

Annex 1
to the Procedure

APPLICATION
for state registration of medicinal product, vaccine or other medical immunobiological product subject to obligations for emergency medical use

“ _____ ” _____, 20____

№ _____

I apply for state registration in Ukraine of a medicinal product, vaccine or other medical immunobiological product for emergency use according to article 9² of the Law of Ukraine “On Medicines” and the Decree of the Cabinet of Ministers of Ukraine of December 29, 2021 № 1446 “Certain issues of the state registration of medicinal products, vaccines or other medical immunobiological products for treatment and/or specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2 subject to obligations for emergency medical use”

Medicinal product, vaccine or other medical immunobiological product
(underline as appropriate) for emergency medical use

Name of medicinal product, vaccine or other medical immunobiological product
(hereinafter – medicinal product)

Trade name _____

Active substance _____

Presentation _____

Packaging:

immediate _____

outer _____

The emergency use authorization granted by the competent authority of the appropriate country (underline as appropriate)

(identification number of the authorization (if any) and

a website of the appropriate regulatory authority, containing information on the authorization granted)

Applicant (holder of registration certificate) (for domestic applicants - in Ukrainian, for foreign applicants - in Ukrainian and English)

Name of legal person or full name of natural person-entrepreneur

Location of legal person or address of natural person-entrepreneur

Telephone/telefax _____

E-mail _____

Head of legal person _____

Manufacturer (for domestic manufacturers - in Ukrainian, for foreign applicants - in Ukrainian and English; all manufacturing sites of manufacturing processes and batch control sites mentioned in the registration dossier should be specified)

Name of legal person or full name of natural person-entrepreneur

Location of activity _____

Telephone/telefax _____

E-mail _____

Head of legal person _____

Short description of applicant's pharmacovigilance system

Applicant's authorized qualified person responsible for pharmacovigilance (QPPV):

full name of QPPV

location of activity

country

24-hour telephone/telefax

e-mail

Contact person responsible for pharmacovigilance (CPPV) in Ukraine if different from the above-mentioned one:

full name of CPPV in Ukraine

location of activity

country

24-hour telephone/telefax

e-mail

Pharmacovigilance system master file (PSMF)

If pharmacovigilance system master file available?

yes

no

If “yes”:

the PSMF number

location of legal person or address of natural person-entrepreneur (where the PSMF is located)

country

Developer of medicinal product for emergency medical use (for domestic manufacturers - in Ukrainian, for foreign manufacturers - in Ukrainian and English)

Name of legal person or full name of natural person-entrepreneur

Location of activity _____

Telephone/telefax _____

E-mail _____

Head of legal person _____

Qualitative and quantitative composition of medicinal product (active substance(s) and excipients)

Active substance(s) should be listed separately from the excipients

Name of substance*	Quantity per unit of pharmaceutical form **

* Only one name should be given in the following order of priority: International Nonproprietary Name (INN), State Pharmacopeia of Ukraine (SPhU), European Pharmacopoeia, common name, scientific (chemical) name.

Name of active substance should be declared by its recommended INN, accompanied by its salt or hydrate form, if necessary.

** In units of weight or biological units per unit of pharmaceutical form: dragee, tablets, suppositories, ampoules, vials; in % or mg/ml, mg/g: ointments, creams, solutions, indivisible powders, collections.

Indications for use and contraindications (specify briefly main indications and contraindications), if the available characteristics of this medicinal product are insufficient, point out this _____

Method of use _____

Dispensing category:

- subject to medical prescription
- in hospital only

Shelf life and storage conditions _____

Details on availability of an emergency use authorization (conditional marketing authorization) of a medicinal product in other countries (specify if there are authorizations issued by several competent authorities of the countries concerned)

Name of country and regulatory authority, which issued an emergency use authorization	Emergency use authorization number and date of issue and reference to website of the appropriate regulatory authority)

Data on the successful conduct of pre-clinical trials/studies, separate phases of clinical trials/studies, including pharmaceutical data are available, and the totality of results obtained contains scientifically sound evidence, including data from adequate and well-controlled studies that allow to believe that the medicinal product may be effective in treatment and/or specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2

Information confirming that the known and potential benefits of a medicinal product when used in treatment and/or specific prevention of acute respiratory disease COVID-19 caused by the coronavirus SARS-CoV-2 outweigh the known and potential risks of using such medicinal product

Proposals for the deadline for fulfillment of obligations _____

This application confirms that all available data on the successful conduct of pre-clinical trials/studies, separate phases of clinical trials/studies, and the totality of

results obtained, which contains scientifically sound evidence, including data from adequate and well-controlled studies, allows to believe that the medicinal product concerned may be effective in treatment and/or specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2, and its known and potential benefits when used to prevent acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2 outweigh the known and potential risks of its use.

List of documents and materials appended to the application for state registration of a medicinal product subject to obligations for emergency medical use	Note
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 (exclusively for vaccines or other medical immunobiological products), Israel 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), or the World Health Organization prequalification on the date of application for state registration of the medicinal product for emergency medical use, certified by the signature of the applicant or his authorized representative) 2. An assessment report on a medicinal product drawn up by the regulatory authority of the country where the medicinal product is authorized (if any, when 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 state registration of the medicinal product for emergency 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 or conditional marketing authorization by the competent authority of the European Union (if any, when 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 state registration of the medicinal product for emergency use); 4. Instructions for use set out in the original language (a language	

List of documents and materials appended to the application for state registration of a medicinal product subject to obligations for emergency medical use	Note
other than the state one), and/or other document concerning the use of the medicinal product in accordance with the legislation of the country, which issued a document confirming the decision to grant an emergency use authorization, stated out in the original language (in a language other than the state one) 5. Summary of product characteristics 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 note shall be made in the application for state registration of the medicinal product for emergency use) 6. Layout of the packaging mockup(s) and the text(s) of the labeling of the immediate and outer (if any) packaging. For the purposes of state registration for emergency use an 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 (information placed on packaging) of the immediate and outer (if any) packaging, instructions for use, summary of product characteristics for a medicinal 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 concerned in order 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 (the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, the People's Republic of China (exclusively for vaccines or other medical immunobiological products), Israel or the European Union countries) 9. A certified copy of document confirming the compliance of manufacturing conditions for the medicinal product submitted for state registration for emergency use with the requirements to manufacture of medicinal products in Ukraine issued by the 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	

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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

10. Materials of the registration dossier submitted for the emergency use authorization or conditional marketing authorization in the appropriate country of authorization

On behalf of the
applicant

(signature)

(full name)

(position)
