

APPROVED

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Health of Ukraine

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Ministry of Health of Ukraine
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_____)

**The Roadmap (NDVP) to the introduction of a vaccine against the acute
respiratory disease COVID-19 caused by the novel coronavirus SARS-
CoV-2, and implementation of mass vaccination in response to the COVID-
19 pandemic in Ukraine for 2021-2022**

(being updated)

INTRODUCTION

The Roadmap (NDVP) to the introduction of the vaccine against acute respiratory disease COVID-19 caused by the SARS-CoV-2 coronavirus (hereinafter – coronavirus disease COVID-19), and implementation of mass vaccination in response to the COVID-19 pandemic in Ukraine for 2021-2022 (hereinafter – the Roadmap) has been developed and recommended to ensure adequate and equal access of eligible population of Ukraine to an effective vaccine against coronavirus disease COVID-19, as well as establish the control of related processes.

The Roadmap has been designed in such a way so that it can be amended, considering a number of currently unknown variables, including the uncertainty about the availability of a vaccine against coronavirus disease COVID-19.

The Roadmap was prepared with the participation of national and international partners in the area of public health and immunization, the National Immunization Technical Advisory Group (NITAG), state executive bodies and reviewed at the meeting of the Task Force on Emergency Response to Prevent the Spread of Vaccine-preventable Diseases (hereinafter – VPDs TF) under Ministry of Health of Ukraine.

The success of the Roadmap's implementation depends on the partnership and close cooperation with the regional offices of public health institutions and healthcare facilities, local authorities, and the public.

Given that not all the information on the vaccine safety, efficacy, storage conditions and logistics was fully available at the time of the Roadmap development, some parts may be subject to change in order to bring them in line with new knowledge and facts.

EPIDEMIC SITUATION WITH COVID-19 IN UKRAINE

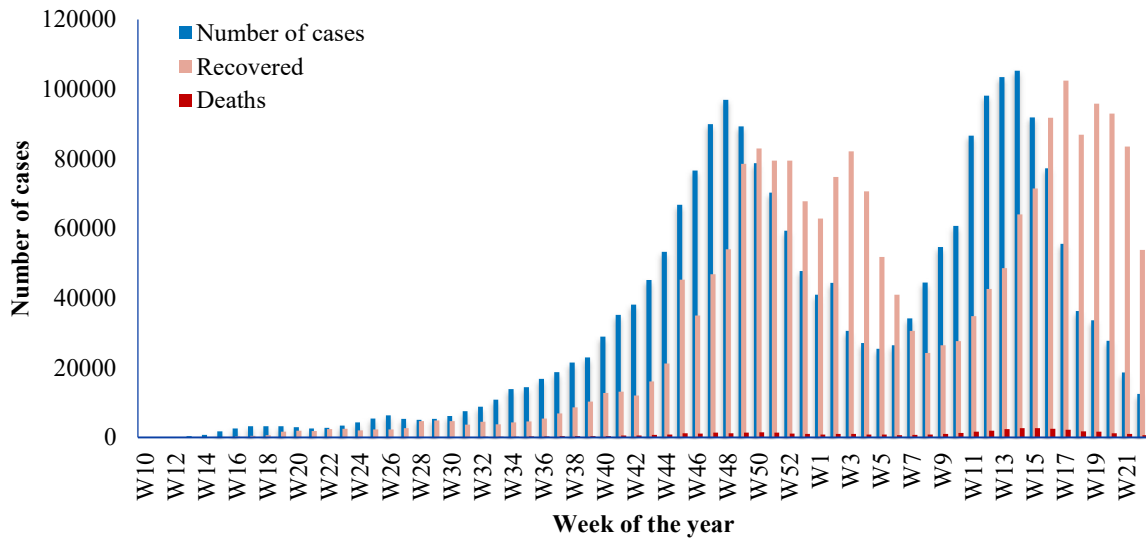
According to the data provided by the State Institution "Public Health Center of the Ministry of Health of Ukraine", since the beginning of the registration of COVID-19 cases in Ukraine, as of the end of the 22nd week of 2021 (June 2021), there had been 2,215,052 of confirmed and registered COVID-19 cases (the incidence rate accounted for 5, 816 per 100,000 population). At the same time, women prevail at the sex structure of confirmed cases (1,318,181 women; 59.5% of the total number for the entire observation period). 2,094,971 people have recovered from COVID-19. For the entire observation period, 51,215 deaths were registered among people with a confirmed diagnosis of coronavirus disease COVID-19 (mortality rate stood at 2.3%). Among the deceased, the majority were women – 25,816; 50.4% of the total number of deaths (Table 1).

Table 1. Gender breakdown of confirmed cases of COVID-19 and deaths among people with a confirmed diagnosis of coronavirus disease COVID-19 over the entire observation period.

Sex	Confirmed cases of COVID-19 N= 2,215,052		Deaths N=51 215	
	abs. number	share, %	abs. number	share, %
Men	896,871	40.5	25,399	49.6
Women	1,318,181	59.5	25,816	50.4

The weekly dynamics of reported cases of coronavirus disease COVID-19 shows the registration of two significant waves of increase in morbidity. As of week 22, there is a steady decline in the incidence rate, the number of people who have recovered exceeds the number of newly detected cases since the 15th week of 2021 (Figure 1).

Figure 1. Dynamics of increase in the number of registered cases of coronavirus disease COVID-19 (weeks of 2020-2021)



In terms of age, people aged 50-59 years accounted for the largest number of all people with confirmed coronavirus disease COVID-19 (20.5%). In general, people under the age of 60 make up 70.8% of all people with a confirmed diagnosis. At the same time, the highest number of deaths from complications caused by coronavirus disease COVID-19 was registered among people aged 70 years and older (52.5%). Moreover, people aged 60 years and older accounted for 81.8% of all deaths from complications caused by coronavirus disease COVID-19 (Table 2).

Table 2. Age distribution of confirmed cases of coronavirus disease COVID-19 and deaths among people with a confirmed diagnosis of coronavirus disease COVID-19 for the entire observation period

Age group, years	Confirmed cases N= 2,215,052		Deaths N=51,215	
	abs. number	share, %	abs. number	share, %
0 - 9	41,298	1,9	17	0,03
10-19	85,604	3,9	28	0,1
20 - 29	211,439	9,5	166	0,3
30 - 39	378,301	17,1	770	1,5
40 - 49	397,167	17,9	2,174	4,2

Age group, years	Confirmed cases N= 2,215,052		Deaths N=51,215	
	abs. number	share, %	abs. number	share, %
50 - 59	454,741	20,5	6,207	12,1
60 - 69	405,720	18,3	14,985	29,3
70 +	240,782	10,9	26,868	52,5

The majority of deceased (47,308 people; 92.4%) had severe cardiovascular diseases, diabetes, diseases of kidney, liver and lungs, neurological diseases, malignant neoplasms, and others in their health history. 3,907 (7,6%) out of 51,215 people who have died, did not have a record of comorbidities and/or diseases in their health history. Among those 47,308 deceased who had a record of comorbidities and/or diseases in their health history, the vast majority (37,808; 79.9%) had suffered from cardiovascular diseases, and 7,866 people (16.6%) had been diagnosed with diabetes. At the same time, the number of deceased persons who had cardiovascular diseases was the highest in the age group of 60-79 years (23,662; 62.6% of all deceased who had been diagnosed with cardiovascular diseases). A similar ratio was observed among those deceased persons who had a record of diagnosed diabetes in their health history: 5,308 (67.5% of all people who have died and had been diagnosed with diabetes) were between the age of 60 and 79. In general, among those who died, concomitant diseases had been diagnosed in people aged 50 years and older (39,639 people), which accounted for 83.8% of the total number of such deaths (Table 3).

Table 3. Presence of comorbid conditions and/or diseases among people who died as a result of complications caused by coronavirus disease COVID-19 during the entire observation period

The name of the comorbid condition	Age groups, years					Total
	0-19	20-39	40-59	60-79	80 and older	
Total deaths	45	936	8,381	30,929	10,924	51,215
Pregnancy	0	14	2	0	0	16
Immunodeficiency	0	42	73	111	36	262
Cardiovascular diseases, including hypertension	8	288	4,833	23,662	9,017	37,808
Diabetes	5	91	1,310	5,308	1,152	7,866

The name of the comorbid condition	Age groups, years					
	0-19	20-39	40-59	60-79	80 and older	Total
Liver diseases	0	75	319	634	192	1,220
Kidney diseases	4	70	373	1,013	354	1,814
Chronic neurological or neuromuscular diseases	10	53	332	1,408	776	2,579
Malignant neoplasms	4	42	365	1,126	253	1,790
Chronic lung diseases	3	59	371	1,311	516	2,260
Deaths with no comorbid conditions/diseases	8	213	1,333	1,982	371	3,907

COORDINATION OF THE PROCESS OF DEPLOYMENT OF VACCINE AGAINST CORONAVIRUS DISEASE COVID-19 AT NATIONAL AND REGIONAL LEVELS

The coordination of the process of COVID-19 vaccine deployment and the roll-out of a vaccination campaign is carried out by the VPDs TF, the composition and regulation of which are approved by the order of the Ministry of Health of Ukraine No. 1319 dated June 7, 2019 (as amended by the order of the Ministry of Health of Ukraine No. 1168 dated June 9, 2021).

The VPDs TF is headed by the Minister of Health of Ukraine. It includes the representatives of the Ministry of Health, the Ministry of Internal Affairs of Ukraine, the Armed Forces of Ukraine, the National Health Service of Ukraine, the State Service of Ukraine for Medicines and Drug Control, the State Institution (SI) “Public Health Center of the Ministry of Health of Ukraine”, the State Institution “State Expert Center of the Ministry of Health of Ukraine”, the National Immunization Technical Advisory Group (hereinafter – NITAG), the representatives of higher medical educational institutions, the representatives of the World Health Organization Country Office in Ukraine (hereinafter – WHO), the United Nations Children's Fund (hereinafter – UNICEF), the Centers for Disease Control and Prevention of the USA, etc.

The preparatory work on the deployment of the COVID-19 vaccination campaign began in September 2020. On the instructions of the Deputy Minister of Health – the Chief State Sanitary Doctor of Ukraine, a working group of national experts was established on the basis of the SI “Public Health Centre of the Ministry of Health of Ukraine” to develop practical recommendations for the

preparation of a campaign for vaccination against coronavirus disease COVID-19 in Ukraine. It was comprised of national experts, the representatives of WHO, UNICEF, Centers for Disease Control and Prevention of the USA etc. The NITAG members were also invited to participate in the process. All the participants have contributed to the development of recommendations on the criteria for priority groups for COVID-19 vaccination in Ukraine¹.

In addition, a permanent Technical Working Group on the Organization of Vaccination against COVID-19 in Ukraine under the Ministry of Health, carries out the general coordination of preparatory processes and prepares detailed developments (including for further consideration at the meeting of VPDs TF of the Ministry of Health of Ukraine) in different directions: communication strategy and its implementation, procurement and logistics, staff training, formation of lists and scheduling of appointments for vaccination, management of vaccination data, pharmacovigilance, etc. The Technical Working Group consists of the representatives of the Ministry of Health, the Ministry of Digital Transformation, the Ministry of Internal Affairs, the Ministry for Reintegration of the Temporarily Occupied Territories, the National Health Service, National Security and Defense Council, Command of the Medical Forces of the Armed Forces of Ukraine, SI “Public Health Center of the Ministry of Health of Ukraine”, State Enterprise (SE) “Medical Procurement of Ukraine”, SE “State Expert Center of the Ministry of Health of Ukraine”, SE “Electronic Health”, SE “Ukrmedpostach” of the Ministry of Health of Ukraine, that provides supply to medical facilities, WHO, UNICEF, USAID Project “Safe, Affordable and Effective Medicines for Ukrainians” (SAFEMed), implemented by Management Sciences for Health (MSH).

At the regional level, the coordination of immunoprophylaxis measures against coronavirus disease COVID-19 is carried out by regional coordinators, who have been assigned in each region and Kyiv city. The list of regional coordinators of the vaccination campaign against coronavirus disease COVID-19 in 2021-2022 in Ukraine has been approved by the order of the Ministry of Health of Ukraine No. 1348 dated July 2, 2021.

THE PURPOSE AND GOALS OF COVID-19 VACCINE INTRODUCTION

Immunization of the population with a safe and effective vaccine against coronavirus disease COVID-19 is an essential component of the Government of Ukraine's strategy to respond to the acute phase of the COVID-

¹ Minutes of the NITAG meeting No.3 dated September 10, 2020

19 pandemic. The overall purpose of mass vaccination of the population is to stop the spread of coronavirus disease COVID-19 in Ukraine.

The implementation of the Roadmap activities pursues the following goals:

- reduce mortality, related to the coronavirus disease COVID-19;
- reduce health complications related to the coronavirus disease COVID-19.
- prevent the collapse of the healthcare system due to the excessive load on technical and infrastructural systems and human resources under the condition of the rapid and wide spread of coronavirus disease COVID-19.

The main task of the Roadmap is to cover at least 50% of the population of Ukraine (20,866,390 people²) with vaccination against coronavirus disease COVID-19. Also, in accordance with the Decree of the President of Ukraine of April 3, 2021 No. 139 "On the Decision of the National Security and Defence Council of Ukraine of April 2, 2021 "On the National Plan for Preventive Vaccination against the Acute Respiratory Disease COVID-19 Caused by Coronavirus SARS-CoV-2 by the end of 2021", the order of the Cabinet of Ministers of Ukraine of April 12, 2021 No. 340 approved the National Plan for Preventive Vaccination against the Acute Respiratory Disease COVID-19 Caused by Coronavirus SARS-CoV-2 until December 31, 2021 (hereinafter – the National plan). The National Plan identifies the need to ensure the vaccination coverage of the majority of the adult population in Ukraine by December 31, 2021 to achieve herd immunity to coronavirus disease COVID-19. According to the National Plan until December 31, 2021, the estimated need for vaccinations is 47,878,388 (for 23,939,194 people, which, according to the State Statistics Service of Ukraine accounts for 70% of the population aged 18 and older).

The results of mathematical simulations indicate that in order to reduce the spread of coronavirus disease COVID-19 and mortality thereof, 60 to 80% of the population³ have to be vaccinated with an effective vaccine against COVID-19.

At the same time, the efficacy of COVID-19 vaccine candidates, which are currently undergoing clinical trials and are in the final stages of testing is measured by their ability to prevent COVID-19 related hospitalization, the development of a severe form of coronavirus disease COVID-19 and mortality due to COVID-19-related complications. It is also currently unknown whether

² As of January 1, 2020, according to the State Statistics Service of Ukraine, the permanent population of Ukraine was 41,732,779 people

(http://database.ukrcensus.gov.ua/PXWEB2007/ukr/publ_new1/2020/zb_nas_2019.pdf).

³ <https://pubmed.ncbi.nlm.nih.gov/32778354/>

the vaccination against coronavirus disease COVID-19 reduces the risk of transmission between those who are vaccinated and those who are not.

It is expected that a mass vaccination campaign will significantly reduce the mortality rate from coronavirus disease COVID-19 and prevent the development of severe COVID-19-related health complications. At this stage, the primary goals of vaccination against COVID-19 in Ukraine are (i) to reduce the rate of COVID-19-related mortality and complications among at-risk groups and (ii) protect the personnel of the healthcare system and other national systems of vital importance. The primary expected outcome of this vaccination campaign is to gain effective control of the COVID-19 pandemic, reduce the burden on the healthcare system, and create conditions for the country's economic recovery.

Vaccination against coronavirus disease COVID-19 in Ukraine will be voluntary for all population and professional groups.

Vaccination against coronavirus disease COVID-19 in Ukraine should be organized and carried out in a way that it does not jeopardize the routine vaccination against other diseases conducted in accordance with the National Immunization Schedule (hereinafter – NIS), approved by the order of the Ministry of Health of Ukraine No. 595 dated September 16, 2011, registered in the Ministry of Justice of Ukraine No. 1159/19897 on October 10, 2011 (as amended by the order of the Ministry of Health of Ukraine No. 551 dated August 11, 2014). This will ensure that the rate of vaccination against other diseases is not reduced.

STATE OF COVID-19 VACCINE DEVELOPMENT

According to the World Health Organization, as of the beginning of June 2021, 287 vaccine candidates were at various phases of its development. Of these,

102 candidates were at various phases of clinical trials, and 23 candidates – at the III or IV phase of clinical trials⁴ (Table 4).

Table 4. General information on vaccine candidates which are in phase III or IV clinical trials⁵

Developer (manufacturer)	Platform	Vaccine type (name)	Phase (stage)
Academy of Military Science (AMS), Walvax Biotechnology and Suzhou Abogen Biosciences	mRNA	SARS-CoV-2 mRNA vaccine (ARCoV)	III
Anhui Zhifei Longcom Biopharmaceutical + Institute of Microbiology, Chinese Academy of Sciences	Protein subunit	Recombinant SARS-CoV-2 vaccine (CHO Cell)	III
AstraZeneca + University of Oxford	Non-replicating viral vectors	ChAdOx1-S - (AZD1222, Covishield, Vaxzevria)	IV
Bharat Biotech International Limited	Inactivated virus	Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152)	III
CanSino Biological Inc./Beijing Institute of Biotechnology	Non-replicating viral vectors	Recombinant novel coronavirus vaccine (Adenovirus type 5 vector)	IV
Center for Genetic Engineering and Biotechnology (CIGB)	Protein subunit	CIGB-66 (RBD+aluminium hydroxide)	III
CureVac AG	mRNA	CVnCoV Vaccine	III
Federal Budgetary Research Institution State Research Center of Virology and Biotechnology "Vector"	Protein subunit	EpiVacCorona	III
Gamaleya Research Institute; Health Ministry of the Russian Federation	Non-replicating viral vectors	Gam-COVID-Vac Adeno-based (rAd26-S+rAd5-S)	III

⁴ According to <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> , as of December 22, 2020.

⁵ According to <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> , as of December 10, 2020.

Institute of Medical Biology + Chinese Academy of Medical Sciences	Inactivated virus	SARS-CoV-2 vaccine (vero cells)	III
Instituto Finlay de Vacunas	Protein subunit	FINLAY-FR-2 anti-SARS-CoV-2 Vaccine	III
Janssen Pharmaceutical	Non-replicating viral vectors	Ad26.COV2.S	III
Moderna + National Institute of Allergy and Infectious Diseases (NIAID)	mRNA	mRNA-1273	IV
Novavax	Protein subunit	SARS-CoV-2 rS/Matrix M1-Adjuvant NVX-CoV2373	III
Pfizer/BioNTech + Fosun Pharma	mRNA	BNT162b2 (3 LNP-mRNAs), Comirnaty	IV
Research Institute for Biological Safety Problems, Rep of Kazakhstan	Inactivated virus	QazCovid-in® - COVID-19 inactivated vaccine	III
Sanofi Pasteur + GSK	Protein subunit	VAT00002: SARS-CoV-2 S protein with adjuvant	III
Shenzhen Kangtai Biological Products Co., Ltd.	Inactivated virus	Inactivated SARS-CoV-2 vaccine (Vero cell)	III
Sinopharm + China National Biotec Group Co + Beijing Institute of Biological Products.	Inactivated virus	Inactivated SARS-CoV-2 vaccine (Vero cell), BBIBP-CorV	III
Sinopharm + China National Biotec Group Co + Wuhan Institute of Biological Products	Inactivated virus	Inactivated SARS-CoV-2 vaccine (Vero cell)	III
Sinovac Research and Development Co., Ltd	Inactivated virus	Inactivated SARS-CoV-2 vaccine (Vero cell), CoronaVac	IV
Valneva, National Institute for Health Research, United Kingdom	Inactivated virus	VLA2001	III

Zydus Cadila	DNA	nCov vaccine	III
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As of June 3, 2021, WHO has included in the Emergency Use Listing 6 vaccines against coronavirus disease COVID-19 from 8 manufacturers (Table 5)⁶. The Emergency Use Listing (EUL) procedure assesses the suitability of novel health products during public health crises and emergencies. The goal is to make medicines, vaccines and diagnostics available within the shortest possible time to address the emergency, while adhering to strict safety, efficacy and quality criteria.

Table 5. Vaccines against coronavirus disease COVID-19, included in the WHO Emergency Use Listing

Developer (manufacturer)	Vaccine type (name)
Pfizer/BioNTech + Fosun Pharma	BNT162b2 (3 LNP-mRNAs), Comirnaty
AstraZeneca + University of Oxford	ChAdOx1-S - (AZD1222, Vaxzevria)
AstraZeneca + University of Oxford (produced in the Republic of Korea, SK Bioscience)	ChAdOx1-S - (AZD1222)
AstraZeneca + University of Oxford (produced in India, Serum Institute of India (SII))	ChAdOx1-S - (Covishield)
Janssen Pharmaceutical	Ad26.COV2.S
Moderna + National Institute of Allergy and Infectious Diseases (NIAID)	mRNA-1273
Sinopharm + China National Biotech Group Co + Beijing Institute of Biological Products.	Inactivated SARS-CoV-2 vaccine (Vero cell), BBIBP-CorV
Sinovac Research and Development Co., Ltd	Inactivated SARS-CoV-2 vaccine (Vero cell), CoronaVac

According to previous WHO recommendations for the use of the vaccine against the coronavirus disease COVID-19 developed by AstraZeneca + University of Oxford ChAdOx1-S (AZD1222, Vaxzevria, Covishield SII, SK

⁶ According to <https://extranet.who.int/pqweb/sites/default/files/documents/Status%20of%20COVID-19%20Vaccines%20within%20WHO%20EUL-PQ%20evaluation%20process%20-%203%20June%202021.pdf>, as of June 3, 2021

Biosciense), the vaccines are considered completely equivalent, even if they are made on different platforms or registered under different product names⁷.

As of the time of preparation of the Roadmap, 4 vaccines against coronavirus disease COVID-19 from 6 manufacturers had been registered in Ukraine. All vaccines against coronavirus disease COVID-19 used in Ukraine at the time of the Roadmap drafting were included in the WHO Emergency Use Listing (Table 6).

Developer (manufacturer)	Vaccine type (name)	Registration date
Pfizer Manufacturing Belgium NV, Belgium, BioNTech Manufacturing Gmb, Germany	COMIRNATY	February 22, 2021 ⁸
Serum Institute of India PVT. LTD	CHADOX1 NCOV-19 CORONA VIRUS VACCINE (RECOMBINANT), COVISHIELD	February 22, 2021 ⁹
Sinovac Life Sciences Co., Ltd	INACTIVATED SARS- COV-2 VACCINE (VERO CELL), CORONAVAC	March 09, 2021 ¹⁰
SK Bioscience Co., Ltd., Republic of Korea	COVID-19 VACCINE ASTRAZENECA	April 20, 2021 ¹¹
Catalent Anagni SRL, Italy	COVID-19 VACCINE ASTRAZENECA	May 31, 2021 ¹²

⁷ <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwjPiLOJ-5bxAhXjo4sKHZILDV>

[oQFjAAegQIAhAD&url=https%3A%2F%2Fapps.who.int%2Firis%2Frest%2Fbitstreams%2F1343289%2Fretrieve&usg=AOvVaw15T3fcljTnrWhm4bfHRRW5](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwjPiLOJ-5bxAhXjo4sKHZILDV)

⁸ <http://www.drlz.com.ua/ibp/ddsite.nsf/all/shlz1?opendocument&style=BEF8DF4FDF228F1EC22586F40035CD91>

⁹ <http://www.drlz.com.ua/ibp/ddsite.nsf/all/shlz1?opendocument&style=EDC22B65541B7E13C22586850028380D>

¹⁰ <http://www.drlz.com.ua/ibp/ddsite.nsf/all/shlz1?opendocument&style=A75A7CAA5F38425CC225869400259332>

¹¹ <http://www.drlz.com.ua/ibp/ddsite.nsf/all/shlz1?opendocument&style=D285C104ACBDB956C22586BE002A4CE7>

¹² <http://www.drlz.com.ua/ibp/ddsite.nsf/all/shlz1?opendocument&style=3F41CFB568E3C2C4C22586E70020E55>

Janssen Pharmaceuticals,
NV, Belgium

COVID-19 VACCINE
JANSSEN

July 2, 2021¹³

In accordance with the Procedure for State Registration of Vaccines or other Medical Immunobiological Drugs for the Specific Prevention of Coronavirus Disease COVID-19, under the Authorization of Emergency Use of Medical Products approved by the Cabinet of Ministers of Ukraine of 08 February 2021 No. 95, the registration of vaccines or other medical immunobiological drugs for the specific prevention of coronavirus disease COVID-19, under the authorization of emergency use of medical products, that have been developed and/or produced in a state recognized by the Verkhovna Rada of Ukraine as an aggressor state, is prohibited¹⁴.

As of the preparation of the Roadmap, the developers of vaccine candidates included in the WHO Emergency Use Listing published the following preliminary information on vaccine efficacy (table 6).

Table 6. Preliminary information on the efficacy of vaccines against coronavirus COVID-19

Developer (manufacturer)	Vaccine type (name)	Preliminary efficacy¹⁵
Pfizer/BioNTech + Fosun Pharma	COMIRNATY	95% ¹⁶
Moderna + National Institute of Allergy and Infectious Diseases (NIAID)	mRNA-1273	94,1% ¹⁷
AstraZeneca + University of Oxford	ChAdOx1-S - (AZD1222, Covishield, Vaxzevria)	76% ¹⁸

¹³ <http://www.drlz.com.ua/ibp/ddsite.nsf/all/shlz1?opendocument&stype=09E1F20212A72173C225870600329F83>

¹⁴ https://www.kmu.gov.ua/npas/deyaki-pitannya-derzhavnoyi-reyestratsiyi-vakcin-abo-inshih-medichnih-%20imunobiologichnih-preparativ-dlya-%20t80221?fbclid=IwAR134Mch7aenD8fwnEtnS5pkbQ69rNfNK6S9v6GUHE8y4LiZz_8kuSaJuJM

¹⁵ The efficacy data for COVID-19 vaccines are more precisely determined and corrected in the process of clinical trials. The data presented in table 5 are not final. The indicated percentage shows the efficacy of vaccines in preventing the symptomatic course of coronavirus disease COVID-19

¹⁶ https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1

¹⁷ <https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mrna-1273-vaccine-against-covid-19>

¹⁸ https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1

Janssen Pharmaceuticals	Ad26.COV2.S	66,9% ¹⁹
Sinovac Research and Development Co., Ltd	Inactivated SARS-CoV-2 vaccine (Vero cell), CoronaVac	51-83,5% ²⁰
Sinopharm + China National Biotec Group Co + Beijing Institute of Biological Products	Inactivated SARS-CoV-2 vaccine (Vero cell), BBIBP-CorV	79% ²¹

THE WAYS OF GETTING VACCINES

Ukraine is utilizing the below listed opportunities to get access to vaccines against coronavirus COVID-19:

- 1) through COVAX AMC (Advanced Market Commitment) as a participating member (opportunity of receiving free supplies of vaccines in the form of donation for priority groups of the population and the possibility of purchasing vaccines at a special reduced price);
- 2) direct procurement from vaccine manufacturers using the following sources of funding:
 - the funds of the state budget of Ukraine;
 - the funds from international donors and other agencies;
 - loan funds under the programs of the World Bank, the European Investment Bank, etc.;
 - other sources not prohibited by law;
- 3) as free supplies of vaccines in the form of donations.

On December 30, 2020, Ukraine entered into an agreement to procure a COVID-19 vaccine developed by the Chinese pharmaceutical company Sinovac Biotech Ltd. through the State Enterprise (SE) “Medical Procurement of Ukraine”. The supplier – Ukrainian pharmaceutical company JSC “Lekhim”. The contract amount is UAH 964 million. The number of vaccines is 1,913,000 doses.

On January 13, 2021, the Cabinet of Ministers of Ukraine declared Crown Agents Limited a specialized organization to procure the vaccines against

¹⁹ <https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Ad26.COV2.S-2021.1>

²⁰ https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-2021.1

²¹ https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BIBP-2021.1

coronavirus disease COVID-19²². Crown Agents Limited also procures safe injection materials for vaccination against coronavirus disease COVID-19 at the request of the state.

UNICEF is involved in the delivery of COVID-19 vaccines to Ukraine, including safe injection materials obtained through the COVAX AMC initiative.

In 2021, 20,001,150 state-funded doses of vaccine produced by Pfizer/BioNTech are planned to be procured through Crown Agents Limited and delivered to Ukraine.

In addition, in 2021 the state budget of Ukraine will cover the procurement and delivery of AstraZeneca + University of Oxford (Covishield) vaccines in the amount of 2,000,000 doses and Novavax (Covovax) vaccines in the amount of 10,000,000 doses (both vaccines are produced by Serum Institute of India Pvt. Ltd). The procurement will be carried out through Crown Agents Limited.

Thanks to the participation in the COVAX AMC mechanism, in 2021-2022 Ukraine expects to receive free vaccines against the coronavirus disease COVID-19 in the quantity of 20% of the population of Ukraine (from 8 to 16 million doses). As of June 2021, Ukraine has received confirmation of the allocation of 2,840,700 doses of vaccines from COVAX AMC during the second and third quarters of 2021.

IDENTIFYING GROUPS FOR TARGETED VACCINATION

The main goal of the Roadmap is to ensure the implementation of the recommendation to cover at least 50% of the population of Ukraine (20,866,390 people) with the vaccination against coronavirus disease COVID-19 during 2021-2022. However, the choice of approaches to implementing a vaccination program will largely depend on the availability of COVID-19 vaccines.

The vaccine production capacity is unable to meet the current global demand for the COVID-19 vaccine. The forecasts are that the demand will exceed vaccine manufacturing capacity throughout the years 2021 and 2022. Accordingly, in a context of limited access to the vaccine, there is a need to identify those groups of the population that should receive the COVID-19 vaccine first. Given the need to develop ethical and practical criteria for prioritizing access to vaccines, WHO, the WHO Strategic Advisory Group on Immunization Experts (hereinafter – SAGE), the European Technical Expert Advisory Group (hereinafter – ETAGE) and other international bodies have developed global and

²² <https://www.kmu.gov.ua/npas/pitannya-finansuvannya-zdijsnennya-zahodiv-povyazanih-z-vakcinaciyeyu-naselennya-vid-gostroyi-respiratornoyi-hvorobi-covid-19-sprichinenoyi-koronavirusom-sars-cov-2-i130121-23>

regional recommendations regarding the identification of priority groups for COVID-19 vaccination under the conditions of limited supply.

In order to provide national recommendations on the vaccination strategy and identification of priority groups for COVID-19 vaccination, National Immunization Technical Advisory Group (NITAG) formed a working group which during September-October 2020 have reviewed the data on the burden of COVID-19 disease in Ukraine (collected by the Electronic Integrated Disease Surveillance System), the data of additionally conducted studies and the results of modelling obtained with the support of international partners. Based on the data findings and recommendations of the WHO, SAGE²³ and ETAGE, the Preliminary Framework for Equitable Allocation of the COVID-19 Vaccine (National Academies of Sciences, Engineering and Medicine; USA)²⁴, as well as the results of the NITAG working group meetings (September, 10 and November, 6 of 2020) and follow-up discussions with the experts, on November 18, 2020, NITAG formed and provided the preliminary recommendations on vaccination strategy and identification of priority groups for COVID-19 vaccination to the Ministry of Health of Ukraine. In accordance with the NITAG recommendations, and as a result of the discussion at the meeting of the Task Force on Emergency Response to Prevent the Spread of Vaccine-preventable Diseases (VPDs TF) under MOH of November 26, 2020, the following nine priority groups were approved by the Ministry of Health as a priority for vaccination against coronavirus disease COVID-19 (in order of priority access to vaccination):

- 1) medical professionals, including those directly engaged in the process of COVID-19 pandemic response;
- 2) workers of the social sphere, including social workers;
- 3) people residing in the long-term care facilities (institutions) and personnel working in these facilities (institutions);
- 4) older adults (60 years and older), including those with comorbidities, who are at higher risk for COVID-19-related complications and death (people diagnosed with endocrine system disease, cardiovascular diseases, chronic diseases of the respiratory tract, chronic diseases of the nervous system, chronic diseases of the urinary system, cancer, chronic diseases of the hematopoietic organs and blood); with further prioritization in this group, starting with people aged 80 and over (the highest priority), and further with the

²³ <https://www.who.int/publications/m/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-context-of-limited-supply>

²⁴ <https://www.nap.edu/resource/25917/25914.pdf>

distribution for cohorts 79-75 years, 74-70 years, 69-65 years, 64-60 years;

- 5) military personnel (including the Armed Forces of Ukraine and the National Guard of Ukraine) engaged in the Joint Forces Operation (Eastern Ukraine);
- 6) personnel of critical state security structures, including the State Emergency Service of Ukraine, the National Police of Ukraine, the National Guard of Ukraine, the Security Service of Ukraine, State Border Guard Service of Ukraine, military personnel of the Armed Forces of Ukraine, personnel of the Ministry of Internal Affairs of Ukraine;
- 7) teachers, educators and people working in the education sphere;
- 8) adults (aged 18 to 59 years; from 16 years for Pfizer/BioNTech + Fosun Pharma) with comorbidities at risk for complications and death due to coronavirus disease COVID-19 (people diagnosed with endocrine system disease, cardiovascular disease, chronic diseases of the respiratory tract, chronic diseases of the nervous system, chronic diseases of the urinary system, cancer, chronic diseases of the hematopoietic organs and blood);
- 9) prison and detention center population, and workers in prisons and detention centers.

The selection of these groups is based on the following criteria and risk factors:

Table 7. Criteria and factors for identification of priority for vaccination against COVID-19 in selected population groups

Group	Criteria and risk factors
Medical professionals, including those directly engaged in the process of COVID-19 pandemic response	High risk of infection due to a lack of choice of placement and organization of work. Critical workers for maintaining essential health services
Workers of the social sphere, including social workers	High risk of infection due to a lack of choice of working conditions. Frequent contact with socially vulnerable people, people aged 60 and over creates additional risks of infection spread and mortality in the population that social workers are constantly in contact with.
People residing in the long-term care facilities (institutions) and personnel working in these facilities (institutions)	High risk of infection due to a lack of choice of living conditions. People over the age of 60 living in such facilities are at a higher risk for death due to high risks of increased internal transmission of infection.

Older adults (60 years and older), including those with comorbidities, who are at higher risk for COVID-19-related complications and death	High risk of serious complications and death
Military personnel (including the Armed Forces of Ukraine and the National Guard of Ukraine) engaged in the Joint Forces Operation (Eastern Ukraine)	The average risk of getting the infection due to a lack of choice of a place of service and living conditions. The high risk of a large number of military personnel falling ill at the same time may lead to significant complications, namely the decrease of their ability to perform duties toward the preservation of the territorial integrity of the country
Personnel of critical state security structures, including the State Emergency Service of Ukraine, the National Police of Ukraine, the National Guard of Ukraine, the Security Service of Ukraine, State Border Guard Service of Ukraine, military personnel of the Armed Forces of Ukraine, the Ministry of Internal Affairs of Ukraine.	High risk of infection due to a lack of choice of placement and organization of work. Critical workers for maintaining safety, law and order and ensuring emergency response.
Teachers, educators and people working in the education sphere	High risk for limitations hampering the proper functioning of society
Adults (aged 18 to 59 years) with comorbidities at risk for complications and death due to COVID-19 disease	Increased risk of severe disease and mortality
Prison and detention center population, workers in prisons and detention centers	High risk of infection due to a lack of choice of living and working conditions. Social insecurity and de facto lack of access to specialized medical care in prisons and/or detention centers.

Since the beginning of the introduction of vaccination against coronavirus disease COVID-19, the VPDs TF has made amendments to the list of priority populations for COVID-19 vaccination in order to effectively manage and increase the vaccination coverage rate.

The main reasons for the amendments were the impact of several factors, namely (i) the number of doses received and the timing of deliveries of vaccines against coronavirus disease COVID-19, (ii) the epidemic situation with coronavirus disease COVID-19 at the time of vaccination, (iii) rational appeals submitted to the Ministry of Health concerning the need for extensions and addition of groups of people for vaccination against coronavirus disease COVID-19, etc.

The amendments on the expansion of priority risk groups following the decisions of the Task Force are presented in Table 8. Regardless the decisions, the target groups of health workers and people over 60 years will remain to be of the highest priority for COVID-19 vaccination.

Table 8. Amendments on the expansion of priority risk groups following the decisions of the Task Force

Date and the number of the VPDs TF decisions	Group	Criteria and risk factors
of 12.03.2021 No. 19	Add to the 1st phase (stage) of vaccination the group of military personnel involved in the next scheduled rotation to the Joint Forces Operation	The high risk of a large number of military personnel falling ill at the same time that may result in significant complications, namely the decrease of their ability to perform duties toward the preservation of the territorial integrity of the country
of 19.03.2021 No. 21	Add to the 2nd phase (stage) of vaccination the group of educators involved in the process of conducting External Independent Evaluation	The high risk of a large number of people falling ill at the same time that may lead to significant complications resulting in the decrease of their ability to perform duties

	low mobility groups and their caregivers	Increased risk of severe disease and mortality
	participants of the Olympic and Paralympic national teams of Ukraine	High risk and conditions of participation in the competition in Tokyo Summer Olympics Games (Japan, 23 Jul-8 Aug, 2021)
	in stage 2, start COVID-19 vaccination for older adults in those regions with the highest incidence of coronavirus disease COVID-19	Increased risk of severe disease and mortality
of 02.04.2021 No. 22	Add other critical national infrastructure facilities and consider changes to the Roadmap: Ministry of Defence of Ukraine, State Migration Service; State Service of Special Communications and Information Protection; prosecutor's offices; personnel of the fuel and energy complex; personnel of sanatorium-resort facilities; personnel of state forest protection bodies, personnel of the state protection service of the nature reserve fund, sea and river transport, postal service, air transport, road management, customs, SC "Ukroboronprom" (Ukrainian Defense Industry), the State Bureau of Investigation, the Department of State Protection of Ukraine, representatives of the diplomatic corps, the National Agency for Prevention of Corruption, etc. Include church ministers (clergy) of officially registered in Ukraine churches and religious organizations in the group of social workers in the 2nd phase (stage) of vaccination	High risk of infection due to a lack of choice of placement and organization of work. Personnel of critical infrastructure to ensure safety, law and order providing emergency response In order to increase the demand for vaccination and trust in vaccines among the elderly population of Ukraine due to high trust in church leaders (clergy).
of 09.04.2021 No. 23	In order to rationalize, use extra doses of the Pfizer/BioNTech + Fosun Pharma vaccine allocated for vaccination of the	High risk of infection due to a lack of choice of placement and organization

	target group of people in nursing homes and homes for the elderly (in case of vaccine refusal, to prevent vaccine wastage) for the personnel of the State Emergency Service and the State Border Guard Service, which belong to the 3rd stage (phase) of vaccination	of work. Personnel of critical infrastructure to ensure safety, law and order providing emergency response
of 07.05.2021 No. 27	include the personnel of the State Food and Consumer Service to the third stage of vaccination	High risk of infection due to a lack of choice of placement and organization of work. Personnel of critical infrastructure to ensure safety, law and order providing emergency response
	include the personnel of executive, judicial and legislative authorities, the personnel of public authorities and local governments to the 3rd stage of vaccination	High risk of infection due to a lack of choice of placement and organization of work. Personnel of critical infrastructure to ensure safety, law and order providing emergency response
	Include citizens of Ukraine currently residing in the temporarily occupied territories of Ukraine (priority – people aged 65 and older) to the 3rd stage (phase) of vaccination	

Given that at the time of the Roadmap development, the efficacy of vaccine candidates was determined by the ability to prevent the development of coronavirus disease COVID-19 and COVID-19-related death due to complications, older age of a person will be considered an additional priority for getting the vaccine.

That is, within the priority groups, older people (aged 60 and over) will be recommended for vaccination first because the risk of developing severe coronavirus disease and related complications is significantly higher in people aged 60 years and older compared to younger people.

THE COVERAGE TARGETS OF VACCINATION CAMPAIGN

Given the availability of vaccines against coronavirus disease COVID-19, operational, logistics, and infrastructure constraints, Ukraine plans to prepare and launch a multi-level COVID-19 vaccination campaign to cover at least 50%²⁵ of the country's population during 2021-2022.

Data on the number of target groups were provided by the State Institution (SI) “Public Health Center of the Ministry of Health of Ukraine” based on the information provided by the regions and central authorities, the State Statistics Service of Ukraine and SI “Center for Medical Statistics of the Ministry of Health”. The data will be updated and reviewed during the next roll-out phases of the nationwide vaccination campaign against coronavirus disease COVID-19.

The recommended groups for vaccination against coronavirus disease COVID-19 are the following (including the groups identified by the VPDs TF and set out in the decisions thereof; these data are estimated):

- 1) medical personnel of the Ministry of Health of Ukraine as well as of other ministries and bodies, including those directly engaged in the process of COVID-19 pandemic response – 681,196;
- 2) workers of the social sphere, including social workers – 156,871;
- 3) people residing in the long-term care facilities (institutions) and personnel working in these facilities (institutions) – 136,353;
- 4) older adults (60 years and older) – 9,978,194 including 7,038,164 people with comorbidities who are at higher risk for COVID-19-related complications and death (people diagnosed with endocrine system disease, cardiovascular disease, chronic respiratory disease, chronic nervous system diseases, chronic diseases of the urinary system, cancer, chronic diseases of the hematopoietic organs and blood).
- 5) military personnel (including the Armed Forces of Ukraine and the National Guard of Ukraine) participating in the Joint Force Operation and military personnel involved in the next scheduled rotation to the Joint Forces Operation – 75,000;
- 6) law enforcement and intelligence bodies, state bodies of special purpose with law enforcement functions, civil defence forces and other bodies entrusted by the Constitution and laws of Ukraine with functions to ensure the national security of Ukraine; the Armed Forces of Ukraine, as well as other military formations, law enforcement and intelligence bodies, special purpose bodies with law enforcement functions formed in accordance with

²⁵ As of January 1, 2020, according to the State Statistics Service of Ukraine, the permanent population of Ukraine was 41,732,779 people
(http://database.ukrcensus.gov.ua/PXWEB2007/ukr/publ_new1/2020/zb_nas_2019.pdf)

the laws of Ukraine, entrusted by the Constitution and laws of Ukraine with functions to ensure state defence, including the Ministry of Defence, State Special Transport Service, Ministry of Internal Affairs of Ukraine, National Guard of Ukraine, National Police, State Border Guard Service of Ukraine, State Migration Service of Ukraine, State Emergency Service of Ukraine, Security Service of Ukraine, Department of State Protection of Ukraine, State Service of Special Communications and Information Protection of Ukraine, National Security and Defence Councils of Ukraine, intelligence bodies of Ukraine, prosecutor's offices, National Anti-Corruption Bureau of Ukraine, state border guards, revenue and collection bodies, penitentiary facilities, pre-trial detention centers, bodies of state financial control, fisheries protection, state forest protection, other bodies performing law enforcement or law application functions, the central executive body that ensures the formation and implementation of state military-industrial policy, other state bodies and local governments which functions include ensuring national security in cooperation with the bodies of the security and defence sector; other state authorities and local governments – 1,088,644;

- 7) teachers, educators and the personnel of the education sphere – 737,705²⁶;
- 8) adults (aged 18 to 59 years) with comorbidities at higher risk for COVID-19-related complications and death (people diagnosed with endocrine system disease, cardiovascular disease, chronic respiratory diseases, chronic diseases of the nervous system, chronic diseases of the urinary system, cancer, chronic diseases of the hematopoietic organs and blood) – 6,370,378;
- 9) other categories of the population and professional groups at risk for getting COVID-19 infection, which are not included in the groups mentioned above, including citizens of Ukraine living in the temporarily occupied territories of Ukraine – 1,716,796.
- 10) prison and detention center population, workers in prisons and detention centers – 78,400;

STAGES (PHASES) OF VACCINATION RESPONSE AGAINST COVID-19

Taking into account the limited availability of vaccines and the need to plan immunization against coronavirus disease COVID-19 in such a way that it does not overload the existing healthcare network of Ukraine or affect the provision of other healthcare services, including routine vaccination against other

²⁶ According to the State Statistics Service on the number of educators for 2019/2020

communicable diseases, the COVID-19 vaccination campaign of 2021-2022 is recommended to be conducted in the following stages:

1) stage 1: vaccination of people at critical risk of infection and development of coronavirus disease COVID-19 and those who perform critical functions in response to the pandemic of coronavirus disease COVID-19:

planned target group: about 367,000 people – <1 % of the total population of Ukraine;

approach to vaccination: vaccination by mobile teams;

2) stage 2: vaccination of people who have a very high risk of infection and development of coronavirus disease COVID-19 and those who provide medical services:

planned target group: about 2.5 million people – 6,1% of the total population of Ukraine;

approach to vaccination: through the network of primary healthcare facilities (hereinafter –HCFs) and mobile teams;

3) stage 3: vaccination of people at high risk of infection and development of coronavirus disease COVID-19 and those who perform functions to maintain the safety and livelihood of the state:

planned target group: about 6.6 million people – 17,1% of the total population of Ukraine;

approach to vaccination: through the network of primary healthcare facilities and mobile teams, mass vaccination centers/sites (starting from June 2021);

4) stage 4: vaccination of people at increased risk of infection and development of coronavirus disease COVID-19 and those who perform functions to maintain the safety and livelihood of the state:

planned target group: about 11 million people – 26% of the total population of Ukraine;

approach to vaccination: through the network of primary healthcare facilities and mobile teams, mass vaccination centers/sites (starting from June 2021);

The launch and deployment of mass vaccination depend on the availability of vaccines duly registered in Ukraine.

It is expected that each stage (phase) of the vaccination against COVID-19 will be conducted in rounds. It is also planned that the targeted group will be vaccinated with one dose of vaccine at each round. In total, there are two rounds

to complete one full vaccination cycle, given that the vaccines against coronavirus disease COVID-19 available in Ukraine at the time of the Roadmap development, will require the administration of two doses of vaccines for full vaccination per person. The duration of the vaccination round can be changed to line with the updated recommendations on the interval between the first and second dose of the vaccine, the number of doses that must be administered for full vaccination.

Considering the speed and volume of vaccine supplies to Ukraine, the vaccination points will gradually be established in healthcare facilities, the number of mobile vaccination teams will increase and mass vaccination centers/sites are created (starting from June 2021) during further stages of the vaccination campaign in order to ensure gradual vaccination of even larger part of the Ukrainian population from vaccination priority groups and expand the access to vaccines for the general population (focusing on people over 60).

It is expected that during the roll-out of the vaccination campaign, the vaccination of certain priority groups may be carried out in parallel, provided that there is a sufficient quantity of vaccines. General information on the stages of vaccination is presented in table 9.

The total number of people to be vaccinated at each stage exceeds the estimated population of Ukraine aged 18 and older due to the duplication of information in statistical reports at the national level. For example, people from different occupational groups may also be included in groups disaggregated by age. Accordingly, the final number of people to be vaccinated is expected to be lower and will be verified during the development of vaccination plans at the micro level (at regional, district and community levels).

The decision to vaccinate children and adolescents against coronavirus disease COVID-19 will be made after receiving additional information on the safety, quality and efficacy of vaccines against coronavirus disease COVID-19 in children and adolescents.

The upper and lower age limits of a person eligible for vaccination against coronavirus disease COVID-19 are determined by the vaccine manufacturer

(vaccine developer) based on the results of clinical trials and specified in the drug information leaflets.

Table 9. Stages of vaccination against coronavirus disease COVID-19 in 2021-2022

Stage 1 (meets phase 1a definition in global guidelines) <1% of the total population of Ukraine	Stage 2 (meets phase 1b definition in global guidelines) 6,1% of the total population of Ukraine	Stage 3 (meets phase 2 definition in global guidelines) 17.1% of the total population of Ukraine	Stage 4 (meets phase 2 definition in global guidelines) 26% of the total population of Ukraine
Target groups for vaccination against COVID-19			
Healthcare workers and staff, working in health care facilities (hereinafter – HCFs) providing inpatient care to patients with coronavirus disease COVID-19 and emergency medical workers and other healthcare professionals directly involved in the process of the COVID-19 response	Healthcare workers and staff, working in HCFs, providing inpatient care to other patients (including primary care, public health workers, etc.) and medical professionals of other agencies and ministries	People aged between 65 to 69, 70 to 74, 75 to 79	People aged 60 to 64
Persons living in long-term care facilities, nursing homes and staff of such facilities	People over the age of 80	Law enforcement and intelligence bodies, state bodies of special purpose with law enforcement functions, civil defence forces and other bodies entrusted by the Constitution and laws of Ukraine with functions to ensure the national security of Ukraine; the Armed Forces of	Adults (aged 18 to 59 years) with comorbidities, at risk for COVID-19-related complications and death

Stage 1 (meets phase 1a definition in global guidelines) <1% of the total population of Ukraine	Stage 2 (meets phase 1b definition in global guidelines) 6,1% of the total population of Ukraine	Stage 3 (meets phase 2 definition in global guidelines) 17.1% of the total population of Ukraine	Stage 4 (meets phase 2 definition in global guidelines) 26% of the total population of Ukraine
		Ukraine, as well as other military formations, law enforcement and intelligence bodies, special purpose bodies with law enforcement functions formed in accordance with the laws of Ukraine, entrusted by the Constitution and laws of Ukraine with functions to ensure state defence, including the Ministry of Defence, State Special Transport Service, Ministry of Internal Affairs of Ukraine, National Guard of Ukraine, National Police, State Border Guard Service of Ukraine, State Migration Service of Ukraine, State Emergency Service of Ukraine, Security Service of Ukraine, Department of State Protection of Ukraine, State Service of Special Communications and Information Protection of	

Stage 1 (meets phase 1a definition in global guidelines) <1% of the total population of Ukraine	Stage 2 (meets phase 1b definition in global guidelines) 6,1% of the total population of Ukraine	Stage 3 (meets phase 2 definition in global guidelines) 17.1% of the total population of Ukraine	Stage 4 (meets phase 2 definition in global guidelines) 26% of the total population of Ukraine
		Ukraine, National Security and Defence Councils of Ukraine, intelligence bodies of Ukraine, prosecutor's offices, National Anti-Corruption Bureau of Ukraine, state border guards, revenue and collection bodies, penitentiary facilities, pre-trial detention centers, bodies of state financial control, fisheries protection, state forest protection, other bodies performing law application or law enforcement functions, the central executive body that ensures the formation and implementation of state military-industrial policy, other state bodies and local governments which functions include ensuring national security in cooperation with the bodies of the security and defence sector; other state authorities	

Stage 1 (meets phase 1a definition in global guidelines) <1% of the total population of Ukraine	Stage 2 (meets phase 1b definition in global guidelines) 6,1% of the total population of Ukraine	Stage 3 (meets phase 2 definition in global guidelines) 17.1% of the total population of Ukraine	Stage 4 (meets phase 2 definition in global guidelines) 26% of the total population of Ukraine
		and local governments	
Military personnel (including the Armed Forces of Ukraine and the National Guard of Ukraine) participating in the Joint Force Operation in the Eastern Ukraine and military personnel involved in the next scheduled rotation	Social workers and the other personnel working in the social sphere, including church ministers (clergy) of officially registered in Ukraine churches and religious organizations	Teachers, educators and the other personnel working in the sphere of education	Other categories of the population and professional groups at risk for COVID-19 infection, and citizens of Ukraine living in the temporarily occupied territories of Ukraine
			Prison and detention center population, workers in prisons and detention centers
Planned coverage within certain stages			
Stage 1	Stage 2	Stage 3	Stage 4
397,491 people	2,543,174 people	7,789,380 people	10,997,269 people
Total planned coverage for 2021-2022			
21,727,314 people			

Following the implementation of stages 1 to 4 of the vaccination campaign and provided there is a sufficient supply of COVID-19 vaccines and resources, the stage 5 will roll-out, which involves the vaccination of adults aged 18 years and older (for vaccination with the vaccine produced by Pfizer/BioNTech + Fosun Pharma – from 16 years) currently not included in the priority groups. It is estimated that there may be as many as 13,100,215 such people.

ORGANIZATIONAL MODALITIES OF THE VACCINATION CAMPAIGN

A mass vaccination campaign against coronavirus disease COVID-19 is planned to be organized and conducted in a manner and on sites that meet the following criteria:

- 1) complies with all the necessary temperature conditions for vaccine storage and handling;
- 2) complies with all the required safety conditions for those getting and carrying out vaccination.
- 3) accessible for target groups;
- 4) has enough capacity to carry out a large number of vaccinations in a limited period of time;

Based on these criteria, the Ministry of Health of Ukraine has developed general organizational and logistics scenarios for the vaccination of the population against coronavirus disease COVID-19. Such scenarios can be implemented at different stages of the vaccination campaign, depending on the technical feasibility of each scenario realization. (Table 10).

Table 10. General organizational and logistics scenarios for vaccination against coronavirus disease COVID-19

Scenario	Implementation process
In healthcare facilities (HCFs) on the basis of vaccination points (platform 1)	For carrying out vaccination against COVID-19, the total estimated number of equipped vaccination points set up in HCFs accounts for up to 4,250. Vaccination points will be established in the HCFs of all forms of ownership or by individuals who have a license for medical practice and a valid agreement under the medical guarantee program with the National Health Service of Ukraine. The total number of vaccination points will depend on the size of the target group to be vaccinated on this platform. Training of the staff of vaccination points/centers in the organization and techniques to administer vaccines, including against coronavirus disease COVID-19, as well as the skills of providing emergency medical care in the event of an Adverse Event Following Immunization (with the certificate issuance) is a prerequisite. In order not to increase the burden on the personnel involved in routine vaccination of children, these points will operate in those facilities that serve the adult population and on the basis of vaccination points for adults. If necessary, on the basis of planning data at the regional level, additional vaccination points will be created (starting from the second stage of vaccination campaign), when a

Scenario	Implementation process
	large number of people are planned to be vaccinated. Health workers will carry out vaccination at vaccination points for all groups of the population who are referred to vaccination points. From the central warehouse, the vaccines against COVID-19 are transported to a warehouse at the regional level. From there, in a predetermined amount, they are transported to the primary healthcare facilities that provide immunization services to the population of Ukraine based on contract agreements established with the National Health Service of Ukraine, where the vaccination points for COVID-19 vaccination are set up.
Mobile vaccination teams (platform 2)	In order to ensure the vaccination among organized groups of the population with no or difficult access to healthcare facilities (vaccination points), mobile teams are formed in each region consisting of at least one doctor, two nurses and a driver who will be backed-up by one doctor and one nurse in case of force majeure. It is estimated that 572 mobile teams (23 per region on average) will be required to implement the vaccination campaign against COVID-19. It is assumed, that at stages 1 and 2, an average of 7 to 8 mobile teams will be needed to ensure the coverage in each region. Mobile teams will be formed in the HCFs of all forms of ownership or by individuals who have a license for medical practice and a valid agreement under the medical guarantee program with the National Health Service of Ukraine. The total number of vaccination points will depend on the size of the target group to be vaccinated on this platform. Each mobile team will be equipped with a complete PPE kit (each including a medical mask, disposable gloves, handrubs) in a quantity sufficient for the vaccination of up to 100 people per day, two cold boxes with a complete set of ice (cold) packs (2 sets of ice (cold) packs per cold box) for transportation and a vaccination session. The mobile will be equipped with first aid kit with a set of medicines and medical devices for the provision of urgent medical care, as well as first aid kits for emergency cases (10 cases) in accordance with the national and WHO guidelines, as well as visual materials with instructions for the differential diagnosis of anaphylaxis and loss of consciousness and provision of first aid for anaphylactic shock. An indicative list of medicines and medical products for the provision of urgent and emergency medical care at

Scenario	Implementation process
Centers for mass vaccination of the population (platform 3)	vaccination points was approved by the order of the Ministry of Health dated 02.02.2021 No. 165.
	It is mandatory to train mobile teams' staff in the organization and techniques to administer vaccines, including against coronavirus disease COVID-19, as well as the skills of providing emergency medical care in case of occurrence of an adverse event following immunization (with the certificate issuance).
	From the central warehouse, the vaccines against COVID-19 are transported to a warehouse at the regional level. From there, mobile teams will take a predetermined number of doses for outreach vaccine sessions. The staff of mobile teams will deliver outreach vaccination services to those eligible for COVID-19 vaccination (at the organized population setting, temporary vaccination points etc.)
	In order to accelerate the rate of vaccination of the general population (with priority for persons over 60 years) against coronavirus disease COVID-19 during mass vaccination, with the support of local executive authorities or local governments, vaccination centers are being established. The algorithm for creating such centers was approved at the VPDs TF meeting on May 14, 2021.
	Authorities ensure the provision of vaccination sites, technical equipment for temporary storage of vaccines for up to 24 hours (cold boxes, refrigerators, etc.), conditions for data management and information support, calculation of staffing needs, both medical and administrative. Undergraduate medical students (students in their last year of studies), interns, etc. can be involved in the work of the centers. The centers are equipped with the necessary equipment that is provided according to the requirements for a mobile team as a temporary vaccination point. Interaction at different levels is also important to facilitate the timely and equitable distribution and administration of COVID-19 vaccines. According to the international experience, the centers can be created on the basis of stationary premises (exhibition halls, concert venues, sports arenas, gyms and assembly halls of educational institutions, etc.) or to be a temporary "drive-through" type of stations that allow a person to receive the vaccination service without leaving their car. The estimated capacity of such centers will depend on the type of center created:

Scenario	Implementation process
	1. A stationary point on the basis of a stadium or concert venue (with a capacity to vaccinate 6,000 people per day) with an area of 1,700 - 2,000 m², with a minimum capacity to accommodate 15,000 people at a time. It is estimated that about 120 healthcare workers (10-40 doctors, 80 healthcare workers qualified to provide vaccinations, 25 registrars), 5 emergency teams and 80 non-medical staff (coordinators, IT, information support, etc.) will be involved. 2. A stationary point on the basis of private institutions (with a capacity to vaccinate 3,000 people per day), with an area of up to 1,200 m²; with a minimum capacity to accommodate 1,000 people at a time. It is estimated that about 65 healthcare workers (5-10 doctors, 40 healthcare workers qualified to provide vaccinations, 12 registrars), 2 emergency teams and 60 non-medical staff (coordinators, IT, information support, etc.) will be involved. 3. A stationary point on the basis of a school/other premises of such type (with a capacity to vaccinate 1,000 people per day) with an area of 300 - 400 m², and a minimum capacity to accommodate 300 people at a time. It is estimated that about 35 healthcare workers (5-10 doctors, 20 healthcare workers qualified to provide vaccinations, 10 registrars), 2 emergency teams and 15 non-medical staff (coordinators, IT, information support, etc.) will be involved. 4. A stationary point on the basis of other premises (with a capacity to vaccinate 250 - 300 people per day) with an area of 250 m² and minimum capacity to accommodate 100 - 150 people at a time. It is estimated that about 15 healthcare workers (1-5 doctors, 10 healthcare workers qualified to provide vaccinations, 3 registrars), 2 emergency care teams and 10 non-medical staff (coordinators, IT, information support, etc.) will be involved. 5. A mobile vaccination point of a "drive-through" type (with a capacity to vaccinate 200 - 250 people per day) with the area size of 900-1,125 m² with separate entry and exit and the division into 2 zones

Scenario	Implementation process
	– for vaccination and follow-up observation (during 30 minutes after vaccination). It is estimated that about 15 healthcare workers (2-4 doctors, 10 healthcare workers qualified to provide vaccinations, 3 registrars), 2 emergency teams and 20 non-medical staff (including coordinators, information, IT support, etc.) will be involved.

The process of setting up and equipping vaccination points (both permanent and temporary vaccination points, including vaccination sites where vaccination is carried out by mobile teams, as well as mass vaccination centers) should be conducted in accordance with the Regulations on the Organization and Conduction of Preventive Vaccination, approved by the order of the Ministry of Health of Ukraine of September 16, 2011 No. 595 (as amended by the order of the Ministry of Health of Ukraine of August 11, 2014 No. 551).

Based on the identified stages of the vaccination campaign and the assessment of the technical feasibility of their implementation, stage-specific macroplans have been developed and are recommended for use during realization of each of the vaccination stages. In the future, it is advisable to develop vaccination plans at the oblast (region) level, which will be based on macroplans and consider the specifics of vaccination of a separate population group.

I. Macro plan of stage 1 of a vaccination campaign against coronavirus disease COVID-19:

target groups (in the order of vaccination):

Target groups	Estimated number (of people)
All staff of mobile vaccination teams	2,500 ²⁷
All healthcare workers (doctors, middle and junior medical personnel) who work in the HCFs that provide inpatient care for patients with coronavirus disease COVID-19	132,825 ²⁸ (+3% administrative and technical staff)
All laboratory staff performing laboratory tests for coronavirus disease COVID-19	2,749 ²⁹ (+5% administrative and technical staff)

²⁷ Estimated data

²⁸ Statistical data of the National Health Service of Ukraine (<https://nszu.gov.ua/e-data/dashboard/likarni-covid> (as of December 15, 2020))

²⁹ Statistical data of SI “Public Health Center of the Ministry of Health of Ukraine”

All emergency medical workers, including drivers	43,942 ³⁰
Persons living in specialized facilities (orphanages, nursing homes)	87,560 ³¹
The staff of specialized facilities (orphanages, nursing homes)	48,793 ³²
Military personnel (including the Armed Forces of Ukraine and the National Guard of Ukraine) participating in the Joint Force Operation in the East of Ukraine and involved in the next scheduled rotation to the Joint Forces Operation	75,000 ³³
Total	397,491 people <1% of the total population of Ukraine

method of vaccination:

Method of vaccination	Location
175 mobile teams (average 7 per region). The teams consist of 1 doctor, 2 nurses and 1 driver (1 doctor and 1 nurse in reserve). One registrar will be identified in advance from each organized team vaccinated by a mobile team. This will ensure that all necessary site activities are carried out before the start of vaccination. Estimated capacity – 100 vaccinations per day. Vaccination rounds lasting 20 days per month (1 round – 1 dose of vaccine).	At the site of organized groups of people eligible for vaccination (for all priority groups that are part of the first stage of vaccination). For the on-site vaccination of organized groups, two rooms should be set up: one room for vaccination and one room for the follow-up medical observation during 30 minutes after vaccination. At the beginning of the corresponding phase of vaccination, each mobile team based on the results of microplanning will have a daily schedule of vaccine sessions for the entire round with the addresses of vaccination sites, target group size and the list of names. The final number of people eligible for vaccination per organized setting will be checked with coordinators and responsible

³⁰ Statistical data of the Center for Medical Statistics of the Ministry of Health of Ukraine. Form N-22 Report of the ambulance station as of 10.03.2020

³¹ Statistical data of SI “Public Health Center of the Ministry of Health of Ukraine”

³² Statistical data of SI “Public Health Center of the Ministry of Health of Ukraine”

³³ Estimated data

	persons appointed for that setting to exclude those who due to illness or other circumstances (family, refusal to vaccinate, etc.) could not attend the vaccination. At the end of the vaccination round, an additional on-site session may be organized for all persons who missed the vaccination dose for the above reasons (depending on the total number) on a certain day in a designated facility.
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II. Macro plan of stage 2 of a vaccination campaign against coronavirus disease COVID-19:

target groups (in the identified order of vaccination):

Target groups	Estimated number (of people)
All primary healthcare workers	62,544 ³⁴ (+3% administrative and technical staff)
All employees of other HCFs who do not provide inpatient care for patients with coronavirus COVID-19, including other departments and ministries	426,273 ³⁵ (+3% administrative staff)
All workers of public health system	23,668 ³⁶ (+3% administrative and technical staff)
People over the age of 80	1,873,818 ³⁷
Social workers and the other staff working in social sphere	156,871 ³⁸
Total	2,543,174 people 6.1% of the total population of Ukraine

method of vaccination:

Method of vaccination	Location
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³⁴ Statistical data of SI “Public Health Center of the Ministry of Health of Ukraine”

³⁵ Statistical data of SI “Public Health Center of the Ministry of Health of Ukraine”

³⁶ Statistical data of SI “Public Health Center of the Ministry of Health of Ukraine”

³⁷ Statistical data of the State Statistics Service of Ukraine (as of 01.01.2020)

³⁸ Statistical data of SI “Public Health Center of the Ministry of Health of Ukraine”

Platform 1: 1,650 vaccination points (average 66 per region). The points staff consist of 1 doctor, 2 nurses and 1 registrar. Estimated capacity – 30 vaccinations per day (15 minutes per person). Vaccination rounds lasting 25 days per month (1 round – 1 dose of vaccine).	At the level of primary healthcare facilities (for primary healthcare workers, people over 80 years old)
Platform 2: 181 mobile teams (average 7 per region) The teams' staff consist of 1 doctor, 2 nurses and 1 driver (1 doctor and 1 nurse in reserve). One registrar will be identified in advance from each organized team vaccinated by a mobile team. This will ensure that all necessary site activities are carried out before the start of vaccination. Estimated capacity – 100 vaccinations per day Vaccination rounds lasting 20 days per month (1 round – 1 dose of vaccine)	At the site of organized groups of people eligible for vaccination (for the employees of other HCFs, (including HCFs of other agencies and ministries), employees of public health system, social workers and the other staff working in the social sphere). For the on-site vaccination of organized groups, two rooms should be set up: one room for vaccination and one room for the follow-up medical observation during 30 minutes after vaccination. At the beginning of the corresponding phase of vaccination, each mobile team based on the results of microplanning will have a daily schedule of vaccine sessions for the entire round with the addresses of vaccination sites, target group size and the list of names. The final number of people eligible for vaccination per organized setting will be checked with coordinators and responsible persons appointed for that setting to exclude those who due to illness or other circumstances (family, refusal to vaccinate, etc.) could not attend the vaccination. At the end of the vaccination round, an additional on-site session may be organized for all persons who missed the vaccination dose for the above reasons (depending on the total number) on a certain day in a designated facility.

III. Macro plan of stage 3 of a vaccination campaign against coronavirus disease COVID-19:
target groups (in the identified order of vaccination):

Target groups	Estimated number (of people)
People aged 75 to 79 years	1,225,016 ³⁹
People aged 70 to 74 years	1,661,698 ⁴⁰
People aged 65 to 69 years	2,385,967 ⁴¹
law enforcement and intelligence bodies, state bodies of special purpose with law enforcement functions, civil defence forces and other bodies entrusted by the Constitution and laws of Ukraine with functions to ensure the national security of Ukraine; the Armed Forces of Ukraine, as well as other military formations, law enforcement and intelligence bodies, special purpose bodies with law enforcement functions formed in accordance with the laws of Ukraine, entrusted by the Constitution and laws of Ukraine with functions to ensure state defence, including the Ministry of Defence, State Special Transport Service, Ministry of Internal Affairs of Ukraine, National Guard of Ukraine, National Police, State Border Guard Service of Ukraine, State Migration Service of Ukraine, State Emergency Service of Ukraine, Security Service of Ukraine, Department of State Protection of Ukraine, State Service of Special Communications and Information Protection of Ukraine, Office of National Security and Defence Councils of Ukraine, intelligence bodies of Ukraine, prosecutor's offices, National Anti-Corruption Bureau of Ukraine, state border guards, revenue and collection bodies, penitentiary facilities, pre-trial detention centers, bodies of state financial control, fisheries protection, state forest protection, other bodies performing law enforcement or law application functions, the central executive body that ensures the formation and implementation of state military-industrial policy, other state bodies and local governments which functions include ensuring national security in cooperation with the bodies of the	National Police of Ukraine: 81,000 State Emergency Service of Ukraine: 35,000 National Guard of Ukraine: 31,000 Security Service of Ukraine: 25,991 State Border Guard Service of Ukraine: 37,000 Personnel of the Ministry of Internal Affairs, the National Police, the State Migration Service of Ukraine, the National Guard of Ukraine, who are serviced in healthcare facilities of the Ministry of Internal Affairs: 23,300 Armed Forces of Ukraine: 195,000 State Service of Special Communications and Information Protection – 1,471, prosecutor's offices – 4,308, personnel of the fuel and energy complex – 75 796, personnel of sanatorium-resort facilities – 1,175, personnel of the state protection service of the nature reserve fund – 3,437, sea and river transport – 3,166, postal service – 5,535, air

³⁹ Statistical data of the State Statistics Service of Ukraine (as of 01.01.2020)

⁴⁰ Statistical data of the State Statistics Service of Ukraine (as of 01.01.2020)

⁴¹ Statistical data of the State Statistics Service of Ukraine (as of 01.01.2020)

security and defence sector; other state authorities and local governments ⁴²	transport – 17,882, road management – 535, customs – 5,898, SC "Ukroboronprom" (Ukrainian Defence Industry) – 1,141, the State Bureau of Investigation – 53, representatives of the diplomatic corps – 1,735, the Ministry of Defence of Ukraine – 1,845, the National Agency for Prevention of Corruption – 200, State Food and Consumer Services – 2,990, staff of executive, judicial and legislative bodies – 25,350 and others.
Teachers, educators and the other staff working in the sphere of education	737,705 ⁴³
Total	7,789,380 people 17.1% of the total population of Ukraine

method of vaccination:

Method of vaccination	Location
Platform 1: 3,850 vaccination points (average 154 per region). The points' staff consist of 1 doctor, 2 nurses and 1 registrar. Estimated capacity – 30 vaccinations per day (15 minutes per person). Vaccination rounds lasting 25 days per month (1 round - 1 dose of vaccine).	At the level of primary healthcare facilities (for people aged 75 to 79, 70 to 74, and 65 to 69)
Platform 2: 212 mobile teams (average 8 per region). The teams' staff consist of 1 doctor, 2 nurses and 1 driver (1 doctor and 1 nurse in reserve). One registrar will be appointed in advance from each organized team that a	At the site of organized groups of people eligible for vaccination (for the personnel of critical state security structures, teachers, educators and other people working in the sphere of education).

⁴² Statistical data of SI "Public Health Center of the Ministry of Health of Ukraine"

⁴³ Statistical data of the State Statistics Service of Ukraine for 2019-2020

mobile team will vaccinate. This will ensure the organization of all necessary pre-vaccination activities at the site. Estimated capacity – 120 vaccinations per day. Vaccination rounds lasting 25 days per month (1 round – 1 dose of vaccine).	For the on-site vaccination of organized groups, two rooms should be set up: one room for vaccination and one room for the follow-up medical observation during 30 minutes after vaccination. At the beginning of the corresponding phase of vaccination, each mobile team based on the results of microplanning will have a daily schedule of vaccine sessions for the entire round with the addresses of vaccination sites, target group size and the list of names. The final number of people eligible for vaccination per organized setting will be checked with coordinators and responsible persons appointed for that setting to exclude those who due to illness or other circumstances (family, refusal to vaccinate, etc.) could not attend the vaccination. At the end of the vaccination round, an additional on-site session may be organized for all persons who missed the vaccination dose for the above reasons (depending on the total number) on a certain day in a designated facility.
Platform 3: Centers for mass vaccination of the population	In order to accelerate the rate of vaccination of the general population (with the priority for persons over 60 years) against coronavirus disease COVID-19 during mass vaccination with the support of local executive authorities or local governments, vaccination centers are being established. The algorithm for creating such centers was approved at the VPDs TF meeting on May 14, 2021. Authorities ensure the provision of vaccination sites, technical equipment for temporary storage of vaccines for up to 24 hours (cold boxes, refrigerators, etc.), conditions for data management and information support, calculation of staffing needs – both medical and administrative. Undergraduate medical students (students in their last year of studies), interns, etc. can be involved in the work of the centers.

	The centers are equipped with the necessary equipment that is provided according to the requirements for a mobile team as a temporary vaccination point. Interaction at different levels is also important to facilitate the timely and equitable distribution and administration of COVID-19 vaccines. According to the international experience, the centers can be created on the basis of stationary premises (exhibition halls, concert venues, sports arenas, gyms and assembly halls of educational institutions, etc.) or to be a temporary "drive-through" type of stations that allow a person to receive the vaccination service without leaving their car. The estimated capacity of such centers will depend on the type of center created: 1. A stationary point on the basis of a stadium or concert venue (with a capacity to vaccinate 6,000 people per day) with an area size of 1,700 - 2,000 m², and a minimum capacity to accommodate 15,000 people at a time. It is estimated that about 120 healthcare workers (10-40 doctors, 80 healthcare workers qualified to provide vaccinations, 25 registrars), 5 emergency teams and 80 non-medical staff (coordinators, IT, information support, etc.) will be involved. 2. A stationary point on the basis of private institutions (with a capacity to vaccinate 3,000 people per day), with an area size of up to 1,200 m² and a minimum capacity to accommodate 1,000 people at a time. It is estimated that about 65 healthcare workers (5-10 doctors, 40 healthcare workers qualified to provide vaccinations, 12 registrars), 2 emergency teams and 60 non-medical staff (coordinators, IT, information support, etc.) will be involved.
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	3. A stationary point on the basis of a school/other premises of this type (with a capacity to vaccinate 1,000 people per day) with an area size of 300 - 400 m² and a minimum capacity to accommodate 300 people at a time. It is estimated that about 35 healthcare workers (5-10 doctors, 20 healthcare workers qualified to provide vaccinations, 10 registrars), 2 emergency teams and 15 non-medical staff (coordinators, IT, information support, etc.) will be involved. 4. A stationary point on the basis of another room (with a capacity to vaccinate 250 - 300 people per day) with an area size of 250 m² and minimum capacity to accommodate 100 - 150 people at a time. It is estimated that about 15 healthcare workers (1-5 doctors, 10 healthcare workers qualified to provide vaccinations, 3 registrars), 2 emergency teams and 10 non-medical staff (coordinators, IT, information support, etc.) will be involved. 5. Mobile vaccination point of a "drive-through" type (with a capacity to vaccinate 200 - 250 people per day), the area size of 900 - 1,125 m² with separate entry and exit and the division into 2 zones – for vaccination and follow-up observation (during 30 minutes after vaccination). About 15 healthcare workers (2-4 doctors, 10 healthcare workers qualified to provide vaccinations, 3 registrars), 2 emergency teams and 20 non-medical staff (including coordinators, information, IT support, etc.) will be involved.
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IV. Macro plan of stage 4 of a vaccination campaign against coronavirus disease COVID-19:
target groups (in the identified order of vaccination):

Target groups	Estimated number (of people)
People aged 60 to 64 years	2,831,695 ⁴⁴
Adults (aged 18 to 59 years) with comorbidities at risk for complications and death due to coronavirus disease COVID-19	6,370,378 ⁴⁵
Other categories of the population and professional groups at risk for COVID-19 infection	1,716,796 ⁴⁶
Prison and detention center population, workers in prisons and detention centers ⁴⁷	Prison and detention center population: 52 000 Personnel of penitentiary facilities of the State Penitentiary Service of Ukraine and the personnel of the State Institution "Probation Center": 26 400
Total	10,997,269 people 26% of the total population of Ukraine

method of vaccination:

Method of vaccination	Location
Platform 1: 4,250 vaccination points (average 170 per region). The teams' staff consist of 1 doctor, 2 nurses and 1 registrar. Estimated capacity – 30 vaccinations per day (15 minutes per person). Vaccination rounds lasting 25 days per month (1 round – 1 dose of vaccine).	At the level of primary healthcare facilities (for people aged 60 to 64 and people aged 18 to 59 who have comorbidities)
Platform 2: 572 mobile teams (average 23 per region). The teams' staff consist of 1 doctor, 2 nurses and 1 driver (1 doctor and 1 nurse in reserve). One registrar will be appointed in advance from each organized team that a	At the site of organized groups of people eligible for vaccination (prison and detention center population, and workers in prisons and detention centers). For the on-site vaccination of organized groups, two rooms should be set up: one room

⁴⁴ Statistical data of the State Statistics Service of Ukraine (as of 01.01.2020)

⁴⁵ Statistical data of SI Public Health Center of the Ministry of Health of Ukraine»

⁴⁶ Estimated data

⁴⁷ Statistical data of SI “Public Health Center of the Ministry of Health of Ukraine”

mobile team will vaccinate. This will ensure the organization of all necessary pre-vaccination activities at the site. Estimated capacity – 120 vaccinations per day. Vaccination rounds lasting 25 days per month (1 round – 1 dose of vaccine).	for vaccination and one room for the follow-up medical observation during 30 minutes after vaccination. At the beginning of the corresponding phase of vaccination, each mobile team based on the results of microplanning will have a daily schedule of vaccine sessions for the entire round with the addresses of vaccination sites, target group size and the list of names. The final number of people eligible for vaccination per organized setting will be checked with coordinators and responsible persons appointed for that setting to exclude those who due to illness or other circumstances (family, refusal to vaccinate, etc.) could not attend the vaccination. At the end of the vaccination round, an additional on-site session may be organized for all persons who missed the vaccination dose for the above reasons (depending on the total number) on a certain day in a designated facility.
Platform 3: Centers for mass vaccination of the population	In order to accelerate the rate of vaccination of the general population (with priority for persons over 60 years) against coronavirus disease COVID-19 during mass vaccination with the support of local executive authorities or local governments, vaccination centers are being established. The algorithm for creating such centers was approved at the VPDs TF meeting on May 14, 2021. Authorities ensure the provision of vaccination sites, technical equipment for temporary storage of vaccines for up to 24 hours (cold boxes, refrigerators, etc.), conditions for data management and information support, calculation of staffing needs – both medical and administrative. Undergraduate medical students (students in their last year of studies), interns, etc. can be involved in the work of the centers. The centers are equipped with the necessary equipment that is provided according to the requirements for a mobile team as a

	temporary vaccination point. Interaction at different levels is also important to facilitate the timely and equitable distribution and administration of COVID-19 vaccines. According to the international experience, the centers can be created on the basis of stationary premises (exhibition halls, concert venues, sports arenas, gyms and assembly halls of educational institutions, etc.) or to be a temporary "drive-through" type of stations that allow a person to receive the vaccination service without leaving their car. The estimated capacity of such centers will depend on the type of center created: 1. A stationary point on the basis of a stadium or concert venue (with a capacity to vaccinate 6,000 people per day) with an area size of 1,700 - 2,000 m², with a minimum capacity to accommodate 15,000 people at a time. It is estimated that about 120 healthcare workers (10-40 doctors, 80 healthcare workers qualified to provide vaccinations, 25 registrars), 5 emergency teams and 80 non-medical staff (coordinators, IT, information support, etc.) will be involved. 2. A stationary point on the basis of private institutions (with a capacity to vaccinate 3,000 people per day), with an area size of up to 1,200 m²; with a minimum capacity to accommodate 1,000 people at a time. About 65 healthcare workers (5-10 doctors, 40 healthcare workers qualified to provide vaccinations, 12 registrars), 2 emergency teams and 60 non-medical staff (coordinators, IT, information support, etc.) will be involved. 3. A stationary point on the basis of a school/other premises of this type (with a capacity to vaccinate 1,000 people per day) with an area size of
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	300 - 400 m², with a minimum capacity to accommodate 300 people at a time. It is estimated that about 35 healthcare workers (5-10 doctors, 20 healthcare workers qualified to provide vaccinations, 10 registrars), 2 emergency teams and 15 non-medical staff (coordinators, IT, information support, etc.) will be involved. 4. A stationary point on the basis of another room (with a capacity to vaccinate 250 - 300 people per day) with an area size of 250 m², the minimum capacity to accommodate 100 - 150 people at a time. It is estimated that about 15 healthcare workers (1-5 doctors, 10 healthcare workers qualified to provide vaccinations, 3 registrars), 2 brigades will be involved. emergency care and 10 non-medical staff (coordinators, IT, information support, etc.). 5. Mobile vaccination point of a "drive-through" type (with a capacity to vaccinate 200 - 250 people per day), the area size of 900 - 1,125 m² with separate entry and exit and the division into 2 zones – for vaccination and follow-up observation (during 30 minutes after vaccination). About 15 healthcare workers (2-4 doctors, 10 healthcare workers qualified to provide vaccinations, 3 registrars), 2 emergency teams and 20 non-medical staff (including coordinators, information, IT support, etc.) will be involved.
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**ENSURING ACCESS TO VACCINATION AGAINST COVID-19 OF
CITIZENS OF UKRAINE RESIDING IN THE TEMPORARILY
OCCUPIED TERRITORIES OF UKRAINE**

Citizens of Ukraine residing in the temporarily occupied territories of Donetsk and Luhansk regions, as well as in the Autonomous Republic of Crimea and city of Sevastopol, will be provided with access to safe and effective vaccines against coronavirus disease COVID-19.

Given the constant threat of military aggression from the side of Russian occupation forces, there are very high risks to the safety of life and health of both the medical personnel conducting COVID-19 vaccinations and those citizens of Ukraine who wish to get vaccinated against coronavirus disease COVID-19.

The Ministry of Health of Ukraine and the SI "Public Health Center of the Ministry of Health of Ukraine" in cooperation with the Ministry of Reintegration of the Temporarily Occupied Territories of Ukraine are developing a detailed action plan for organizing access to vaccination against coronavirus disease COVID-19 for Ukrainian citizens currently residing in the temporarily occupied territories of Ukraine.

Considering the possibility that the Russia-backed armed groups may hinder the access of Ukrainian citizens to vaccination, it is planned that the vaccination points will be set up in the government-controlled territory of Ukraine.

SYSTEM OF SUPPLY AND STORAGE OF VACCINES AGAINST CORONAVIRUS DISEASE COVID-19 IN UKRAINE

Depending on the source of a vaccine supply, two mechanisms for vaccines supply and delivery are used parallelly in the country:

- 1) for vaccines procured using the state budget funds of Ukraine
- 2) for vaccines delivered to Ukraine as humanitarian aid.

Logistics of vaccines procured using state budget funds of Ukraine

By the Resolution of the Cabinet of Ministers of 13.01.2021 No. 23 "Issues of Financing the Implementation of Measures Related to Vaccination of the Population against Acute Respiratory Disease COVID-19 caused by Coronavirus SARS-CoV-2", the company Crown Agents was identified as a specialized organization procuring vaccines against acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2. The capacities of the State Enterprise "Ukrmedpostach" of the Ministry of Health of Ukraine" will be used at the national level for storage and delivery of vaccines procured with state budget funds based on the mandate agreement of the Ministry of Health of Ukraine.

Once vaccines are at the airport premises, the State Enterprise “Ukrmedpostach” of the Ministry of Health of Ukraine” provides customs clearance and delivery of vaccines to the national warehouse.

As for the vaccines requiring a "cold chain" with storage conditions from +2°C to +8°C, the existing capacities of SE “Ukrmedpostach” of the Ministry of Health of Ukraine” (hereinafter – SE “Ukrmedpostach”) allow to accommodate up to 15,000,000 vaccine doses in a warehouse at the national level, store them there and ensure their further delivery to the regions.

For the vaccines with a "cold chain" and storage temperature requirement of -20°C, the existing capacity of SE “Ukrmedpostach” allows to accommodate up to 200,000 vaccine doses in the warehouse at the national level and store them there for further delivery to the regions.

For the vaccines with a "cold chain" and storage temperature requirements -70°C for their storage, the existing capacity of SE “Ukrmedpostach” allows to receive up to 234,000 vaccine doses at the national level warehouse and store them there for further delivery to the regions.

At the regional level, vaccine distribution is carried out in accordance with the orders of the Ministry of Health of Ukraine. SE “Ukrmedpostach” provides vaccine transportation by specialized transport (refrigerator trucks) to 25 designated warehouses of the subnational (regional) level. Vaccines are distributed upon admission to the central warehouse. The Ministry of Health of Ukraine prepares the orders on the distribution of the entire received batch of vaccines and brings them to the notice of the SE “Ukrmedpostach”. The distribution is based on technical calculations of the regions verified by the Ministry of Health of Ukraine in accordance with the defined priority target groups for vaccination, the confirmed number of population eligible for immunization and the possibility to use vaccines before their expiration date. Under national law, such distribution shall be completed no later than one month after the official receipt of the relevant batch of vaccines, unless otherwise specified by the manufacturer.

After receiving vaccines from the national level and depending on their transportation and storage temperature requirements, regional vaccine storage points either distribute the entire received supply of vaccines immediately (according to the regional distribution orders prepared by the Health Departments of Regional (oblast) and Kyiv City State Administrations with the indication of

vaccines quantity allocated for each primary healthcare facility involved in the vaccination process), or store them and periodically distribute as needed (at least once a month).

25 designated oblast storage points are directly subordinated to the Regional Health Departments, thus ensuring the public sector responsibility for vaccines use.

From the regional level, vaccines are delivered to vaccination points by vehicles, which in most cases belong to healthcare facilities. Delivery of vaccines to vaccination points is carried out directly by HCFs, where the vaccination points are set up (if necessary or at least once a month).

Healthcare facilities that provide primary healthcare services have the capacity to store vaccines at a temperature of +2°C - +8°C for up to one month. The HCFs are directly subordinated to the Regional Health Departments which ensures the continuity of responsibility for receiving and using vaccines during their transfer from the regional to the primary healthcare level.

Cold boxes are used to transport vaccines from the regional level to a particular vaccination point. The decision on the use of a type of cooling elements depends on the duration of transportation and the requirements set out in the current relevant regulatory framework of the Ministry of Health of Ukraine.

Logistics of vaccines received by Ukraine as humanitarian aid

All vaccines arriving in Ukraine under the global COVAX initiative have the status of humanitarian aid, which is determined by the relevant orders of the Ministry of Social Policy of Ukraine. According to the order of the Ministry of Health of Ukraine dated 03.02.2021 №170 “Some Issues on Humanitarian Aid and Charitable Donation to Help Fight the Spread of Acute Respiratory Disease COVID-19 Caused by Coronavirus SARS-Cov-2”, the Ministry of Health of Ukraine authorized the SI “Public Health Center of the Ministry of Health of Ukraine” to receive vaccines, health products and consumables required for vaccinations (syringes, safe disposal boxes, solvent, etc.) obtained through the COVAX AMC mechanism.

In order to ensure proper storage and transportation conditions in accordance with the requirements of the vaccine manufacturer, a private logistics company is involved in the process of handling the vaccines which arrive in

Ukraine in the form of humanitarian aid. “Farmasoft LLC” was selected as a result of open tenders conducted by the USAID project “Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed)” (for vaccines with storage temperature requirement from -60°C to -80°C) and SI “Public Health Center of the MoH of Ukraine” (for vaccines with storage temperature requirement $+2^{\circ}\text{C}$ до $+8^{\circ}\text{C}$) at the request of the Ministry of Health of Ukraine. The logistics practices of this private company meets GDP standards (Good distribution practice). The logistics company “Farmasoft LLC” is certified according to the ISO 9001: 2015 standard.

Once the vaccines arrive at the airport, “Farmasoft LLC” provides customs clearance and delivery of vaccines to the national warehouse.

For the vaccines with a "cold chain" and storage temperature requirement from $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$, the existing capacity of “Farmasoft LLC” allows to accept an estimated 8,000,000 doses of vaccines in the warehouse at the national level, store and transport them to the regions.

As for the vaccines with a "cold chain" and storage temperature requirement from -70°C , the existing capacity of “Farmasoft LLC” allows to simultaneously accept up to 600,000 doses of vaccines in the warehouse at the national level, store and transport them to the regions.

At the regional level, vaccine distribution is carried out in accordance with the letters of the Ministry of Health of Ukraine on vaccines distribution. “Farmasoft LLC” provides vaccine delivery by specialized transport (refrigerated trucks) to 25 determined warehouses of the subnational (regional) level. Vaccines are distributed upon admission to the central warehouse. According to the distribution letters of the Ministry of Health of Ukraine, SI “Public Health Center of the Ministry of Health of Ukraine” prepares distribution letters and delivery schedules for each received batch of vaccines and submits these documents to “Farmasoft LLC”. The distribution is based on technical calculations made by regions and verified by the Ministry of Health of Ukraine in accordance with the defined priority target groups for vaccination, the confirmed number of the population eligible for immunization and the possibility to use vaccines before their expiration date.

After receiving vaccines from the national level and depending on transportation and storage temperature requirements, regional vaccine storage points either distribute the entire received supply of vaccines immediately

(according to the regional distribution orders prepared by the Health Departments of Regional (oblast) and Kyiv City State Administrations with the indication of vaccines quantity allocated for each primary healthcare facility involved in the vaccination process), or store them and periodically distribute as needed (at least once a month).

25 designated oblast storage points are directly subordinated to the Regional Health Departments, thus ensuring the public sector responsibility for vaccine use.

From the regional level, vaccines are delivered to vaccination points by vehicles, which in most cases belong to healthcare facilities. The delivery of vaccines to vaccination points is carried out directly by HCFs where the vaccination points are set up (if necessary or at least once a month).

Healthcare facilities that provide primary healthcare services have the capacity to store vaccines at a temperature of $+2^{\circ}\text{C}$ - $+8^{\circ}\text{C}$ for up to one month. The HCFs are directly subordinated to the Regional Health Departments which ensures the continuity of responsibility for receiving and using vaccines during their transfer from the regional to the primary healthcare level.

Cold boxes are used to transport vaccines from the regional level to a particular vaccination point. The decision on the use of the type of cooling elements depends on the duration of transportation and the requirements set out in the current relevant regulatory framework of the Ministry of Health of Ukraine.

Thus, for vaccines storage, distribution and logistics, Ukraine uses the existing capacities of public and private sectors.

The system of supply and storage of vaccines in Ukraine has the following levels:

- 1) national level – one point of storage and supply – the SE “Ukrmedpostach” of the Ministry of Health of Ukraine” (for state-funded vaccines) and “Farmasoft LLC” (vaccines delivered to Ukraine as humanitarian aid), capable of receiving vaccines at the national airport, carry out customs clearance and store the necessary number of vaccines during 6 months at a range of required temperatures and provide their transportation to the regional level.

- 2) regional (oblast) level – 25 storage points capable of storing vaccines for 3 months at a temperature of $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ and during 1 month at a

temperature regime from -60°C to -80°C providing the constant delivery of dry ice in accordance with the manufacture requirements. After receiving vaccines from the national level, the regional vaccine storage points either distribute the entire received supply of vaccines immediately (according to the regional distribution orders prepared by the Health Departments of Regional (oblast) and Kyiv City State Administrations with the indication of vaccines quantity allocated for each primary healthcare facility involved in the vaccination process), or store them and periodically distribute as needed (at least once a month).

3) the lowest level of distribution – includes 1,335 healthcare facilities of communal property that carry out vaccinations.

Centers providing primary healthcare services (hereinafter – Primary Healthcare Centers (PHCCs) receive vaccines from the regional level independently. From the regional level, vaccines are delivered to vaccination points by vehicles, which in most cases belong to healthcare facilities. The delivery of vaccines to vaccination points is carried out directly by HCFs where the vaccination points are set up (if necessary or at least once a month).

Healthcare facilities have the capacity to store vaccines at a temperature of $+2^{\circ}\text{C}$ - $+8^{\circ}\text{C}$ for up to one month. The HCFs are directly subordinated to the Regional Health Departments which ensures the continuity of responsibility for receiving and using vaccines during their transfer from the regional to the primary healthcare level.

Cold boxes are used to transport vaccines from the regional level to a particular vaccination point. The decision on the use of the type of cooling elements depends on the duration of transportation and the requirements set out in the current relevant regulatory framework of the Ministry of Health of Ukraine

4) 5,245 permanent vaccination points and 3,110 vaccination points conducting vaccination against coronavirus disease COVID-19. Vaccination points can provide vaccine storage at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ for 1 month and for 5 days after thawing the vaccine, with storage temperature requirement from -60°C to -80°C .

According to the Assessment of Effective Vaccine Management conducted with WHO and UNICEF support at the end of 2018, and based on preliminary inventory data carried out by the Ministry of Health of Ukraine and SI “Public Health Center of the Ministry of Health of Ukraine” in September-November

2020, given the scale of the implementation of COVID-19 coronavirus vaccination campaign, there is a need to properly provide the administrative territories of the country including vaccination points and mobile vaccination teams with appropriate refrigeration and additional equipment to ensure compliance with required "cold chain" conditions at all levels (thermal bags, temperature loggers, etc.). In the future, it is advisable to redistribute an additional equipment procured using state budget funds, donor assistance, as well as received as humanitarian/charitable aid based on the needs of routine immunization programs.

In order to properly assess the potential of the existing equipment of the "cold chain", and implement the process of forming applications for both the supply of additional refrigeration and auxiliary equipment and the replacement/renewal of the existing, in the Q4 2020, the Public Health Center of the Ministry of Health of Ukraine carried out an inventory of existing refrigeration equipment in the regions by analyzing the information from Regional Health Departments regarding the state of available refrigeration equipment used for the storage of immunobiological medical drugs in healthcare facilities at different levels of the "cold chain".

Also, Public Health Center, together with UNICEF, conducted an assessment using the Sizing Tool, a tool for determining the size and operation of the "cold chain". This tool makes it possible to obtain and evaluate data on the planned and additional immunization ("cold chain" capacity), costs incurred in the course of transportation from the initial (national) to the lower level of distribution (vaccination points), entry requirements for immunization per recipient (vaccine, solvent, injection tool, etc.), the amount of waste generated and the cost of its disposal, a general idea of the analysis of distribution routes, etc.

When making calculations, the tool takes into account four scenarios depending on the used vaccine:

- 1) Scenario 1 – injectable vaccine in syringes, with storage temperature requirement from +2°C to +8°C
- 2) Scenario 2 – vaccine in vials with a solvent, with storage temperature requirement from +2°C to +8°C
- 3) Scenario 3 – vaccine in vials, with storage temperature requirement -20°C
- 4) Scenario 4 – vaccine in vials, with storage temperature requirement -60°C.

The conducted analysis made it possible to determine the useful volumes of refrigeration equipment needed to ensure routine vaccination at both national

and regional levels and determine an additional number of such volumes that will be used during the vaccination campaign against coronavirus COVID-19, as well as take into account the data obtained during the upgrade of obsolete refrigeration equipment.

UNICEF provides ongoing expert and technical assistance to the Ministry of Health and partners in the context of nationwide inventory of equipment required to support “cold chain”, including assistance in developing a National Vaccine Refrigeration Equipment Procurement Plan for vaccine storage in accordance with the needs of various levels and requirements specified below.

Main requirements for the infrastructure, cold chain and temperature monitoring for vaccines storage and transportation in Ukraine, recommended by UNICEF and WHO and approved by the Task Force on Emergency Response to Prevent the Spread of Vaccine-preventable Diseases:

General requirements for cold-chain (CCE) and temperature monitoring equipment:

- Prequalified specialized refrigeration/freezing equipment for storage of vaccines and immunobiological drugs, which also meets the following criteria:
 - ozone-safe refrigerants/technologies (in compliance with the Montreal Protocol);
 - protection from freezing: class A (+2°C to +8°C);
 - range of ambient operating temperature: (+5°C to +43°C);
 - additional functions (time to maintain cold regime in the absence of power, energy-saving power consumption, appropriate materials, insulation, the presence of a lid or door with a lock, shelves, baskets, a cable, connectors standards for power supplies, etc.)
- Availability of recommended kits of spare parts which are supplied with cold-chain equipment and stored in a dry warehouse of all levels to ensure a rapid response in the event of equipment failure.
- Availability of devices to protect refrigeration equipment from voltage drops, change/shift of phase, etc. – voltage stabilizers/regulators.
- Availability of temperature monitoring (TM):

prequalified remote temperature monitoring (RTM) – for national, regional (subregional) levels, and backup conventional thermometers;

prequalified 30-day temperature recorder (for the lowest level of distribution and vaccination points);

prequalified freezing indicators and temperature loggers (for vaccines transportation in cold boxes and thermal containers).

1. Basic requirements for infrastructure, cold chain and temperature monitoring (national level):

- Prequalified refrigeration/freezing equipment with double refrigeration capacity reservation to store vaccines at different temperatures: +2°C to +8°C, -20°C, -70°C (+/-10°C) and ensure proper operation and maintenance.
- Availability of prequalified remote temperature monitoring (RTM) in real time for 24 hours a day.
- Prequalified or certified calibrated backup conventional thermometers.
- Ensure an uninterrupted power supply for 24 hours a day: ensure the availability of backup generators of electric current directly connected to refrigeration equipment with automatic switching in the event of a power cutoff in the national network; uninterruptible power supplies to ensure the operation of temperature monitoring systems (UPS)
- Availability of security systems or round-the-clock security, ensuring the preservation of vaccines, automatic fire extinguishing systems operating 24/7.
- Availability of prequalified cold boxes and ice (cold) packs to ensure vaccines transportation to the regional (oblast) level with continuous RTM.
- Availability of specialized vehicles to transport vaccines to the oblast level with continuous RTM and positioning system in the GPS.
- Provide the necessary capacity of a dry warehouse to receive and store the tools for safe injections and solvents (if the storage temperature for the solvent differs from storage temperature required for vaccines).

2. Basic requirements for infrastructure, "cold chain" and temperature monitoring (oblast/regional level):

- Ensure the necessary capacities provided by prequalified refrigeration/freezing equipment with double reservation of refrigeration capacity for storage of vaccines under different temperatures: +2°C to +8°C, -20°C and ensure its proper functioning and maintenance.
- Ensure the availability of prequalified remote temperature monitoring (RTM) in real time for 24 hours a day.
- Provide the availability of prequalified or certified calibrated backup conventional thermometers.
- Ensure an uninterrupted power supply for 24 hours a day: provide the backup generators of electric current directly connected to refrigeration equipment with automatic switching in the event of a power cutoff in the national network; availability of UPS to ensure the operation of temperature monitoring systems
- Ensure the availability of security systems or round-the-clock security, ensuring the preservation of vaccines, automatic fire extinguishing systems operating 24/7.
- Provide the availability of prequalified cold boxes and ice (cold) packs to ensure transportation with temperature monitoring (temperature logger and freeze indicator).
- Provide the availability of specialized transport and personnel to ensure the transportation of vaccines with prequalified constant temperature monitoring and positioning system in the GPS.
- Provide the necessary capacity of a dry warehouse to receive and store the tools for safe injections and solvents (if the storage temperature for the solvent differs from storage temperature required for vaccines).

In there is a decision to create subregional warehouses, they have to meet the requirements set for the regional level.

3. Basic requirements for infrastructure, "cold chain" and temperature monitoring of the district level/level of the lowest distribution:

- Ensure the necessary capacities provided by prequalified refrigeration/freezing equipment for vaccines storage under different temperatures: +2°C to +8°C, -20°C.
- Availability of prequalified temperature monitoring – 30-day electronic temperature recorder (temperature logger).
- Prequalified or certified calibrated backup conventional thermometers.
- Ensure 24-hour uninterruptible power supply: the availability of backup generators of electric current connected directly to

refrigeration/freezing equipment or uninterruptible power supply (UPS).

- Ensure the availability of a separate protected room (preferably equipped with security system or with engaging security staff) to provide vaccines safety, the presence of fire extinguishers.
- Availability of prequalified cold boxes and ice (cold) packs to ensure transportation with temperature monitoring (temperature logger and freeze indicator).
- Availability of transport (preferably specialized) to ensure the delivery of vaccines from the district level to vaccination points.
- Provide the necessary capacities of dry storage (a room) ready to accommodate and store the tools to carry out safe injections and solvents (if the storage temperature of the solvent differs from the storage temperature of vaccines).

4. Basic requirements for infrastructure, "cold chain" and temperature monitoring at vaccination points:

- Availability of refrigerators with freezer compartment designed to store drugs/immunobiological drugs preferably to be prequalified (COVID-19 vaccines should be stored separately from other vaccines that require a storage temperature of +2°C to +8°C).
- Availability of prequalified temperature monitoring – 30-day electronic temperature recorder (temperature logger)
- Availability of prequalified or certified calibrated backup conventional thermometers.
- Ensure 24-hour uninterruptible power supply: the availability of backup generators of electric current connected directly to refrigeration/freezing equipment or uninterruptible power supply (UPS)
- Ensure the presence of separate protected premises (preferably equipped with a security system or security staff) to ensure vaccines safety, the presence of fire-extinguishing appliances.
- Availability of prequalified thermal containers and refrigeration elements to ensure vaccines transportation with temperature monitoring (temperature logger and freeze indicator).
- Ensure the necessary capacities for dry storage (a room) ready to accommodate and store the tools to carry out safe injections and solvents (if the storage temperature of the solvent differs from the storage temperature of vaccines).

Based on the results of the assessments conducted, the following areas have been identified as such that need additional attention and improvement to ensure the effective implementation of the process of mass vaccination in Ukraine:

- available equipment at the regional (oblast) and the lowest level of distribution practically does not allow to store vaccines requiring low storage temperatures (-20°C and -70°C). Respectively, it was recommended to store the main volume of these vaccines at the national level (for vaccines with storage temperature requirement ranging from -60°C to -80°C and involve a private company which has an appropriate capacity, and as for the vaccines requiring temperature regime of -20°C – to store them using the capacities of SE “Ukrmedpostach” of the Ministry of Health of Ukraine”);
- part of the existing "cold-chain equipment" at the regional and district levels needs to be updated and re-equipped;
- insufficient equipment for temperature monitoring at regional and district levels;
- the necessity for comprehensive additional training on such topics as: "cold chain" during transportation and storage (especially for the vaccines with the requirements for ultra-low temperatures), stock balance and vaccine supply management;
- the necessity for training on the disposing procedure of used syringes and needles, in order to minimize the risks for healthcare workers (occupational risks), as well as to strengthen the personnel knowledge on vaccines handling.

Additional procurement of syringes and safe disposal boxes in the volume required for vaccination is planned to be carried out with state budget funds, as well as with donor funds, in particular the USAID and World Bank projects funds, UNICEF, European Investment Bank, etc.

Sources of additional "cold chain" equipment for vaccines storage and transportation (refrigerators, cold boxes, loggers, etc.) are the following:

- 1) request for the supply of refrigeration, freezing and auxiliary equipment and remote temperature monitoring devices to COVAX Facility;
- 2) direct procurements from equipment manufacturers using the following sources of funding:
 - the state budget funds of Ukraine;

the funds of international donors and other structures, in particular, projects of the United States Agency for International Development (USAID), UNICEF; credit funds under the programs of the World Bank, the European Investment Bank, etc.;

other sources not prohibited by law.

The United States Agency for International Development (USAID) will cover the procurement (via UNICEF) of WHO prequalified "cold chain" equipment with passive cooling to meet the needs of vaccination points and ensure temperature monitoring in 1,034 PHCCs, other 2,066 vaccination points and 540 mobile teams and ensure safe transportation of vaccines. The list of equipment includes the procurement of the following items (approximate number): 5,643 cold boxes of various capacities, 8,100 thermal bags, 132,284 cooling elements (ice packs), 47,400 temperature monitoring devices, including 35,000 thermal indicators for freezing and 12,400 of 30-day temperature recorders (temperature loggers). In accordance with the need, refrigeration and freezing equipment, as well as temperature monitoring devices for PHCCs and vaccination points will be procured using credit/loan funds of the European Investment Bank.

It is also planned that with the financial assistance of the World Bank programs, the refrigeration and freezing equipment, as well as temperature monitoring devices for 200 PHCCs and 600 vaccination points will be procured through UNICEF. The mentioned equipment includes approximately: 400 horizontal type refrigerators with ice protection (with spare parts kits), 200 horizontal type freezers for storing vaccines and freezing of cold packs (with sets of spare parts), 600 combined refrigerators with freezer and ice protection (with spare parts kits), 1,800 units of 30-day electronic temperature recorders (temperature loggers), 600 units of uninterruptible power supply.

It is expected that the credit funds of the European Investment Bank will cover the procurement of refrigeration and freezing equipment, as well as the temperature monitoring devices for the PHCCs and vaccination points, in accordance with the needs that will still be topical after the procurement of CCE by other donors and that procured with state budget funds for the facilities at a low level of distribution (PHCCs) and vaccination points.

It is also preliminarily planned that the UNICEF funds will cover the procurement of refrigeration and freezing equipment, temperature monitoring

devices and other auxiliary equipment for vaccines storage for 24 oblast vaccines storage facilities, which will still be needed after the procurement of "cold chain" equipment for the oblast level through the COVAX mechanism, with consideration given to the needs identified by the conducted inventory.

LOGISTICS SCENARIOS FOR THE DELIVERY OF VACCINES WITH DIFFERENT STORAGE REQUIREMENTS TO VACCINATION SITES

For the vaccines requiring storage at temperatures ranging between +2°C and +8°C, it is advisable to follow the recommended general logistics scenario for the delivery of vaccines to vaccination sites:

Vaccination method	Logistics scenario for the delivery of vaccines requiring storage temperatures ranging between +2°C and +8°C
Platform 1 – vaccination points	The required doses of vaccines will be stored at the central level in compliance with the temperature regime ranging between +2°C and +8°C. Based on the distribution plan of vaccination needs carried out at the regional and local levels, the total supply of vaccines and the necessary equipment (syringes, safe disposal boxes, etc.) will be determined for each region for a certain period of time. The duration of time needed to cover the priority groups with vaccination at the regional and local levels will be determined by the number of vaccination points and their capability to maintain the continuity of the vaccination process. Considering the estimated need for vaccination, the number and capacity of vaccination points, the technical capacity at the regional level to store the vaccine, and the necessary equipment and other provision, vaccines will be moved from the central level to warehouses at the regional level. The delivery will comply with the temperature regime between +2°C and +8°C. Vaccines will be stored centrally at the regional level at the temperature range between +2°C and +8°C. The necessary equipment and supplies will be stored at the regional level in the appropriate conditions in the amount required for vaccination. The vaccines and the necessary equipment and supplies will be delivered to health facilities where vaccination points are organized from the warehouses at the regional level. The volumes of vaccines and the necessary equipment/medical products that will be delivered to the healthcare facilities where the vaccination points are organized, will be determined with consideration to the capacity of the points to carry out a continuous vaccination

	process over a certain period of time. At the HCF level, vaccines will be stored at +2°C to +8°C. Once the stock of vaccines at the HCF level is exhausted, the next supply of vaccines and the necessary equipment/medical products will be delivered from the regional level warehouses. All logistics cycles should be carried out according to the principle of ensuring the continuity of vaccination that is performed at the level of vaccination points so that it covers the representatives of priority groups with all the necessary doses of vaccinations in the quickest possible time
Platform 2 – mobile teams	The main stock of vaccines will be stored at the central level in compliance with the temperature regime between + 2 ° C and + 8 ° C. Based on the distribution plan of vaccination needs carried out at the regional and local levels, the total supply of vaccines and the necessary equipment (syringes, safe disposal boxes, etc.) will be determined for each region for a certain period of time. The period of time needed to cover the priority groups with vaccination at the regional and local levels will be determined by the number of mobile teams and their capacity to maintain the continuity of the vaccination process. Considering the estimated need for vaccination, the number and capacity of mobile teams, technical capacity at the regional level to store vaccines and the necessary equipment and supplies, vaccines will be delivered from the central level to warehouses at the regional level. The delivery will comply with the temperature regime between +2°C and +8°C. Vaccines will be stored centrally at the regional level at the recommended temperature range between +2°C and +8°C. The necessary equipment and supplies will be stored at the regional level in the appropriate conditions in the amount required for vaccination. According to a pre-arranged schedule, mobile teams will receive vaccines and the necessary equipment/medical products at the regional level in the amount needed to carry out the planned vaccination in one working day. They will then transport the vaccines to vaccination sites in compliance with the transportation conditions requirements (in special cold boxes). It is planned that mobile teams will receive the vaccines and the necessary equipment and supplies on a daily basis from regional level warehouses in the quantities specified in their daily plans. Once the stock of vaccines at the regional level warehouses is exhausted, the next supply of vaccines and the necessary

	equipment/medical products will be delivered from the central level warehouse. All logistics cycles should be carried out according to the principle of ensuring the continuity of vaccination performed by mobile teams so it covers the representatives of priority groups with all the necessary doses of vaccinations in the quickest possible time.
Platform 3 – mass vaccination centers	The centers are equipped with the necessary equipment according to the requirements set out for a mobile team as a temporary vaccination point. At the regional level, vaccines will be stored centrally, with a temperature regime ranging from +2 °C to +8 °C. The necessary tools will be stored at the regional level in the appropriate conditions in the amount required for vaccination. Staff involved in the vaccination process on the basis of mass vaccination centers, including mobile teams working on the basis of the centers, will receive vaccines at the regional level and the necessary tools in the amount needed for the planned vaccinations based on a pre-arranged schedule. Vaccines will be transported to vaccination sites in compliance with the conditions of transportation and the "cold chain" requirements (in special cold boxes). It is planned that mass vaccination centers will receive the vaccines and the necessary tools in the required quantity at the warehouses at the regional level based on the previously developed vaccination plans. Once the stock of vaccines at the regional level warehouses is exhausted, the next supply of vaccines and the necessary equipment/medical products will be delivered from the central level warehouse. All logistics cycles should be carried out according to the principle of ensuring the continuity of vaccination performed on the basis of mass vaccination centers so it covers the representatives of priority groups with all the necessary doses of vaccinations in the quickest possible time, with a special focus on people over 60 years of age.

The currently available capacities of Ukraine for the storage and transportation of vaccines requiring temperature between +2 °C and +8 °C are sufficient to ensure a full logistics cycle. It is expected that SE "Ukrmedpostach" of the Ministry of Health of Ukraine" and LLC "Farmasoft" will provide the logistics (storage, transportation, etc.) of such vaccines.

At the national level, the documentary and customs brokerage support of vaccines entering the territory of Ukraine is performed by the SE "Ukrmedpostach" (for state-funded vaccines) and Farmasoft LLC (for vaccines received in the form of humanitarian aid). After customs clearance and receipt of products, the representatives of the mentioned enterprises check the integrity and the quantity of thermocontainers, the availability of quality certificates for the vaccine and other commodity-based documents, as well as the expiration dates specified on the shipping containers and the quality certificates.

SE "Ukrmedpostach" and "Farmasoft LLC", which have relevant experience in the logistics of medicines in ultra-low temperatures and sufficient equipment to comply with the requirements of the "cold chain", on the basis of orders of the Ministry of Health, deliver vaccine batches to the storage sites at the regional levels in the amount and according to the schedule set by the Ministry of Health until the complete exhaustion of vaccines at the central warehouse. Vaccines are delivered by specialized refrigerated transport and/or in appropriate thermal containers, and, if necessary, together with syringes for injection/solvent and safe disposal boxes. SE "Ukrmedpostach" and "Farmasoft LLC", are responsible for the delivery of vaccines in compliance with the conditions of the "cold chain" and provision of the needed temperature regime during transportation.

Based on the calculations of the need for vaccination, carried out at the regional and local levels, the total volume of vaccines and the necessary supplies (syringes, boxes of safe disposal, solvent, etc.) is determined for each region for a certain period of time. It is preliminary planned that the delivery from the national warehouse to the regional warehouses will be carried out quarterly.

The delivery of vaccines from the central to the regional level warehouses will be done based on the estimated need for vaccines in regions, the number and capacity of vaccination points and the technical capacity at the regional level to store the vaccine and the necessary medical equipment/supplies.

At the regional level, vaccines will be stored centrally, in compliance with the temperature regime ranging between +2°C and +8°C and will be delivered to healthcare facilities (or by mobile teams to the designated vaccination sites).

In order to effectively coordinate the process of distribution and the use of vaccines at the regional level, focal points will be appointed. Their duties will include preparing calculations and orders for weekly deliveries and maintaining close collaboration with the representatives of SI "Public Health Center of the Ministry of Health of Ukraine". In this case, the vaccine distribution algorithm will look as follows.

At the first stage, SI "Public Health Center of the Ministry of Health of Ukraine" prepares the distribution proposals and coordinates them with the Regional Health Departments, which in turn have to confirm the readiness to accept the vaccine and provide the information on the sole vaccine recipient designated at the regional level. The agreed distribution proposal is submitted for approval to the Ministry of Health and approved by the relevant order/letter of distribution. On the basis of the document, the Ministry of Health forms a preliminary delivery schedule and submits it to the logistics company.

A similar algorithm is used to distribute vaccines at the regional level. Based on the approved order of the Ministry of Health of Ukraine, Health Departments approve regional distribution orders and organize the delivery of vaccines on a monthly basis in accordance with the verified applications.

For vaccines requiring storage temperature at -20°C , it is advisable to observe the following general logistics scenario of their delivery to vaccination sites:

Vaccination method	Logistics scenario for the delivery of vaccines requiring storage at -20°C and lower
Platform 1 – vaccination point	The main stock of vaccines will be stored at the central level in compliance with the temperature regime of -20°C. Based on the distribution plan of vaccination needs carried out at the regional and local levels, the total supply of vaccines and the necessary equipment (syringes, safe disposal boxes, etc.) will be determined for each region for a certain period of time. The period of time needed to cover the priority groups with vaccination at the regional and local levels is determined by the number of vaccination points and their capacity to maintain the continuity of the vaccination process. Considering the estimated need for vaccination, the number and capacity of vaccination points, technical capacity at the regional level to store the vaccines and the necessary equipment and supplies, the vaccines will be delivered from the central level to the warehouses at the regional level. The delivery will comply with the temperature regime, and the vaccines will be kept in special cold boxes with ice (cold) packs. It should be noted that these vaccines can be stored for up to a month at a temperature of $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ after their delivery to the regional level, which should be taken into account when planning deliveries. Vaccines will be stored centrally at the regional level, at a temperature between $+2^{\circ}\text{C}$ and $+8^{\circ}\text{C}$. The necessary equipment and supplies will be stored at the regional level under proper conditions in the amount required for vaccination.

	From the warehouses at the regional level, vaccines and the necessary equipment and supplies will be delivered to healthcare facilities where vaccination points are set up. The volume of vaccines and the necessary equipment and supplies that will be delivered to healthcare facilities where vaccination points are set up will be determined taking into account the capacity of the points to carry out a continuous vaccination during a certain period of time. At the health facility level, the vaccines will be stored at a temperature regime ranging between +2°C and +8°C. Once the stock of vaccines at the HCF level is exhausted, the next supply of vaccines and the necessary equipment/medical products will be moved from the regional level's warehouses. All logistics cycles should be carried out according to the principle of ensuring the continuity of vaccination that is performed at the level of vaccination points so that it covers the representatives of priority groups with all the necessary doses of vaccinations in the quickest possible time
Platform 2 – mobile teams	The main stock of vaccines will be stored at the central level at a temperature regime of -20°C. Based on the distribution plan of vaccination needs carried out at the regional and local levels, the total supply of vaccines and the necessary equipment and supplies (syringes, safe disposal containers, etc.) will be determined for each region for a certain period of time. The period of time needed to cover the priority groups with vaccination at the regional and local level is determined by the number of mobile teams and their capacity to maintain the continuity of the vaccination process. Considering the estimated need for vaccination, the number and capacity of mobile teams, technical capacity at the regional level to store vaccines and the necessary equipment and supplies, vaccines will be delivered from the central level to the warehouses at the regional level. The delivery will comply with the temperature regime – vaccines will be kept in special cold boxes with ice (cold) packs. It should be noted that these vaccines can be stored for up to a month at temperature between + 2 ° C and + 8 ° C after their delivery to the regional level, which should be taken into account when planning deliveries. At the regional level, vaccines will be stored centrally, at a temperature between +2°C and +8°C. The necessary equipment and supplies will be stored at the regional level under proper conditions in the amount required for vaccination.

	According to a pre-arranged schedule, mobile teams will receive vaccines and the necessary equipment and supplies at the regional warehouses in the amount required to carry out the planned vaccination within one working day. Mobile teams will transport the vaccines to the vaccination points in compliance with the transportation conditions requirements (in special cold boxes). It is planned that mobile teams will receive the vaccines and the necessary equipment and supplies on a daily basis from regional level warehouses in the quantities specified in their daily plans. Once the stock of vaccines at the regional level warehouses is exhausted, the next supply of vaccines and the necessary equipment/medical products will be delivered from the central level warehouse. All logistics cycles should be carried out according to the principle of ensuring the continuity of vaccination performed by the mobile teams so it covers the representatives of priority groups with all the necessary doses of vaccinations in the quickest possible time.
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For the vaccines requiring storage temperatures between -60°C and -80°C, it is advisable to adhere to the following logistics scenario for the delivery of vaccines to the vaccination sites.

It is assumed that the use of vaccines requiring storage temperatures between -60°C and -80°C will take place only on the platform of mobile teams. This is due to the lack of technical capabilities for long-term storage of such vaccines in the required temperature in healthcare facilities, where vaccination points are set up.

Logistics company SE "Ukrmedpostach" (for state-funded vaccines) or Farmasoft LLC (for vaccines received in the form of humanitarian aid) provide the documentary and customs brokerage support of vaccines entering the territory of Ukraine as humanitarian aid. After customs clearance and receipt of products, the representatives of the mentioned enterprises check the integrity and the quantity of thermocontainers, the availability of quality certificates for the vaccine and other commodity-based documents, as well as the expiration dates specified on the shipping containers and the quality certificates.

The logistics company provides services of responsible storage of the vaccine at ultra-low temperatures at the central level warehouse, which belongs to the company or leased and provides delivery of vaccines to the central storage warehouse in compliance with the temperature regime of -70 ° C and required conditions. During the entire period of transportation of vaccines in thermal

containers to the warehouse, the contractor ensures monitoring and compliance with the temperature regime.

The logistics company on a weekly basis ensures the delivery of batches of vaccine to the storage sites at the regional level in quantities and according to the schedule set by the Ministry of Health or the SI "Public Health Center" until the stockpile of vaccines at the central warehouse is exhausted. The vaccines are delivered in appropriate thermal containers filled with dry ice, and, if necessary, together with syringes for injection/dilution and safe disposal boxes. The logistics company is responsible for the delivery of vaccines at a temperature of $-70^{\circ}\text{C} \pm 10^{\circ}\text{C}$ and maintenance of the required temperature during transportation.

Based on the calculations of the need for vaccination, carried out at the regional and local levels, the total volume of delivery of vaccines and the necessary supplies (syringes, boxes of safe disposal, solvent, etc.) is determined for each region for a certain period of time. Given that vaccines that require temperatures from -60°C to -80°C can be stored at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ for no more than 5 days, the need for vaccination should be calculated in such a way as to ensure timely use of the vaccine during limited period of time.

Taking into account the estimated need for vaccination, the number and capacity of mobile teams, technical capacity at the regional level to store the vaccine and the necessary tools, vaccines will be delivered from the central level to the warehouses at the regional level. To ensure longer storage of the vaccine at the regional level (up to 1 month), the logistics company provides the delivery and distribution of dry ice on a regular basis (1-2 times a week).

Mobile teams, based on the pre-arranged schedule, will receive the vaccines and the necessary tools at the regional level in the amount needed to carry out the planned vaccination in one working day. Mobile teams will transport the vaccines to vaccination sites in compliance with the required conditions for vaccine transportation (in special thermal containers). It is planned, that the mobile teams will draw up daily plans for field vaccination sessions and receive vaccines and the necessary tools on a daily basis in the required quantities at the regional level warehouses. Vaccination sessions will last no more than 6 hours, as vaccines that require a temperature of -60°C to -80°C can be stored at room temperature for no longer than 6 hours. Given this, such vaccines will be used on the day of their receipt from the regional warehouses, within 6 hours from the moment of receipt of vaccines from the regional warehouse.

Once the vaccine stocks in the regional level warehouses are exhausted, the next delivery of vaccines and the necessary tools will be made from the central level warehouse.

In order to effectively coordinate the process of distribution and the use of vaccines at the regional level, focal points will be appointed. Their duties will include preparing calculations and orders for weekly deliveries and maintaining close collaboration with the representatives of SI "Public Health Center of the Ministry of Health of Ukraine". In this case, the vaccine distribution algorithm will look as follows.

At the first stage, SI "Public Health Center of the Ministry of Health of Ukraine" prepares the distribution proposals and coordinates them with the Regional Health Departments, which in turn have to confirm the readiness to accept the vaccine and provide the information on the sole vaccine recipient designated at the regional level. The agreed distribution proposal is submitted for approval to the Ministry of Health and approved by the relevant order/letter of distribution. On the basis of the document, the Ministry of Health or the SI "Public Health Center of the Ministry of Health of Ukraine" forms a preliminary delivery schedule and submits it to the logistics company.

Weekly, Regional Health Departments submit Applications for the Distribution until its Full Use to SI "Public Health Center of the Ministry of Health of Ukraine" in accordance with the quantities specified in the order of the Ministry of Health of Ukraine. SI "Public Health Center" verifies the submitted applications and, on a weekly basis, submits to the logistics company the finalized Applications for the Distribution until its Full Use in accordance with the quantities specified in the order of the Ministry of Health of Ukraine.

A similar algorithm is used to distribute vaccines at the regional level. Based on the approved order (a letter on distribution) of the Ministry of Health of Ukraine, Health Departments approve regional distribution orders and organize the delivery of vaccines on a monthly basis in accordance with the verified applications.

It is assumed that this procedure will provide an additional level of control and verification and minimize the risks associated with non-use of the vaccine within 5 days of delivery from the national level.

MEDICAL WASTE MANAGEMENT

During the roll-out of the vaccination campaign, healthcare facilities produce a great deal of waste, including hazardous waste. Wastes generated during vaccination carry the risks of causing chemical, toxic, carcinogenic and mutagenic impact on a human body, as well as the risk of injury and the development of infectious diseases. The risk of injury and acquiring infection as a result of encountering medical waste is not uncommon, and can be inflicted in

different ways: skin damage (puncture, cut), contact with mucous membranes or damaged skin. Needles contaminated with biological fluids (blood) are the most dangerous medical waste generated during vaccination. The risks of adverse impact resulting from encountering chemical substances (chemical, toxic, carcinogenic and mutagenic) during vaccination are minimal and are associated exclusively with the possible effects of disinfectants and drugs that are not directly related to vaccinations.

Inadequate and improper management of medical waste can have serious consequences for human health, both through direct impact and through negative impact on the environment. Thus, the rational and safe management of medical waste, its transportation and disposal is an important component of occupational safety and health protection, control of infectious diseases and environmental protection. In addition, given the current shortage of COVID-19 vaccines, there is an additional and specific risk pertinent to this category of medical waste – the reuse of used vaccine containers for refilling and selling.

In Ukraine, the medical waste management (collection, transportation, storage, sorting, treatment (recycling), utilization, export, disinfection, disposal, destruction) in the HCFs is carried out in accordance with the provisions of the Law of Ukraine "On Waste" and State Sanitary and Epidemic Rules and Regulations regarding the treatment of medical waste, approved by the order of the Ministry of Health of Ukraine dated June 08, 2015 No. 325. However, a significant part of hazardous medical waste is transported to landfills and unauthorized landfills due to irresponsible approach of some HCFs and businesses, which acquired their licenses under the Licensing Conditions for Hazardous Waste Management, approved by the Cabinet of Ministers of Ukraine dated July 13, 2016. No. 446 (hereinafter – licensees). Waste that is transferred for disposal to licensees is often subjected to chemical disinfection and transportation, which creates additional risks for healthcare workers and licensees themselves. In most cases, licensees dispose of hazardous medical waste by throwing it in landfills without prior physical treatment (incineration). This approach creates an additional burden on the environment due to the combined effects of medical waste and disinfectants. Disposal and burying of waste in uncontrolled areas can have a direct impact on the environment resulting in soil and water pollution.

In order to eliminate the risks of improper handling of hazardous medical waste generated during the vaccination campaign against coronavirus disease COVID-19, the Ministry of Health will approve uniform requirements for medical waste management, which will be mandatory when concluding a contract with the National Health Service of Ukraine. It is planned that infectious and especially dangerous sharp objects will be collected in safe disposal boxes and

handed over to licensees for their disposal exclusively by incineration. This approach will simplify the approaches to the management of hazardous medical waste, reduce the risk of the adverse impact of waste and the cost of disposal.

SOCIAL AND ENVIRONMENTAL RISK MANAGEMENT

Implementation of environmental and social management during vaccination is a requirement of the Environmental and Social Standards (ESS) of the World Bank.

Information on the Environmental and Social Standards (ESS) of the World Bank and, in particular, their application during vaccination can be found in the handbook "Framework Requirements for Social and Environmental Management" of the World Bank Project "Ukraine Emergency COVID-19 Response and Vaccination", officially published on the website of the Ministry of Health. Additional information on the new environmental and social standards can be found on the World Bank's website – <https://projects.vsemirnyjbank.org/ru/projects-operations/environmental-and-social-framework>.

Environmental and social standards and their application during vaccination

Environmental and social standards	Application during vaccination
ESS 1 Assessment and Management of Environmental and Social Risks and Impacts	Yes
ESS 2 Labor and Working Conditions	Yes
ESS 3 Resource Efficiency and Pollution Prevention and Management	Yes
ESS 4 Community Health and Safety	Yes
ESS 5 Land Acquisition, Restrictions on Land Use and Involuntary Resettlement	No
ESS 6 Biodiversity Conservation and Sustainable Management of Living Natural Resources	No
ESS 7 Indigenous Peoples	No
ESS 8 Cultural Heritage	No

ESS 9 Financial Intermediaries	No
ESS 10 Stakeholder Engagement and Information Disclosure	Yes

It is important to note that the World Bank's Environmental and Social Standards, in particular the ESS 10, specify that environmental and social risks during vaccination can be minimized or mitigated by ensuring timely identification and engagement with stakeholders.

Active stakeholder involvement supports the development of strong, constructive and effective relationships important for the successful management of the environmental and social risks identified under the Project. Timely and clear communication with stakeholders helps to manage mutual expectations and avoid potential conflicts and delays.

A number of consultations were held within the framework of the preparation of the World Bank's Project "Ukraine Emergency COVID-19 Response and Vaccination", which resulted in the development and publication of a Stakeholder Engagement Plan.

In addition, the involvement of stakeholders to the process of resolving the problematic issues of the vaccination process will take place through the operation of a separate Internet platform, which will provide an opportunity for stakeholders to express their suggestions and provide comments. The non-governmental sector, whose direction of activities agree with that of the World Bank, will also be involved in cooperation with stakeholders.

Based on the preliminary assessment and consultations with stakeholders, it was determined that the main environmental and social risks of vaccination would be related to the following areas:

- 1) medical waste management, including medical waste disposal;
 - 2) occupational health and safety, the safety of medical workers, as well as workers engaged in the collection, sorting, transportation and disposal of medical waste;
 - 3) "cold chain" (may not take into account the environmental consequences; contain refrigerants with ozone-depleting substances (hereinafter – ODS));
 - 4) delivery and distribution of vaccines;
 - 5) health and safety of the population (especially related to AEFI).
- a. The above risks can be regulated by:

- 6) strict adherence to standard procedures for medical waste management and disposal;
- 7) the use of personal protective equipment (hereinafter – PPE) by medical workers, as well as workers involved in the management of medical waste;
- 8) use of appropriate refrigeration equipment that does not contain ODS;
- 9) providing access to vaccination services for vulnerable categories of people;
- 10) proper maintenance (keeping in good working condition) of CCE (cold chain equipment) to preserve the suitability of vaccines.

REGULATORY ISSUES OF VACCINE INTRODUCTION

The quality of vaccines imported to Ukraine is ensured in accordance with article 9 of the Law of Ukraine "On Medicinal Products" under which medicinal products are allowed for use in the territory of Ukraine after their state registration, except as provided by this Law. Herewith, Article 2 of the Law of Ukraine "On Medicinal Products" defines a medicinal product as any substance or combination of substances (one or more APIs and excipients) that has properties and is intended for the treatment or prevention of diseases in humans or any substance or combination of substances (one or more APIs and excipients) that may be intended to prevent pregnancy, restore, correct or alter physiological functions in a human via pharmacological, immunological or metabolic action or in order to establish a medical diagnosis.

The state registration of medicines is carried out in accordance with the Procedure for state registration (re-registration) of medicinal products approved by the Resolution of the Cabinet of Ministers of Ukraine No.376 dated May 26, 2005 on the basis of an application submitted to the Ministry of Health.

In order to ensure greater flexibility of the healthcare system in responding to emergencies and optimize the process of COVID-19 vaccine access to Ukraine, the Verkhovna Rada of Ukraine (the Parliament), the Government of Ukraine and the Ministry of Health of Ukraine have elaborated and approved the following procedures.

On January 29, 2021, the Government of Ukraine adopted the Law "On Amendments to the Law "On Medicinal Products" on state registration of medicinal products under the obligations for emergency medical use. The Law of Ukraine "On Medicinal Products" is supplemented by a new Article 9-2, which regulates the possibility of state registration of vaccines or other medical immunobiological drugs for the specific prevention of coronavirus disease

COVID-19, whose clinical trials are not completed under the conditions specified in this article, in particular, under the obligation of the applicant to complete the clinical trial program during the period agreed with the Ministry of Health.

Such amendments to the current legislation provide the possibility of registration in Ukraine of immunobiological drugs against COVID-19, which have received the emergency use authorization. According to the adopted amendments, the decision on state registration of vaccines or other medical immunobiological drugs for the purpose of emergency medical use, taking into account certain obligations, is approved, in particular, if:

- 1) data is available on successful completion of preclinical trials/studies, individual phases of clinical trials/vaccine studies or other medical immunobiological drugs;
- 2) permission for emergency use authorization has been granted by the competent authority of the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, the People's Republic of China, India or under a centralized procedure by the competent authority of the European Union in accordance with the national legislation of the country of granting permission or the European Union, or a vaccine or other medical immunobiological drug have been pre-qualified by the World Health Organization;
- 3) such a medicinal product was not developed in the state recognized in the prescribed manner as the aggressor state;
- 4) the known and potential benefits of vaccines or other medical immunobiological drugs, when used to prevent coronavirus disease COVID-19, outweigh the known and potential risks of such vaccines or other immunobiological medical medicines.

Also, in order to speed up the registration of medicines for the treatment and prevention of coronavirus disease COVID-19, under the Law of Ukraine No. 4314 of November 4, 2020 "On the Introduction of Amendments to some Legislative Acts of Ukraine Concerning the Prevention of Coronavirus Disease (COVID-19)" the 5-day procedure for the examination of registration materials was developed. This was done following the requirements outlined in the Procedure for Carrying out the Examination of Registration Materials for Medicines Submitted for State Registration (re-registration), as well as the Examination of Materials on Amendments made to Registration Materials during the Validity of Registration Certificate approved by the order of the Ministry of Health of Ukraine on August 26, 2005 No. 426 (as amended by the order of the Ministry of Health of Ukraine of July 23, 2015 No. 460).

The Cabinet of Ministers of Ukraine exempted vaccines and medicines against coronavirus disease COVID-19 from taxation under the Resolution of the

Cabinet of Ministers of Ukraine No. 224 dated March 20, 2020 "On Approval of the List of Goods (Including Medicines, Medical Devices and/or Medical Equipment) Necessary for Implementing Measures on Preventing the Occurrence and Spread, Localization and Elimination of Outbreaks of Epidemics and Pandemics of Acute Respiratory Disease COVID-19 Caused by Coronavirus SARS-Cov-2, the Import and/or the Supply Operations of which in the Customs Territory of Ukraine are Exempt from Value Added Tax".

In addition, a 7-day registration procedure for products intended for the procurement by a specialized procurement agency may be applied in accordance with the procurement agreement with the Ministry of Health of Ukraine. This procedure is used to simplify the state registration of medicinal products procured with the participation of international organizations and was approved by the Order of the Ministry of Health of Ukraine No.1391 dated June 15, 2020 "On Approval of the Procedure for the Authenticity Verification of Medical Product Documentation, Submitted for the State Registration with the Purpose of its Procurement by a Person Authorized for Such Procurement in the Healthcare Sector or by a Specialized Organization", registered with the Ministry of Justice of Ukraine on July 14, 2020 under No. 659/34942.

In accordance with the Procedure for the authenticity verification of registration materials on a medicinal product submitted for state registration for the purpose of its procurement by a person authorized to make procurements in the area of healthcare or a specialized organization, approved by the order of the Ministry of Health No. 1391 of June 15, 2020 , registered in the Ministry of Justice of Ukraine on July 14, 2020 under No. 660/34943, registration materials for the vaccine submitted for state registration undergo fast track authenticity verification. The registration materials for the vaccine submitted for state registration undergo a fast-track authenticity verification procedure. The fast-track registration procedures can be used for the procurement of pharmaceutical products by an authorized entity, a procurement organization or a specialized procurement organization. The list of documents required for submission is as follows:

- 1) materials of medicinal product dossier, submitted for the registration to the regulatory authority of the country in which the product is registered, or for the prequalification of the medicinal product by WHO;
- 2) report on the evaluation of the medicinal product – a document indicating a positive assessment of medicinal product regarding its efficacy, safety and quality, compiled by the regulatory body of the country where this medicinal product is registered, or the World Health Organization. The applicant submits a report on the evaluation of the medicinal product on paper;

- 3) methods of quality control of the medicinal product (final product) (information on quality control of the medicinal product (final product));
- 4) instruction on the use of a medicinal product or information on the use of a medicinal product approved in accordance with the regulatory requirements of the applicant/manufacture's country or country whose regulatory body is guided by high-quality standards that meet the standards recommended by the WHO, and/or in accordance with the results of clinical trials, set forth in the language of the original (language other than the state) in accordance with the requirements for the language specified by the legislation;
- 5) sample of the original packaging of the medicinal product;
- 6) translation into the official language, the authenticity of which is confirmed by the Applicant or the authorized representative, the text of labelling of the package of the medicinal product in the official language, evidenced by the signature of the Applicant or the representative authorized by him;
- 7) translation into the official language, the authenticity of which is confirmed by the Applicant or the authorized representative, instructions on the use of the medicinal product or information on the use of the medicinal product approved by the regulatory requirements of the applicant/manufacture or country, the regulatory body of which is guided by high-quality standards that meet the standards recommended by the WHO, and/or according to the results of clinical trials, evidenced by the signature of the Applicant or his authorized representative.

There is also a possibility for the medicinal product to receive the state registration within 10 days according to the Procedure for Consideration of Registration Materials for Medicines Submitted for State Registration (re-registration), and Materials on Amendments to the Registration Materials during the Validity of the Registration Certificate for Medicines Registered by the Competent Authorities of the United States of America, the Swiss Confederation, Japan, Australia, Canada, and medicines, Registered under a Centralized Procedure by the Competent Authority of the European Union, approved by the order of the Ministry of Health of Ukraine of 17.11.2016 No.1245 and registered with the Ministry of Justice of Ukraine on December 14, 2016 under No. 1619/29749. This Procedure applies to ready-made medicines registered by the competent authority of the United States, the Swiss Confederation, Japan, Australia, Canada, and medicines registered by a competent authority of the European Union and on the territory of the stated countries or the EU Member States. According to the Registration Procedure, along with the application for registration, the following list of documents should be submitted:

- 1) materials on the methods of the medicinal product quality control (in Ukrainian).
- 2) materials of the registration dossier, which served as a ground for the registration of the medicinal product by the competent authority of the United States of America and the Swiss Confederation, Japan, Australia, Canada or a centralized procedure by the competent authority of the EU for its use in the stated countries or the EU Member States, with the data on the registration of the drug in such countries, including the name of the country of registration, the registration authority and the registration dates, as confirmed by the applicant and/or his representative, taking into account any changes made after the registration of the medicinal product.
- 3) packages of amendments to the dossier approved in the reference country should be provided as the annexes after the dossier's full content or maybe a part of the dossier, replacing the previous version of the sections. The copies of the request for amendments and the document confirming their approval in the reference country should precede the amendments' package.
- 4) samples of the packaging (graphic image of the package layout) of the medicinal product and the text of the marking of the primary and secondary (if any) packages of the medicinal product, in accordance with the requirements of Annex 23 to the Procedure for Examination.
- 5) instructions on the use of the medicinal product set out in accordance with the requirements of Annex 20 to the Procedure for the Examination of Registration Materials for Medicinal Products Submitted for State Registration (re-registration), as well as examination of materials on the changes made to registration materials during the period of the registration certificate validity approved by the Ministry of Health of Ukraine of August 26, 2005 No. 426, registered with the Ministry of Justice of Ukraine on September 19, 2005 under No. 1069/1134 and a brief description of the medicinal product set out in accordance with Annex 22 to the same Procedure;
- 6) document confirming the payment of the registration fee.
- 7) certified copy of the document, issued by the State Drug and Drug Control Service of Ukraine, in accordance with the procedure established by the Ministry of Health, confirming that the conditions for the production of the medicinal product submitted for registration conform with the relevant requirements of Good Manufacturing Practice (GMP) in Ukraine, or a written undertaking by the manufacturer to produce the appropriate medicinal product intended for the delivery and use in Ukraine at the same production facilities used in the manufacture of a medicinal product

intended for the use in the territory of the United States or the Swiss Confederation, Japan, Australia, Canada or EU Member States.

- 8) letter of guarantee from the applicant or the applicant's representative guaranteeing the completeness and reliability of the information he provides in the registration dossier (if the applicant so desires).

In accordance with paragraph 5 of the Procedure for Monitoring the Compliance of Immunobiological Drugs used in Medical Practice with the Requirements of State and International Standards approved by the order of the Ministry of Health of Ukraine No. 698 dated 01.10.2014, registered with the Ministry of Justice of Ukraine on October 29, 2014 under No. 1356/26133, immunobiological drugs imported into Ukraine, in particular, as humanitarian aid, as well as those that have undergone the WHO prequalification procedure and were procured according to the results of the procurement procedure conducted by a specialized procurement agency, that conducts procurements in pursuance of the procurement agreement between the Ministry of Health of Ukraine and the relevant specialized agency that carries out such procurements, are not subject to mandatory laboratory control.

Within the framework of participation in the COVAX AMC mechanism for obtaining vaccines against COVID-19, and in accordance with the procedures defined at the global level for all COVAX AMC participants, Ukraine will fulfil the following obligations:

According to part B of the request for vaccines against COVID-19 submitted to COVAX Facility by Ukraine on January 6, 2021 under the signature of the Minister of Health of Ukraine and the Minister of Finance of Ukraine, Ukraine should conclude agreements on the exemption from liability with manufacturers of vaccines to be delivered to Ukraine under the COVAX mechanism. Under such agreements, Ukraine assumes responsibility for all losses incurred by the vaccine manufacturer as a result of claims, demands, lawsuits or legal actions (including claims for loss of property, idle production or economic damages arising from death or injury (including physical, mental and emotional trauma, illness and disability) or in connection with them, as a result of the use or administration of a vaccine or the inefficiency of the vaccine. Exemption from liability of vaccine manufacturers' does not apply to the violation of good manufacturing practices to certifying a batch of vaccines for export, which has led to a defect in the quality of the vaccine or improper intent on the part of the manufacturer for the development, production, use or administration of the vaccine.

This commitment reflects global approaches to the use of new immunobiological drugs developed to combat the COVID-19 pandemic in

emergency situations. The Law of Ukraine of March 25, 2021 No. 1353-IX "On Amendments to Article 9-2 of the Law of Ukraine "On Medicinal Products" regarding the state registration of vaccines or other medical immunobiological drugs under the obligation" provides for release from liability of the manufacturer and/or owner registration certificate, if the use of vaccines was carried out in accordance with the medicine information leaflets approved in Ukraine, for any consequences caused by the use of such vaccines or other drugs against coronavirus disease COVID-19. In the event of such consequences, the state shall ensure the implementation of appropriate compensation payments in the manner prescribed by the Cabinet of Ministers of Ukraine.

In cases of occurrence of serious adverse events following immunization as a result of vaccination against coronavirus disease COVID-19, the settlement of legal issues, compensations, etc. are carried out within the framework of the legislation in force in Ukraine (including the Law of Ukraine "Fundamentals of Legislation on Health Protection of Ukraine", the Civil Code of Ukraine, the Law of Ukraine "On Compulsory State Social Insurance", etc.).

PHARMACOVIGILANCE OF VACCINES

Pharmacovigilance in Ukraine is carried out by the State Enterprise "State Expert Center of the Ministry of Health of Ukraine" (hereinafter – the SE "State Expert Center of the MOH of Ukraine") by applying international standards, in accordance with the provisions of Directive 2001/83/EC of the European Parliament and the Council, Regulation (EC) No 726/2004 of the European Parliament and the Council in accordance with the "Pharmacovigilance Procedure" approved by the order of the Ministry of Health of Ukraine on 27.12.2006 under No. 898 (as amended by the Order of the Ministry of Health of Ukraine of 26.09.2016 No. 996), registered with the Ministry of Justice of Ukraine on January 29, 2007 under No. 73/13340 (hereinafter – Pharmacovigilance Procedure). According to paragraph 5 of the Order of the Ministry of Health of Ukraine of 27.12.2006 No. 898, healthcare pharmacovigilance is carried out at the local, administrative-territorial and central levels, and in the pharmaceutical industry, it is carried out by applicants. All amendments introduced into the order No. 898 were developed based on the current global WHO recommendations and documents on the procedure for monitoring, reporting and accounting of AEFI signals, identification of cases requiring investigation, case investigation algorithm and causality assessment, and the final classification of cases.

Review of the reporting forms on the adverse events following immunization against coronavirus disease COVID-19 and proper response will

be carried out following the applicable law and the updated WHO recommendations at the global level. The order of the Ministry of Health of Ukraine of 26.09.2016 No. 996, registered with the Ministry of Justice of Ukraine on December 19, 2016 under No. 1650/29780, approved the Provisions on the Central and Regional Rapid Response Teams to AEFI/ tuberculinodiagnosis.

Under paragraphs 10 and 12 of the Provisions on the Central and Regional Rapid Response Teams, the Central AEFI Rapid Response Team is a permanent advisory body of the Ministry of Health of Ukraine. Its tasks include the analysis of information about the AEFI based on the information received from the SE "State Expert Center of the MOH of Ukraine" and the provision of advisory assistance on the issues related to the safety and effectiveness of vaccines.

The Central Rapid Response Team analyzes the information on AEFI, based on the data received from the SE "State Expert Center of the MOH of Ukraine" in case of causality established between such AEFI and the use of a batch/batches of vaccine/vaccines in reporting forms, in particular:

- on the clinical manifestations of adverse events not specified in the medicine information leaflets or the list of clinical manifestations of events after administration of vaccines;
- those that became the ground for reporting the signal event;
- associated with immunization program error when using the vaccine,
- on the AEFI (resulting in death, resulting in disability/incapacity) registered within 30 days after immunization;
- on AEFI (resulting in death, resulting in disability/incapacity) registered within 30 days after immunization and the "Protocol of Investigation and Establishing a Causal Relationship between the Serious and/or Cluster AEFI/Tuberculin Diagnostics and the Use of a Vaccine, Tuberculin" (hereinafter – the Investigation Protocol) in case, if the Regional Rapid Response Team has established the degree of causality not lower than possible.

Following paragraphs 17 and 19 of the Provisions on the Central and Regional AEFI Rapid Response Teams, the Regional Teams is a permanent advisory body of the structural healthcare departments of the Autonomous Republic of Crimea, Oblast, Kyiv and Sevastopol cities State Administrations, and its tasks include, in particular, the following:

- 1) receipt of the reporting forms on all cases of AEFI occurred in the administrative-territorial unit;

- 2) analysis of reporting forms on all cases of AEFI to determine their severity;
- 3) submission of all reporting forms received to the SE "State Expert Center of the MOH of Ukraine";
- 4) conduction of investigation of all serious and cluster AEFI and the establishment of causality between an AEFI and the use of a vaccine, etc.

The AEFI Reporting forms are filled and submitted by medical staff, patients, and the applicants for a medicinal product (registration certificate holders) to the Pharmacovigilance Automated Information System of the SE "State Expert Center of the MOH of Ukraine", available at <https://aisf.dec.gov.ua>. The system provides for the possibility to receive online all the information on the AEFIs around the clock.

Thanks to PAIS electronic system, the SE "State Expert Center of the MOH of Ukraine" has the opportunity to exchange information on AEFI cases with the VigiBase, Global Database of the World Health Organization.

In order to improve the conduction of differential diagnosis and establish a causal link between the AEFI cases and vaccine administration, the SE "State Expert Center of the MOH of Ukraine" has adapted standard case definitions to those defined by Brighton Collaboration. For now, 29 cases have been combined and designed in the format of guidelines and are currently being reviewed.

The pharmacovigilance plan for the use of the COVID-19 vaccine in Ukraine (hereinafter – Pharmacovigilance Plan) is based on the existing pharmacovigilance system and has been developed considering current aspects of the COVID-19 pandemic.

The pharmacovigilance in Ukraine is implemented with the participation of:

- healthcare system,
- the applicant of the medicinal product representing the vaccine against coronavirus disease COVID-19 on the territory of Ukraine,
- regulatory authorities (Ministry of Health of Ukraine, State Service of Ukraine for Medicines and Drug Control, SE "State Expert Center of the Ministry of Health of Ukraine").

Healthcare system carries out pharmacovigilance activities by using the following algorithm:

1. Submission of spontaneous reports on AEFIs (signals) when using the COVID-19 vaccine:

1.1 vaccination is carried out in accordance with the information specified in the instructions for medical use of the COVID-19 vaccine in compliance with the requirements of the current legislation;

1.2 the period for reporting on the development of AEFIs (onset/occurrence) after the immunization with the COVID-19 vaccine is 30 days;

1.3 in case of the AEFI detection, the healthcare professional fills out the "Reporting Form on the Adverse Event to the Medicinal Product, Vaccine, Tuberculin, and/or Lack of Expected Efficacy of the Medicinal Product, and/or Adverse Event Following Immunization/tuberculinodiagnosis" (hereinafter – the Reporting form) within 24 hours from the moment of the AEFI detection;

1.4 the Reporting form is provided to the SE "State Expert Center of the MOH of Ukraine" through the Pharmacovigilance Automated Information System (hereinafter – PAIS) at the <https://aisf.dec.gov.ua>;

1.5 the Regional Rapid Response Team for AEFIs/tuberculinodiagnosis (hereinafter – the RRRT), established in each administrative-territorial unit and the city of Kyiv (25 RRRTs) should review the PAIS information block on the AEFIs cases of the respective region on a daily basis. The Head of the RRRT is responsible for the revision of the information block.

1.6 on the basis of the data provided in the PAIS on the AEFIs signal, the RRRT analyzes the AEFI signals reported after the administration of the COVID-19 vaccine in terms of their severity;

1.7 in case of detection of serious and/or a cluster of AEFIs, the RRRT conducts investigation and collection of information within the first 48 hours after the AEFI signal registration;

1.8 based on the results of the investigation, the RRRT fills in the Investigation Protocol;

1.9 the Investigation Protocol is submitted to the SE "State Expert Center of the MOH of Ukraine" within 15 days from the AEFI detection date. The Head of the RRRT is responsible for submitting the Investigation Protocol;

1.10 upon receipt of additional data on a serious and/or cluster AEFI requiring the reassessment of the causal relationship between the AEFI and the COVID-19 vaccine administration, the RRRT draws up an updated Investigation Protocol and submits it to the SE "State Expert Center of the MOH of Ukraine" no later than 15 days from the date of the receipt of additional data.

2. Reporting of aggregated data on the cases of adverse events following COVID-19 immunization:

- 2.1 a person responsible for pharmacovigilance in the healthcare facility keeps records of adverse events following COVID-19 immunization;
- 2.2 based on the information on the number of doses and manifestations of adverse events, the aggregated data on the cases of adverse events following COVID-19 immunization, occurred in the respective healthcare facility, are compiled;
- 2.3 a person responsible for pharmacovigilance in the healthcare facility submits the consolidated data on the cases of AEFI following COVID-19 immunization to the responsible person of a structural health care unit of the administrative-territorial unit and the city of Kyiv on a monthly basis, by the 5th day of the month following the month of reporting in the form provided in Appendix 3 of the Procedure;
- 2.4 the responsible person of a structural health care unit of the administrative-territorial unit and the city of Kyiv summarizes the consolidated data on cases of AEFI due to COVID-19 vaccine administration;
- 2.5 the consolidated data on the cases of adverse events following COVID-19 immunization from administrative and territorial units and the city of Kyiv are further submitted to the SE "State Expert Center of the MOH of Ukraine" on a monthly basis by the 10th day of the month following the month of reporting;
- 2.6 the consolidated data on the cases of adverse events following COVID-19 immunization are provided electronically with a cover letter signed by the Head of the relevant structural healthcare unit. The Head of the structural healthcare unit is responsible for providing aggregated data on adverse events following COVID-19 immunization.

The applicant carries out pharmacovigilance activities by using the following algorithm:

- 1) reports of adverse events to the COVID-19 vaccine are provided to the SE "State Expert Center of the MOH of Ukraine" by the applicant through PAIS. The report should contain the following information: patient identification, vaccination date, the start date of clinical manifestations, description of clinical manifestations and their impact, category of seriousness, the trade name of the vaccine, information about the informant, results of laboratory tests (in case of suspicion of the inefficiency of the vaccination);
- 2) reports of all cases of suspected adverse events following the administration of COVID-19 vaccine, laboratory-confirmed cases of the

inefficiency of the vaccination, registered in Ukraine and having medical confirmation of the causal link, are provided by the applicant to the SE "State Expert Center of the MOH of Ukraine" within 48 hours from the date of receipt of such information;

- 3) reports of serious adverse events following COVID-19 immunization, leading to death or endangering life, laboratory-confirmed cases of the inefficiency of the vaccination, having medical confirmation of the causal link, registered on the territory of another country are provided by the applicant to the SE "State Expert Center of the MOH of Ukraine" within 15 calendar days from the date of receipt of such information. Information on all other cases of adverse events following COVID-19 immunization, which the applicant became aware of, is provided to the SE "State Expert Center of the MOH of Ukraine" as part of a routine regularly updated COVID-19 Vaccine Safety Report;
- 4) a regularly updated COVID-19 Vaccine Safety Report is compiled by the applicant in accordance with the structure of the regularly updated Safety Report provided in Annex 12 of the Procedure;
- 5) a regularly updated COVID-19 Vaccine Safety Report is provided by the applicant to the Center monthly, starting from the date of the first registration or emergency use authorization;
- 6) the COVID-19 Vaccine Risk Management Plan is drawn up by the applicant in accordance with the structure of the Risk Management Plan provided in Annex 14 of the Procedure;
- 7) a new version of the COVID-19 Vaccine Risk Management Plan is provided by the applicant to the Center when new safety and/or efficacy data are detected in accordance with the requirements of the current legislation;
- 8) on the basis of the developed additional measures to risks minimization to the COVID-19 Vaccine Risk Management Plan, the applicant provides letters of appeal to the specialists of the healthcare system, the public, medical and/or pharmaceutical workers for their further approval to the the SE "State Expert Center of the MOH of Ukraine";
- 9) in case of detection of violations arising during the production of the COVID-19 vaccine, including the input device, the applicant must notify the SE "State Expert Center of the MOH of Ukraine" no later than 48 hours from the date of receipt of such information.

The SE "State Expert Center of the MOH of Ukraine" carries out pharmacovigilance activities by using the following algorithm:

- 1) the SE "State Expert Center of the MOH of Ukraine" analyzes the Reporting Forms from the healthcare workers, applicants and patients submitted via PAIS;
- 2) the SE "State Expert Center of the MOH of Ukraine" receives from the RRTs protocols of investigation of serious and/or cluster AEFIs with an established category of the causal link between the AEFI case and the use of the vaccine against COVID-19;
- 3) the SE "State Expert Center of the MOH of Ukraine" forwards to the State Service of Ukraine on Medicines and Drugs Control the copies of the Reporting Forms on serious and/or cluster AEFIs, related to the violations occurring in the process of production of the COVID-19 vaccine, including the input devices provided by the vaccine manufacturer, in the presence of a causal link between them and the use of the vaccine – no later than 48 hours from the date of the receipt by the SE "State Expert Center of the Ministry of Health of Ukraine" of the information confirming the existence of a causal link between them and the use of the vaccine;
- 4) the SE "State Expert Center of the MOH of Ukraine" provides the Ministry of Health of Ukraine with:
 - copies of received AEFIs Reporting Forms (resulting in death, resulting in disability/incapacity) registered within 30 days after COVID-19 immunization – no later than 48 hours from the date of receipt by the SE "State Expert Center of the MOH of Ukraine" of the respective Reporting Forms;
 - copies of received AEFI Reporting Forms for serious and/or cluster AEFIs related to violations occurring in the process of the COVID-19 vaccine production, including the input device/s provided by the vaccine manufacturer, if there is a causal link between them and the use of the vaccine
 - copies of received Reporting Forms on AEFI related to the program immunization error when using the COVID-19 vaccine in the presence of information in accordance with the Investigation Protocol on AEFI – no later than 48 hours from the date of receipt by the SE "State Expert Center of the MOH of Ukraine" of the information confirming the existence of a causal link between them and the use of the vaccine.
 - copies of received Reporting Forms on AEFI (resulting in death, resulting in disability/incapacity) registered within 30 days after

immunization and the "Protocol of Investigation and Establishing a Causal Relationship between the Serious and/or Cluster AEFI/Tuberculin Diagnostics and the Use of a Vaccine, Tuberculin" in case, if the Regional Rapid Response Team has established the degree of causality not lower than "possible".

5) the SE "State Expert Center of the MOH of Ukraine" provides to the Central Rapid Response Team (CRRT) the following documents concerning the AEFIs:

- copies of Reporting Forms on AEFI containing information about clinical manifestations that are not specified in the instructions for medical use – no later than 48 hours from the date of receipt by the SE "State Expert Center of the MOH of Ukraine" of the information, confirming the existence of a causal link between such AEFIs and the use of series, vaccine (vaccines) against COVID-19;
- copies of received Reporting Forms on AEFI (resulting in death, resulting in disability/incapacity), registered within 30 days after immunization with the COVID-19 vaccine – no later than 48 hours from the date of receipt by the SE "State Expert Center of the MOH of Ukraine" of the respective Reporting Forms;
- copies of received Reporting Forms on AEFI related to the program immunization error when using the COVID-19 vaccine in the presence of information in accordance with the Investigation Protocol on AEFI – no later than 48 hours from the date of receipt by the SE "State Expert Center of the MOH of Ukraine" of the information confirming the existence of a causal link between them and the use of the vaccine.
- copies of received Reporting Forms on AEFI (resulting in death, resulting in disability/incapacity) registered within 30 days after immunization and the "Protocol of Investigation and Establishing a Causal Relationship between the Serious and/or Cluster AEFI/Tuberculin Diagnostics and the Use of a Vaccine, Tuberculin" in case, if the Regional Rapid Response Team has established the degree of causality not lower than "possible".

The CRRT analyzes the information provided by the SE "State Expert Center of the MOH of Ukraine". Based on the analysis results, the CRRT informs the Ministry of Health of Ukraine and/or the applicant (if necessary) on a decision

in the form of a meeting minutes, which is of a recommendation nature. The decision of the CRRT is mandatory in case of its enactment by the order of the Ministry of Health of Ukraine. The copies of the CRRT meeting minutes are provided to the SE "State Expert Center of the MOH of Ukraine".

- 6) the SE "State Expert Center of the MOH of Ukraine" provides the applicant with the following:
 - cases of group adverse reactions and/or serious adverse reactions, related to violations arising in the production of vaccines against COVID-19, including the input device provided by the manufacturer of vaccines against COVID-19 in the presence of a causal relationship between them and the use of vaccines against COVID-19 – no later than 48 hours from the date of receipt of the SE "State Expert Center of the MOH of Ukraine" information confirming the existence of a causal relationship between them and the use of vaccines against COVID-19;
 - about cases of AEFI after the use of the COVID-19 vaccine, and lack of its efficacy (cases of development of COVID-19 disease after vaccination), information about which was received by the SE "State Expert Center of the MOH of Ukraine" during a certain period – at its request;

The SE "State Expert Center of the MOH of Ukraine" analyzes the received information on the lack of efficacy of vaccination (taking into account the laboratory-confirmed cases). Information about these cases is provided to the CRRT for the appropriate decision-making.

- 7) the SE "State Expert Center of the MOH of Ukraine" receives, analyzes and summarizes monthly the aggregated data on cases of adverse events following COVID-19 immunization. In case of detecting an increase in the frequency of adverse events following COVID-19 immunization, the Center communicates this information to the Ministry of Health.
- 8) the SE "State Expert Center of the MOH of Ukraine" analyzes the regularly updated COVID-19 Vaccine Safety Report received from the applicant;
- 9) the SE "State Expert Center of the MOH of Ukraine" analyzes the Risks Management Plans related to the COVID-19 vaccine received from the applicant in accordance with the requirements of the current legislation;
- 10) the SE "State Expert Center of the MOH of Ukraine" and the applicants agree upon the information letters provided by the applicant to the specialists of the healthcare system, the public, medical and/or pharmaceutical workers, which are then published on the official website of the SE "State Expert Center of the MOH of Ukraine";

- 11) in case of obtaining by the SE "State Expert Center of the MOH of Ukraine" of the information from the applicant on the detection of violations occurred in the process of COVID-19 vaccine production, including concerning the input device, the SE "State Expert Center of the MOH of Ukraine" informs the Ministry of Health and the State Service of Ukraine on Medicines and Drugs Control no later than 48 hours from the date of receipt of such information;
- 12) in case of detection of previously unknown dangerous properties of the COVID-19 vaccine, which led or can lead to serious consequences for public health and in the cases where the risk from the use of the COVID-19 vaccine exceeds the benefits, the SE "State Expert Center of the MOH of Ukraine" informs the MOH of such event;
- 13) information on the cases AEFI following COVID-19 immunization, the SE "State Expert Center of the MOH of Ukraine" provides to the VigiBase, Global Database of the World Health Organization;
- 14) the SE "State Expert Center of the MOH of Ukraine" publishes on its website up-to-date information on the safety and effectiveness of the use of the COVID-19 vaccine, which is posted on the official websites of medical regulatory agencies of other countries with strict regulatory legislation.

Additionally, the Order of the Ministry of Health of Ukraine of 22.11.2011 No. 809, registered with the Ministry of Justice of Ukraine on January 30, 2012 under No. 126/20439, defines the Procedure for Prohibition (temporary prohibition) and Resumption of Circulation of Medicines in the Territory of Ukraine. Following paragraph 3.1.3 of the Procedure, the grounds for temporary prohibition of circulation of a medicinal product include, in particular, the receipt from the Ministry of Health of Ukraine and territorial authorities of the State Service of Ukraine on Medicines and Drugs Control of reporting forms about unforeseen adverse events and/or death due to the use of a batch or batches of medicine, prior to the investigation of the causes.

Given the current legislation of Ukraine, the pharmacovigilance of the vaccine against coronavirus disease COVID-19 should be carried out in a way that provides for the continuity of the vaccination campaign against coronavirus disease COVID-19.

Once the vaccination campaign against coronavirus diseases COVID-19 rolls out, the process of the vaccine introduction will be analyzed through supportive supervision, that will be focused directly on the processes of introduction of COVID-19 vaccine, with due consideration given to the immunization practices (such as safety of injections, ensuring compliance with

“cold chain” requirements, pharmacovigilance), as well as the overall effectiveness of the immunization program.

Within the frameworks of the development and support of the pharmacovigilance system, Ukraine has established cooperation with Uppsala Monitoring Centre (UMC), an independent center for drug safety and scientific research. Moreover, in 2019 in 12 regions of Ukraine, training sessions for the the Rapid Response Teams were conducted with the WHO's support (trainings will continue in 2021).

In March 2021, with the technical support of the WHO, the global document "COVID-19 VACCINES: A GUIDE TO SAFETY SUPERVISION" was translated into Ukrainian. It sets out the requirements for the supervision of adverse events after immunization, which are of particular interest and the list of signals recommended for pharmacovigilance in the framework of vaccination against coronavirus disease COVID-19.

FORMATION OF LISTS AND SCHEDULING APPOINTMENTS FOR VACCINATION

The Ministry of Health of Ukraine and its partners have designed a special information portal addressing the issues related to COVID-19 vaccination. The portal will contain information on COVID-19 vaccination, including types of vaccines, a roadmap with defined stages of vaccination, approaches to its organization, staff training, etc., as well as information panels (dashboards) with statistics that will be generated with the participation of the National Security and Defence Council of Ukraine.

The mechanism of lists formation and scheduling of appointments for the vaccination against coronavirus disease COVID-19 currently considers two approaches:

- 1) forming lists via employers, i.e. by the reference to the place of work;
- 2) open appointments for the vaccination against coronavirus disease COVID-19 for target groups that are not linked to the place of work (for example, older adults).

Open appointments for the vaccination against COVID-19 will be made no later than one month before the launch of vaccination for the category to which the target group belongs according to the defined stages of vaccination, and will provide an opportunity to make an appointment using one of the following options:

- 1) self-scheduling of appointment for vaccination through the information portal on the vaccination against COVID-19, web portals of electronic medical information systems, which form a part of the electronic health care system;
- 2) scheduling an appointment for vaccination through the National Contact Center of the Ministry of Health of Ukraine for Countering COVID-19 Spread;
- 3) scheduling an appointment for vaccination at a health care facility.

Scheduling an appointment by a patient willing to receive COVID-19 vaccination will consist of three steps:

- 1) step 1 – identification of a vaccination priority (target) group;
- 2) step 2 – the selection of a vaccination site;
- 3) step 3 – scheduling an appointment.

An appointment to receive the next dose of the vaccine can be scheduled by a healthcare worker during the first dose administration, or after, by notifying the patient via phone or any other convenient channel of communication.

VACCINATION COVERAGE MONITORING AND THE USE OF ELECTRONIC TOOLS

The vaccination and the monitoring of coverage with vaccination against COVID-19 will be carried out using appropriate information and telecommunication systems and tools:

1. Electronic Health system (hereinafter – e-Health).

In order to improve the quality of immunization data and their use in decision-making, an immunization module was created in the e-Health, according to the international standard of medical data transfer. This module will allow:

- 1) store information about the immunization in a convenient for both the doctor and the patient format (the doctor will be able to enter information on the type of vaccine that was administered to the patient, its dosage, method of vaccine administration, causes of conducting or not conducting vaccination, etc. in the system);
- 2) store and analyze information on AEFI signals;
- 3) exchange data on the performed vaccination between different levels of medical care;
- 4) collect qualitative and quantitative statistics on vaccinated patients and patients in need of vaccination, etc.

Also, the central e-Health database has incorporated the Register of medical records, referrals and prescriptions and the Register of patients as well as other registers, which will provide for the availability and completeness of patients' medical data in their electronic health card.

The e-Health will cover the needs of the vaccination component on data collection and analysis (personal patient's data, reasons for vaccination or non-vaccination, the vaccine data: full international name according to the register, batch number, manufacturer, expiration date, first or second administered dose, date of administration, the number of administered vaccine dose, the volume of the administered dose, information about the solvent, etc.).

2. MedData information system.

To implement and monitor the COVID-19 vaccination campaign, the capacities of the MedData information system will cover the following needs in analytical accounting and logistics, in particular on:

- 1) supply of vaccines to Ukraine;
- 2) tracking the movement of the vaccine from the national level warehouse to the regions and the end-user;
- 3) tracking and administration of warehouses' stocks (monitoring of available space in vaccine storage warehouses, the capacity of regional warehouses to receive a certain number of vaccine doses);
- 4) forecasting the need for certain management decisions regarding the distribution of vaccines;
- 5) feature for submitting daily reports on the use of vaccines at the local level;
- 6) feature for accounting refrigeration devices at the local level;
- 7) data integration from various IT systems (API);
- 8) providing information on the current state of transportation and the use of vaccines for dashboards (API).

3. PAIS electronic tool.

The pharmacovigilance system in Ukraine collects data on AEFI, including signals and final classification following the World Health Organization recommendations on the algorithm for AEFI monitoring. The data are reported electronically via the electronic PAIS tool. Vaccination against COVID-19 will be included in the current AEFI reporting system. Accordingly, the regulatory conditions for the operation of the COVID-19 vaccination pharmacovigilance system, as well as the tools for such surveillance, will be updated to take into account international recommendations concerning the specifics of pharmacovigilance of new vaccines against coronavirus disease COVID-19.

The capacity of these systems is sufficient to ensure timely and complete reporting and compliance with the WHO and UNICEF Joint Reporting Form requirements.

Protection of patients' personal data is enshrined in the Law of Ukraine "On Personal Data Protection". Collection, processing of personal data of patients in the electronic health care system is in compliance with the Laws of Ukraine "On Personal Data Protection", "On State Financial Guarantees of Medical Care", the Law of Ukraine "On Information Protection in Information and Telecommunication Systems", resolutions of the Cabinet of Ministers of Ukraine of April 25, 2018 No. 411 "Some Issues of the Electronic Healthcare System", of March 1, 2021 No. 178 "Some Issues of the Functioning of the Electronic Database of the Waiting List for Vaccination against Acute Respiratory Disease COVID-19 Caused By Coronavirus SARS-CoV-2".

The State Service for Special Communications and Information Protection has issued a certificate of compliance of the integrated information protection system (hereinafter – IIPS) to the central database of the electronic healthcare system (hereinafter – CDB e-Health). e-Health is a system that implements the most sophisticated means of data protection, including the use of qualified electronic signatures (hereinafter – QES), the implementation of architectural principles GDPR (separate storage of medical and personal data), blockchain-like algorithms that ensure data integrity, running of regular vulnerability tests. To ensure uninterrupted operation, the services of the main and backup data centers with the appropriate comprehensive information protection system are used.

It is expected that in the process of rolling out of vaccination campaign against coronavirus disease COVID-19, there will be a large number of requests for generalized statistics from the public, media, managers of various levels, etc. To address this issue, information panels (dashboards) have been developed and information and analytical materials with depersonalized data in different sections are prepared on a daily basis: basic statistics, vaccination dynamics, disaggregation of patients by sex and age, regional distribution, table of healthcare providers, information on the number of vaccinations per day, the number of used doses of vaccines, the stock of unused doses of vaccines, etc.

In order to provide the harmonized reporting to the European Surveillance System (TESSy) on the introduction of COVID-19 vaccination in Ukraine, the "Public Health Center of the Ministry of Health of Ukraine" will periodically provide the necessary information to the European Center for Disease Control (ECDC) and the WHO Regional Office for Europe.

During the first year of the vaccine implementation, the Ministry of Health of Ukraine, with the involvement of national and international partners, will

evaluate the success of the deployment of mass vaccination against coronavirus disease COVID-19. The evaluation will help identify positive features and areas for improvement of processes, related to the introduction of the vaccine against coronavirus disease COVID-19 as well as ways to address the existing challenges and draw appropriate conclusions that will allow to take into account and prevent shortcomings in the future introduction of new vaccines. It is planned that within the first stage of the assessment, monitoring visits will be organized to the regions of Ukraine. Their task will involve the assessment of the on-site implementation of the vaccination campaign. Such visits will be organized with the support of the WHO.

OBTAINING VACCINATION DOCUMENTS

The current International Health Regulations adopted by the 58th WHO Assembly on 23.05.2005 and the Resolution of the Cabinet of Ministers of Ukraine of 22 August 2011 No. 893 "On Approval of the Rules of Sanitary Protection of the Territory of Ukraine" define the conditions and approve the form for issuing the International Certificate of Vaccination or Prevention that can be obtained by a person who has undergone a full course of vaccination. The certificate is only valid if the vaccine is approved for use by the WHO.

In Ukraine, such certificates will be generated in electronic format through medical information systems that are part of the electronic healthcare system (the form is filled with the available data, and in the process of entering the client's first and last name, they are transliterated into a foreign language with the possibility of their editing). If necessary, and at the request of a person, the facility which issues the certificate can print it out and certify in accordance with the respective requirements set out for the certificate in a paper format issued for the presentation at the state border.

In addition, the Ministry of Health is currently working with the Ministry of Digital Transformation of Ukraine, the National Health Service of Ukraine, the Ministry of Foreign Affairs of Ukraine, the State Border Guard Service of Ukraine and other partners on the possibility of introduction of a COVID Certificate on the example of EU Digital COVID Certificate.

Such certificates will contain the information on vaccinations against coronavirus disease COVID-19, negative results of PCR testing for coronavirus disease COVID-19, statement of recovery from coronavirus disease COVID-19.

The electronic document can be generated independently in the application or through Diia (Action), the public services portal. A paper version can then be obtained from a family doctor. The possibility of issuing such certificates in administrative service centers is also being considered.

The certificate will contain a security QR code and will be issued free of charge.

TRAINING OF PERSONNEL FOR CARRYING OUT THE VACCINATION

Qualified, well-trained, motivated healthcare workers are essential to the processes of proper organization of the supply and distribution of the vaccine against coronavirus disease COVID-19 as well as prompt vaccination of the target population.

It is also equally important to ensure that infection control measures, set out in the national infection prevention policies, are in place to reduce the risk of spreading coronavirus disease COVID-19 during vaccination to both healthcare workers, who will carry out the vaccination, and those vaccinated.

The Ministry of Health, together with the SI "Public Health Center of the Ministry of Health of Ukraine", the SE "State Expert Center of the Ministry of Health of Ukraine", the World Health Organization Country Office in Ukraine, UNICEF and other national and international partners are developing detailed training plans for carrying out vaccination, which will include the topics on vaccine efficacy and safety data, vaccination contraindications, immunization schedules, information on characteristics, composition management, vaccine dosing and administration, temperature requirements for storage and transportation, "cold chain" monitoring information, accounting requirements and reporting, monitoring of AEFI.

Training on the implementation of COVID-19 vaccination will help increase the confidence of healthcare workers and public health managers in the safety of the vaccine and improve their communication skills, so they are equipped to work with those hesitant about vaccination.

The implementation of educational activities takes place both in a face-to-face format (in-person) and in the form of distance learning – synchronous (webinars) and asynchronous (online courses on the platform of the State Institution "Public Health Center of the Ministry of Health of Ukraine").

In order to quickly scale the training activities and cover the staff needed for vaccinations, the State Institution "Public Health Center of the Ministry of Health of Ukraine" has designed two distance courses on vaccinating population with AstraZeneca + University of Oxford and Sinovac Biotech vaccines. All relevant activities were carried out in compliance with infection control requirements. As of June 8, 2021, 6,876 and 8,675 people, respectively, have successfully completed their studies. These courses can then be used for additional training activities and training of healthcare professionals involved in

vaccination. Also, with the supply of new vaccine products to Ukraine, depending on the training needs, the specialists of "Public Health Center of the Ministry of Health of Ukraine" can further organize the production of additional training products.

Full-time training of medical workers of mobile teams and vaccination points is organized in a cascade format and is implemented with the WHO support. Regional trainings are conducted on the basis of temporary vaccination training centers established at healthcare facilities. About 250 trainers have been trained and continue working in the regions, conducting face-to-face trainings.

Trainings for medical workers of mobile teams and vaccination points include topics on general information on the spread of coronavirus disease COVID-19 in Ukraine and the world, information on vaccines, risk groups. The measures also include training in vaccine handling, preparation and the actual conduction of a vaccination session using a specific vaccine product, equipment for safe injection, diagnosis and emergency responses for severe allergic reaction (anaphylaxis). The content of the training is determined depending on the vaccine product to be used by the mobile team or at the vaccination point.

A total of 476 trainings for healthcare workers of mobile vaccination teams and vaccination points were conducted at the regional level. More than 11,000 primary healthcare workers, including the healthcare workers of mobile vaccination teams and vaccination points involved in COVID-19 vaccination, received comprehensive two-day training based on a standard WHO program and the relevant materials with a special focus on Pfizer/BioNTech, AstraZeneca + University of Oxford vaccines.

These trainings are designed for medical staff of mobile and field teams as well as those working at vaccination points, both the main staff and the reserve. All in-person trainings were conducted in compliance with the infection control guidelines and recommendations on conducting training in the classroom. In addition, both trainings for trainers and the trainings conducted at the regional level involve the personnel of the medical service of the Armed Forces of Ukraine, the Ministry of Internal Affairs and other agencies in accordance with the determined priority groups and the vaccination stages identified in the Roadmap, as well as the specialists of mobile and field teams, carrying out vaccination in mass vaccination points in the regions of Ukraine.

With the increase in the supply of vaccines in the regions, and depending on the needs as new mobile teams are formed and additional medical workers are involved, there might be a need for organizing of additional training activities. In the prospect of further scaling up of the vaccination campaign, the possibility of

involving and training interns and students majoring in healthcare is being considered.

In addition, with the WHO technical support, the following activities within the vaccination campaign framework have been planned (or have already been implemented): an online coordination meeting for regional vaccination campaign coordinators, a combined (online and three-day in-person) seminar on macro- and micro-planning and curatorial support for those responsible for the coordination of vaccination campaign against coronavirus disease COVID-19 at the regional level. These activities included topics on determining the exact number of people eligible for vaccination within the administrative-territorial unit, calculating the needs for human, material, financial resources needed for successful implementation of vaccination, coordination of the process of vaccine supply to the regional level etc. These activities had been carried out with the support of the WHO by 5-11 February, 2021.

The first trainings for mobile vaccination teams (before the introduction of the cascade training system) were conducted in the format of three-day training sessions (one day online and two days in-person) covering the topics on general information on the spread of coronavirus disease COVID-19 in Ukraine and the world, information on vaccines, risk groups. The activities also included training in practice on handling the vaccine, preparation and conduction of a vaccination session using a specific vaccine product, equipment for safe injection. Additionally, training was conducted on the diagnosis of anaphylactic shock and collapse, and the provision of emergency (first-aid) response for severe allergic reactions. The first trainings involved the medical staff of at least two mobile teams for each region and the city of Kyiv – one on the administration of the Pfizer/BioNTech vaccine, the other – on the administration of the AstraZeneca + University of Oxford vaccine within the "first wave" of vaccination stage 1. These trainings had been conducted by February 24, 2021.

Starting from February 2021, the WHO and the "Public Health Center of the Ministry of Health of Ukraine", within the cooperation framework, have been conducting separate trainings for regional coordinators, trainers and healthcare workers of the primary healthcare level. These sessions are held on a monthly basis, covering about 500 people per month.

Special three-day combined (online and in-person) coordination meetings on crisis management and crisis communication (including monitoring, reporting, investigation and final classification of AEFI) for all parties involved were held by WHO on 30-31 March, 2021.

Technical trainings and exercises on improving pharmacovigilance of vaccine safety in the framework of vaccination against coronavirus COVID-19

with the support of WHO will be conducted jointly with the State Institution "Public Health Center of the Ministry of Health of Ukraine" and the involvement of the specialists of "State Expert Center of the Ministry of Health of Ukraine" for all regions starting in July 2021.

All training events conducted by WHO are carried out in close cooperation and coordination with the "Public Health Center of the Ministry of Health of Ukraine", the involvement of specialists from the "State Expert Center of the Ministry of Health of Ukraine" and the National Health Service of Ukraine.

In the future, with the addition of new vaccine products and tools for safe injection to the WHO Emergency Use Listing, the respective training will be organized and conducted for healthcare workers of all mobile teams and vaccination points, according to the standard program and format.

As mass vaccination centers are currently being set up, WHO will also support the training of healthcare workers in such centers (including senior medical students, interns, etc.) based on a standard curriculum and materials.

WHO has also provided technical materials for all training sites: on the "cold chain" for the primary healthcare level (vaccination points and mobile teams) – 15,000 pcs.; on injection safety – 15,000 pcs. In addition, WHO has developed and delivered a set of materials (consisting of three documents) for each mobile team and vaccination point working with vaccines produced by AstraZeneca + University of Oxford and Pfizer/BioNTech, namely: a guide on vaccine handling, a vaccine information leaflet, a technical manual on diagnosis and emergency response for severe allergic reaction (anaphylaxis).

Also, with the support of UNICEF, the trainings on the requirements of supply organization, transportation, storage, disposal, monitoring of supply and accounting of vaccines, safety and protection of workers in the process of implementing of all stages of vaccine logistics, etc. were organized and conducted.

There are plans that with the support of UNICEF, during the third and fourth phases of the vaccination campaign, a series of training sessions, seminars and trainings (online and in-person) on infection control in the course of vaccination will be carried out. These trainings will be aimed at health workers, managers of various levels of the healthcare system and are expected to address the gaps in the practice of infection control, including at vaccination points and mass vaccination centers.

UNICEF will provide training for primary healthcare professionals on the effective implementation of vaccination campaigns on the example of the deployment of vaccination campaign against coronavirus disease COVID-19. A

series of trainings on communicating the issues of safety and efficacy of COVID-19 vaccines are also planned. Moreover, UNICEF will provide the oversight support of the vaccination campaign in the regions, which will include the capacity building for health leaders and local authorities to support the effective implementation of vaccination against coronavirus disease COVID-19, including through the dialogue platforms and exchanges of experience.

UNICEF will additionally provide staff with the skills on conducting a consultation on vaccination. It is expected that during trainings, seminars (online and in-person) and online sessions on this issue, the involved staff will gain knowledge and practical skills on effective and persuasive communication with the public on vaccination issues, handling of questions before and after vaccination, and responding to misinformation (myths) about vaccines. Within the framework of these training activities, UNICEF is planning to develop information and training materials, including manuals, videos and posters for medical staff.

VACCINATION COMMUNICATION AND INFORMATION SUPPORT

One of the important factors in conducting a successful vaccination campaign against coronavirus disease COVID-19 in Ukraine is daily and planned communication, public involvement and counteraction to misinformation about vaccination against coronavirus disease COVID-19. It is necessary to inform Ukrainians about COVID-19 vaccines, details and features of the vaccination campaign, prevent the spread and/or refute inaccurate information about vaccination, as well as strengthen people's knowledge about the importance of vaccination as the most effective way to protect themselves from the coronavirus disease COVID-19 or its severe course, and boost their trust in vaccination.

To coordinate, develop and implement a communication strategy for the deployment and roll-out of vaccination against coronavirus disease COVID-19, in February 2021 with the support of international partners, the Communication Center for Vaccination against Coronavirus Disease COVID-19 was established at the SI "Public Health Center of the MOH" (hereinafter – the Communication Center). Key tasks of the Communication Center are as follows:

development of communication strategy and information campaigns on the launch, course and features of the vaccination campaign against coronavirus disease COVID-19 in Ukraine, counteraction of misinformation about vaccination for the general public, as well as certain priority groups (doctors, military, older adults, social and educational workers, etc.) at national and regional levels;

information support of the vaccination campaign (current activities):

development and distribution of information materials on vaccination against coronavirus disease COVID-19 in Ukraine for mass communication channels: television, radio, print and online media, social networks, outdoor advertising;

work with national and regional mass media outlets, including the provision with materials (statistics, photos, videos), work with inquiries and training of speakers;

involvement of public opinion leaders, experts in the fields of medicine, education, science, etc. in information campaigns;

filling and updating the site <https://vaccination.covid19.gov.ua> ;

coordination of the representatives of the Cabinet of Ministers of Ukraine, the Office of the President of Ukraine, regional state administrations and Kyiv City State Administration, ministries and international partners on COVID-19 communication campaigns to ensure a common position on this issue;

prompt response to crisis situations (crisis communications);

other functions related to communication support for COVID-19 vaccination.

Accordingly, in February 2021, Ukraine with the support of international partners (UNICEF, WHO, the United States Agency for International Development (USAID)) developed a strategic communication framework, that sets out five strategic priorities:

1. Communication activities on COVID-19 vaccination are effective, coordinated and sound.
2. Population, especially priority groups (medical and social workers, older adults, education workers) has access to verified, well-reasoned information on COVID-19 vaccines and vaccination.
3. The demand for COVID-19 vaccination has increased, especially among priority groups (medical and social workers, the elderly, education workers).
4. The negative impact of probable AEFI on the level of demand for COVID-19 vaccination is minimized.
5. The negative impact of infodemic on the level of demand for COVID-19 vaccination is minimized.

Taking into account the current stages of the vaccination campaign and the priority groups to be vaccinated, the Communication Center develops quarterly and operational weekly communication plans. It also monitors public sentiment

and evaluates the effectiveness of the communication campaign on vaccination, coordinates with partners the conduction of sociological research and uses its results to update and adjust the communication strategy, update key messages and priorities of behavioral campaigns.

The reporting on the results of the Communication Center's work takes place at the Task Force meetings.

Key outputs of the Communication Center work in February - May 2021

Provision of information, behavioral campaigns, community involvement and other activities aimed at increasing the demand for vaccination among the population in the first two stages of vaccination campaign directed at priority groups eligible for vaccination, namely: medical, social and educational workers, the military, older adults. The provided information included the information on the types of vaccines available in Ukraine at a particular moment for particular priority groups.

The communication campaign began with the delivery of the first supply of vaccine to Ukraine on February 23, 2021. The results of proactive communication since the end of February are as follows:

The website covering the vaccination campaign against coronavirus disease COVID-19 in Ukraine <https://vaccination.covid19.gov.ua> has been developed and is constantly updated. The site publishes prompt updates on multiple issues: COVID-19-related statistics, news, answers to frequently asked questions, stages of the vaccination campaign against coronavirus disease COVID-19, types of vaccines, the course of the vaccination campaign, debunking of myths, a list of vaccination points, the ability to sign up for a waiting list, etc. A special section for doctors has been developed separately. The site is included in the Google and YouTube partner promo to increase the traffic. The banners leading to the website are placed on the websites of the Cabinet of Ministers of Ukraine, ministries and Regional and Kyiv State Administrations. The website visitors have the opportunity to subscribe to the weekly newsletter.

A single visual identity (brandbook) has been designed to communicate the COVID-19-related vaccination issues. This allows to produce all information materials for the population in a single style, as well as indicate (highlight or mark) the verified and reliable information, as well as official sources of information.

Databases of information materials on vaccination have been created and are constantly updated: brochures, infographics, videos: bit.ly/vac_covid19_info and photobank: bit.ly/photovacua;

5 informational videos on television within the social quota were launched: 1 video – on the deployment and principles of the vaccination campaign, 2 videos called "Infodemia Virus" where opinion leaders explain the importance of adhering to the principles of information hygiene and getting information from reliable sources (March 2021), 2 videos on the importance of vaccinating the older adults (May 2021).

An audio clip about the launch of the vaccination campaign was provided to radio stations within the social quota (March 2021).

Information leaflets with details about vaccines against coronavirus disease COVID-19 available for vaccination in Ukraine, expected side effects, AEFI and recommendations on how to address them were printed and distributed: 1,218,000 (for Covishield and AstraZeneca-SKBio), 473,850 – for Comirnaty/Pfizer-BioNTech, the leaflets on CoronaVac vaccine were forwarded to the regions in electronic form.

A weekly update of information materials and answers on the course and features of the vaccination campaign against coronavirus disease COVID-19 for the Contact center of the Ministry of Health.

In places of mass points of contact with citizens:

100,000 A3 posters about the vaccination campaign against coronavirus disease COVID-19 and 100,000 A3 posters about infection control during vaccination were provided for distribution at the regional level;

379 posters for billboards and 534 for citylights were transferred to the regional state administration for further placement on advertising planes within the social quota;

Informational videos on the video screens of the partners: Intercity trains (9 directions), Oschadbank, Privatbank (1200 screens), Boryspil International Airport (7 screens).

All printing and logistics are carried out with the support of partners, and the placement of the abovementioned materials – within the social quota.

Online communication:

The social networks of the Ministry of Health, the "Public Health Center of the Ministry of Health of Ukraine" and its regional offices, the National Health Service publish daily content about the process of vaccination against coronavirus disease COVID-19, vaccines against coronavirus disease COVID-19, explanations of contraindications, recommendations for priority groups, refutation of inaccurate information, photo- and video stories about the vaccination of priority groups (doctors, military, educators, older adults), etc. In

February-May, social networks had more than 144 million contacts of (non-unique) audiences. Separately, line ministries publish content on vaccination of their priority groups, for example, the Armed Forces of Ukraine on the vaccination of military personnel, the Ministry of Education and Science of Ukraine – on the vaccination of educators, and others.

Together with the partners, online broadcasts involving experts are held for target groups (physicians, social workers, educators) and the general public. The invited experts cover the issues on the specifics and the course of the vaccination campaign, debunk the myths about vaccination and provide up-to-date information about vaccines and vaccination.

An information resource on vaccination against coronavirus disease COVID-19 for businesses (covidbiz.info) has been developed with the support of UNICEF and the European Business Association (EBA).

Content promotion on YouTube and Facebook has been implemented within the partnership cooperation framework.

Moreover, the Communication Center provides experts and data to inform the public through the media and maintains the weekly distribution of updated materials, statistics, photo and video content to national and regional media. The Communication Center also supports the media coverage of the events of vaccines arrival to Ukraine. It also conducts daily media monitoring to assess the dynamics of publications and analyze the needs of the info field.

Together with partners, the Communication Center developed and distributed handbooks and manuals for physicians and those involved in the vaccination campaign against coronavirus disease COVID-19, namely:

"100+ questions about vaccination" together with the experts from the Ministry of Health, State Institution "Public Health Center of the Ministry of Health of Ukraine" and NGO "Parents for Vaccination";

COVID-19 Vaccination: Principles for Effective Communication with Patients (with UNICEF support).

The Communication Center has also been involved in the conduction of measures aimed to inform about the course of the vaccination campaign and refute inaccurate information in the regions that needed it most, namely in Chernihiv, Volyn, Sumy, Donetsk, Zakarpattia and Chernivtsi regions. In addition, information support is provided for vaccination activities, such as vaccination of members of religious communities.

Information cooperation has been established with international organizations, state enterprises, relevant public organizations and experts to prevent the spread of unreliable information about vaccination against

coronavirus disease COVID-19, including SC "Ukroboronprom", JSC "Ukrposhta", Red Cross, BO "100% life", etc.

To monitor public sentiment and assess the effectiveness of the communication campaign on vaccination, a public opinion poll on vaccination⁴⁸ and qualitative surveys with the representatives of priority groups were conducted. Such surveys will also be conducted during the year to assess the dynamics of public sentiment and study the opinion of priority vaccination groups on vaccines and the course of the vaccination campaign against coronavirus disease COVID-19 in Ukraine. With the support of UNICEF and the World Bank, behavioral analysis of research results and the development of appropriate recommendations will continue.

Next steps

According to various surveys conducted in early 2021, less than half of Ukrainians express an intention to be vaccinated against coronavirus disease COVID-19. For example, in March 2021, the percentage of those willing to be vaccinated ranged from 33% (Kyiv International Institute of Sociology⁴⁹) to 48% (WHO). At the same time, WHO⁵⁰ surveys showed an increase in the willingness to get vaccinated, so at the end of April, 54% of the population stated they were ready to be vaccinated if the vaccine was available and recommended for their population group. The research results of some agencies, in particular, Razumkov Center⁵¹, Kyiv International Institute of Sociology, the group "Rating"⁵² show that the older people are, the more inclined they are to get vaccinated. Also, people residing in the western and central regions of Ukraine are more likely to get vaccinated than those living in the eastern and southern regions. The main reasons for the unwillingness to be vaccinated are the doubts about the safety and efficacy of vaccines, as well as fears of side effects. Some believe that the risks of vaccinations outweigh the risks of the disease (COVID-19), and some refuse vaccination because have recovered from COVID-19 or have contraindications to vaccination (according to the information provided by the respondents).

⁴⁸ COVID-19 Vaccination Attitude Survey, March 2021, Info Sapiens, supported by the United States Agency for International Development (USAID) uni.cf/3zekV8x

⁴⁹ Survey "Attitudes of Ukrainians to vaccination and possible introduction of quarantine", March 2021, Kyiv International Institute of Sociology bit.ly/3iDENfb

⁵⁰ 12 wave of a panel study of behaviors and attitudes in the context of the COVID-19 pandemic in Ukraine, WHO, April 2021

⁵¹ Survey "Attitudes of Ukrainian citizens to vaccination against COVID-19", March 2021, Razumkov Center bit.ly/3glDVKQ

⁵² Survey "Socio-political sentiments of Ukrainians", May 2021, sociological group "Rating" commissioned by the Center for Analysis and Sociological Research of the International Republican Institute, bit.ly/3vjmsXp

Respectively, in order to raise public awareness of the importance of vaccination, facilitate in overcoming of the population fears toward vaccination, as well as refute inaccurate information and increase the demand for vaccination among target groups and adults in general, the Communication Center together with the Cabinet of Ministers of Ukraine, the line ministries, local authorities and international partners plan to increase the intensity of communication on the vaccines used in Ukraine, their efficacy and safety, vaccination recommendations, AEFI and other details that are important for Ukrainians.

The following steps include:

- Support of current communication on the course and features of vaccination campaign against coronavirus disease COVID-19 on official resources of the Ministry of Health, State Institution "Public Health Center of the Ministry of Health of Ukraine" and its regional offices, National Health Service, <https://vaccination.covid19.gov.ua> and partners.
- Implementation of communication campaigns on the importance of vaccination of priority groups (older adults, medical, educational and social workers, etc.) through mass communication channels
- Involvement of communities, primary healthcare workers and specialized experts to inform and build knowledge of the population about the importance and necessity of vaccination against coronavirus disease COVID-19, explain the features and inform on the course of the vaccination campaign.
- Production and dissemination of information materials covering the topical issues of vaccination against coronavirus disease COVID-19, for example:
 - with the support of UNICEF, 220,000 frequently asked questions about vaccination for educators, social workers and older adults have been published and distributed;
 - with the support of the Red Cross, the printing and distribution of 135,000 information materials (posters and flyers) about vaccination against coronavirus disease COVID-19, vaccination recommendations for people with comorbidities, etc.
- Development of materials and information support of the Centers for Mass Vaccination of the Population.
- Work with national and regional mass media, rapid informing about the course of the vaccination campaign, provision of photo and video materials.

- Conducting online events with experts on vaccines and vaccination against coronavirus disease COVID-19.
- With the support of UNICEF, conducting a series of training events for communications professionals at the local, regional and national levels. The training will include courses on strategic communication in the area of health and behavior change during pandemics, courses (online and in-person) for health managers, primary healthcare providers and non-governmental organizations on effective counseling, and behavioral and social communications, with a special focus on pandemics, vaccination, and outbreak response. Other educational opportunities within the framework of communication and information support of vaccination will include trainings and online sessions for journalists covering vaccination, as well as information support within the collaboration with opinion leaders.
- Involvement of partners among public and international organizations for the dissemination of information materials in communities and among target groups.
- Conducting public opinion polls and media monitoring to assess the dynamics of vaccination information, analysis of the demand for coverage of certain aspects of the vaccination campaign, etc.

As part of communication support, one of the strategic priorities would also be to conduct the analysis and combat false information and misinformation about vaccines and vaccination against coronavirus disease COVID-19. Work in this direction includes the analysis of information in the media and social networks, the development of content and information materials that debunk myths and respond to current information requests, involving young people in the verification of information on social networks, and more. With the support of UNICEF, the Communication Center is planning to implement a new system of analysis and response to misinformation on social networks.

Given that the vaccination campaign against coronavirus disease COVID-19 is considered a national security issue in Ukraine, communication strategies in support of the vaccination campaign will be constantly updated in order to effectively reach the target audience and create an appropriate information environment.

WAYS OF FUNDING THE COSTS RELATED TO VACCINATION

The main ways of funding the costs related to the implementation of the vaccination campaign against coronavirus disease COVID-19 (including the procurement of vaccines, the cost of logistics services for vaccines transportation,

procurement of personal protective equipment, necessary tools such as injection syringes, safe disposal containers, thermal bags for vaccines transportation, antishock first aid kits, etc.) are the following:

- funds of the state budget of Ukraine;
- funds of international donors and other structures;
- loan funds under the programs of the World Bank, the European Investment Bank, etc.;
- other sources not prohibited by the law.

According to the preliminary estimates, the total financial need for the implementation of the vaccination campaign in February 2021 – March 2022 is about 9 billion UAH, taking account of the estimated needs for financial support within the following priority areas:

- 1) procurement of vaccines and tools for safe injections;
- 2) procurement of personal protective equipment;
- 3) procurement of antishock kits;
- 4) procurement of thermal containers (portable cold boxes);
- 5) costs of cold chain provision, logistics and waste management;
- 6) financing of vaccination services as part of the Program of medical guarantees;
- 7) capacity building measures with a focus on compliance with infection control during vaccination;
- 8) monitoring and evaluation;
- 9) crisis communication, community involvement and behavioural interventions;
- 10) monitoring of vaccination safety, monitoring and response to AEFIs and crisis management.

Currently, it is planned that the costs associated with the implementation of the vaccination campaign against COVID-19 in Ukraine will be covered from the following resources:

- 1) free delivery of vaccines, tools for safe injections and safe disposal boxes through the COVAX AMC mechanism for 20% of the Ukrainian population;
- 2) 3.9 billion UAH from the state budget of Ukraine (procurement);
- 3) 1.9 billion UAH from the state budget of Ukraine (Medical Guarantees Program);
- 4) Nearly 2.7 billion UAH (USD 90 million) of credit funds under the World Bank program;

- 5) Nearly 1,5 billion UAH (USD 50 million) of loan funds under the European Investment Bank program.

In order to fully cover all the costs necessary to implement the vaccination campaign to the declared extent, the Ministry of Health will initiate additional negotiations with international donors on the provision of support to cover all necessary costs.

**Deputy Minister of Health –
Chief State Sanitary Doctor of Ukraine**

Ihor KUZIN