instruction for medical use	□
Module 2	□
Module 3	□
Module 4	□
Justification of the homeopathic nature	□

General registration procedure

Parts of registration dossier	Available in dossier (tick the necessary)
Module 1	□
Manufacturing license	□
SPC, approved according to the applicant's/manufacturer's national legislation	□
Package leaflet, approved according to the applicant/manufacturer national legislation	□
Labelling of immediate and outer packaging (if available), draft instruction for medical use	□
Module 2	□
Module 3	□
Module 4	□
Justification of the homeopathic nature	□

□ **Changes requiring new registration**

(the appropriate parts of registration dossier materials shall be submitted justifying the indicated changes and being sufficient for expert evaluation)

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.

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.

This registration form may be used for medicinal product with complete dossier, generic medicinal product, medicinal product with well-established medical use, medicinal product with fixed combination and with informed consent.

Registered medicinal product for which the appropriate changes are made

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

2. REGISTRATION FORM PARTICULARS

2.1. Name and ATC code

2.1.1. N**ame of homeopathic medicinal product**

2.1.2. Name of homeopathic stock and potency*

***Name should be given in the following order of priority: scientific name of the European Pharmacopoeia or State Pharmacopeia of Ukraine (SPhU), in absence of a specific monograph, a scientific Latin name (botanical scientific name) followed by the Homeopathic(s) name(s) should be provided.

2.2. Pharmaceutical form, route of administration, container and pack sizes

2.2.1. Pharmaceutical form (use current list of standard terms of SPhU or European Pharmacopoeia)

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).

2.3. Legal status

2.3.1. Proposed dispensing category:

□ subject to medical prescription

□ not subject to medical prescription

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 (it is not used for homeopathic products described in Annex 7 of Procedure). **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 letter of guarantee (subitem 4.16, item 4 of this Annex). **Contact person in Ukraine of the applicant qualified person for pharmacovigilance,** if different from the above:	
Full name of contact of the applicant qualified person 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, please specify:

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 materials must be consistent regarding their names, location and types of activity.

2.5.1. Manufacturer(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).

2.5.2. Manufacturer(s) of the homeopathic 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 appropriate).

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).

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, please indicate:

Date of last inspection of GMP	
Name of competent authority conducting inspection	
Type of inspection (pre-/post-registration/special/re-inspection)	
Category of medicinal products and activities inspected	

Conclusion:

Compliance with GMP: □ No □ Yes

2.5.3. Manufacturer(s) of the dilutions and sites of manufacture

(If different from the manufacturer of the finished homeopathic medicinal product)

Name of legal person or full name of physical person-entrepreneur (manufacturer)	
Location of activity	
Country	

Tel./fax	
e-mail	

Brief description of operations performed at manufacturing site

□ Attach a 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).

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, please specify:

Date of last inspection	
Name of competent authority conducting inspection	
Type of inspection (pre-/post-registration/special/repeated)	
Category of medicinal products and activities inspected	

Conclusion:

Compliance with GMP: □ No □ Yes

2.5.4 Manufacturer(s) of the Homeopathic stock(s):
Only the final manufacturer(s) to be mentioned

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

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

□ No □ Yes

If yes, please specify:

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).

Where inspection for GMP compliance has been conducted:
The following information should be provided:
last inspection date;
name of competent authority which carried out the inspection
type of inspection (pre/post-registration/special/re-inspection)
categories of substance and activities inspected

Conclusion:

□ positive □ negative

2.5.5. Source/manufacturer(s) of the raw material(s):	
Raw material	
Name of legal person or full name of physical person-entrepreneur (manufacturer)	
Location of activity	
Country	
Tel./fax	
e-mail	
Has a Ph.Eur. Certificate of suitability been issued for the raw material(s)? □ no □ yes If yes:	
Name of legal person or full name of physical person-entrepreneur (manufacturer)	
Certificate №	
Date of last update	
□ Attach copy of Ph.Eur. Certificate of suitability (subitem 4.8, item 4 of this Annex). **Where inspection for GMP compliance has been conducted:** The following information should be provided: last inspection date; name of competent authority which carried out the inspection type of inspection (pre/post-registration/special/re-inspection) categories of substance and activities inspected Conclusion: □ positive □ negative	

2.6. Qualitative and quantitative composition

2.6.1. Qualitative and quantitative composition of medicinal product **(homeopathic active substance(s) and the excipient(s)):** Please indicate to which quantity the composition refers (e.g. 1 capsule) List the homeopathic active substance(s) 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.*

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 item 4.10, item 4 of this Annex.

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 4.13, item 4 of this Annex
❑ For state registration of medicinal products based on or related to intellectual property objects 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 item 4.14, 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. 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 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 the 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 applicant authorized person responsible for pharmacovigilance and/or contact person in Ukraine (if different).

□ 4.6. Copy of manufacturing license (if according to the 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 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 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 of medicinal product.

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

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

□ 4.15. Letter whose template is provided in Annex 25 of this Procedure.

□ 4.16. 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).

□ 4.17. 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).

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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 2 in wording of MoH Ukraine Order №460 as of 23.07.2015)