

OPINION
based on the results of verification of documents pertinent to medicinal product,
medical immunobiological product, blood product submitted for state
emergency registration

Based on the results of verification of registration materials appended to the application for state emergency registration of medicinal product, medical immunobiological product, blood product (hereinafter – medicinal product):

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 emergency registration

a medicinal product meets requirements of the State Pharmacopeia of Ukraine and/or European Pharmacopoeia, or other leading pharmacopeias (the British Pharmacopoeia, the Japanese Pharmacopoeia, the United States Pharmacopeia etc.)

yes • no •

availability of a document confirming the authorization of medicinal product by the regulatory authority in the appropriate country of authorization (except for medicinal products produced by domestic manufacturers) 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

yes • no •

availability of 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)

yes • no •

availability of a summary of product characteristics of 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 (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)

yes • no •

availability of 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)

yes • no •

availability of materials of the registration dossier submitted for authorization in the appropriate country of authorization (except for medicinal products produced by domestic manufacturer) (if any)

Summary of opinion

All materials are available

yes • no •

If “no” indicate the missing materials

Availability of 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);

yes • no •

A medicinal product meets requirements of the State Pharmacopeia of Ukraine and/or European Pharmacopoeia, or other leading pharmacopeias (the British Pharmacopoeia, the Japanese Pharmacopoeia, the United States Pharmacopeia etc.)

yes • no •

Based on the results of verification of documents pertinent to the medicinal product

(name, pharmaceutical form, strength, packaging, manufacturer)

at the meeting of the temporary advisory body of the State Expert Center of the Ministry of Health of Ukraine composed of:

(full name, position)

on “_____” _____ 20__ it has been determined (in the video-conference format) that the verification of documents pertinent to the medicinal product submitted for state emergency registration allows to recommend the MoH Ukraine to make a decision on state emergency registration of such a medicinal product for one year and/or for the period of martial law or for six months after termination or

yes • no •

cancellation of martial law

On behalf of the State Expert
Center of the Ministry of
Health of Ukraine

(signature of authorized person)

(full name of authorized person)

(position of authorized person)
