

OPINION

based on the results of expert assessment of the benefit/risk balance, expert evaluation of registration materials and results of quality control 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 is manufactured from "in bulk" in Ukraine, 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), expert evaluation of registration materials and results of quality control 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 is manufactured from "in bulk" in Ukraine, for emergency medical use:

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

Pharmaceutical	form,	strength	(dose)
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Packaging:
immediate

outer (if any) _____
Applicant (holder of registration certificate)

Manufacturer(s) of the medical immunobiological product for specific prevention of acute respiratory disease COVID-19

Manufacturer(s) of the in bulk product (in case of concurrent registration)

Manufacturer(s) of Active Pharmaceutical Ingredient (API) (in case of concurrent registration)

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

the following has been determined:

concerning medical immunobiological product for specific prevention of acute respiratory disease COVID-19 submitted for state registration for emergency use

The known and potential benefits of the medical immunobiological product for specific prevention of acute respiratory disease COVID-19 when used for a specific prevention of the acute

respiratory disease COVID-19 caused by coronavirus SARS-CoV-2 outweigh the known and potential risks of its use

The applicant is committed to provide comprehensive data after completion of the post-registration studies:

yes • no •

of safety if there are risks related to a medical immunobiological product for specific prevention of acute respiratory disease COVID-19 registered for emergency use

yes • no •

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

yes • no •

Results of expert evaluation of registration materials, which confirm safety and efficacy of medical immunobiological product for specific prevention of acute respiratory disease COVID-19 (specify data of preclinical study)

Expert (s)	
Results of expert evaluation	
Opinion	

Expert

Results of expert evaluation of registration materials, which confirm safety and efficacy of medical immunobiological product for specific prevention of acute respiratory disease COVID-19 (specify data of clinical trials)

Expert (s)	
Results of expert evaluation	
Opinion	

Expert

Results of expert evaluation of registration materials on quality of medical immunobiological product for specific prevention of acute respiratory disease COVID-19

Expert (s)	
Results of expert evaluation	
Opinion	

Expert

Results of expert evaluation of registration materials on manufacture of medical immunobiological product for specific prevention of acute respiratory disease COVID-19

Expert (s)	
Results of expert evaluation	
Opinion	

Expert

Results of quality control of medical immunobiological product for specific prevention of acute respiratory disease COVID-19

Name of medical immunobiological product for specific prevention of acute respiratory disease COVID-19	
Presentation (pharmaceutical form, packaging)	
Batch	
Details on a laboratory	
Opinion based on results of quality control	

Expert

Results of expert evaluation of materials on safety of medical immunobiological product for specific prevention of acute respiratory disease COVID-19 during the registration procedure

Expert (s)	
Results of expert evaluation	
Opinion	

Expert

Opinion concerning a draft instructions for medical use of medical immunobiological product for specific prevention of acute respiratory disease COVID-19 and labeling	
Expert (s)	
Results of expert evaluation	
Dispensing conditions	
Opinion	

Expert			
		Summary of opinion	
All materials are available		yes	no
If “no” indicate the missing materials			
The known and potential benefit of a medical immunobiological product for specific prevention of acute respiratory disease COVID-19 submitted for registration for emergency use, if used for 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 medical immunobiological product for specific prevention of acute respiratory disease COVID-19 for emergency use have been assessed with regards to the benefit-risk balance, and results of their expert evaluation allow to make a decision on state registration of such a medical immunobiological product for specific prevention of acute respiratory disease COVID-19 for emergency use subject to specific obligations (if “no”, grounds for this opinion shall be provided)		yes	no

On behalf of the
State Expert
Center of MoH
of Ukraine

(signature of authorized person)

(full name of authorized person)

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(position of authorized person)