APPROVED

by the Decree of the Cabinet of Ministers of Ukraine

of February 8, 2021 № 95

PROCEDURE

for the state registration of vaccines or other medical immunobiological products for specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2 subject to obligations for emergency medical use

1. This Procedure establishes the mechanism of the state registration of vaccines or other medical immunobiological products for specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2 (hereinafter – medicinal products (medical immunobiological products)), subject to obligations for emergency medical use (hereinafter - the state registration of medicinal product (medical immunobiological product) for emergency use).

2. The state registration of medicinal products (medical immunobiological products) for emergency use is conducted by the Ministry of Health of Ukraine (MoH) based on the application and substantiated opinion of the State Expert Center of the Ministry of Health of Ukraine (hereinafter - the Center) considering the results of expert assessment of benefit/risk balance and verification of registration materials of a medicinal product (medical immunobiological product) for their authenticity, taking into account certain obligations.

MoH conducts the state registration of a medicinal product (medical immunobiological product) for emergency use with an absence of comprehensive clinical data on the safety and efficacy of a medicinal product (medical immunobiological product) used for the prevention, diagnosis and treatment of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2, but if the following requirements are met:

the known and potential benefits of vaccines or other medical immunobiological products when used to prevent acute respiratory disease COVID-19 caused by the coronavirus SARS-CoV-2 outweigh the known and potential risks of using such vaccines or other medical immunobiological products;

the applicant - a legal or natural person responsible for the quality, safety and efficacy of a vaccine or other medical immunobiological product for the specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2 (hereinafter - the applicant), is obliged to provide the Center with the comprehensive data after completion of the appropriate clinical trials.

3. The application for state registration of a medicinal product (medical immunobiological product) subject to the obligations for emergency medical use (hereinafter - the application for state registration for emergency use), drawn up in the form given in Annex 1, submitted by the applicant to the MoH, shall specify the obligations of the applicant as follows:

to conduct post-registration safety studies in availability of risks of a medicinal product (medical immunobiological product) registered for emergency use;

to conduct post-registration efficacy studies when the understanding of disease or clinical methodology indicates the need for a substantial revision of previous efficacy evaluations.

4. The application for state registration for emergency use submitted to the Center shall be supplemented by the following:

1) a document confirming the decision to grant an emergency use authorization or conditional marketing authorization in the appropriate country or conditional marketing authorization by the competent authority of the European Union (or other essentially identical decision under the applicable law of the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, the People's Republic of China, India or via a centralized procedure by the competent authority of the European Union in accordance with the national legislation of the country of authorization or the European Union) on the date of application for state registration for emergency medical use, certified by the signature of the applicant or his authorized representative;

2) an assessment report of a medicinal product (medical immunobiological product) drawn up by the regulatory authority of the country where the medicinal product (medical immunobiological product) is registered (if such a document is provided for by the legislation of the appropriate country; if there is no such document the appropriate note shall be made in the application for the state registration for emergency medical use);

3) a risk assessment and management document approved by a decision on granting an emergency use authorization or conditional marketing authorization in the appropriate country by the competent authority of the European Union (if available, if such a document is provided for by the legislation of the appropriate country; if there is no such document the appropriate note shall be made in the application for the state registration for emergency use);

4) instructions for use of the medicinal product (medical immunobiological product), set out in the original language (a language other than the state one);

5) summary of product characteristics for a medicinal product (medical immunobiological product) in the original language (a language other than the state one) (if any, when such a document is envisaged by the legislation of the appropriate country; if there is no such document the appropriate tick shall be made in the application for state registration for emergency use);

6) 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 product (medical immunobiological product). For the purposes of state registration for emergency use the applicant has the right to submit several such mockups and labeling texts at the same time to ensure the delivery as prompt as possible in packaging and with the labeling available at the time of delivery;

7) translations of the text(s) of the labeling of the immediate and outer (if any) packaging, instructions for use, summary of product characteristics for a medicinal product (medical immunobiological product) in the state language, which are certified by signature of the applicant or his authorized representative;

8) a written commitment of a manufacturer to produce the medicinal product (medical immunobiological product) concerned, which has been registered in Ukraine for emergency use, in order to supply it in Ukraine at the same production capacities as those employed for production of this medicinal product (medical immunobiological product) intended for the use in the appropriate country of authorization (the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, the People's Republic of China, India);

9) a certified copy of document confirming the compliance of manufacturing conditions for the medicinal product (medical immunobiological product) submitted for state registration for emergency use with the requirements to manufacture of medicinal products in Ukraine issued by the State Service of Ukraine for Medicinal Products and Narcotics Control (hereinafter – Derzhliksluzhba) or Derzhliksluzhba’s decision on recognition of the results of GMP compliance inspections conducted by the national competent authority of the country of manufacture, which is issued according to the procedure established by the MoH, provided that the medicinal product is produced in compliance with the requirements of good manufacturing practice.

With the purpose to enable a proper expert assessment of the benefit/risk balance of a medicinal product (medical immunobiological product) during the state registration for emergency use, the applicant may provide other registration materials that were the basis for the emergency use authorization of this medicinal product (medical immunobiological product) issued by the competent authority of the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, the People's Republic of China, India or the competent authority of the European Union via a centralized procedure according to the national legislation of the country of authorization, or the European Union, or for its prequalification by World Health Organisation. Such materials may include links to the websites of these regulatory authorities and/or websites of organizations that summarize data on preclinical and clinical trials of medicinal products, including vaccines for prevention of acute respiratory disease COVID-19 caused by coronavirus SARS- CoV-2.

Annexes to the application for state registration for emergency use may be submitted to the Center in paper or electronic format at the applicant’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 the applicant's representative shall provide their translation into Ukrainian or English.

5. Upon receipt of the application for state registration for emergency use, the MoH shall send the Center a copy of the application for state registration for emergency use within one working day.

6. The Center shall conduct expert assessment of the benefit/risk balance of the medicinal product (medical immunobiological product) and verifies the authenticity of registration materials for the purpose of state registration of a medicinal product (medical immunobiological product) for emergency use within five working days from the date of receipt of the MoH’s letter of referral and receipt from the applicant of the materials specified in item 4 of this Procedure. Based on the results of the expert assessment of the benefit/risk balance and verification of authenticity of registration materials, the Center shall draw up a substantiated opinion according to the form given in Annex 2 (hereinafter - the opinion on registration of a medicinal product (medical immunobiological product) for emergency use) and send it to the MoH together with the verified authentic translations of the text(s) of the labeling of the immediate and outer (if any) packaging, instructions for use, summary of product characteristics (if any) for the medicinal product (medical immunobiological product) in the state language.

7. Based on an opinion on registration of a medicinal product (medical immunobiological product) for emergency use prepared by the Center the MoH shall make a decision on state registration of a medicinal product (medical immunobiological product) for emergency use or refusal of such registration within three working days. The instruction for medical use is approved by the decision on state registration of a medicinal product (medical immunobiological product) for emergency use and a registration number is assigned to the medicinal product (medical immunobiological product), which is entered into the State Register of Medicinal Products of Ukraine. In the State Register of Medicinal Products of Ukraine, a medicinal product (medical immunobiological product) is registered in accordance with the requirements of this Procedure and is specified as a “medicinal product for emergency use”.

8. The fact of state registration of a medicinal product (medical immunobiological product) for emergency use is confirmed by a registration certificate in the form given in Annex 3. The registration certificate is issued for a period of one year. The validity period of the registration certificate may be extended annually for the next year provided that the Center does not have information on the revealed negative benefit/risk balance as well as pharmacovigilance data indicating the identified harmful properties. The total validity period of the registration certificate may not exceed the validity period of the emergency use authorization granted by the competent authority of the United States, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, the People's Republic of China, India or via the centralized procedure by the competent authority of the European Union in accordance with the national legislation of the country of authorization or the European Union for such a medicinal product (medical immunobiological product).

The registration certificate may contain obligations imposed on the holder of the registration certificate of a medicinal product (medical immunobiological product) as follows:

to conduct the post-registration safety studies in availability of risks of a medicinal product (medical immunobiological product) registered for emergency medical use;

to conduct post-registration efficacy studies when understanding of the disease or clinical methodology indicates the need for a substantial revision of previous efficacy evaluations.

9. The state registration of a medicinal product (medical immunobiological product) for emergency use may be refused only in the case of: failure to submit the appropriate materials provided for in item 4 of this Procedure, or incomplete materials, or discrepancies revealed in the submitted materials affecting efficacy, safety and quality of the medicinal product (medical immunobiological product), or inauthenticity of translation of the text (texts) of the package (packages) labeling, the instructions for use or a summary of product characteristics (if any).

When the applicant of the medicinal product (medical immunobiological product) registered according to this Procedure does not fulfill the obligations specified in item 8 of this Procedure the state registration of the medicinal product (immunobiological medicinal prоduct) concerned shall be terminated by the MoH prior to expiration of the validity period of registration certificate.

10. Changes in registration materials shall be introduced 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, based on the decision made by the same competent authority of the United States of America, the United Kingdom, Swiss Confederation, Japan, Australia, Canada, the People's Republic of China, India or the competent authority of the European Union via a centralized procedure according to the national legislation of the country of authorization or the European Union, which was submitted during the state registration procedure for emergency use.

11. During the validity period of the registration certificate, the applicant shall:

inform the Center about adverse reactions to the medicinal product (medical immunobiological product) according to the procedure and within the timeframe established by the Pharmacovigilance Procedure, approved by the MoH;

provide the Center with information about the clinical trials completed, including their results, which are to be the basis for expert assessment of the benefit/risk balance.