



Ministry of Health of Ukraine

ORDER

17.11.2016 № 1245

Registered at the Ministry of Justice
of Ukraine on December 14, 2016
under № 1619/29749

**On Approval of 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**

{Title amended by the MoH Ukraine Order № 1391 of 15.06.2020}

*{As amended by the MoH Ukraine Order № 1202 of 02.10.2017,
№ 1391 of 15.06.2020}*

According to [article 9](#) of the Law of Ukraine "On Medicines", the Procedure for State Registration (Re-registration) of Medicinal Products approved by the Decree of the Cabinet of Ministers of Ukraine of May 26, 2005 № 376, and for the purpose of aligning the regulatory documents of the Ministry of Health of Ukraine with the current legislation of Ukraine

I ORDER:

1. To approve 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 (attached).

{Item 1 amended by the MoH Ukraine Order № 1391 of 15.06.2020}

2. To delete [item 2](#) of the MoH Ukraine Order of July 23, 2015 № 460 "On Introduction of Changes to the Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products, which are Submitted for State Registration (Re-Registration) and Expert Evaluation of Materials about Introduction of Changes to the Registration Materials during the Validity Period of Registration Certificate, and Approval of the Procedure for Checking Materials Supplemented (in Support of) to Application for State Registration of Specific Medicinal Products

for Their Completeness", registered at the Ministry of Justice of Ukraine on October 07, 2015 under № 1210/27655.

3. That Pharmaceutical Activity and Pharmaceutical Product Quality Administration submits this order to the Ministry of Justice of Ukraine for state registration.

4. I hereby authorise R.R. Ilyk, Deputy Minister of Health of Ukraine, to supervise execution of this order.

5. The order shall take effect from the date of its official publication.

U. Suprun

Acting Minister

AGREED UPON WITH:

V.P. Zahorodnii

**Acting Head, State Regulatory Service
of Ukraine**

APPROVED

**Order of the Ministry of Health
of Ukraine of 17.11.2016 № 1245
Registered with the
Ministry of Justice of Ukraine
on December 14, 2016
under № 1619/29749**

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

{ Title amended by the MoH Ukraine Order № 1391 of 15.06.2020 }

*{ In text of Procedure and its Annexes 1,3 -5,8 "for use" is replaced by "and used"
according to the MoH Ukraine Order № 1391 of 15.06.2020 }*

*{ In text of Procedure and its Annexes "Switzerland" in all cases is replaced by "the Swiss
Confederation" in appropriate cases according to the MoH Ukraine Order № 1391 of
15.06.2020 }*

I. General

1. This Procedure has been developed according to the Law of Ukraine "On Medicines" and Procedure for State Registration (Re-registration) of Medicinal Products approved by the Decree of the Cabinet of Ministers of Ukraine of May 26, 2005 № 376.

This Procedure shall apply to finished medicinal products registered by the competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, medicinal products registered by competent authority of the European Union through centralized procedure and used on the territory of these countries or Member States of the European Union.

2. In this Procedure, the following terms shall bear the following meanings:

Applicant (holder of the registration certificate) and/or his representative to conduct procedure for state registration of medicinal product registered by a competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, medicinal product registered by a competent authority of the European Union through centralized procedure and used on the territory of these countries or Member States of the European Union is a legal or natural entity that is responsible for efficacy, safety and quality of a medicinal product and performs pharmacovigilance in Ukraine, and responsible for reliability of information included in the registration materials submitted by him in support to an application. The applicant may be a legal or a natural entity, which is different from that in the United States of America, the Swiss Confederation, Japan, Australia, Canada, and, for medicinal products registered by a competent authority of the European Union through centralized procedure, different from that in the European Union;

{Paragraph 2 of item 2 of Part I as amended by the MoH Ukraine Order № 1202 of 02.10.2017}

Review of registration materials and materials about introduction of changes in the 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, medicinal products registered by a competent authority of the European Union through centralized procedure and used on the territory of these countries or Member States of the European Union (hereinafter – Review of registration materials) is a check of the fact of registration (introduction of changes to the registration materials) of medicinal products by a competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, registration (introduction of changes to the registration of materials) of medicinal product by a competent authority of the European Union through centralized procedure, for completeness of the registration materials submitted by the applicant without expert evaluation of materials of the registration dossier submitted to the regulatory authority, which has registered this medicinal product, and materials about introduction of changes to the registration materials;

{Paragraph 3 of item 2 of Part I amended by the MoH Ukraine Order № 1391 of 15.06.2020}

Manufacturer of finished medicinal product is an economic entity, which performs at least one of the manufacturing stages and has a license (authorization) to manufacture medicinal products (if the latter is envisaged by the legislation of the country, on whose territory the manufacturer's facilities are located). For registration, introduction of changes to the registration materials, re-registration of the medicinal product according to this Procedure any manufacturer specified in the registration dossier based on which the registration of the medicinal product has been performed in the reference country (as amended, if applicable) or only those of them, which are to be involved in the manufacture of medicinal product for Ukraine. The manufacturers not specified in the registration dossier based on which the registration of the medicinal product has been performed in the reference country (as amended if applicable) shall not be specified in the application for registration, introduction of changes to the registration materials, re-registration according to this Procedure. The name and address of the final manufacturer responsible for batch release of the medicinal product shall be sufficient to specify on the packaging. Other manufacturers involved in the manufacturing and specified in the registration dossier for this medicinal product may be indicated on the packaging and in the registration certificate at the applicant's discretion;

{New paragraph 4 is added to item 2 of Part I according to the MoH Ukraine Order № 1202 of 02.10.2017}

Secondary packaging is a packaging, in which the medicinal product in the primary packaging is enclosed and which has a protective function for the medicinal product and primary packaging. Secondary packaging type and size envisaged for registration in Ukraine are at the applicant's discretion. All secondary packaging types and sizes approved in the reference country or some of them may be submitted for registration in Ukraine. The medicinal product in the secondary packaging, whose type and size are not approved in the reference country, shall not be registered in Ukraine according to this Procedure;

{New paragraph 5 is added to item 2 of Part I according to the MoH Ukraine Order № 1202 of 02.10.2017}

Common name of medicinal product is the international non-proprietary name (hereinafter - INN) of active substance recommended by the World Health Organization, or, in its absence, the usual common name;

{New paragraph 6 is added to item 2 of Part I according to the MoH Ukraine Order № 1202 of 02.10.2017}

Name of medicinal product is the name given to a medicinal product, which may be either invented by applicant (manufacturer), or a common or scientific name, along with a trade mark or applicant's (manufacturer's) name. The name of medicinal product for registration in Ukraine may differ from the name under which the medicinal product is registered in the reference country. If the name of medicinal product for registration in Ukraine differs from the name, under which the medicinal product is registered in the reference country the applicant shall provide the substantive clarifications of optional format concerning the reasons for such a difference (based on an application);

{New paragraph 7 is added to item 2 of Part I according to the MoH Ukraine Order № 1202 of 02.10.2017}

Primary packaging is an individual packaging that is in direct contact with the medicinal product and contributes to the preservation of its main properties. Primary packaging type and size to be registered in Ukraine are at the applicant's discretion. All primary packaging types and sizes approved in the reference country or some of them may be submitted for registration in Ukraine. The medicinal product in the primary packaging, whose type and size are not approved in the reference country, shall not be registered in Ukraine according to this Procedure;

{New paragraph 8 is added to item 2 of Part I according to the MoH Ukraine Order № 1202 of 02.10.2017}

Applicant's representative is an authorised person acting on behalf of the applicant, a legal entity or a natural person who is given by an applicant, according to the respective authorization, a right to represent his interests during procedures for registration, re-registration and/or introduction of changes to registration materials on the territory of Ukraine, and who is responsible as an applicant for reliability of the information submitted;

{New paragraph 9 is added to item 2 of Part I according to the MoH Ukraine Order № 1202 of 02.10.2017}

Reference country (country of origin of the dossier) is one of the following countries where the medicinal product is registered by a competent authority: the United States of America, the Swiss Confederation, Japan, Australia, Canada and the European Union only for the medicinal products registered through centralized procedure.

{New paragraph 10 is added to item 2 of Part I according to the MoH Ukraine Order № 1202 of 02.10.2017}

Other terms used in this Procedure are applied based on the definitions stated by the Ukrainian health care laws and regulations.

II. Procedure for review of the registration materials pertinent to medicinal products submitted for state registration (re-registration)

1. For conducting review of registration materials an applicant shall submit to the Ministry of Health of Ukraine an application for state registration of a medicinal product registered by a competent authority of the reference country according to the form given in annex 1 to this Procedure (hereinafter – Application for state registration);

{Paragraph 1 of item 1 of Part II as amended by the MoH Ukraine Order № 1202 of 02.10.2017}

MoH shall send to the Public Enterprise “The State Expert Center of the Ministry of Health of Ukraine” (hereinafter - the Center) a copy of the application for state registration within 1 working day.

{Paragraph 3 of item 1 of Part II is deleted according to the MoH Ukraine Order № 1202 of 02.10.2017}

Information on the registration materials submitted shall be entered into the integrated e-database.

If the applicant or applicant’s representative fails to submit to the Center the registration materials within 90 months after receipt of a MoH’s letter of referral by the Center with a copy of the application, the Center shall inform the applicant in writing on withdrawal of the medicinal product from the review within 3 working days.

{New paragraph is added to item 1 of Part II according to the MoH Ukraine Order № 1202 of 02.10.2017}

Further on, the registration materials for this medicinal product may be repeatedly submitted to the Center for the review as required by this Procedure.

{New paragraph is added to item 1 of Part II according to the MoH Ukraine Order № 1202 of 02.10.2017}

2. After the application for review is received, the Center shall conclude a contract with the applicant, if necessary, and issue an invoice for payment of cost of the review of registration materials within 14 calendar days after the applicant’s request.

After payment of an invoice the applicant or applicant’s representative shall submit to the Center registration materials according to the list of registration materials to be submitted for review with the purpose of registration, which is given in annex 2 to this Procedure;

The Center shall accept registration materials for review on the day of the submission by the applicant or applicant’s representative.

The materials shall be submitted to the Center in one copy.

Materials of the registration dossier shall be submitted in English or Ukrainian at the applicant’s discretion. Materials of the registration dossier shall be submitted as follows: Modules 1, 2 and 3

shall be submitted as a hard copy, Modules 4 and 5 – as a hard copy or in e-format at the applicant's discretion.

Materials of the dossier's Administrative Part (a part of documents in Module 1 of the Common Technical Document (hereinafter – CTD)) submitted in English or other language shall be accompanied, upon the Center's request, with the Ukrainian translation certified and signed by a translator and applicant's authorized person.

{Item 2 of Part II as amended by the MoH Ukraine Order № 1202 of 02.10.2017}

3. The Center shall review the registration materials, among other things, verify the fact of registration of the medicinal product based on the data on websites of the U.S. Food and Drug Administration (FDA), the Swiss Agency for Therapeutic Products (Swissmedic); the Pharmaceuticals and Medical Devices Agency of Japan (PMDA), the Therapeutic Goods Administration of Australia (TGA), Ministry of Health of Canada (Health Canada), the European Medicines Agency and use on the territory of the United States of America, the Swiss Confederation, Japan, Australia, Canada or Member States of the European Union.

{Paragraph 1 of item 3 of Part II as amended by the MoH Ukraine Order № 1202 of 02.10.2017, № 1391 of 15.06.2020}

The Center may singly request the applicant or applicant's representative to provide clarifications/additional data and/or information necessary for further review of the registration materials.

{New paragraph 2 is added to item 3 of Part II according to the MoH Ukraine Order № 1202 of 02.10.2017}

The applicant or applicant's representative shall provide clarifications/additional data and/or information within 30 working days after receipt of the Center's request.

{Paragraph 3 is added to item 3 of Part II according to the MoH Ukraine Order № 1202 of 02.10.2017}

The time taken by the applicant or applicant's representative to prepare and submit an answer/additional data and/or information shall not be included in the timeframe for conducting review of registration materials.

{Paragraph 4 is added to item 3 of Part II according to the MoH Ukraine Order № 1202 of 02.10.2017}

The Center shall accept an answer/additional data and/or information provided by the applicant on the day of submission by the applicant or applicant's representative and enter the information obtained into the e-database.

{Paragraph 5 is added to item 3 of Part II according to the MoH Ukraine Order № 1202 of 02.10.2017}

The date of signing the conclusion by the Center's head shall be considered the end date of the review of registration materials. The period of the review of registration materials shall be not more than 10 working days.

4. The Center shall draw the conclusion based on the results of review of registration materials pertinent to the medicinal product registered by a competent authority and used on the territory of its country or Member States of the European Union according to the form given in Annex 3 to this Procedure (hereinafter – Conclusion on registration), and inform the applicant within 2 working

days about the end of review of registration materials, prepare a draft registration certificate, draft materials pertinent to methods of quality control for the medicinal product, draft labelling text of primary and secondary (if available) packaging, draft instructions for medical use of the medicinal product for editing and agreeing upon with the applicant:

Information on issuing a draft registration certificate, draft materials pertinent to methods of quality control for the medicinal product, draft labelling text of primary and secondary (if available) packaging, draft instructions for medical use to the applicant for editing and agreeing upon shall be entered into the integrated e-database.

The time taken by the applicant to edit and agree upon a draft registration certificate, draft materials pertinent to methods of quality control for the medicinal product, draft labelling text of primary and secondary (if available) packaging, draft instructions for medical use shall not be included in the timeframe of review of the registration materials.

5. In case of drawing the Conclusion on registration the Center shall prepare, within 2 working days, a list of medicinal products, the review of whose registration materials has been terminated (hereinafter – List), supplement it with specimen copies of documents checked by the Center: materials pertinent to methods of quality control of the medicinal product, labelling text of primary and secondary (if available) packaging, instructions for medical use of the medicinal product stated according to the requirements specified in annex 23 to the Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products, which are Submitted for State Registration (Re-Registration) and Expert Evaluation of Materials about Introduction of Changes to the Registration Materials during the Validity Period of Registration Certificate approved by the MoH Ukraine Order of August 26, 2005 № 426, registered at the Ministry of Justice of Ukraine on September 19, 2005 under N 1069/11349 (as amended) (hereinafter - Procedure for Conducting Expert Evaluation), summary of product characteristics (if any), and transfer them together with the Conclusion on registration and a cover letter to MoH.

After the approval of state registration, re-registration of medicinal product and introduction of changes to registration materials by the MoH Ukraine Order the Center shall transfer specimen copies of the documents checked by the Center: materials pertinent to methods of quality control of the medicinal product, labelling text of primary and secondary (if available) packaging, instructions for medical use of the medicinal product, summary of product characteristics (if any) together with a cover letter to the State Service of Ukraine for Medicinal Products and Narcotics Control in order to perform the state quality control of medicinal products being in circulation on the territory of Ukraine.

Information on transfer of the List with conclusions to MoH shall be entered into the integrated e-database.

6. Information on the date of submission of registration materials and the date of termination of their review shall be published on the Center's official website.

7. In case of submission of the Conclusion on registration MoH shall make a decision about state registration of the medicinal product or rejection in it, which is approved by MoH order, within 7 working days.

8. Decision about rejection in state registration shall be made only in case of the established fact of:

Submission of incomplete set of documents according to annex 2 to this Procedure;

{Paragraph 2 of item 8 of Part II as amended by the MoH Ukraine Order № 1202 of 02.10.2017}

Detection of invalid or incomplete information in the above documents;

Discrepancy between the name of the medicinal product manufacturer, its location and address of manufacturing facilities specified in the application for state registration and the information based on which this medicinal product has been registered by an appropriate competent authority of the reference country. For the purpose of this Procedure the abbreviations of types of business entities, forms of property of legal entity or formulations of name or types of business entities, forms of property of legal entity in different languages in the dossier documents (for example, Ltd – Limited; SA – AG; GmbH – BV; Inc. – Incorporated; Corp. – Corporation; S.A. – A.V.E. etc.); changing of word order; postal code with and without alphabetic identifier of the country (for example, LT-08409 – 0409, D-73614 – 73614, CH-4147 – 4147); abbreviation of the pharmaceutical form in some parts of the dossier (for example, powder for injection – lyophilizate for solution for injection or infusion, or FCT – film-coated tablets etc), other minor technical deviations shall not be considered such discrepancy between the manufacturer's name of such medicinal product, its location and address of manufacturing facilities specified in the application for state registration and the information based on which this medicinal product has been registered by an appropriate competent authority of the reference country.

{Paragraph 4 of item 8 of Part II in wording of the MoH Ukraine Order № 1202 of 02.10.2017}

9. A registration certificate for a medicinal product shall certify the fact of state registration of the medicinal product, a registration certificate for a medicinal product (medical immunobiological product) shall certify the fact of state registration of the medical immunobiological product (hereinafter – Registration certificate).

The MoH Order on state registration of medicinal product shall approve methods of quality control, instructions for use of medicinal product (instructions for medical use), and assign a registration number to be entered into the State Register of Medicinal Products and Interdepartmental Database of the Medicinal Products Registered in Ukraine. An information on the possibility of medicinal product advertising shall be entered into the State Register.

{Paragraph 2 of item 9 of Part II in wording of the MoH Ukraine Order № 1391 of 15.06.2020}

10. After receiving the MoH order on state registration of the medicinal product the Center shall inform the applicant within 2 working days on the MoH's decision, prepare the registration certificate and transfer it to MoH for signing.

11. The medicinal product is allowed for use in Ukraine during 5 years as from the date of its state registration. After finishing the term, within which the medicinal product is allowed for use in Ukraine, its further use is possible subject to re-registration. After the re-registration the term of use of medicinal product in Ukraine shall not be limited except for cases, when MoH makes a decision on additional re-registration in 5 years based on justified grounds relating to pharmacovigilance.

The MoH shall perform re-registration of medicinal product registered by a competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, medicinal product registered by a competent authority of the European Union through centralized procedure and used on the territory of these countries or Member States of the European Union based on an application for re-registration of medicinal product registered by a competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, medicinal product registered by a competent authority of the European Union through centralized procedure and used on the territory of these countries or Member States of the European Union, which is given in Annex 4 to this Procedure, registration materials according to a List of documents submitted for re-registration of medicinal product given in Annex 15 to the Procedure for Conducting Expert Evaluation, and the Center's conclusion drawn according to the Procedure for Conducting Expert Evaluation, which contains, in particular, information on the expected benefit-possible risk balance during the use of the medicinal product.

The Center shall conduct expert evaluation of documents pertinent to re-registration according to the Procedure for Conducting Expert Evaluation.

12. According to this Procedure the applicant shall specify in the application for state registration a competent authority, which registered the given medicinal product in one of the following states: the United States of America, the Swiss Confederation, Japan, Australia, Canada and, in case of registration of the medicinal product through centralized procedure, the European Union and use on the territory of these countries or Member States of the European Union. In case of re-registration of such medicinal product and/or introduction of changes to the registration documents during the validity period of registration certificate for such medicinal product the applicant shall confirm the fact(s) of re-registration and/or introduction of changes to the registration materials by the appropriate competent authority specified in the application for state registration of such medicinal product.

{Item 12 of Part II amended by the MoH Ukraine Order № 1391 of 15.06.2020}

13. After receiving the registration certificate for finished medicinal product the applicant shall introduce on timely basis any changes to the registration materials pertinent to the registered medicinal product according to the changes introduced to the registration dossier submitted to an appropriate competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada and the European Union, based on which the state registration of this medicinal product has been performed in Ukraine.

III. Procedure for review of materials about introduction of changes in registration materials during the validity period of registration certificate

1. For review of materials about introduction of changes in the registration materials during the validity period of registration certificate the applicant shall submit to MoH an application for introduction of changes in the registration materials pertinent to medicinal product registered by the competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, medicinal product registered by competent authority of the European Union through centralized procedure and used on the territory of these countries or Member States of the European Union according to a form given in Annex 5 to this Procedure (hereinafter – Application for introduction of changes), and for changes, which require a new registration the applicant shall submit to MoH an application for state registration. Administrative changes required by the legislation of Ukraine shall be submitted according to the Procedure for Conducting Expert Evaluation.

{Paragraph 1 of item 1 of Part III as amended by the MoH Ukraine Order № 1202 of 02.10.2017}

MoH shall send to the Center a copy of application for introduction of changes or application for state registration in case of changes, which require a new registration, within 1 working day.

After receiving a copy of Application for introduction of changes submitted to MoH, the Center shall issue an invoice for payment of cost of the review of materials about introduction of changes in the registration materials within 7 working days. After the payment of an invoice is made the applicant or applicant's representative shall submit to the Center materials about introduction of changes in registration materials. The Center shall accept materials about introduction of changes in the registration materials for the review within 7 working days as from the day of submission of the request by the applicant or applicant's representative. The applicant or applicant's representative shall submit materials to the Center for the review according to the list of materials about introduction of changes to registration materials submitted for review, which is given in annex 6 to this Procedure.

{Paragraph 3 of item 1 of Part III in wording of the MoH Ukraine Order № 1202 of 02.10.2017}

Information on the materials about introduction of changes in the registration materials submitted shall be entered into the integrated e-database.

2. The materials listed in annex 6 to this Procedure shall be submitted to the Center in one copy.

A set (?description) of changes with appropriate sections of the registration dossier, where the changes have been introduced in the reference country, and a document, which confirms the registration of changes in the reference country (a certificate, a public report, or a letter of acceptance/approval of changes, etc.) shall be submitted in English or Ukrainian at the applicant's discretion.

{New paragraph is added to item 2 of Part III according to the MoH Ukraine Order № 1202 of 02.10.2017}

If the appropriate set of changes or a document, which confirms the registration of changes in the reference country (if any), are submitted in other language the applicant or applicant's representative shall be provided them with the English or Ukrainian translation upon the Center's request.

{New paragraph is added to item 2 of Part III according to the MoH Ukraine Order № 1202 of 02.10.2017}

The translation shall be certified and signed by a translator and applicant's authorized person.

{New paragraph is added to item 2 of Part III according to the MoH Ukraine Order № 1202 of 02.10.2017}

The Center may singly request the applicant or applicant's representative to provide clarifications/additional data and/or information necessary for further review of materials about introduction of changes to the registration materials.

{New paragraph 2 is added to item 2 of Part III according to the MoH Ukraine Order № 1202 of 02.10.2017}

The applicant or applicant's representative shall provide clarifications/additional data and/or information within 30 working days after receipt of the Center's request.

{New paragraph is added to item 2 of Part III according to the MoH Ukraine Order № 1202 of 02.10.2017}

The time taken by the applicant or applicant's representative to prepare and submit an answer/additional data and/or information shall not be included in the timeframe for conducting review of materials about introduction of changes to registration materials.

{New paragraph is added to item 2 of Part III according to the MoH Ukraine Order № 1202 of 02.10.2017}

The Center shall accept an answer/additional data and/or information provided by the applicant or applicant's representative on the day of submission by the applicant or applicant's representative and enter the information obtained into the e-database.

{New paragraph is added to item 2 of Part III according to the MoH Ukraine Order № 1202 of 02.10.2017}

3. Changes introduced in the registration materials pertinent to medicinal product registered by a competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, medicinal product registered by a competent authority of the European Union through

centralized procedure and used on the territory of these countries or Member States of the European Union shall be categorized by circumstances, which require an introduction of changes, and types according to the classification of types in the reference country.

{Item 3 of Part III as amended by the MoH Ukraine Order № 1202 of 02.10.2017}

4. Changes introduced in the registration materials based on the circumstances, which require an introduction of changes, shall be divided into:

Changes, whose introduction to the appropriate dossier in the United States of America, the Swiss Confederation, Japan, Australia, Canada, or the European Union (for the medicinal product registered through centralized procedure) according to the legislation of the appropriate country is performed with issuing a separate confirmation document by the appropriate authority;

Changes, introduction of which to the appropriate dossier in the United States of America, the Swiss Confederation, Japan, Australia, Canada, or the European Union (for the medicinal product registered through centralized procedure) according to the legislation of the appropriate country is performed without issuing a separate confirmation document by the appropriate authority;

Changes as required by the legislation of Ukraine;

Changes of administrative nature;

Changes relating to the correction of technical mistakes made at drawing registration documents during state registration, re-registration and introduction of changes in registration materials.

5. Change of applicant (holder of registration certificate) refers to the procedure for transfer of ownership of the registered medicinal product from the approved applicant (the holder of registration certificate) to another legal entity/natural person as a new applicant (an assignee). MoH shall perform a change of applicant (holder of registration certificate) based on an application, registration materials submitted according to the list given in annex 28 to the Procedure for conducting expert evaluation.

If change of the applicant (the holder of registration certificate) applies to several registered medicinal products a separate application shall be submitted for each registration certificate.

6. Change of the applicant's name and/or location shall not be classified as a change of the applicant if the applicant is the same legal entity/natural person. In case of a change of the holder of registration certificate name the registration certificate insert specifying the new applicant name shall be issued but with no prolongation of its validity.

Variations requiring a new registration of the medicinal product shall be introduced based on the fact of introduction of the specified changes in the registration dossier submitted to the competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, or the European Union based on which this medicinal product has been registered in Ukraine. This fact shall be confirmed according to the legislation of the appropriate country.

7. After the entry of materials about introduction of changes for review the Center shall conclude a contract with the applicant, if applicable, and conduct the review of registration materials.

8. The Center shall review within 10 working days the materials about introduction of changes in the registration materials:

1) introduction of which to the appropriate dossier in the United States of America, the Swiss Confederation, Japan, Australia, Canada, or the European Union (for the medicinal product registered through centralized procedure) according to the legislation of the appropriate country has been performed with issuing a separate confirmation document by the appropriate authority;

2) introduction of which to the appropriate dossier in the United States of America, the Swiss Confederation, Japan, Australia, Canada, or the European Union (for the medicinal product registered through centralized procedure) according to the legislation of the appropriate country has been performed without issuing a separate confirmation document by the appropriate authority.

9. The Center shall review materials about introduction of changes as required by the legislation of Ukraine, and in case of the applicant change according to the provisions and timelines established by the Procedure for Conducting Expert Evaluation for the appropriate type of changes.

10. The Center shall review the materials pertinent to changes requiring a new registration of the medicinal product according to the timelines established by this Procedure for registration of the medicinal product.

11. Based on the results of review of materials about introduction of changes to the registration materials the Center shall draw a conclusion on the results of review of materials about introduction of changes to the registration materials according to the form given in annex 8 to this Procedure (hereinafter – Conclusion on changes), and notify the applicant of termination of the review of materials within 2 working days, prepare a draft registration certificate insert (if applicable) or a new registration certificate for editing and agreeing upon with the applicant (for changes requiring a new registration).

12. In case of drawing the Conclusion on changes the Center shall prepare within 2 working days a list of medicinal products for which the review of materials about introduction of changes in the registration materials has been terminated (hereinafter – List of changes), supplement it by specimen copies of documents checked by the Center, which have been prepared by the applicant and submitted to the Center after editing and agreeing upon, namely: revised materials about methods of quality control for the medicinal product (if any), revised labelling text of packaging of the medicinal product in compliance with the requirements established in Ukraine (if any), revised text of instructions for medical use of medicinal products in compliance with the requirements established in Ukraine (if any), revised text of summary of product characteristics of the medicinal product (if any), and transfer them together with the Conclusion on changes and a cover letter to MoH, and in case of the approval of introduction of changes in registration materials by the MoH Order - to the State Service of Ukraine for Medicinal Products and Narcotics Control in order to perform state quality control of medicinal products being in circulation on the territory of Ukraine.

Information on transfer of the List of changes with the conclusion on changes to MoH shall be entered into the integrated e-database.

13. Information on the date of submission of materials about introduction of changes in the registration materials and the date of termination of their review shall be published on the Center's official website.

14. In order to correct a technical mistake the applicant shall submit to MoH a letter of request of optional form specifying a mistake and substantiating its correction, which shall be sent to the Center for review.

The Center shall review the correction of technical mistakes within 5 working days as from the date of submission of a letter-request by the applicant through the comparison of the revised materials of registration dossier with materials of the original registration dossier of the applicant.

In case of correction of technical mistakes, including spelling and/or grammatical mistakes in the registration certificate of the medicinal product, the Center shall give recommendations to MoH on approval of such corrections, and inform the applicant in writing thereof within 1 working day, and enter the appropriate information to the e-database.

The correction of other technical mistakes shall be approved by MoH Order.

15. When the state registration of the medicinal product is performed by MoH based on application and results of an expert evaluation of the registration materials pertinent to such medicinal product, which has been conducted by the Center the introduction of changes in registration materials during the validity period of registration certificate shall be performed according to this Procedure provided such medicinal product has been registered by a competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, or by a competent authority of the European Union through centralized procedure.

In order to confirm the fact of registration the applicant shall submit to the Center together with the materials envisaged in item 1 of this section a letter of optional form, where he specifies a country of registration of the medicinal product and number of its registration in the United States of America, the Swiss Confederation, Japan, Australia, Canada, or registration by a competent authority of the European Union through centralized procedure. The Center shall verify the validity of the information given in the letter on the official online resource of the competent authority of the appropriate country.

16. Changes shall come into effect within 6 months as from the date of approval of the change by MoH Ukraine Order unless otherwise is substantiated and refers to urgent safety-related variations pertinent to a medicinal product.

{New item is added to Part III according to the MoH Ukraine Order № 1202 of 02.10.2017}

T. Liaskovskyi

Chief, Pharmaceutical Activity and Pharmaceutical Product Quality Administration