

No _____

APPLICATION
for state registration of vaccine or other medical
immunobiological product for specific prevention of acute
respiratory disease COVID-19 caused by coronavirus
SARS-CoV-2, which has a full production cycle or
manufactured from "in bulk" in Ukraine, subject to
obligations for emergency medical use

“ _____ ” _____, 20____

I apply for state registration in Ukraine of a vaccine or other medical immunobiological product for specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2, which has a full production cycle or manufactured from "in bulk" in Ukraine, subject to obligations for emergency medical use (hereinafter - medical immunobiological product for specific prevention of acute respiratory disease COVID-19) 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”

medical immunobiological product for specific prevention of acute respiratory disease COVID-19, which has in Ukraine a full production cycle

medical immunobiological product for specific prevention of acute respiratory disease COVID-19, which is manufactured from "in bulk"

Name of medical immunobiological product for specific prevention of acute respiratory disease COVID-19 _____

Trade name _____

Active substance _____

Presentation _____

Packaging:

immediate _____

outer _____

Applicant (holder of registration certificate)

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 _____

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

Manufacturers

Manufacturer of the finished medical immunobiological product for specific
prevention of acute respiratory disease COVID-19. Name of legal person or full name
of natural person-entrepreneur

Location of activity _____

Telephone/telefax _____

E-mail _____

Head of legal person _____

Manufacturer of the in bulk product. Name of legal person or full name of natural
person-entrepreneur

Location of activity _____

Telephone/telefax _____

E-mail _____

Head of legal person _____

Manufacturer of Active Pharmaceutical Ingredient (API). Name of legal person or full name of natural person-entrepreneur

Location of activity _____

Telephone/telefax _____

E-mail _____

Head of legal person _____

Developer of medical immunobiological product for specific prevention of acute respiratory disease COVID-19 (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 medical immunobiological product for specific prevention of acute respiratory disease COVID-19 (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 medical immunobiological product for specific prevention of acute respiratory disease COVID-19 are insufficient, point out this)

Strength (dose)

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 or conditional marketing authorization of a medical immunobiological product for specific prevention of acute respiratory disease COVID-19 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 medical immunobiological product for specific prevention of acute respiratory disease COVID-19 may be effective for specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2

Information confirming that the known and potential benefits of a medical immunobiological product for specific prevention of acute respiratory disease COVID-19 when used for specific prevention of acute respiratory disease COVID-19 caused by the coronavirus SARS-CoV-2 outweigh the known and potential risks of using such medical immunobiological product for specific prevention of acute respiratory disease COVID-19

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 a medical

immunobiological product for specific prevention of acute respiratory disease COVID-19 concerned may be effective for 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.

On behalf of the
applicant

(signature)

(full name)

(position)

Note

The scope and main requirements for the materials of the registration dossier in support of the application for state registration, which are submitted to the State Expert Center of the Ministry of Health of Ukraine, are specified in 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 taking into consideration the conditions specified in item 12 of the Procedure for 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