



Ministry of Health of Ukraine
Kyiv

REGISTRATION CERTIFICATE
for medicinal product (medical immunobiological product)
for emergency medical use

№ _____

Decision on state registration of medicinal product, vaccine or other medical immunobiological product (vaccine or other medical immunobiological product, which has a full production cycle, or is manufactured from "in bulk" in Ukraine) for emergency use adopted by MoH Order of _____, 20__ №_____.

According to article 9² of the Law of Ukraine “On Medicines” and 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 (vaccine or other medical immunobiological product), which has a full production cycle, or is manufactured from "in bulk" in Ukraine)

(underline as appropriate)

has been registered in Ukraine for a period of one year and may be renewed for one year/five years provided the specific obligations are fulfilled.

The validity period of registration certificate in Ukraine is until _____.

The medicinal product (medical immunobiological product) has been registered for emergency use subject to obligations:

a conduct of post-registration safety studies (if there is any risk)/conduct of post-registration efficacy studies (when the understanding of the disease or the clinical methodology indicate that previous efficacy evaluations might have to be revised significantly).

The deadline for the fulfillment of such obligations is _____.

The Applicant and his location _____

The registration certificate has been drawn up on _____, 20____.

INFORMATION
on medicinal product
(medical immunobiological product)

Name _____

Pharmaceutical form, strength _____

Route of administration _____

The Anatomical Therapeutic Chemical (ATC) code _____

Indications for use of the finished medicinal product (medical immunobiological product), the available characteristics of the medicinal product concerned are insufficient _____

Type, size and contents of package _____

Shelf life _____

Manufacturer of medicinal product (medical immunobiological product) _____

OPINION
on qualitative and quantitative composition of medicinal product
(medical immunobiological product)

1. Name of medicinal product (medical immunobiological product),
pharmaceutical form, strength _____

2. Qualitative and quantitative composition of medicinal product (medical immunobiological product):

active substances _____

excipients _____

(position of a person who signed
the registration certificate)

(signature)

(full name)