

Annex 2
to the Procedure

OPINION

based on the results of expert assessment of the benefit/risk balance and authenticity verification of registration materials for a medicinal product, vaccine or other medical immunobiological product subject to obligations for emergency medical use

Based on the results of expert assessment of the benefit/risk balance (taking into consideration the available data) and authenticity verification of registration materials appended to the application for state registration of medicinal product, vaccine or other medical immunobiological product (hereinafter – medicinal product) for emergency use:

Name of medicinal product

pharmaceutical form, strength (dose)_____

packaging:

immediate _____

outer (if any) _____

Applicant (holder of registration certificate) _____

Manufacturer of medicinal product _____

Developer of medicinal product _____

the following has been determined:

concerning the medicinal product submitted for state registration for emergency use

The known and potential benefits of the medicinal product when used for a treatment or specific prevention of the acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2 outweigh the known and potential risks of its use

☐ Yes ☐ No

The applicant is committed to provide comprehensive data after completion of the relevant studies:

for post-registration safety studies if there are risks related to a medicinal product

registered for emergency use

☐ Yes ☐ No

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

☐ Yes ☐ No

Availability of a document confirming the decision to grant an emergency use authorization or conditional marketing authorization in the appropriate country or a 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, Israel, the People's Republic of China (exclusively for vaccines or other medical immunobiological products), 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 Organisation's decision on prequalification, certified by the signature of the applicant or his authorized representative.

☐ Yes ☐ No

Availability of an assessment report of 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)

☐ Yes ☐ No

Availability of 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 any, when such a document is provided for by the legislation of the appropriate country)

☐ Yes ☐ No

Availability of instructions for use of the medicinal product in the original language (a language other than the state one)

☐ Yes ☐ No

Availability of a summary of product characteristics for a medicinal 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)

☐ Yes ☐ No

Availability of layout of the packaging mockup(s) and the text(s) of the labeling of the immediate and outer (if any) packaging of a medicinal product

☐ Yes ☐ No

Availability of 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 in the state language, which are certified by signature of the applicant or his authorized representative

☐ Yes ☐ No

Availability of a written commitment of a manufacturer to produce the medicinal 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 (the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, Israel, the People's Republic of China) (exclusively for vaccines or other medical immunobiological products)

☐ Yes ☐ No

Availability of a certified copy of document confirming the compliance of manufacturing conditions for the medicinal product submitted for 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 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.

☐ Yes ☐ No

Summary of opinion

All materials are available

If "no" indicate the missing materials

Availability of a translation in the state language (the

☐ Yes

☐ No

☐ Yes

☐ No

authenticity of which is confirmed by the applicant or his authorized representative) of the text(s) of the labeling, instructions for use or information on the use of a medicinal product submitted for registration for emergency use, approved in accordance with regulatory requirements of an applicant's/manufacturer's country or a country the regulatory authority of which has granted the emergency use authorization

☐ Yes

☐ No

The known and potential benefit of a medicinal product submitted for registration for emergency use, if used for treatment or specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2, outweighs its known and potential risks; if "no", indicate which information is inadequate

☐ Yes

☐ No

Materials pertinent to a medicinal product for emergency use, the benefit-risk balance and authenticity of which have been assessed and verified, allow to make a decision on state registration of such a medicinal product for emergency use subject to specific obligations (if "no", grounds for this opinion shall be provided)

On behalf of the
State Expert Center
of MoH of Ukraine

(signature of authorized person)

(full name of authorized person)

(position of authorized person)

"_____" _____, 20____
