



CABINET OF MINISTERS OF UKRAINE

DECREE

of May 26, 2005 № 376

Kyiv

On Approval of the Procedure for State Registration (Re-registration) of Medicinal Products and Amounts of Fees for Their State Registration (Re-Registration)

(Amended by the Decrees of the Cabinet of Ministers

№ 503 of 21.03.2007,

№ 1277 of 31.10.2007,

№ 372 of 17.04.2008,

№ 1165 of 14.11.2011,

№ 717 of 27.06.2012

№ 125 of 18.03.2015

№ 597 of 12.08.2015

(changes introduced by the CMU Decree № 597 of 12.08.2015 are valid till 31.03.2019)

№ 312 of 20.04.2016,

№ 558 of 08.08.2016

№ 296 of 27.03.2019

№ 916 of 06.11.2019

№ 282 of 15.04.2020

№ 471 of 15.04.2022)

According to the Article 9 and 9¹ of the Law of Ukraine “On Medicines” the Cabinet of Ministers of Ukraine **decides:**

{Introduction in wording of the CMU Decree № 282 of 15.04.2020}

1. To approve as being added:

The Procedure for State Registration (Re-registration) of Medicinal Products;

Amounts of Fees for State Registration (Re-registration) of Medicinal Products.

1¹. To establish that during the period of martial law:

and during six months after termination or cancellation of the martial law the countdown to the deadline for submitting an application for re-registration of a medicinal product specified in paragraph seven of item 10 of the Procedure approved by item 1 of this Decree shall be paused. Six months after termination or cancellation of the martial law the countdown for the deadline specified shall be resumed taking into account the time elapsed before the clock stop;

the time limits for use, import and circulation in Ukraine of medicinal products, including those to be procured based on the results of procurement procedure conducted by a specialized procurement organization in pursuance of a procurement agreement between the Ministry of Health of Ukraine and the specialized procurement organization concerned, and/or a person authorized to make health care procurement, the registration certificates of which have expired during the period of martial law and/or during six months after termination or cancellation of the martial law

shall be prolonged by means of extension of the validity period of registration certificate of such medicinal products for one year after its expiry and/or for the period of martial law, and/or for six months after termination or cancellation of martial law, and entering the information on extension of the validity period of registration certificate of such a medicinal product into the State Register of Medicinal Products of Ukraine. Updated information on the extended validity period of the registration certificate for such a medicinal product in the State Register of Medicinal Products of Ukraine proves the validity of the state registration of this medicinal product and does not require the issue of a new registration certificate or replacement of a valid registration certificate;

a medicinal product registered according to the requirements of the Procedure approved by item 1 of this Decree in case of its procurement based on the results of procurement procedure conducted by a specialized procurement organization in pursuance of a procurement agreement between the Ministry of Health of Ukraine and the specialized procurement organization concerned may be imported and used in the foreign packaging intended for markets of other countries that does not correspond with the approved registration materials for the medicinal product, accompanied by the instructions for medical use approved in Ukraine and a letter of guarantee from the manufacturer/applicant, which specifies that the imported medicinal product is identical to that registered in Ukraine;

the State Expert Center of the Ministry of Health of Ukraine shall not conduct an expert evaluation of the registration materials submitted for re-registration of medicinal products prior to the imposition of martial law until termination or cancellation of martial law, except in cases specified in this item, and shall take measures aimed at conducting an expert evaluation of registration materials in order to introduce changes into the registration materials for medicinal products, except for the medicinal products the applicants of which have ceased their activity during the period of martial law in Ukraine and have informed the Ministry of Health and the State Expert Center of the Ministry of Health of Ukraine of this, and to conduct state registration of medicinal products, including state emergency registration of medicinal products, medical immunobiological products, blood products produced or supplied to Ukraine during the period of martial law, subject to obligation. At the applicant's discretion and if he is able to ensure appropriate interaction with the State Expert Center of the Ministry of Health of Ukraine the expert evaluation of registration materials may be continued by the State Expert Center of the Ministry of Health of Ukraine according 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 Ministry of Health.

{Item 1¹ is added according to the CMU Decree № 471 of 15.04.2022 – valid for six months after termination or cancellation of martial law}

2. To declare as being invalid:

The Decree of the Cabinet of Ministers of Ukraine of September 13, 2000 № 1422 "On Approval of the Procedure for State Registration (Re-registration) of Medicinal Product and Amounts of Fees for State Registration (Re-registration) of Medicinal Product" (Official Bulletin of Ukraine, 2000, № 37, Art. 1587);

Item 4 of Changes introduced to the Decrees of the Cabinet of Ministers of Ukraine approved by the Decree of the Cabinet of Ministers of Ukraine of June 21, 2001 № 678 (Official Bulletin of Ukraine, 2001, № 26, Art. 1170);

Item 3 of Changes introduced to the Decrees of Cabinet of Ministers of Ukraine approved by the Decree of the Cabinet of Ministers of Ukraine of July 24, 2003 № 1146 (Official Bulletin of Ukraine, 2003, № 31, Art. 1605);

Paragraphs four - six of item 1 of the Decree of the Cabinet of Ministers of Ukraine of October 28, 2004 № 1419 "Some measures for ensuring quality of medicinal products" (Official Bulletin of Ukraine, 2004, № 44, Art. 2877)

APPROVED
by the Decree of the Cabinet of Ministers of Ukraine
of May 26, 2005 № 376

PROCEDURE
for State Registration (Re-registration) of Medicinal Products

{In the text of the Procedure the word “Switzerland” in all cases is replaced by the words “the Swiss Confederation” in the appropriate case according to CMU Decree № 282 of 15.04.2020}

1. This procedure establishes the mechanism for conducting state registration (re-registration) of medicinal products, including medical immunobiological products, specified by the Article 2 of the Law of Ukraine "On medicines", which are allowed for use in Ukraine only after such registration.

{Paragraph 1 of item 1 amended by CMU Decree № 717 of 27.06.2012}

Not subject to state registration are the medicinal products prepared in pharmacies on prescription of physicians (magistral formulas) and as requested by health care settings (official formulas) using active substances and excipients permitted for use.

2. The MoH performs the state registration of medicinal products based on application and results of expert evaluation of registration materials of such product conducted by the State Expert Center MoH (hereinafter — the Center) through the procedure established by MoH.

If the medicinal product has been registered by the European Medicines Agency, the state registration of original medicinal product shall be performed without above expert evaluation based on application, registration materials including assessment report of registration dossier of the given Agency and conclusion of the Center pertinent to compliance of instruction for use and quality control methods of medicinal product with the registration materials. Such compliance shall be verified through the procedure established by MoH.

State registration of the medicinal product, which has been registered by competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, by competent authority of the European Union via centralized procedure and used in those countries or EU member states shall be performed according to the application and Center's conclusion drawn up based on the results of the MoH-established procedure for review of the materials attached to the application.

{Paragraph 3 of item 2 in wording of CMU Decree of 08.08.2016 № 558; as amended by CMU Decree № 282 of 15.04.2020}

MoH conducts the state registration of medicinal product to be purchased based on results of procurement procedure conducted by a specialized procurement organization in pursuance of a procurement agreement between MoH and appropriate specialized procurement organization based on application and the Center's conclusion drawn up based on results of the authenticity verification of registration materials conducted according to the procedure established by MoH.

{Item 2 amended by new paragraph according to CMU Decree № 597 of 12.08.2015 – valid till 31.03.2019; in wording of CMU Decree № 296 of 27.03.2019 – amendments are valid till}

31.03.2020, № 282 of 15.04.2020 – valid till 31.03.2022)

MoH conducts the state registration of a medicinal product to be purchased by a person authorized to make health care procurement, which has been registered by competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada and used in these countries or by competent authority of the European Union via centralized procedure and used in the EU member states, based on application and the Center's conclusion drawn up based on results of the authenticity verification of registration materials conducted according to the procedure established by MoH.

{New paragraph is added to item 2 according to the CMU Decree № 282 of 15.04.2020 – valid till 31.03.2022}

MoH conducts the state registration of a medicinal product to be purchased by a person authorized to make health care procurement, regardless of the country of manufacture, based on application and the Center's conclusion drawn up based on results of expert evaluation of registration materials according to the procedure established by MoH, which includes recommendations concerning the state registration of a medicinal product.

{New paragraph is added to item 2 according to the CMU Decree № 282 of 15.04.2020 – valid till 31.03.2022}

On the submission date of an application for state registration of a medicinal product to be purchased by a person authorized to make health care procurement this medicinal product shall be put on the List of medicinal products, medical devices and accessories to them, procured using the funds under the state budget to execute programs and take centralized health care measures approved by the Cabinet of Ministers of Ukraine for the appropriate year.

{New paragraph is added to item 2 according to the CMU Decree № 282 of 15.04.2020 – valid till 31.03.2022}

At applicant's request the active pharmaceutical ingredient may be registered as a part of finished medicinal product.

Information about the applications for state registration submitted, status of the review of documents and decisions taken based on its results are published at the Center's website free of charge.

{Paragraph is added to item 2 according to the CMU Decree № 558 of 08.08.2016}

During the period of martial law and/or during six months after termination or cancellation of martial law, an application for state registration (re-registration) (if any) of medicinal products or introduction of changes into registration materials for medicinal products shall be submitted to the MoH in paper format or, at the applicant's discretion, in electronic format to the e-mail address specified by the Center as scanned documents with or without a qualified e-signature of the applicant (his authorized representative). MoH's letter of referral concerning the relevant review of the application accepted shall be sent to the Center in electronic format.

{Paragraph is added to item 2 according to the CMU Decree № 471 of 15.04.2022 – valid for six months after termination or cancellation of martial law}

During the period of martial law and/or during six months after termination or cancellation of martial law, the applicant shall submit to the Center a registration form, registration materials and other documents for the state registration (re-registration) (if any) of medicinal products or introduction of changes to the registration materials pertinent to medicinal products in paper format according to the procedure established by the MoH or, at the applicant's discretion, in electronic format to the e-mail address specified by the Center as scans without a qualified e-signature of the applicant (his authorized representative), or as electronic documents using a qualified e-signature of the applicant via appropriate tools that enable user to create an informed authorized electronic signature or its equivalent (for example, DocuSign, Adobe Sign, etc.), subject to the submission of a letter of guarantee (according to the form given in annex to this Procedure) in electronic format using a qualified e-signature. Registration materials pertinent to a medicinal product may also be submitted to the Center after providing the Center with a read access to the applicant's electronic resources (repositories).

{Paragraph is added to item 2 according to the CMU Decree № 471 of 15.04.2022 - valid for six months after termination or cancellation of martial law}

An application for state re-registration and supporting documentation pertinent to medicinal products, the period of validity of registration certificates of which have expired during the period of martial law and/or during six months after termination or cancellation of martial law, and been extended, shall be submitted according 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 after termination or cancellation of martial law, but not no later than six months after termination or cancellation of martial law.

{Paragraph is added to item 2 according to the CMU Decree № 471 of 15.04.2022 – valid for six months after termination or cancellation of martial law}

In case of discontinuation of the applicant's activity during the period of martial law with an appropriate notification provided to the MoH and/or the Center, the applicant may resume activities related to the procedure for re-registration of the medicinal product commenced prior to the imposition of martial law after its termination or cancellation, but not later than six months after termination or cancellation of martial law.

{Paragraph is added to item 2 according to the CMU Decree № 471 of 15.04.2022 - valid for six months after termination or cancellation of martial law}

{Item 2 as amended by the CMU Decrees № 372 of 17.04.2008, № 1165 of 14.11.2011; in wording of the CMU Decree № 125 of 18.03.2015}

3. An application for the state registration of medicinal product, submitted to MoH by a legal or natural person responsible for quality, safety and efficacy of medicinal product (hereinafter — the Applicant) shall specify name and address of the Applicant, legal address and address of the place of performing

activity by the manufacturer of medicinal product, name of the medicinal product, its trade name, name of active substance, synonyms, presentation, full composition of medicinal product, indications and contraindications for use, dosage, dispensing conditions, methods of use, shelf-life and conditions of storage, information about package, data about registration of medicinal product in other countries.

(Paragraph 1 of item 3 amended by CMU Decree № 717 of 27.06.2012, № 312 of 20.04.2016)

To perform expert evaluation of registration materials the applicant shall submit to the Center:

(Paragraph 2 of item 3 in wording of CMU Decrees № 717 of 27.06.2012, № 312 of 20.04.2016)

1) materials of the registration dossier, requirements for the content and volume of which are established by MoH;

(Sub-item 1 of item 3 amended by CMU Decree № 372 of 17.04.2008; in wording of CMU Decree № 282 of 15.04.2020)

2) materials pertinent to quality control methods of a medicinal product;

(Sub-item 2 in wording of CMU Decree № 282 of 15.04.2020)

3) information about production technology of medicinal product, and a copy of official authorization to manufacture issued by competent authority of a manufacturing country concerned;

(Sub-item 3 of item 3 amended by CMU Decree № 717 of 27.06.2012; in wording of CMU Decree № 282 of 15.04.2020)

4) text of the packaging labelling;

(Sub-item 4 of item 3 in wording of CMU Decree № 282 of 15.04.2020)

4¹) a duly certified copy of a document which is issued by the State Service of Ukraine for Medicinal Products and Narcotics Control (hereinafter – Derzhliksluzhba) according to the procedure established by MoH (for domestic manufacturers – a duly certified copy of valid authorization to manufacture medicinal products) based on the results of verification envisaged by paragraph fourteen of this item, and confirms a compliance of the manufacturing conditions of the medicinal product (except for active substances) submitted for registration with the current good manufacturing practice requirements in Ukraine;

(Sub-item 4¹ added to item 3 according to CMU Decree № 717 of 27.06.2012, amended by CMU Decree № 296 of 27.03.2019; in wording of CMU Decree № 282 of 15.04.2020)

5) Document confirming payment of the registration fee.

MoH shall establish the procedure for expert evaluation of registration materials, listed in subitems 1-5 of this item, requirements to them as agreed upon with the Ministry of Economic Affairs.

(New paragraph added to item 3 according to CMU Decree № 312 of 20.04.2016; amended by CMU Decree № 916 of 06.11.2019)

(Paragraph 10 of item 3 is deleted according to CMU Decree № 558 of 08.08.2016)

(Paragraph 11 of item 3 is deleted according to CMU Decree № 558 of 08.08.2016)

MoH shall establish procedure for adaptation to the European Union standards and the WHO recommendations including approval of standards for circulation of medicinal products, as well as registration of medicinal products of limited use and those produced according to the MoH approved specifications (information on composition, production technology, quality control and use of a medicinal product). Expert evaluation of registration materials shall be conducted by experts with appropriate level of qualification and expertise in the Ukrainian legislation, the European Union rules and standards, WHO recommendations pertinent to medicinal product circulation, provisions of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. At the same time an expert shall not perform functions including those outside an expert body which result in conflict of interests. MoH shall establish requirements to expert qualifications and procedure of their certification.

(Paragraph of item 3 in wording of CMU Decrees № 1277 of 31.10.2007, № 372 of 17.04.2008; amended by CMU Decrees № 717 of 27.06.2012, № 125 of 18.03.2015, № 312 of 20.04.2016)

(Paragraph of item 3 is deleted according to CMU Decree № 1277 of 31.10.2007)

Inspection of manufacture of the medicinal products (except for active substances) submitted for state registration for good manufacturing practice compliance shall be conducted during the expert evaluation of registration materials according to the procedure established by MoH.

(Paragraph added to item 3 according to CMU Decree № 372 of 17.04.2008; in wording of CMU Decree № 1165 of 14.11.2011, amended by CMU Decree № 717 of 27.06.2012, № 296 of 27.03.2019)

Inspection of manufacture of the medicinal products (except for active substances) submitted for state registration for good manufacturing practice compliance shall not be conducted if there is a document verifying the compliance of manufacture with the requirements of good manufacturing practice (for domestic manufacturers – a valid license for manufacturing medicinal products) issued by Derzhliksluzhba.

(Paragraph added to item 3 according to CMU Decree № 1165 of 14.11.2011; amended by CMU Decree № 717 of 27.06.2012, № 296 of 27.03.2019)

3¹. Information included in an application for state registration of medicinal product and its annexes (hereinafter – the registration information) is subject to state protection against disclosure and unfair commercial use in compliance with the Law of Ukraine “On Medicines” and other regulatory documents. The MoH and the Center must protect such information against disclosure and prevent its unfair commercial use. The MOH shall provide on its official web-site free access to all results of pre-clinical and clinical studies of medicinal products (preclinical study reports and clinical study reports approved in form established by MoH), being the public indormation. Report forms and aspects of their preparation are set by the MoH.

(Item 3¹ added to the Procedure according to CMU Decree № 503 of 21.03.2007, in wording of CMU Decree № 296 of 27.03.2019)

3². It is prohibited to use the registration information on safety or efficacy of the registered medicinal product contained in the application and its annexes for submission of the application for state registration of another medicinal product during five years after the date of state registration of medicinal product

(regardless of the validity period of any patent related to the medicinal product) except for cases when the right to refer to or use such information has been obtained according to the procedure established by the law from a person or organization who has submitted the information, or the information has been prepared by the applicant or for the applicant.

(Item 3² added to the Procedure according to CMU Decree № 503 of 21.03.2007)

3³. 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 the patent or license to manufacture or sell the registered medicinal product as well as a letter indicating that the rights of third parties being patent-protected are not violated because of the registration of the medicinal product.

(Item 3³ added to the Procedure according to CMU Decree № 503 of 21.03.2007)

3⁴. Instead of documents specified in sub-items 1-5 of item 3 of this Procedure, attached to the application for state registration of medicinal product, which has been registered by competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, by competent authority of the European Union via centralized procedure and used in these countries or EU member states, shall be:

(Paragraph 1 of item 3⁴ in wording of CMU Decree of 08.08.2016 № 558; as amended by CMU Decree № 282 of 15.04.2020)

1) a duly certified copy of document which is issued by the Derzhliksluzhba according to the MoH established procedure based on the results of verification envisaged by paragraph 10 of item 3, and confirms the compliance of manufacturing conditions of the medicinal product submitted for registration with current good manufacturing practice; or a commitment letter of a manufacturer to produce the medicinal product concerned for supply in Ukraine at the same production capacities as those used for producing medicinal products intended for the use in the USA, the Swiss Confederation, Japan, Australia, Canada or EU member states;

2) materials pertinent to quality control methods of a medicinal product;

3) layout of the packaging mockup of the medicinal product and the text of the labeling of the immediate and outer (if any) packaging in the language for the labeling of medicinal products according to the requirements of the legislation;

(Subitem 3 of item of 3⁴ in wording of CMU Decree № 282 of 15.04.2020)

3¹⁾ The materials of registration dossier based on which the medicinal product has been registered by competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada or by competent authority of the European Union via centralized procedure for use in these countries or EU member states indicating data on registration of the medicinal product in such countries including name of a country of registration, body of registration and date of registration confirmed by the applicant and/or his authorized representative.

(Sub-item 3¹⁾ added to item 3⁴ according to CMU Decree of 08.08.2016 № 558; as amended by CMU Decree № 282 of 15.04.2020)

4) instructions for use of medicinal product in the language according to the language requirements of the legislation;

(Subitem 4 of item of 3⁴ in wording of CMU Decree № 282 of 15.04.2020)

5) A document confirming the payment of registration fee.

The term of review of the mentioned materials pertinent to the medicinal product registered by competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, or by competent authority of the European Union via centralized procedure and used in these countries or EU member states shall not exceed ten working days.

(Paragraph added to item 3⁴ according to CMU Decree of 08.08.2016 № 558; as amended by CMU Decree № 282 of 15.04.2020)

(Item 3⁴ added to the Procedure according to CMU Decree № 125 of 18.03.2015)

3⁵. The application for state registration of medicinal product to be purchased based on results of procurement procedure conducted by a specialized procurement organization in pursuance of the procurement agreement between the MoH and appropriate specialized procurement organization shall be accompanied by the following documents instead of those specified in sub-items 1-5 of item 3 of this Procedure:

Materials of registration dossier submitted for registration of medicinal product to regulatory authority of a country where the medicinal product concerned has been registered or for WHO prequalification of the medicinal product;

Assessment report for the medicinal product concerned drawn up by regulatory authority of the country, where such medicinal product has been registered, or issued by WHO if the medicinal has been prequalified;

Quality control methods of the medicinal product (finished product);

Instructions for use of the medicinal product in the language according to the language requirements specified by legislation;

specimen of original packaging of the medicinal product;

translations of the text of packaging labelling of the medicinal product and instructions for use of the medicinal product or information about use of the medicinal product in the language meeting the language requirements as foreseen by legislation, which are certified by signature of the applicant or his authorized representative.

(Procedure amended by item 3⁵ according to CMU Decree № 597 of 12.08.2015 – valid till 31.03.2019, in wording of CMU Decree № 296 of 27.03.2019 – valid till 31.03.2020; № 282 of 15.04.2020 – valid till 31.03.2022)

3⁶. The application for state registration of medicinal product to be purchased by a person authorized to make health care procurement, which has been registered by competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada and used in these countries or which has been registered by competent authority of the European Union via centralized procedure and used in EU member states shall be accompanied by the following documents instead of those specified in sub-items 1-5 of item 3 of this Procedure:

a document confirming the registration of the medicinal product in the corresponding country or the registration by a EU competent authority via centralized procedure and use in EU member states on the submission date of an application for state registration, which is certified by signature of the applicant or his authorized representative;

materials of the registration dossier based on which the registration of the medicinal product was conducted by competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada or by competent authority of the European Union via centralized procedure for use in these countries or EU member states;

quality control methods of the finished medicinal product (final product);

assessment report of the medicinal product concerned drawn up by regulatory authority of the country, where this medicinal product has been registered;

instructions for use of the medicinal product in the original language (a language, which differs from the state one); summary of product characteristics in the original language (a language, which differs from the state one);

layout of the packaging mockup of the medicinal product and the text of the labeling of the immediate and outer (if any) packaging of the medicinal product;

translations of the text of the labeling of the immediate and outer (if any) packaging and instructions for use, summary of product characteristics of the medicinal product in the language meeting the language requirements as foreseen by legislation according to the procedure specified by MoH, which are certified by signature of the applicant or his authorized representative;

a certified copy of document confirming the compliance of manufacturing conditions for the medicinal product submitted for registration with the requirements to the manufacture of medicinal products in Ukraine, which is issued by the Derzhliksluzhba according to the procedure established by MoH, or a commitment letter of a manufacturer to produce the appropriate medicinal product for supply in Ukraine with the same manufacturing capacities as those used to manufacture medicinal products intended for use in the corresponding country of registration (the USA, the Swiss Confederation, Japan, Australia, Canada or EU Member States).

The term of verification of authenticity of the registration materials for a medicinal product to be purchased by a person authorized to make health care procurement, which has been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada and used in these countries or which has been registered by the competent authority of the European Union via centralized procedure and used in EU Member States, shall not exceed seven working days from the date of their submission. During the verification of authenticity of the registration materials the expert evaluation of materials of the registration dossier submitted to the regulatory authority, which has registered this medicinal product shall not be conducted.

*(Item 3⁶ added to the Procedure according to
CMU Decree № 282 of 15.04.2020 – valid till
31.03.2022)*

3⁷. If the state registration of the medicinal product is conducted with the labelling and the instructions for use of the medicinal product, which meet the requirements of parts one, two, three and five of Article 12 of the Law of Ukraine “On Medicines” instead of documents specified in sub-items 1-5 of item 3 of this Procedure, an application for state registration of the medicinal product to be purchased by a person authorized to make health care procurement (regardless of the country of manufacture) shall be accompanied by:

materials of registration dossier;

materials pertinent to quality control methods of a medicinal product;

a document confirming payment of registration fee;

labeling of the immediate and outer (if any) packaging of the medicinal product;

instructions for use of the medicinal product;

a certified copy of the document confirming the compliance of manufacturing conditions for the medicinal product submitted for the registration with the requirements to manufacture of medicinal products in Ukraine, which is issued by the Derzhliksluzhba according to the procedure determined by MoH (for domestic manufacturer – a copy of valid license to manufacture medicinal products certified according to the established procedure).

*(Item 3⁷ added to the Procedure according to
CMU Decree № 282 of 15.04.2020 – valid till
31.03.2022)*

3⁸. If the state registration of the medicinal product is conducted with the labelling, instructions for use of the medicinal product, and summary product characteristics of the medicinal product in the original language (in a language other than the state language) instead of documents specified in sub-items 1-5 of item 3 of this Procedure, an application for state registration of the medicinal product to be purchased by a person authorized to make health care procurement (regardless of the country of manufacture) shall be accompanied by:

materials of registration dossier;

materials pertinent to quality control methods of a medicinal product;

a document confirming payment of registration fee;

a layout of the packaging mockup of the medicinal product;

a specimen of original instructions for use of the medicinal product, and summary product characteristics of the medicinal product;

translations of the text of the labeling of the immediate and outer (if any) packaging, instructions for use, summary of product characteristics of the medicinal product in the language meeting the language requirements specified by legislation according to the procedure established by MoH, which are certified by signature of the applicant or his authorized representative;

a certified copy of document confirming the compliance of manufacturing conditions for the medicinal product submitted for registration with the requirements to the manufacture of medicinal products in Ukraine, which is issued by the Derzhliksluzhba according to the procedure established by MoH.

The term of expert evaluation of the registration materials for a medicinal product to be purchased by a person authorized to make health care procurement (regardless of the country of manufacture) shall not exceed 30 working days. The term of the expert work shall not include the time the applicant needs to finish up the materials, the time needed to receive answers from the third parties (including from the competent authorities of Ukraine and/or other countries) related to the expert evaluation, and the time needed to carry out laboratory tests.

*(Item 3⁸ added to the Procedure according to
CMU Decree № 282 of 15.04.2020 – valid till
31.03.2022)*

4. If required the Center shall conduct an additional testing of medicinal product and/or additional expert evaluation of registration materials in accordance with the procedure established by MoH.

Additional expert evaluation (testing) shall be conducted after payment of its cost, specified in the contract between the Applicant and the entity conducting such expert evaluation (testing). Materials pertinent to the results of work performed shall be sent to the Center.

5. The Center shall draw up motivated conclusions pertinent to efficacy, safety and quality of medicinal product based on the results of expert evaluation of registration materials or conclusions envisaged by paragraphs two-six of item 2 of this Procedure and recommend to perform state registration of appropriate medicinal product or to refuse it.

(Paragraph 1 of item 5 in wording of CMU Decree

№ 125 of 18.03.2015; amended by CMU Decree № 597 of 12.08.2015 – valid till 31.03.2019, in wording of CMU Decree № 296 of 27.03.2019; amended by CMU Decree № 282 of 15.04.2020)

Based on the applicant's application and the Center's conclusions and recommendations MoH shall make a decision to register or refuse such registration within ten working days (for a medicinal product, which has been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, medicinal product registered by the competent authority of the European Union via centralized procedure and used in these countries or EU member states) or within seven working days (for a medicinal product to be purchased based on results of the procurement procedure conducted by a specialized procurement organization in pursuance of procurement agreement between MoH and appropriate specialized procurement organization), or within five working days (for medicinal product to be purchased by a person authorized to make health care purchases).

(Paragraph 2 of item 5 amended by CMU Decrees № 125 of 18.03.2015, № 597 of 12.08.2015 – valid till 31.03.2019, № 312 of 20.04.2016, in wording of the CMU Decrees № 558 of 08.08.2016, № 282 of 15.04.2020 – valid till 31.03.2022)

MoH Order on state registration approves the quality control methods of a medicinal product, instructions for use of medicinal product (instructions for medical use) and assigns a registration number to the medicinal product that is entered in the State Register of Medicinal Products of Ukraine and the Interdepartmental Database of Registered Medicinal Products in Ukraine. Information on possibility of advertising of medicinal product, and data on previous registration, re-registration or cancellation of the medicinal product registration and on the medicinal product registration in the USA, the Swiss Confederation, Japan, Australia, Canada, and EU member states if such medicinal product has undergone the state registration as a medicinal product registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, medicinal product, registered by the competent authority of the European Union via centralized procedure and used in these countries or EU member states, including name of a country of registration and body of registration, and date of registration.

(Paragraph 3 of item 5 in wording of CMU Decree № 1165 of 14.11.2011; amended by CMU Decrees № 717 of 27.06.2012, № 558 of 08.08.2016, № 282 of 15.04.2020)

For the medicinal products registered by competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada and used in these countries, or by competent authorities of the European Union via centralized procedure and used in EU member states, which are to be purchased by a person authorized to make health care purchases, and for the registered medicinal products, regardless of the country of manufacture, to be purchased by a person authorized to make health care purchases, if the state registration has been conducted with the labeling, instructions for use and summary of product characteristics of the medicinal product in the original language (in a language other than the state language), in addition to the details provided for by this item, the State Register of Medicinal Products of Ukraine shall contain data on referring the medicinal product to the medicinal products that can be used in Ukraine solely for the purpose of free supply to the health care units of the regional state administrations, and the state administrations of the city of Kyiv and the city of Sebastopol, or entities licensed to conduct economic activity relating to medical practice based on the results of the procurement using the funds under the state budget and made by a person authorized to make health care purchases, in order to execute programs and take centralized health care measures.

(New paragraph added to Item 3 of the Procedure according to CMU Decree № 282 of 15.04.2020 – valid till 31.03.2022)

The Center shall keep registration materials. Copies of documents, which approve quality control methods of the medicinal product, copy of registration certificate and copy of instructions for use of medicinal product (instructions for medical use) shall be sent to the Derzhliksluzhba.

(Paragraph of item 5 in wording of CMU Decree № 717 of 27.06.2012)

6. 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 – the registration certificate).

MoH shall issue a registration certificate specifying a validity period for use of medicinal product in Ukraine within 10 working days after taking decision about state registration of the medicinal product.

(Paragraph 2 of item 6 amended by CMU Decree № 125 of 18.03.2015)

MoH shall establish a Form of registration certificate and procedure for its issue.

The medicinal product is allowed for use in Ukraine during 5 years of the date of its state registration, except for cases specified in item 8 of this Procedure.

(Paragraph 4 of item 6 amended by CMU Decree № 125 of 18.03.2015)

Registration certificate for medicinal product to be purchased based on results of procurement procedure conducted by a specialized procurement organization, which acts in pursuance of the procurement agreement between the MoH and appropriate specialized procurement, including a registration certificate effective till March 31, 2020, shall be valid till March, 2022 solely in order to execute programs and take centralized health care measures. The validity period of the registration certificates granted for medicinal products shall be extended by issuing the updated registration certificates with the relevant information entered in the State Register of Medicinal Products of Ukraine.

(Paragraph is added to item 6 according to CMU Decree № 597 of 12.08.2015 – valid till 31.03.2019, in wording of CMU Decrees № 296 of 27.03.2019 – valid till 31.03.2020, № 282 of 15.04.2020 – valid till 31.03.2022)

(Item 6 in wording of the Decree CMU № 717 of 27.06.2012)

7. During the validity period of registration certificate the applicant shall be responsible for efficacy, safety and quality of the registered medicinal product, take measures for enhancing scientific and technical level of production and quality assurance of the registered medicinal product, which are established in Ukraine.

If facts (circumstances) are revealed about the registered medicinal products, which require an introduction of changes to the registration materials, the applicant shall submit an appropriate application to MoH; based on results of its review the MoH shall send an assignment letter together with a copy of application for introduction of appropriate changes to the Center. As soon as the Center receives an assignment letter, the applicant shall submit full information about reasons for such changes and their potential effect on efficacy, safety, and quality of the medicinal product to the Center.

(Paragraph 2 of item 7 in wording of the Decree CMU № 717 of 27.06.2012)

Expert evaluation of changes proposed to be introduced in registration materials shall be conducted based on MoH's assignment letter after payment of their cost specified in the contract between the applicant and the Center, which gives recommendations on introducing changes in registration materials or new registration of medicinal product in accordance with the procedure established by MoH.

(Paragraph 3 of item 7 amended by the Decree CMU № 717 of 27.06.2012)

MoH shall establish a procedure for conducting expert evaluation, including calculation of its cost, list of changes which are introduced in registration materials, procedure for their introduction and circulation of medicinal products before and after introduction of such changes.

Review of materials pertinent to introduction of changes into registration materials for medicinal product, which has been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, by the competent authority of the European Union via centralized procedure and used in these countries or EU member states, shall be performed according to the procedure established by MoH.

(Paragraph added to item 7 according to CMU Decree № 558 of 08.08.2016; amended by CMU Decrees № 282 of 15.04.2020)

If after introduction of changes to the registration materials, in particular to the instructions for use of medicinal product in part of the indications for use, the medicinal product becomes subject (not subject) to the MoH approved criteria applied for determining medicinal products, advertising of which is prohibited, the MoH based on the Center recommendations shall make a decision on the classification of medicinal product as medicinal product, advertising of which is prohibited (does not prohibited), and appropriate changes shall be introduced to the advertising status of medicinal product in the State Register of Medicinal Products of Ukraine.

(Paragraph is added to item 7 according to the CMU Decree № 296 of 27.03.2019)

During the period of martial law the MoH shall approve the production and sale until the end of shelf life of the registered medicinal product, taking into account changes not introduced into the registration materials, provided the applicant submits a letter stating that the implementation of changes will not adversely affect the quality, efficacy, safety of the medicinal product, and ensures that all relevant studies will be conducted and the above-mentioned changes will be introduced into the registration dossier as required by the legislation after termination or cancellation of martial law, but not later than six months after termination or abolition of martial law.

{Paragraph is added to item 7 according to the CMU Decree № 471 of 15.04.2022 - valid for six months after termination or cancellation of martial law}

8. According to the established procedure MoH can decide on absolute or temporary prohibition of use of medicinal product by terminating a registration certificate with no reimbursement of fee for state registration of this medicinal product in case of revealing previously unknown dangerous properties, in particular if:

medicinal product is harmful for human health and/or therapeutic efficacy of medicinal product is lacking when used according to the instructions;

composition of medicinal product does not correspond to that stated in registration documents;

registration documents or information about introduction of changes in them, which are submitted by the applicant, are unreliable;

applicant fails to fulfill all types of quality control of the finished medicinal product and/or its ingredients, which are stated in registration documents, as well as intermediate control of production stages according to the registration materials;

applicant fails to fulfill the requirements specified by paragraph 1 and 2 of item 7 of this Procedure within the timeframe specified by MoH;

(Paragraph 6 of item 8 amended by CMU Decree № 125 of 18.03.2015)

other dangerous properties of medicinal product have been revealed which are specified by MoH with due account of international practices;

medicinal product has not been put into circulation on the territory of Ukraine within three years of its state registration (re-registration) if this isn't caused by a specificity of manufacture and/or use of such medicinal product.

(Paragraph added to item 8 according to CMU Decree № 717 of 27.06.2012, amended by CMU Decree № 125 of 18.03.2015)

9. The decision to refuse state registration medicinal product shall be made if during expert evaluation of registration materials the data pertinent to efficacy, safety and quality of such medicinal product has not been confirmed.

(Paragraph one of item 9 as amended by CMU Decree № 296 of 27.03.2019)

The grounds for rejection of state registration of a medicinal product, which has been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, by the competent authority of the European Union via centralized procedure and used in these countries or EU member states, shall be a failure to submit appropriate materials for such medicinal product that are specified in item 3⁴ of this Procedure or submission of incomplete set of them, a detection of inconsistencies affecting efficacy, safety and quality of such medicinal products in the submitted documents, a lack of correspondence revealed between the manufacturer's name of such medicinal product, his location and addresses of his manufacturing capacities mentioned in the application for state registration and the information on the basis of which this medicinal product has been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada or the European Union. The grounds for rejection of state registration of a medicinal product to be purchased based on the results of procurement procedure conducted by a specialized procurement organization in pursuance of a procurement agreement between MoH and appropriate specialized procurement organization shall be a failure to submit the appropriate materials for such medicinal product that are specified in item 3⁵ of this Procedure or a submission of incomplete set of them, a detection of inconsistencies affecting efficacy, safety and quality of such medicinal products in the submitted documents, a lack of correspondence revealed between the manufacturer's name of such medicinal product, his location and addresses of his manufacturing capacities mentioned in the application for state registration and the information, on the basis of which this medicinal product has been registered, a detection of inauthentic translation of the text of packaging labelling of such medicinal product or instructions for use of such medicinal product. The grounds for rejection of state registration of a medicinal product to be purchased by a person authorized to make health care purchases, which has been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada and used in these countries, or, which has been registered by the competent authority of the European Union via centralized procedure and used in EU member states, shall be a failure to submit the appropriate materials pertinent to such medicinal product that are specified by item 3⁶ of this Procedure or a submission of incomplete set of them, a detection of inconsistencies affecting efficacy, safety and quality of such medicinal products in the

submitted documents, lack of correspondence between the manufacturer's name of such medicinal product, his location and address of his manufacturing capacities mentioned in the application for state registration and the information, on the basis of which this medicinal product has been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada or the European Union, a detection of inauthentic translation of the text of packaging labelling of such medicinal product, instructions for use of such medicinal product or summary of product characteristics for such medicinal product. The grounds for rejection of state registration of a medicinal product to be purchased by a person authorized to make health care purchases (regardless of the country of manufacture) if the state registration of the medicinal product is conducted with the labelling and the instructions for use of the medicinal product, which meet the requirements of parts one, two, three and five of article 12 of the Law of Ukraine "On Medicines" shall be a failure to submit the appropriate materials pertinent to such medicinal product that are specified by item 3⁷ of this Procedure or a submission of incomplete set of them, a failure to confirm conclusions on its efficacy and safety, and a lack of correspondence between translations of the text of packaging labelling of medicinal product, instructions for use of medicinal product or summary of product characteristics for medicinal product. The grounds for rejection of state registration of a medicinal product to be purchased by a person authorized to make health care purchases (regardless of the country of manufacture) if the state registration of the medicinal product is conducted with the labelling, instructions for use of the medicinal product, and summary product characteristics of medicinal product in the original language (in a language other than the state language) shall be a failure to submit the appropriate materials pertinent to such medicinal product that are specified by item 3⁸ of this Procedure or a submission of incomplete set of them, a failure to confirm conclusions on its efficacy and safety, and a lack of correspondence between translations of the text of packaging labelling of medicinal product, instructions for use of medicinal product or summary of product characteristics for medicinal product.

(Paragraph 2 of item 9 amended by CMU Decrees № 597 of 12.08.2015 - valid till 31.03.2019, № 558 of 08.08.2016, № 296 of 27.03.2019 – valid till 31.03.2020, № 282 of 15.04.2020 – concerning the validity of changes see also item 2 of the CMU Decree № 282 of 15.04.2020)

The state registration of medicinal product may be rejected if such registration causes a violation of patent-protected intellectual property right, in particular, relating to manufacture, use or sale of medicinal product.

MoH shall send the applicant a motivated answer in writing concerning the rejection of registration of a medicinal product within ten working days. For a medicinal product to be purchased by a person authorized to make health care purchases or to be purchased based on results of procurement procedure conducted by a specialized procurement organization which acts in pursuance of a procurement agreement between the MoH and appropriate specialized procurement organization an answer concerning the rejection shall be sent within three working days.

(Paragraph 4 of item 9 in wording of CMU Decree № 597 of 12.08.2015 – valid till 31.03.2019, № 296 of 27.03.2019 – valid till 31.03.2020, № 282 of 15.04.2020 – valid till 31.03.2022)

The rejection decision may be appealed according to the procedure established by legislation.

(Paragraph 5 of item 9 in wording of CMU Decree № 597 of 12.08.2015 – valid till 31.03.2019, № 296 of 27.03.2019 – valid till 31.03.2020, № 282 of 15.04.2020 – valid till 31.03.2022)

(Item 9 in wording of CMU Decree № 125 of 18.03.2015)

10. If the term within which the medicinal product is allowed for use in Ukraine has expired its further use is permissible after its re-registration only.

Re-registration of medicinal products including medicinal product, which has been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, by the competent authority of the European Union via centralized procedure and used in these countries or EU member states, a medicinal product to be purchased by a person authorized to make health care purchases, which has been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada and used in these countries, or, which has been registered by the competent authority of the European Union via centralized procedure and used in EU member states, a medicinal product to be purchased by a person authorized to make health care purchases (regardless of the country of manufacture) shall be performed by MoH based on the application, registration materials and the Center's conclusion drawn up according to the MoH established procedure. In particular, such conclusion shall contain an information on balance of expected benefit in relation to potential risk at use of the medicinal product (except for active pharmaceutical ingredient and "in bulk" product).

(Paragraph 2 of item 10 in wording of the CMU Decree № 558 of 08.08.2016, № 282 of 15.04.2020 – valid till 31.03.2022)

The MoH shall make a decision to re-register medicinal product or refuse such re-registration within one month after the receipt of the above-mentioned conclusion.

A decision to refuse a state re-registration of medicinal product shall be made when during expert evaluation of registration materials based on expert assessment of updated data on benefit/risk ratio no confirmation of positive expected benefit/potential risk ratio during the use of medicinal product has been received, and therefore, it has established based on results of post-registration surveillance that the medicinal product is harmful to human health (the risk of using medicinal product outweighs the expected benefit).

(New paragraph is added to item 10 according to CMU Decree № 296 of 27.03.2019)

After re-registration the period of use of medicinal product in Ukraine shall not be limited except for cases envisaged by item 8 of this Procedure.

After re-registration of the finished medicinal product the term of registration of active pharmaceutical ingredient or "in bulk" product (being a part of medicinal product and data on which are stated in the registration materials pertinent to the finished medicinal product) shall be prolonged.

Application for re-registration of medicinal product shall be submitted to the MoH not earlier than one year, but not later than 180 calendar days prior to the expiry date of registration certificate. When medicinal products are submitted for re-registration they shall be supported by a valid authorization to manufacture medicinal products. If application is submitted after the specified term, the re-registration shall be performed according to the procedure envisaged for state registration of medicinal product.

(Paragraph seven of item 10 in wording of CMU Decree № 296 of 27.03.2019)

(Item 10 in wording of the Decree CMU № 125 of 18.03.2015)

11. Re-registration of medicinal product shall be conducted according to the procedure established by MoH.

(Item 11 amended by CMU Decree № 717 of 27.06.2012)

	Annex to the Procedure
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LETTER OF GUARANTEE

1. Application number, date _____, _____. 20__
2. Registration form number, date _____, _____. 20__

3. Name of medicinal product, dosage form _____
4. Applicant _____

Hereby _____ (applicant) undertakes

to submit printed versions of the documents submitted before in electronic format no later than six months after the termination or cancellation of martial law according to the established procedure.

Applicant (his authorized representative)

(date) (signature) (applicant's full name)

Accepted _____
(date) (signature) (full name)

(Annex is added to the Procedure according to the CMU Decree № 471 of 15.04.2022 – valid for six months after termination or cancellation of martial law)

Approved
by the Decree of the Cabinet of Ministers of Ukraine
of May 26, 2005 № 376

**AMOUNTS
of Fees for State Registration (Re-Registration)
of Medicinal Products**

1. For state registration (re-registration) of a medicinal product there are fees to be transferred by the applicant to the State Budget.

The fee for state registration of medicinal product to be purchased based on the results of procurement procedure conducted by a specialized procurement organization in pursuance of a procurement agreement between MoH and appropriate specialized procurement organization shall not be paid.

(Paragraph is added to item 1 according to CMU Decree № 597 of 12.08.2015 – valid till 31.03.2019, in wording of CMU Decree № 296 of 27.03.2019 - valid till 31.03.2020, № 282 of 15.04.2020 – valid till 31.03.2022)

The fee for state registration of a medicinal product to be purchased by a person authorized to make health care purchases, which has been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada and used in these countries, or by the competent authority of the European Union via centralized procedure and used in EU member states shall not be paid.

(Paragraph is added to item 1 according to CMU Decree № 282 of 15.04.2020 – valid till 31.03.2022)

2. The registration fee does not include the cost of expert evaluation of a medicinal product and that of additional expert evaluation.

3. Fee for state registration (re-registration) of medicinal products shall be paid in the national or foreign currency.

Exchange to Hryvnias shall be made at an official rate specified by the National Bank of Ukraine on the day of making out an Invoice-Notification about the transfer of fee for state registration (re-registration).

4. Fee for state registration (re-registration) of the medicinal products shall be paid in the following amount:

1) For state registration (re-registration) of medicinal products, including medical immunobiological products (except for radioactive medicinal products, diagnostic products, simple or complex (galenicals) products of herbal materials) — equivalent of 100 Euros for each pharmaceutical form, 10 Euros for each subsequent strength, 10 Euros for each subsequent package of a medicinal product;

(Sub-item 1 of item 4 amended by CMU Decree № 717 of 27.06.2012)

2) For state registration (re-registration) of radioactive medicinal products, diagnostic products, simple and complex (galenicals) products of herbal materials, preparations of limited use and those produced according to the MoH approved specifications (information on composition, production technology (manufacture), quality control and use of a medicinal product) and donor blood or plasma products — equivalent of 25 Euros for each item, 5 Euros for each subsequent strength, 5 Euros for each subsequent package of a medicinal product.

(Amounts in wording of CMU Decree № 1277 of 31.10.2007)