

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

of _____, 20____ №

I apply for state emergency registration in Ukraine of medicinal product, medical immunobiological product, blood product produced or supplied to Ukraine during the period of martial law, subject to obligations due to the imposition of martial law in Ukraine according to the Decrees of President of Ukraine “On imposition of martial law in Ukraine” of February 24, 2022 № 64 and “On extension of the period of martial law in Ukraine” of March 14, 2022 № 133:

name of medicinal product, medical immunobiological product, blood product (hereinafter – medicinal product) _____

(underline as appropriate)

trade name _____

presentation _____

packaging:

immediate _____

outer _____

developer of medicinal product _____

a document confirming the authorization of medicinal product by the regulatory authority of the applicant's/manufacturer's country (except for medicinal products produced by domestic manufacturers)

(identification number of the authorization (if any) and

a website of the appropriate regulatory authority, containing information on the authorization for use 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 foreign applicants - in Ukrainian and English; all manufacturing sites of production processes and quality control sites mentioned in the registration dossier should be specified)

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

Address of 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

telephone/telefax

e-mail

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

full name of CPPV

location of activity

country

telephone/telefax

e-mail

Pharmacovigilance system master file

Is a pharmacovigilance system master file (PSMF) available?

yes • no •

If "yes":

the PSMF number

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

country

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, 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)

Method of use _____

Dispensing category:

subject to medical prescription •

in hospital only •

Shelf life and storage conditions _____

Details on availability of an authorization for use of 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 authorization for use	Authorization for use number and date of issue and reference to website

Proposals for fulfillment of obligations

This application confirms the efficacy, safety and quality of a medicinal product.

List of documents and materials appended to the application for state emergency registration of a medicinal product	Note
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1. A document confirming the authorization of medicinal product by the regulatory authority in the appropriate country of authorization on the date of submission of application for state emergency registration of the medicinal product, certified by the signature of the applicant or his authorized representative

2. Instructions for use set out in the original language (a language other than the state one), and/or other document concerning the use of the medicinal product in accordance with the legislation of the country, where a document

confirming the authorization of the medicinal product was issued by the regulatory authority of the appropriate country of authorization stated out in the original language (in a language other than the state one)

3. 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 emergency registration of the medicinal product)

4. 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 emergency registration of medicinal product 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 (if any)

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) of the 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 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 (except for medicinal products produced by domestic manufacturers)

7. Materials of the registration dossier submitted for the authorization in the appropriate country of authorization (except for medicinal products produced by domestic manufacturers) (if any)

On behalf of the
applicant

(signature)

(full name)

(position)