



CABINET OF MINISTERS OF UKRAINE

DECREE

of April 15, 2022 № 471

Kyiv

Some issues of state emergency registration of medicinal products, medical immunobiological products, blood products produced or supplied to Ukraine during the period of martial law, subject to obligations

In accordance with the Decrees of the President of Ukraine of February 24, 2022 № 64 “On the imposition of martial law in Ukraine” and of March 14, 2022 № 133 “On the extension of martial law in Ukraine” the Cabinet of Ministers of Ukraine **decides**:

1. To approve the Procedure for state emergency registration of medicinal products, medical immunobiological products, blood products produced or supplied to Ukraine during the period of martial law, subject to obligations (attached).
2. To amend the Decrees of the Cabinet of Ministers of Ukraine as follows.
3. To suspend for the period of martial law paragraph 3 of the Procedure for declaring changes in retail prices for goods of significant social importance and anti-epidemic goods required to prevent the spread of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2 approved by the Decree of the Cabinet of Ministers of Ukraine of April 22, 2020 № 341 "On measures to stabilize prices for goods of significant social importance, anti-epidemic goods" (Official Gazette of Ukraine, 2020, № 39, p. 1273), in part of the declaration of changes in retail prices for anti-epidemic goods required to prevent the spread of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2, in order to provide on continuous basis the health care settings with the necessary anti-epidemic goods.
4. To establish that:

the issue of liability of manufacturers of medicinal products, medical immunobiological products, blood products registered in accordance with the Procedure approved by item 1 of this Decree shall be regulated by written commitments provided to the Ministry of Health;

verification of documents attached to the application for state emergency registration of medicinal products, medical immunobiological products, blood products produced or supplied to Ukraine during martial law, subject to obligations, is carried out by the State Expert Center of the Ministry of Health of Ukraine free of charge;

state emergency registration of medicinal products, medical immunobiological products, blood products produced or supplied to Ukraine during martial law, subject to obligations, developed and/or produced in a state officially recognized by Ukraine as an aggressor state, is prohibited.

5. This Decree shall enter into force on the day of its publication and shall be valid for six months from the date of termination or abolition of martial law.

D. SHMYGAL

Prime Minister of Ukraine

APPROVED
by the Decree of the Cabinet of Ministers of
Ukraine
of April 15, 2022 № 471

PROCEDURE

for state emergency registration of medicinal products, medical immunobiological products, blood products produced or supplied to Ukraine during the period of martial law subject to obligations

1. This Procedure establishes the mechanism for conducting the state emergency registration of medicinal products, medical immunobiological products, blood products (hereinafter - medicinal products) produced or supplied to Ukraine for the period of martial law subject to obligations.

2. The state emergency registration of medicinal products is conducted by the MoH based on the application and the opinion of the State Expert Center of the Ministry of Health of Ukraine (hereinafter - the Center) according to the results of verification of registration materials free of charge.

3. The MoH conducts the state emergency registration of medicinal products provided the following requirements are met:

applicant - a legal or natural person responsible for quality, safety and efficacy of medicinal products and pharmacovigilance (hereinafter - the applicant);

medicinal products are registered by the regulatory authority of the applicant's/manufacturer's country (except for medicinal products manufactured by domestic manufacturers);

medicinal product complies with the requirements of the State Pharmacopoeia of Ukraine and/or the European Pharmacopoeia, or other leading pharmacopoeias (British Pharmacopoeia, Japanese Pharmacopoeia and the United States Pharmacopoeia etc);

commitments are duly made for further use of medicinal product (if necessary).

medicinal products intended for use by health care professionals in health care settings having a license to carry out economic activity in the health care sector may be purchased by business entities engaged in wholesale of medicinal products in accordance with the requirements of the Licensing conditions for conducting economic activity for production of medicinal products, wholesale and retail of medicinal products, import of medicinal products (except for active pharmaceutical ingredients), approved by the Cabinet of Ministers of Ukraine of November 30, 2016 № 929 (Official Gazette of Ukraine, 2016, № 99, p. 3217), may be dispensed and/or transferred by them to health care settings having a license to carry out economic activity in the health care sector, military administrations, units of the Armed Forces, legal entities, in particular those who volunteer and provide humanitarian and/or charity support, without the right to further retail sale.

4. Applications for state emergency registration of medicinal products are submitted to MoH through the Center for Administrative Services of MoH "Single Window", and the registration materials for medicinal products and other documents to the application for state emergency

registration of medicinal product are submitted to the Center in paper or electronic form at the applicant's discretion to the e-mail address specified by the Center as a scanned copy of documents without a qualified electronic signature or as electronic documents with a qualified electronic signature of the applicant (authorized representative), or a qualified electronic signature of the applicant using the appropriate programs that provide an informed authorized electronic signature or its equivalent (e.g. DocuSign, Adobe Sign, etc.). Submission of registration materials for medicinal products to the Center may also take place by providing the Center with Access (Read) to the applicant's electronic resources (repositories).

5. Simultaneously with the application for state emergency registration to the MoH in the form according to Annex 1 the applicant shall submit to the Center the following:

- 1) a document confirming the authorization of the medicinal product by the regulatory authority of the appropriate country of authorization (except for medicinal products produced by domestic manufacturers);
- 2) instructions for use of the medicinal products set out in the original language (a language other than the state one) (if available, if such a document is provided for by the legislation of the appropriate country; if there is no such document the appropriate mark shall be inserted in the application for the state emergency registration of medicinal product);
- 3) summary of product characteristics for medicinal products in the original language (a language other than the state one) (if available, if such a document is provided for by the legislation of the appropriate country; if there is no such document the appropriate mark shall be inserted in the application for state emergency registration of medicinal product);
- 4) layout of the packaging mockup(s) of the medicinal product and the text(s) of the labeling of the immediate and outer (if any) packaging of the medicinal products. For the purposes of state emergency registration of medicinal product the applicant has the right to submit several such mockups and labeling texts at the same time to ensure maximum prompt delivery in packaging and with the labeling available at the time of delivery;
- 5) translations of the text(s) of the labeling (information placed on packaging) of the immediate and outer (if any) packaging, instructions for use, summary of product characteristics (if any) for medicinal product in the state language, which are certified by signature of the applicant or his authorized representative (except for medicinal products produced by domestic manufacturers);
- 6) a written commitment of the manufacturer to produce medicinal product concerned to supply it in Ukraine at the same production capacities as those employed for production of this medicinal product intended for the use in the appropriate country of authorization (except for medicinal products produced by domestic manufacturers);
- 7) the materials of registration dossier submitted for authorization in the appropriate country of authorization (except for medicinal products produced by domestic manufacturers) (if available).

With the purpose to enable a proper expert assessment during the state emergency registration of medicinal product the applicant or his authorized representative may provide other registration materials that were the basis for authorization of this medicinal product issued by the appropriate regulatory authority in country of authorization. Such materials may include links to the appropriate websites of the specified regulatory authorities and/or websites of organizations that summarize data on preclinical and clinical trials of medicinal products.

If the applicant or his authorized representative submits all the materials specified in subitems 1-7 of this item, any other materials/letters from the applicant or his authorized representative and/or written commitments shall not be required by the Center.

Annexes to the application for state emergency registration of medicinal product may be submitted to the Center in paper or electronic form at the applicant's or his authorized representative's discretion.

Registration materials are submitted to the Center in Ukrainian or English at the applicant's discretion. If the materials are submitted in any other language, at the Center's request, the applicant or his authorized representative shall provide their translation into Ukrainian or English.

6. Upon receipt of the application for state emergency registration of medicinal product, the MoH shall send a copy of such application followed by letter of referral in electronic form on the verification of registration materials to the Center within one working day.

7. The Center shall verify the registration materials and draw up a substantiated opinion on state emergency registration of medicinal product according to the form given in Annex 2 and send it to the MoH together with the verified translations of the text(s) of the labeling of the immediate and outer packaging, instructions for use, summary of product characteristics for the medicinal products in the state language (if available) within five working days from the date of receipt of the MoH's letter of referral and receipt from the applicant or his authorized representative of the materials specified in item 5 of this Procedure.

The Center verifies the documents provided by the applicant in any convenient and accessible way (taking into account the measures of martial law and situation in Ukraine), recommendations for state emergency registration of medicinal product are considered by temporary advisory body in the video-conference format (with appropriate recording).

In case of a negative opinion on the state emergency registration of medicinal product, the Center submits a motivated justification for its proposal.

8. Based on the application and opinion on the state emergency registration of medicinal product prepared by the Center the MoH shall make a decision on state emergency registration of medicinal product or refusal of such registration within three working days.

If the Center's opinion contains information on discrepancies between the registration materials and the application submitted by the applicant or his authorized representative and/or other materials attached to the application for state emergency registration of medicinal product, the applicant or his authorized representative may submit to the MoH an explanation of such discrepancies in order to take them into account when the MoH decides on the state emergency registration of medicinal product.

The instruction for medical use and its translation are approved by the decision on state emergency registration of medicinal product and a registration number is assigned to the medicinal product, which is entered into the State Register of Medicinal Products of Ukraine together with information about the medicinal product according to the list of information specified by legislation. In the State Register of Medicinal Products of Ukraine, the medicinal product is registered in accordance with the requirements of this Procedure and has a mark "state emergency registration".

9. The fact of state emergency registration of medicinal product is confirmed by a registration certificate in the form given in Annex 3. The registration certificate is issued for a period of one year and/or for the period of martial law, and/or for six months from the date of termination or

abolition of martial law. These medicinal products may be used in Ukraine until the expiration date specified by the manufacturer and indicated on the packaging.

10. The state emergency registration of medicinal product may be refused only in the case of: failure to submit the materials provided for in item 5 of this Procedure, or incomplete materials, or discrepancies revealed in the submitted materials affecting efficacy, safety and quality of medicinal products.

The state registration of such a medicinal product may be terminated by the MoH before the expiration of the validity period of the registration certificate in connection with termination or abolition of martial law.

11. During the validity period of the registration certificate, the applicant shall inform the Center about the adverse reactions to medicinal products according to the procedure and within the timeframe established by the Pharmacovigilance Procedure, approved by the MoH.