REPUBLIC OF MOLDOVA

EMERGENCY COVID-19 RESPONSE PROJECT (P173776) and VACCINES ADDITIONAL FINANCING (P175816)

ENVIRONMENTAL AND SOCIAL MANAGEMENT FRAMEWORK

Updated for the Additional Financing in Support to Procurement and Deployment of Vaccines

CHISINAU, 2021

Table of Contents

ABBREVIATIONS AND ACRONYMS

AMR	Antimicrobial Resistance
CNAM	Compania Naţională de Asigurări în Medicină / National Health Insurance Company
CNAS	Casa Naţională de Asigurări Sociale / National Social Insurance House
DLI	Disbursement Linked Indicators
EA	Environmental Agency
EU	European Union
EIA	Environmental Impact Assessment
ESCP	Environmental and Social Commitment Plan
ESF	Environmental and Social Framework
ESMF	Environmental and Social Management Framework
ESMP	Environmental and Social Management Plan
ESS	Environmental and Social Standard
NBS	National Bureau of Statistics of the Republic of Moldova
GIIP	Good International Industry Practice
GBV	Gender Based Violence
GMI	Guaranteed Minimum Income
GoM	Government of the Republic of Moldova
GRM	Grievance Redress Mechanism
IBRD	International Bank for Reconstruction and Development
ICU	Intensive Care Unit
IEP	Inspection for Environmental Protection
ICP	Infection prevention and control
ICU	Intensive Care Unit
ICWMP	Infection Control and Waste Management Plan
ILO	International Labor Organization
JEE	Joint External Evaluation
LEPL	Legal Entity of Public Law

LMP	Labor Management Procedures
MRT	Magnetic Resonance Tomography
MoE	Ministry of Environment
MIA	Ministry of Internal Affairs
MoH	Ministry of Health
MoD	Ministry of Defense
NARNRA	National Agency for the Regulation of Nuclear and Radiological Activities
PBC	Performance-Based Conditions
PCR	Polymerase Chain Reaction
POPs	Persistent Organic Pollutants
PPE	Personal Protective Equipment
SEA	Sexual Exploitation and Abuse
SH	Sexual Harassment
SEP	Stakeholder Engagement Plan
SWMC	LLC Solid Waste Management Company
TSA	Targeted Social Assistance
UNECE	United Nations Economic Commission for Europe
WHO	World Health Organization

Executive Summary

Project Development Objective Statement: The project development objective is to prepare for and respond to the COVID-19 pandemic in the Republic of Moldova.

The Project consists of the following two components:

COMPONENT 1: Emergency COVID-19 Response (EUR 55.26 million)

Subcomponent 1.1 Case Confirmation (EUR 3.06 million): the project will support strengthening diseases surveillance systems and the capacity of the selected public health laboratories to confirm cases by financing medical supplies and equipment. It will include PPE and hygiene materials, COVID-19 test kits, laboratory reagents, Polymerase chain reaction (PCR) equipment, specimen transport kits, and light vehicles for safe and rapid transportation of samples.

Subcomponent 1.2 Health System Strengthening (EUR 30.0 million): the project will finance the strengthening of public health facilities to provide critical care to COVID-19 patients and minimize the risk of health staff and other patients becoming infected. It will finance PPE and hygiene materials, as well as training on infection prevention and control (IPC) practices, with a focus on staff providing care to suspected and confirmed cases. It will also provide equipment, drugs and medical supplies, in particular ICU units and beds in designated hospitals, as well as training on COVID-19 treatment and intensive care to respond to the surge in patients requiring admission in ICUs. It will support interior minor refurbishment to remodel ICUs and increase the availability of isolation rooms. The project will also finance ambulances to support urgent transportation of patients across the hospital network to designated reference facilities as per the algorithm of the Government Preparedness and Response Plan. As of February 8, 2021, EUR 18.8 million (US$ 21.35 million equivalent) in 46 contracts have been committed, and the following have been delivered: ICU beds (396 units), electrocardiographs (42 units), syringe pumps (1,400 units), patient monitors (500 units), ventilators (92 units), pulse oximeters (150 units), personal protective equipment (330,000 units), oxygen concentrators (400 units), laparoscopic trolleys (3 units), mobile x-rays (11 units), vehicles for laboratories (4 units), extracorporeal membrane oxygenation machine (1 unit), and supplies and equipment for testing for EUR 3.94 million (US$ 4.5 million equivalent).

Subcomponent 1.3 Communication Preparedness (EUR 0.3 million): the project will support information and communication activities to increase the attention and commitment of government, private sector, and civil society to the COVID-19 pandemic, and to raise awareness, knowledge and understanding among the general population about the risk and potential impact of the pandemic. Specific activities will include, inter alia, (a) the development and implementation of a national communication and outreach strategy, including social and behavioral communication change across multiple channels; and (b) developing and distributing communication materials on COVID-19 and general preventative measures to the general public, which will be complementary to the UN actions.

Subcomponent 1.4 Social and Financial Support to Households (EUR 21.9 million): the project will support strengthening the social protection for the poor by amending the design of Ajutor Social program[1] so that it is better able to target vulnerable populations who stand to be adversely affected by COVID-19. This amendment is simultaneously an emergency response and a reform. First, the reform aspect would strengthen support for families with children, better aligning the program design with the social policy goals of supporting the poorest and improving targeting and efficiency of social

[1] The Ajutorul Social Program was set in 2009 based on **Law on Social Assistance # 133** (June 13, 2008), which regulates the legal framework on guaranteeing equal opportunities for disadvantaged families by providing social assistance at a state-guaranteed level. More details in section 3.3.

expenditures. Second, the income eligibility threshold (GMI) for all beneficiaries will be temporarily increased (by 23% instead of the planned indexation of 4.8%). GMI threshold is used both to determine eligibility, filtering out families with incomes higher than GMI per adult equivalent, and to determine the benefit size, which is the gap between guaranteed minimum income for the family (GMI x adult equivalents of family members) and the actual income. This measure will result in expanding the coverage of the poor who as a group will be disproportionately affected by increased prices and loss of income associated with COVID-19. Third, employment status checks will be temporarily dropped, which will enable inclusion of returning migrant workers and families with members in informal employment, thus including these vulnerable categories. Also, for the emergency period, the government will automatically extend eligibility for families that are up for re-certification, accept remote applications (e.g., by phone), and replace income verification documents with the applicant's declaration. It is expected that as a result, for the emergency period, the average benefit for current recipients will increase from MDL 828 to MDL 1,520 (84% increase), while for families with children it will be MDL 2,800This subcomponent will disburse against two Disbursement Linked Indicators (DLI). The three DLIs will include (i) necessary legislation changes and increased budget allocation to the Ajutor Social program, and (ii) measures of increased benefit and coverage.

The project disbursements under "Social and Financial Support to Households" sub-component is linked to the Government's poverty-targeted cash benefit program Ajutor Social and verified achievement of Performance-Based Conditions (PBC). In this respect the project would rely on the existing benefits payments system managed by the National Social Insurance House (CNAS) and the Government's budget management and reporting systems. As of February 8, 2021 the Government of Moldova had paid EUR 22.1 million (US$ 26.31 million equivalent) to support 54,000 low-income households since 2020. On August 26, 2020, the Government submitted the justification for the achievement of the two performance-based conditions (PBCs) under Subcomponent 1.4, that is PBC 1 – Supplement budget increasing allocations for the Ajutor Social Program by 39% adopted; and PBC 2 – Increase of the benefit and the coverage by 10% achieved. The Government proposes to change the eligibility criteria to reduce the benefit for families with unemployed members to decrease the dependency on social assistance. The disbursement linked to the achievement of the two PBCs will be conditional on the commitment to maintain the coverage and budget of the Ajutor Social program.

Subcomponent 1.5: Vaccine Procurement and Deployment (EUR 24.8 million) will finance vaccine procurement, supply chain, and service delivery activities through this new Subcomponent 1.5, while the increase in the project scope will be reflected in an increase in allocation to Component 1 from EUR 55.26 million to EUR 80.06 million, with the full amount of EUR 24.80 million allocated to Subcomponent 1.5. More details on the new Subcomponent 1.5 are provided in Chapter 2 Project Description.

COMPONENT 2: Implementation Management and Monitoring and Evaluation (EUR 0.6 million)

This component will provide financing for project implementation, coordination, and management, including support for procurement, financial management, environmental and social safeguards, monitoring and evaluation of prevention and preparedness including third-party monitoring of progress.

Project location. The project will be implemented countrywide.

In addition, Moldova has received additional US$3.48 million (equivalent to EUR 2.96 million) grant from the Pandemic Emergency Financing Facility Fund (PEF). The grant is an additional financing (AF) (i) to increase the testing and laboratory capacity (under Component 1.1), and (ii) to procure additional mobile X-Rays and to train health care workers (under Component 1.2) in line with

Moldova's strategic preparedness and response plan. As of February 7, 2021, the Credit has disbursed EUR 15.94 million (US$ 18.98 million equivalent), which is 29.84% of the net commitment of EUR 52.90 million (US$ 57.90 million equivalent).[2] The grant from the Pandemic Emergency Financing Facility is 100% disbursed.

Potential key environmental and social risks related to the project include:

1) Occupational health and safety for medical staff, laboratory staff and communities in due course of detection, transportation of patients/tests/chemicals and reagents, and treatment stages of the COVID-19 cycle;
2) Occupational health and safety related to collection, transportation and disposal of medical waste management;
3) Security and efficiency of logistics and distribution of the vaccine, determined by the fact that COVID-19 vaccines require specific temperatures during storage and distribution to maintain efficacy and safety;
4) Waste management;
5) Vulnerable and disadvantaged groups (low-income, disabled, elderly, isolated communities, including potentially Roma communities) encountering obstacles to access facilities and services provided by the project activities;
6) Handling of quarantining interventions (including dignified treatment of patients; attention to specific, culturally determined concerns of vulnerable groups; and prevention of sexual exploitation and abuse and sexual harassment as well as meeting minimum accommodation and servicing requirements);
7) Social tensions that could be exacerbated by the project and community health and safety-related outcomes (especially related to spread of disease and waste management);
8) Social exclusion which is widespread in Moldova due to variance in communities' or individual's ability to pay;
9) Ensuring transparency and equity for financial support to households targeting specifically vulnerable populations.
10) Misinformation, lack of information, and disinformation on COVID-19 or the adverse health effects of vaccines.

To mitigate social and environmental risks the Ministry of Health (former Ministry of Health , Labour and Social Protection) prepared an Environmental and Social Management Framework (ESMF was developed in August-September 2020 and disclosed in November 2020. Following negotiations held in March 2021 between the Government of Moldova and the WB related to Additional Financing for procurement and deployment of vaccines, the ESMF was updated to reflect the risks and mitigation measures associated with procurement and deployment of vaccines. It is assessed that the residual environmental risks for AF remain substantial; however the nature of these risks is different given the new vaccination-related activities.

The main environmental risks identified at this stage are: (a) Occupational Health and Safety issues related to testing and handling of supplies during vaccination; (b) logistical challenges in transporting vaccines

[2] It is estimated that by the end of March 2021, the original project would have disbursed EUR 26.9 million or 55.27% of the net commitment of EUR 52.90 million (US$ 57.90 million equivalent).

across the country in a timely and safe manner, adhering to the recommended temperature and transportation requirements; (c) production and management of medical healthcare waste; (d) community health and safety issues related to handling, transportation, and disposal of hazardous and infectious healthcare waste associated with vaccination, including sharps and used vaccine vials; and (e) minor environmental impacts—noise and dust emissions—from minor construction work in vaccine storage facilities. These risks are covered by ESS 1, ESS 2, ESS 3, ESS 4, and ESS 10.

To mitigate these risks, in September 2020, the Ministry of Health prepared an ESMF, which contains provisions for storing, transporting, and disposing of contaminated medical waste. The document also outlines guidance in line with good international practice and WHO standards on COVID-19 response on limiting viral contagion in healthcare facilities. The ESMF was updated by project effectiveness to account for the AF-funded activities. Environmental risks mainly relate to vaccine procurement and deployment, including minor works in vaccine storage facilities. The current draft includes a template for the Infection Prevention and Control and Waste Management Plan, which will also be revised to reflect evolving procedures for managing waste associated with vaccination by the AF Effectiveness Date.

The social risk is substantial. There is a risk of inequity in vaccines' access due to political pressures to provide vaccines to groups that are not prioritized based on need or vulnerability. Political pressure may exclude the elderly and other vulnerable groups. There may also be traffic and road safety risks to community health and safety that arise during nationwide transportation of vaccines for deployment, including the risk of injuries. Social tensions could be exacerbated by the Project and community health and safety-related outcomes, primarily related to the spread of disease and waste management. To mitigate these risks, the updated ESMF and the SEP will outline the components of the communication and outreach campaign to ensure vaccine delivery targets the most vulnerable populations according to criteria specified in this AF. Risks associated with the distribution and transport of vaccines were assessed and appropriate mitigation actions are outlined in the present updated ESMF and Labor Management Procedure, which is a standalone document. These are in line with the Environmental and Social Commitment Plan, which outlines the mitigation measures by implementing agencies to address evolving environmental and social risks associated with new project activities.

In addition, it is expected that there will be a moderate residual risk related to data collection, processing, and privacy during deployment. The identification of priority groups will require access to individually identifiable electronic medical records. Risks to data collection, processing, and privacy may arise from: (a) access to personally identifiable and sensitive information by unauthorized personnel; (b) gaps in regulation on data privacy and protection; and (c) breaches to cybersecurity. There are regulations under the national immunization program that provide adequate guidance for the appropriate use and processing of data, privacy considerations that limit access to essential personnel, and precise institutional arrangements for childhood vaccine delivery. In addition, the AF will provide support for software and hardware investments that further mitigate the risk of cybersecurity breaches. These investments may be vulnerable to vendor lock-in that will be mitigated through prior review of relevant tenders by relevant technical experts in the World Bank team. The updated Project Operational Manual also specifies mechanisms to ensure personal data protection.

A Stakeholder Engagement Plan was prepared for the original project and disclosed in March 2020. The SEP was updated and disclosed on November 11, 2020 to reflect emerging changes, and then it was

updated and disclosed on 02 March 2021 as part of consultations and preparations of Vaccine AF (P174761). A stakeholder's consultation meeting was held on February 26, 2021 with representatives of the civil society (active on social and environmental protection), employers' national organization, workers' organization, state labour inspection, state agencies working in the health sector and the management of healthcare institutions from allover the country. The consultation meeting was held online.

The SEP may be updated in course of project implementation to ensure effective communication and engagement of stakeholders and communities. The project is engaged with civil society organizations to support outreach and community engagement to enhance transparency and accountability. A beneficiary feedback indicator in the results framework measures the effectiveness of the community engagement platform of activity.

Institutional Arrangements: the Ministry of Health is the implementing agency for the project and ensuring compliance with provisions of the present ESMF. The Ministry of Health is designated as the central operational body within the GoM and standing headquarters for COVID-19 prevention and response. The Ministry of Health will request compliance of all contractors and subcontractors with provisions set in this ESMF. For Subcomponent 1.4 "Social and Financial Support to Households", Casa Nationala de Asigurari Sociale (CNAS) will be responsible for managing the payment of benefits: receiving the lists of eligible beneficiaries from social assistance departments at local level, submitting payment requests to the Ministry of Finance, monitoring the cash distribution through designated commercial banks and post offices, and accepting their monthly reports on benefit execution. The project disbursements under "Social and Financial Support to Households" sub-component is linked to the Government's poverty-targeted cash benefit - Ajutor Social Program and verified achievement of Performance-Based Conditions (PBC).

The Ministry of Health as the implementing agency for the original project and will lead the coordination and implementation of activities under the AF for vaccine procurement and deployment.

The Project Implementation Unit located in the premises of the MoH is responsible for the day-to-day management of project activities and supervision of implementation of ESMF provisions by relevant contractors and stakeholders. The PIU consists of a team of consultants with expertise in project coordination, procurement, FM, environmental and social management, and monitoring and evaluation. The Ministry of Health is responsible for the national COVID-19 vaccination program's overall governance and will facilitate the program's alignment of activities under the project. The Ministry of Health is also responsible for developing a project report at the end of each calendar semester.

1. Introduction and Background

An outbreak of COVID-19, caused by the 2019 novel COVID-19 (SARS-CoV-2), has been spreading rapidly across the world since December 2019, when the initial cases were diagnosed in Wuhan, Hubei Province, China. On March 11, 2020, the World Health Organization (WHO) declared a global pandemic.

The COVID-19 outbreak in Moldova started on March 8th and on March 17th, Moldova's Parliament declared a State of Emergency until May 15, 2020. Following Parliament's declaration of the state of emergency, the Exceptional Situations Commission met and introduced an increasing set of measures aimed at slowing the spread of the virus. Critical restrictions were imposed on movement, in line with social distancing practices that are emerging worldwide. Following the announcement of the Code Red Alert, on March 13th, all educational institutions, and many public venues, including gyms, museums, and theaters, bars and restaurants were closed. Strict transportation restrictions were introduced, including the suspension of air and rail traffic, as well as the closure of 70 of Moldova's 81 land border crossings with Romania and Ukraine. Additional quarantine measures have followed, including: the establishment of a special working regime for all entities (public sector working hours 7:30 – 16:00); prohibition of meetings, public events and other mass events; requiring that schools and universities shift to on-line and distance-learning methods; and the near-all, temporary suspension of courts processing criminal and administrative cases (with exceptions). The commission also decided to make all medical care related to COVID-19 free, regardless of whether patients have medical insurance.

The Ministry of Health has taken a leading role in managing the response to the pandemic and acting quickly on all aspects related to the COVID-19 outbreak. The development partners have mobilized and joined efforts to strategically contribute to the most urgent needs. The UN Regional Coordination has assured country-level coordination of the donor response through regular coordination meetings with the participation of key development partners, such as WHO, UNICEF, UNFA and the World Bank as well as bilateral donors. The support included methodological, logistical and operational support and included: the needs assessment and costs for health system needs based several scenarios of pandemic development; the development of risk communication plan and public communications materials; the implementation of technical guidelines on COVID-19 EPI surveillance and contacts investigation, quarantine and restriction measures. The country progress on pandemic preparedness and response capacity ("health security") is monitored by the World Bank and WHO as part of the Universal Health Coverage index[3].

The COVID-19 pandemic poses serious social and economic challenges to the country and represents a severe risk of losing important gains in the fight against poverty. The lockdown and closure of all non-essential business activities slowed down the production, increased layoffs, reduced labor income - especially for private sector workers - with significant adverse impacts on employment and poverty. Economic activities, particularly in the tourism and hospitality sectors, have come to a standstill.

To Government of Moldova requested the World Bank support in early March 2020 to help Moldovan authorities deal both with the response and address the social and economic consequences of the pandemic. The World Bank responded by fast-tracking the preparation of the 52.9 million-euro Moldovan Emergency Covid-19 Response Project which was approved by the World Bank Board on April 24, 2020 and ratified by the Moldovan Parliament on May 21, 2020. The project became effective on May 28, 2020 and it is expected to complete on April 30, 2022. Ministry of Health is the project implementing entity.

[3] *https://www.who.int/healthinfo/universal_health_coverage/en/*

In addition to the financing provided by the World Bank under the original project, a US$3.48 million *Pandemic Emergency Financing Facility Fund* (PEF) Grant ("PEF Grant") was implemented to support activities already defined under the original Project under the same project development objective.

Under the original project, the detection of COVID-19 cases in Moldova has been supported by the procurement of test kits, laboratory reagents, polymerase chain reaction equipment, and specimen transport kits. Testing is performed for suspected and probable cases, including symptomatic medical workers or individuals in closed settings. Following the pandemic's onset, capacity for case management was expanded to 2,780 beds, including 481 beds for intensive care, in 53 hospitals. The number of ventilators for respiratory support was increased to 452, and 3,570 health workers were mobilized to provide care to COVID-19 cases. A triage center was established in Chisinau, with a capacity of 250 beds, in response to an increase in community spread and the need for additional triage capacity.[4]

The intermittent surge in cases highlights the potential for an effective COVID-19 vaccine, contributing to mitigating the virus's spread better. New therapies have emerged, and there are safe and effective COVID-19 vaccines in the global market.

As of February 2021, more than 200 vaccine candidates were being developed and tested around the world, but not all of them meet WHO's science-driven prerequisites for controlling the pandemic. In addition to the target profile, the vaccine candidates — tested in different labs and evaluated by varying regulators around the world — have to meet rigorous safety requirements to receive WHO's final stamp of approval, vouching for their efficacy, safety, and quality[5].

As of mid March 2021, twenty-two vaccines were in large-scale phase 3 clinical trials and researches were testing 78 vaccines in clinical trials on humans, and 22 have reached the final stages of testing. At least 77 preclinical vaccines were under active investigation in animals. [6] As of mid March 2021, four vaccines received WHO approval[7] and a total of 363,691,238 vaccine doses have been administered worldwide[8]. Israel has the highest number of vaccinations administered per capita, and the pioneer in COVID-19 immunization.

In Moldova, the need for additional resources to support COVID-19 vaccine procurement and deployment was formally conveyed by the Ministry of Finance (MoF) on December 17, 2020. The Government of Moldova aims to procure and deploying COVID-19 vaccines to cover 70% of its population. World Bank financing will support the procurement of eligible COVID-19 vaccines to cover 30% of the population in the second and third stages of vaccination and will provide technical and financial support for vaccine deployment for 50% of the population.

Vaccines supported under the project will meet Bank regulatory standards, and the investments under the AF will strengthen immunization systems to ensure successful vaccine deployment. All COVID-19 vaccines will be provided free of charge. The staged rollout will be guided by the National COVID-19 Vaccine Deployment Plan, which identifies priority groups in line with the World Health

[4] Covid19healthsystem.org. 2021. Republic of Moldova. [online] Available at: <https://www.covid19healthsystem.org/countries/moldova/countrypage.aspx> [Accessed 17 February 2021].

[5] WHO https://www.who.int/news-room/feature-stories/detail/inside-the-mammoth-undertaking-of-global-vaccine-distribution

[6] New York Times. 2021. Coronavirus Vaccine Tracker. [online] Available at: <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html> [Accessed 18 March 2021].

[7] https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_17March2021_0.pdf [Accessed 18 March 2021]

[8] https://covid19.who.int/

Organization SAGE values framework. The National Vaccine Deployment Plan was approved under Decision #41 of January 13, 2021 of the National Extraordinary Public Health Commission[9]. The Additional Financing for vaccine procurement contributes to the expanded pandemic response that other development partners support. These partners include the WHO, United Nations Children's Fund (UNICEF), Gavi, and the Global Fund, under the coordination of the Ministry of Health.

The International Development Association, member of the World Bank Group, extended a credit, which is deemed as Concessional Financing for purposes of the General Conditions, in the amount of twenty four million eight hundred thousand Euro (EUR 24,800,000). The negotiations for the proposed IDA Credit of EUR 24.8 million (USD 30 million equivalent) for the AF for Moldova Emergency COVID-19 Response Project, under the COVID-19 Strategic Preparedness and Response Program, using the Multiphase Programmatic Approach, were held between representatives of the Republic of Moldova, and IDA through videoconference connections to Chisinau and Washington during March 11-12, 2021.

The Bank and the Government of Moldova have agreed that tools such as Environmental and Social Management Frameworks may be revised from time to time during Project implementation to reflect adaptive management of Project changes and/or unforeseen circumstances. Accordingly, the ESMF already prepared and updated in October 2020 is being updated in March 2021 to reflect vaccine-related activities.

The overall objective of the Environmental and Social Management Framework (ESMF) is to help Moldovan authorities identify and manage environmental and social risks associated with the implementation of the Moldova Emergency Covid-19 Response Project and the deployment of a safe and effective vaccine in response to COVID-19, and in developing the environmental and social management measures in accordance with the World Bank's Environmental and Social Framework (ESF).

The World Bank is providing support to Governments for preparedness planning to provide optimal medical care, maintain essential health services and to minimize risks for patients and health personnel (including training health facilities staff and front-line workers on risk mitigation measures and providing them with the appropriate protective equipment and hygiene materials). As COVID-19 places a substantial burden on inpatient and outpatient health care services, support is provided for a number of different activities, all aimed at strengthening national health care systems, including systems for the deployment of a safe and effective vaccine.

Thus, this ESMF is developed in response to such needs and it includes templates for the *Environmental and Social Management Plan* (ESMP) (Annex 3) and the *Infection Control and Waste Management Plan* (ICWMP) (Annex 4) and other tools. The ESMP template identifies potential environmental, social, health and safety issues associated with the construction and operation of healthcare facilities in response to COVID-19. The ICWMP template focuses on infection control and healthcare waste management practices during the operation of healthcare facilities. The ESMP and ICWMP set out appropriate measures for infection control and waste management during operation of the relevant healthcare facility. The ESMF provides guidelines for working out appropriate prevention and mitigation measures against adverse impacts that might result from project activities.

The ESMF is one of several environmental and social instruments developed by Ministry of Health for Emergency COVID-19 Response Project implementation purposes as required under the Environmental and Social Commitment Plan of March 12, 2021. Others are the Stakeholder Engagement Plan (SEP) and Labor Management Procedures (LMP). LMP were developed for the

[9] https://gov.md/sites/default/files/hotarire_cnesp_nr._41_din_13.01.2021.pdf

main project as Annex of the ESMF and were updated during March-April 2021 as a standalone document.

Taking into consideration the groups of stakeholders defined by SEP, a Grievance Redress Mechanism (GRM) was developed for the Project, as recommended by this ESMF and the World Bank ESF. Types of environmental and social instruments and timing of their development and implementation are defined in the Environmental and Social Commitment Plan (ESCP) formally agreed between the Government of Republic of Moldova and the World Bank in the negotiations held during 11-12 March 2021.

2. Project Description

The project development objective is to prevent, detect, and respond to the threat posed by the COVID-19 pandemic in the Republic of Moldova and strengthen national systems for public health preparedness.

Under the two project components, immediate support will be provided to respond to the COVID-19 outbreak, with a focus on strengthening the technical capacity of health facilities to protect staff and handle severe cases and mitigating the negative financial impact at the household level. More specifically, recognizing the importance of a well-balanced intervention mix, the project will provide support to increase case detection capacity, improve the safety of frontline staff at all levels, and to bolster the human and technical capacity of intensive care units (ICUs) to handle a surge in severe cases. In addition, the project will support social assistance efforts to mitigate the effect of containment measures on the poor.

Besides supporting COVID-19 preparedness and response in the health sector, the project also includes response in the social protection sector through mitigation measures to help the poor and vulnerable cope with the immediate impact of the pandemic.

The AF changes will expand the scope of activities in the Original Project the Moldova Emergency COVID-19 Response Project (P173776). The Additional Financing will provide funding for the procurement and deployment of safe and effective COVID-19 vaccines, including vaccine-related communication and outreach, planning and management, supply and distribution, digital health information, and other supporting systems. The project also involves minor works in vaccine storage facilities.

The project will fund vaccination, therefore a fair, equitable and inclusive vaccine access and allocation is considered. The national immunization program provides all vaccines for free such that affordability may not pose a significant barrier to access, regardless of financial or social status, such as gender or other criteria. Also, to assess equitable access to vaccines, a PDO indicator was introduced to monitor the proportion of females and males in priority groups that have received a COVID-19 vaccination in Moldova.

As the proposed activities to be funded under the AF are aligned with the original PDO, the PDO will remain unchanged.

Detailed description of components and sub-components are provided in the sections below.

Project Beneficiaries

The expected project beneficiaries will be the population at large given the nature of the disease, infected people, at-risk populations, particularly the elderly and people with chronic conditions, medical and emergency personnel, medical and testing facilities, and public health agencies engaged

in the response.

Front-line health workers, who are disproportionately at risk, but also disproportionately benefitting from the project (through its investment in PPE); statistics reveal that the largest number of frontline health workers are women.

Workers and families, affected by the COVID-19 outbreak through job loss or other income loss will be better protected, especially in case of the vulnerable groups, by the expansion in coverage and benefit of the Ajutor Social program.

The additional financing for vaccine procurement and deployment will benefit the entire population through slowing the incidence rate and mortality. Moldova has identified priority groups for preferential access to COVID-19 vaccines, drawing on the WHO SAGE values framework to allocate and prioritize COVID-19 vaccination. The framework advocates for prioritizing groups for vaccination based on the principles of human well-being, equal respect, equity, reciprocity, and legitimacy. These principles advocate preferential access to groups at significant risk of mortality, such as the aged and individuals living with comorbidities. The principles also prioritize those that bear a significant burden of the COVID-19 response, such as health and social workers. In line with these principles, the Republic of Moldova has prioritized health and social workers, the elderly, people living with comorbidities, and teachers for preferential access to COVID-19 vaccines. The definition of health and social workers includes service providers, such as doctors, community health workers and nurses, and support staff, such as cleaners and hospital administrators. A national digital registry is developed with WHO support to enable the empanelment of priority groups, vaccine certification, and deployment monitoring.

Component 1: Emergency COVID-19 Response (55.26 million)

Subcomponent 1.1: Case Confirmation (EUR 3.06 million).

This project supports strengthening diseases surveillance systems and the capacity of the selected public health laboratories to confirm cases by financing medical supplies and equipment. It will include PPE and hygiene materials, COVID-19 test kits, laboratory reagents, Polymerase chain reaction (PCR) equipment, specimen transport kits, and light vehicles for safe and rapid transportation of samples.

Subcomponent 1.2 Health System Strengthening (EUR 30.0 million).

This project supports the strengthening of public health facilities to provide critical care to COVID-19 patients and minimize the risk of health staff and other patients becoming infected. PPE and hygiene materials are being financed, as well as training on infection prevention and control (IPC) practices, with a focus on staff providing care to suspected and confirmed cases. It provides equipment, drugs and medical supplies, in particular ICU units and beds in designated hospitals, as well as training on COVID-19 treatment and intensive care to respond to the surge in patients requiring admission in ICUs. It will support interior minor refurbishment to remodel ICUs and increase the availability of isolation rooms. The project also finances ambulances to support urgent transportation of patients across the hospital network to designated reference facilities as per the algorithm of the Government Preparedness and Response Plan.

Subcomponent 1.3 Communication Preparedness (EUR 0.3 million).

The project supports information and communication activities to increase the attention and commitment of government, private sector, and civil society to the COVID-19 pandemic, and to raise awareness, knowledge and understanding among the general population about the risk and potential impact of the pandemic. Specific activities will include, inter alia, (a) the development and implementation of a national communication and outreach strategy, including social and behavioral

communication change across multiple channels; and (b) developing and distributing communication materials on COVID-19 and general preventative measures to the general public, which will be complementary to the UN actions. The communication approach is tailored to ensure outreach to marginalized communities, poor and vulnerable groups of population aimed at ensuring the poor and marginalized groups can approach and are supported under the project. The communication strategy and approach will seek active involvement of Territorial Structures of Social Assistance who will play an essential role in ensuring outreach to the poor and marginalized groups. Local Public Authorities and Mayors' office will also be involved in supporting an adequate outreach to these groups of population.

Subcomponent 1.4 Social and Financial Support to Households (EUR 21.9 million)

The project is supporting the strengthening the social protection for the poor by amending the design of Ajutor Social program so that it is better able to target vulnerable populations who stand to be adversely affected by COVID-19. This amendment is simultaneously an emergency response and a reform. First, the reform aspect would strengthen support for families with children, better aligning the program design with the social policy goals of supporting the poorest and improving targeting and efficiency of social expenditures. Second, the income eligibility threshold (GMI) for all beneficiaries will be temporarily increased (by 23% instead of the planned indexation of 4.8%). GMI threshold is used both to determine eligibility, filtering out families with incomes higher than GMI per adult equivalent, and to determine the benefit size, which is the gap between guaranteed minimum income for the family (GMI x adult equivalents of family members) and the actual income. This measure will result in expanding the coverage of the poor who as a group will be disproportionately affected by increased prices and loss of income associated with COVID-19. Third, employment status checks will be temporarily dropped, which will enable inclusion of returning migrant workers and families with members in informal employment, thus including these vulnerable categories. Also, for the emergency period, the government will automatically extend eligibility for families that are up for re-certification, accept remote applications (e.g., by phone), and replace income verification documents with the applicant's declaration. In-home visits to verify eligibility for families that are subject to such checks will also be cancelled for the period of emergency.

As a result, for the emergency period, the average benefit for current recipients will increase from MDL 828 to MDL 1,520 (84% increase), while for families with children it will be MDL 2,800. This subcomponent will disburse against two Disbursement Linked Indicators (DLI). The two DLIs will include (i) necessary legislation changes and increased budget allocation to the Ajutor Social program, and (ii) measures of increased benefit and coverage. The Ajutor Social cash transfers will serve as Eligible Expenditures for the DLIs.

Subcomponent 1.5: Vaccine Procurement and Deployment (EUR 24.8 million)

The AF will finance vaccine procurement, supply chain, and service delivery activities through this new Subcomponent 1.5, while the increase in the project scope will be reflected in an increase in allocation to Component 1 from EUR 55.26 million to EUR 80.06 million, with the full amount of EUR 24.80 million allocated to Subcomponent 1.5. Thus, the Additional Financing under the new component will finance the procurement of vaccines in line with the national COVID-19 vaccine deployment plan in stages two and three, for an estimated US$ 20.4 million equivalent. Priority groups have been identified, including health and social workers, law enforcement agents, the elderly, and individuals with chronic diseases. Retroactive Financing of up to 40% of the Credit amount will be available to respond to urgent needs, including cold chain investments and social mobilization.

The priority groups and stages for vaccination are presented in the table below.

Table 1. Priority groups for COVID-19 vaccination

Stage (Share of total population)	Priority group	Estimated population	Share of total population (%)	Share of priority group (%)
Stage 1 (20%)	Frontline health workers	55,000	1.6	100
	Elderly aged 80+ years	63,000	1.8	100
	Elderly aged 70-79 years	140,000	4.1	100
	Individuals that are immunodeficient including organ transplant recipients and those undergoing cancer therapy	70,000	2.0	100
	Elderly aged 60-69 years	114,000	3.3	32
	Adults below 60 years with comorbidities	80,000	2.2	11
	Educational staff	108,000	3.1	100
	Law enforcement officers	53,000	1.5	100
	Social workers	12,000	0.4	100
Stage 2 (10%	Elderly aged 60-69 years	240,000	6.9	68
	Adults below 60 years with comorbidities	107,500	3.1	14
Stage 3 (20%)	Adults below 60 years with comorbidities	646,000	18.6	86
	Rest of population	49,000	1.4	-
Stage 4 (20%)	Rest of population	695,000	20	-
Total (people)		2,432,500	70	-
Total (doses, assuming 3% wastage and 2-dose vaccine)		2,505,475	-	-

Thus, funding under Subcomponent 1.5 will support:

1) Vaccine procurement: the AF will finance the procurement of vaccines in line with the national COVID-19 vaccine deployment plan in stages two and three, for an estimated US$ 20.4 million equivalent. Priority groups have been identified, including health and social workers, law enforcement agents, the elderly, and individuals with chronic diseases. There is potential to expand vaccine coverage depending on supply constraints, vaccine price, and available resources. If revaccination is required, the above priority groups will be targeted in line with the WHO SAGE values framework. The COVAX AMC will be the predominant vaccine source in the short-term for vaccines for the first and second stages of vaccine deployment. Under the COVAX AMC, Moldova will receive fully donor-subsidized doses to cover 20% of the population depending on vaccine price, funding availability, and supply. Depending on vaccine availability, the country will procure additional doses through COVAX for an additional 10% (of the population) in the second stage. The cost of procurement will be covered with World Bank funding. The AF will provide financing towards

the procurement of eligible vaccines from COVAX (through UNICEF as procurement agent), manufacturers, or other countries, the second and third stages.[10] The national COVID-19 deployment plan also acknowledges the possibility of procuring eligible vaccines through direct purchases from manufacturers, donations from other countries,[11] and the purchase of excess stocks from other countries for the second and third deployment stages. All COVID-19 vaccines financed by the Bank must meet the Board-approved standard.

If revaccination is required, the above priority groups will be targeted in line with the WHO SAGE values framework.

2) Supply chain: Subcomponent 1.5 will also support activities to strengthen the vaccination supply chain, including investments in climate-sensitive cold chain capacity and transportation, for an estimated US$ 3.8 million equivalent. These activities will include technical support for planning new investments in cold chain infrastructure; a rapid vulnerability assessment to identify vaccine logistics planning risk due to climate change-induced extreme weather events; a contingency plan to ensure access to vaccines during climate change-induced weather events and natural disasters; and a distribution assessment that evaluates resilience of delivery routes to climate change and natural disasters, particularly in high-risk areas. Technical support may be provided through WHO and UNICEF. Investments will support transportation, remote temperature monitoring, and cold chain equipment. These investments will prioritize sustainable, climate-friendly, energy-efficient cold chain infrastructure, including for transportation, minor works, and storage equipment, including (a) for transportation – improved route planning and electric motorcycles and charging infrastructure; (b) for infrastructure – solar photovoltaic and battery systems, energy-efficient cooling with low global warming potential refrigerants, thermal insulation, solar reflective roofs, and built-in temperature controls; (c) for cold storage equipment – the adoption of low global warming potential refrigerants for solar refrigerators and freezers, cyclopentane insulation, solar direct drive on-site freezers, sterling cycle refrigeration with helium as the coolant for ultra-low freezers, and non-energy consuming coolant packs in shipping units; and (d) for training – to incorporate training content related to the procurement and use of low-carbon equipment and disaster risk management. Safety boxes for disposal of syringes may also constitute an adaptation and mitigation measure by reducing the risk of medical waste exposure during climate-related extreme events, and reducing the requirement for incineration, and thus, green-house gas emissions. The total estimate for climate adaptation for these measures is estimated at 20% of Subcomponent 1.5

3) Service delivery: investments will be made in service delivery, for an estimated US$ 5.8 million equivalent. This support will include technical assistance towards developing regulations to protect manufacturers from product liability claims, strengthen digital data systems for monitoring vaccination, and forecast needs in terms of vaccines, supplies, and equipment. The AF will also finance the procurement of consumables and supplies through UNICEF; implementing the national communications strategy; AEFI monitoring and response; training and incentives for vaccinators; minor facility refurbishments; investments in hardware and software to support facility-level health information systems; and improvements in waste management infrastructure.

Component 2: Implementation Management and Monitoring and Evaluation (EUR 0.6 million)

[10] The AF will not channel funds to COVAX. Funds for the vaccines secured through COVAX will flow to UNICEF Supply Division, which has been selected as the procurement agent for Moldova under the COVAX facility.

[11] Potentially including Russia, Romania, and other EU countries.

This component will provide financing for project implementation, coordination, and management, including support for procurement, financial management, environmental and social safeguards, monitoring and evaluation of prevention and preparedness including third-party monitoring of progress.

In addition, Moldova has received additional US$3.48 million (equivalent to EUR 2.96 million) grant from the Pandemic Emergency Financing Facility Fund (PEF). The grant is being processed as an additional financing (AF). The proposed AF will scale-up activities under Component 1 to support measures to respond to the COVID-19 outbreak, with a focus on strengthening the testing capacity of medical and laboratory facilities to diagnose positive cases of infection. In addition, recognizing the importance of a well-balanced intervention mix, the project will provide support to improve the safety of frontline staff at all levels, and bolster the human and technical capacity of medical and laboratory facilities to handle a surge in cases. The proposed AF is fully aligned with, and will maintain, the PDO of the parent project. It is also consistent with the COVID-19 Strategic Preparedness and Response Program using the Multiphase Programmatic Approach (P173789).

Table 2 ***Project Components and Costs***

Component	**Current allocation**	**AF**	**Revised allocation**
Component 1: Emergency COVID-19 Response	55.26	24.80	80.06
Subcomponent 1.1: Case Confirmation	3.06	0.00	3.06
Subcomponent 1.2: Health System Strengthening	30.00	0.00	30.00
Subcomponent 1.3: Communication Preparedness	0.30	0.00	0.30
Subcomponent 1.4: Social and Financial Support to Households	21.90	0.00	21.90
Subcomponent 1.5: Vaccine Procurement and Deployment	-	24.80	24.80
Component 2: Implementation Management and Monitoring and Evaluation	0.60	0.00	0.60
Total (EUR million)	**55.86**	**24.80**	**80.66**
Total (US$ million equivalent)	**61.40**	**30.00**	**91.40**

3. Policy, Legal and Regulatory Framework

3.1. Overview of National Environmental Legislation Relevant for the Project

The following environmental laws and regulations are relevant to the Emergency COVID-19 Response Project:

Law #1515 on Environmental Protection[12] (1993) establishes the basic legal framework for drafting special normative acts and instructions in particular issues of environmental protection in order to:

- ensure the right of each person to a healthy and aesthetically pleasant environment;
- achieve the ultimate responsibility of each generation for environmental protection towards the future generations;
- obtain a wider range of use of natural resources without exceeding the allowable limits, avoiding their depletion and degradation, the risk for people's health and other unwanted and unpredictable consequences;
- protect the soil and subsoil, water and air from chemical, physical and biological pollution;
- maintain the biodiversity and genetic resources, integrity of natural systems, historical and cultural national values; and
- restore ecosystems and components affected by human activity or natural disasters.

Law #851 on Ecological Expertise[13] (1996) determines goals, objectives and principles of State Ecological Expertise (SEE), as well as basics of procedures.

Law describes in detail SEE procedures, demands the reporting, rules for conducting the SEE. The State Ecological Expertise is a part of a group of activities working toward environmental protection through which the potential impacts on environment from planned economic activity, compliance of parameters of these activities with legislation and normative acts, norms and standards in force are identified and mitigated.

According to the Law, project documentation for the objects that may adversely affect the environment is a subject of State Ecological Expertise, which in turn determines whether it complies or not with environmental protection requirements. Decisions on Ecological Expertise can be considered as the basis for approval or refusal of the project.

Ecological Expertise is conducted prior to making decisions on planned economic activities, and it is mandatory for all economic activities that may have a negative impact on the environment regardless of their destination, ownership, investments, location, source of financing etc. In case the objects can affect the environment severely, their planning documentation is a subject of Environmental Impact Assessment.

The Ecological Expertise is obligatory for the project documentation for the areas and activities listed in Annex 1 to Law #851. In the case where the activities specified in Annex 1 to Law #851 fall under Annex 1 or Annex 2 of the Law #86/2014 on Environmental Impact Assessment and have been subject to environmental impact assessment, the Ecological Expertise of the project documentation is not needed.

[12] https://www.legis.md/cautare/getResults?doc_id=112032&lang=ro
[13] https://www.legis.md/cautare/getResults?doc_id=109128&lang=ro

Law #86 on Environmental Impact Assessment[14] (2014) establishes the goal of preparing documentation on the Environmental Impact Assessment (EIA), its procedure, coordination and approval, and includes the List of objects and types of activities for which an EIA is compulsory prior to their design.

The EIA is carried out to determine the requisite measures to prevent adverse ecological impacts due to the implementation of certain planned objects and types of activities. The Law describes the requirements for documentation on the EIA (materials in which the direct and indirect impacts of planned objects on air, water, soil, landscape, protected areas, fauna, flora, cultural and historic monuments, socio-economic situation are establishing, describing and evaluating; comparison of alternative solutions and substantiation of the best one; suggested mitigation activities). On the basis of the developed documentation for the EIA, the client designs a Statement on the EIA in which all materials, calculations and research are presented and systematized, as well as the EIA content (title of the project; character of activity; location; substantiation for location; project duration; technical and technological characteristics of the project; suggested technical solutions; project cost; localities affected by projects; information of direct impacts on the environment (water, soil, air, etc.); land to be occupied by project; water abstraction; water use, water source; sources of raw materials, transport and other infrastructure, emissions to air, wastes and their utilization, etc.); order of elaboration and submission documentation on EIA, evaluation of EIA documentation, environmental decision on EIA documentation, etc.

Law #209 on waste[15] (2016) establishes the basic legal framework for waste management in the country. The Law on waste transposes the Waste Directive 2008/98/CE of the European Parliament and of the Council of 19 November 2008 repealing certain directives, but it also includes provisions of the directives on special waste flows.

This law establishes the legal basis, state policy and measures necessary for the protection of the environment and public health by preventing or reducing the adverse effects of waste generation and management and by reducing the overall effects of resource use and increasing the efficiency of their use.

According to provisions of the law, the control and monitoring of the implementation of medical waste management is done by the local public health authorities. The article 55 of the law on waste describes procedures for waste management resulting from medical activity.

Governmental Decision # 696 on Sanitary regulation regarding waste management from medical activity[16] (2018) regulates the manner of separate collection by type, packaging, labeling, temporary storage, transportation within the producing institutions, treatment, delivery, disposal and record of waste resulting from medical activity.

Governmental Decision #5 on Regulation regarding medical waste management (2001)[17].

Governmental Decision #637 on the control of transboundary shipments of waste and its disposal (2003)[18] establishes the mechanism for implementing the provisions of the Basel

[14] https://www.legis.md/cautare/getResults?doc_id=106006&lang=ro
[15] https://www.legis.md/cautare/getResults?doc_id=118272&lang=ro
[16] https://www.legis.md/cautare/getResults?doc_id=108829&lang=ro
[17] http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=306414
[18] https://www.legis.md/cautare/getResults?doc_id=112863&lang=ro

Convention, designed to ensure compliance with environmental safety requirements for the export, transit and disposal of waste.

Governmental Decision #99 for the approval of the Waste List (2018)[19]. This document is a classifier of waste, including hazardous waste.

Governmental Decision #589 for the approval of the Regulation of transportation of dangerous goods (2017)[20] establishes the framework for the application in the Republic of Moldova of the provisions of the European Agreement on the International Carriage of Dangerous Goods by Road, concluded in Geneva on 30 September 1957, to which the Republic of Moldova acceded by Parliament Decision no. 44-XIV of June 4, 1998.

Governmental Decision #501 for the approval of the Instruction on the keeping of records and the transmission of data and information on waste and its management (2018)[21] sets out how to keep records and transfer data and information on waste and its management.

Order #1346 on the approval of the checklist no.1.2 / ANSP applied within the State control over the entrepreneurial activity regarding the management of the waste resulting from the medical activity (2018)[22].

3.2. Institutional Framework for Environmental Management

Ministry of Environment (MoE) is the central public authority responsible for the policy development in the environmental protection area of activity. The Ministry's mission is to analyze the situation and problems in its fields of activity, to develop effective public policies in the areas of environmental protection and climate change, natural resources, to monitor the quality of policies and normative acts and to propose justified interventions of the state to provide solutions. efficient in the areas of competence, ensuring the best ratio between the expected results and the expected costs.

The main functions of the Ministry are:

1) development of ex ante analyzes, policy documents, draft normative acts in the fields of activities mentioned above;
2) ensuring cooperation with other relevant institutions from abroad in its fields of activities;
3) monitoring the rank of the Republic of Moldova regarding the international indicators related to its specific fields and development of proposals for their improvement;
4) monitoring the perception of citizens and economic agents regarding public policies, normative acts and state activity in the fields of activity specific to the Ministry and development of proposals for its improvement;
5) monitoring the quality of public policies and normative acts in the fields of activity specific to the Ministry, including in cooperation with the civil society and the private sector;

[19] https://www.legis.md/cautare/getResults?doc_id=102107&lang=ro
[20] https://www.legis.md/cautare/getResults?doc_id=110137&lang=ro
[21] https://www.legis.md/cautare/getResults?doc_id=108614&lang=ro
[22] https://www.legis.md/cautare/getResults?doc_id=121282&lang=ro

6) drafting the normative acts and implementing the international treaties of the Republic of Moldova in the fields of activity of the Ministry, drawing up the reports on their execution;
7) examination and approval of draft normative acts developed by other public administration authorities and submitted for examination; and
8) coordination and monitoring of the activity of the administrative authorities and of the subordinated decentralized public services and of the public institutions in which he has the quality of founder.

Environmental Agency (EA) is a public entity responsible for the implementation of the environmental protection policy in the country, in the field of:

a. prevention of environmental pollution;
b. air protection and climate change;
c. protection and regulation of the use of water resources;
d. protection and regulation of the use of the animal kingdom and the vegetable kingdom, of aquatic biological resources;
e. biodiversity conservation and management of protected areas;
f. waste management; and
g. biosecurity.

The Agency is subordinated to the Ministry of Environment. The main functions of the Agency are:

1) ensuring the implementation of public policy documents and environmental protection legislation both at national and local level;
2) providing technical support to the Ministry of Environment in development of public policy documents and normative acts in the field of environmental protection;
3) regulation and authorization of activities with an impact on the quality of the environment, issuing permitting documents to natural and legal persons that are practicing entrepreneurial activities with environmental impact (authorizations, environmental agreements, permits, certificates, notifications, opinions and coordination), provided in the Nomenclature of permissive acts, approved by Law no. 160 of July 22, 2011 on the regulation by authorization of the entrepreneurial activity;
4) monitoring the quality of environmental factors (monitoring the quality of water, air, soil, monitoring of forest and protected areas, monitoring the condition and use of water and soil resources, monitoring the plant and animal kingdom, monitoring fisheries, monitoring the state of the subsoil, air pollution monitoring, geological monitoring, environmental pollution monitoring) in order to provide individuals and legal entities with information on environmental quality, development of the system of statistical indicators in the field of environmental protection, as well as in drafting and publishing the National Environmental Report in Moldova; and
5) creation and administration of cadasters and special registers, administration of the information and data system for its fields of activity and ensuring public access to environmental information.

Inspection for the Environmental Protection (IEP) is the public authority that is responsible for the enforcement of the environmental legislation in the country. The Inspection is subordinated to the Ministry of Environment. The mission of the Inspectorate is to implement the state policy in the field of environmental protection and rational use of natural resources, to exercise state control and supervision, to prevent and counteract violations in the areas of competence, to ensure a high level of supervision and protection of the environment, public interests, ecological safety of the state and other values protected by legislation. The areas of competence of the IEP are:

a. implementation of environmental policy;
b. protection of atmospheric air;
c. protection of aquatic resources;
d. protection of flora, fauna and protected natural areas;
e. soil and subsoil protection;
f. waste and chemical management;
g. rational use of natural resources;
h. planned activities; and
i. occupational safety.

The main functions of the IEP are:

1) control of the implementation of the legislation in the field of environmental protection and rational use of natural resources at enterprises, institutions, organizations, with any type of property and legal form of organization;
2) preventing, counteracting infringements of environmental protection legislation and the rational use of natural resources;
3) coordination of activities with an impact on the environment, likely to harm and change the state of the environment or natural resources; and
4) finding and analyzing of the infringements of environmental protection legislation and the rational use of natural resources, including contraventions, imposing sanctions in accordance with the legislation, calculating and recovering damage to environmental components in accordance with the "polluter pays" principle.

National Agency for the Regulation of Nuclear and Radiological Activities (NARNRA) is the public authority that is responsible for the development and implementation of policy in the nuclear and radiological field.

3.3. Overview of National Property, Health, Social and Labor Legislation Relevant for the Project

It is appraised under PAD that Land Acquisition, Restrictions on Land Use and Involuntary Resettlement are not currently relevant for the project. Hence, social standards and related Labor and Working Conditions, Community Health and Safety issues are relevant and an overview of national social and labour legislation relevant for the project is provided below.

The Republic of Moldova introduced substantial reforms to its health system in 2004 with the establishment of a mandatory system of health insurance, and a single pool of funds combining

both payroll contributions and budget transfers. Under this system, however, around one-quarter of the population makes no insurance contribution, and hence has very limited financial risk protection when accessing health services.

The national legislation regarding training and response for public health emergencies transposes the provisions of WHO and other international bodies. The legal framework provides measures to prevent, prepare and respond to public health emergencies, risk assessment, public health emergency triggering, declaration / cancellation, special powers regarding facilities and goods, including isolation and / or quarantine measures, establishing rules on entering / leaving the area subjected to isolation or quarantine, informing the population about the public health emergency, the mechanisms for coordinating and mobilizing emergency funds.

Other relevant laws include:

Constitution of the Republic of Moldova guarantees in Article 36 the right to health protection and the minimum health insurance provided by the State free of charge.

Law on Mandatory Health Insurance of the Republic of Moldova, # 1585 (27 February 1998) provides that the individuals insured under the scheme include citizens of the Republic of Moldova, foreign citizens, and persons without citizenship living permanently on the territory of the Republic of Moldova.

Law on the size, manner and term of payment of compulsory health insurance fees # 1593–XV (26 December 2002) specifies that the compulsory health insurance is an autonomous system guaranteed by the state of financial protection of the population in the field of health care. The law provides that health insurance is based on principles of solidarity, from the insurance taxes and it is intended to cover the costs of treating conditions arising from the occurrence of insured events (illness or other sickness conditions). It also stipulates that the economically active population is obliged to contribute according to their wage levels (through a payroll tax) or to make a flat-rate contribution if self-insured.

Law on Pharmaceutical Activity #1456/1993 provides under Article 14 that pharmaceutical enterprises and institutions shall be liable in the established manner for compliance of the manufactured medicines and para-pharmaceutical products with the requirements of the analytical-normative documentation in force, approved by the Ministry of Health.
Law on State Supervision of Public Health # 10/2009 under Article 52. Prophylactic vaccination of population provides:
(1) The prophylactic vaccination of population against infectious diseases includes systematic prophylactic vaccination, vaccination according to epidemiological indications and recommended vaccination.
(2) The systematic prophylactic vaccination is guaranteed and ensured by the state at the ages and for groups of population established in the National Program for Immunization.
(3) The list of infectious diseases against which the systematic prophylactic vaccination is applied and the list of risk groups are approved by the Ministry of Health.
(4) The conditions, indications and organization of vaccinations according to the epidemiological indications are established by the Ministry of Health.

(5) The organization of recommended vaccinations is established by the Ministry of Health. **Order 358 of 12 May 2017 "On Approving the Regulation on the Performance of Pharmacovigilance Activities** established the approval of the following:

1) The Regulation on the Performance of Pharmacovigilance Activities, as per Annex 1 of the respective order;
2) Communication Sheet on Adverse Reactions and/or Lack of Effectiveness of Medicines and Other Medicinal Products as per Annex 2 of the same Order.
3) Communication Sheet on Adverse Reactions to Medicines and Other Medicinal Products "Patient Communicates" as provided by Annex no. 3 of the Order.
2. The holder of the medicine registration certificate, or his official representative, must at all times have at his disposal an appropriately qualified person responsible for pharmacovigilance activities to establish and maintain a system to ensure that all information collected on the safety of medicinal products are accessible to the Medicines and Medical Devices Agency;
3. Chiefs of health facilities, regardless of the legal form of organization and type of ownership:
1) to appoint persons responsible for pharmacovigilance in their health facilities within 1 month from the date of issue of the Order;
2) to ensure the recording and reporting of adverse reactions or the ineffectiveness of medicines and other medicinal products to the Medicines and Medical Devices Agency.

Decision #41 of January 13, 2021 of the National Extraordinary Public Health Commission on approving the National Covid-19 Vaccine Deployment Plan[23]. The National Vaccine Deployment Plan sets out the key components of the national COVID-19 vaccination strategy and describes the general process of organizing population vaccination according to international and national standards and of implementing this important public health intervention in organizing a long-term response for managing the COVID-19 pandemic. The plan is based on the analysis of the epidemiological situation of the spread of SARS-CoV-2 virus at national and European regional levels, as well as the analysis of the situation of severe cases and mortality generated by COVID-19. The national COVID-19 vaccine deployment plan notes that, after the first stage, the government will explore procurement of vaccines via a range of options, including the COVAX Facility, direct purchase from pharmaceutical companies, donations by other countries, or facilitated by UNICEF.It also notes that vaccines not authorized in the Republic of Moldova, but authorized in their country of origin, will be imported under Law no. 1496/1993 on the pharmaceutical activity, according to the procedure established by the Order of the Ministry of Health no. 559/2017. In this case, NAPH will apply for an import authorization for each batch of vaccine separately

Law on Social Inclusion of Persons with Disabilities #60 (Mar 30, 2012) regulates the rights of persons with disabilities for their social inclusion, guaranteeing the possibility of their participation in all areas of life without discrimination, at a level identical to the other members of the society, having as a basis the respect of fundamental human rights and freedoms.

Law on Social Services #123 (June 18, 2010) establishes the general framework for creation and functioning of the integrated system of social services, determines the tasks and responsibilities of the central and local public administration authorities and other legal and natural persons responsible for the provision of social services and protection of rights of the beneficiaries of social services.

Law on Social Assistance # 133 (June 13, 2008) regulates the legal framework on guaranteeing equal opportunities for disadvantaged families by providing social assistance at a state-guaranteed

[23] https://gov.md/sites/default/files/hotarire_cnesp_nr._41_din_13.01.2021.pdf

level. The law serves as legal framework for regulating the Ajutor Social Program. Administered by the Labor and Social Protection, and previously supported by the WB, the Ajutor Social program is the main anti-poverty program in Moldova . The social assistance program Ajutor Social began in 2009. It was conceived as a proxy means-tested program of cash transfers to replace categorical benefits (prestații categoriale). Ajutor Social was introduced to counter the fragmentation of social protection programs and the inefficiency of public financing. To qualify for the Ajutor Social program benefits, applicants must meet three sets of criteria related to: family income being below the guaranteed minimum income (GMI); the employment status of family members[24]; and, family welfare (confirmed through the proxy means test). The amount of the benefit depends on the income gap between household monthly income and the GMI threshold, which is established annually in the budget. The means-tested Ajutor Social is channeling significant funds to the poorest quintile. However, despite expansion of the program in 2014-2017, when its coverage increased from 4 to 7% of the total population, it reached only about 20% of the poorest, and the benefit size remains inadequate, especially for families with children.

Decision of the Government # 474 of 08-07-2020[25] amending section 19 of the Regulation on the establishment and payment of social assistance, approved by Government Decision no.1167 / 2008 provides that the amount of the minimum guaranteed monthly income calculated for each child will be increased from 50% to 75%, which is an increase of 276.75 lei / per child for the assessment and calculation of the right to social assistance and by 608.85 lei / per child to assess entitlement to aid for the cold period of the year.

Law on ensuring equal opportunities between women and men #5-XVI (Feb 09, 2006) pertains to ensuring the exercise by women and men of their equal rights in the political, economic, social, cultural, and other spheres of life, rights guaranteed by the Constitution of the Republic of Moldova, with a view to preventing and eliminating all forms of discrimination based on the criterion of sex.

Strategy for ensuring equality between women and men in the Republic of Moldova for 2017-2021 and the Action plan on its implementation (April 28, 2017) empowering women and the de facto implementation of the equality between women and men in Moldova, by achieving five general objectives on fields of reference.

Law on Access to Information #982/2000 (amended in 2003-2011-2015) regulates the interaction between the providers of information and individuals and/or legal entities during the exercise of their constitutional right to access information, the rights of applicants for obtaining the information, the obligations of information providers to ensure access to official information, methods of safeguarding the right to information.

Law on Freedom of Expression #64 (2010, amended in 2012-2013-2015) guarantees right to freedom of expression and regulates the balance between right to freedom of expression and defense of private and family life

Law on Transparency in Decision Making #239 (2008) refers to the transparency of information linked with the decision-making process and to the consultation of stakeholders when drafting decisions.

[24] All able-bodied members of a family must be either employed (self-employed), registered as unemployed, be on parental leave or look after a member of the family that requires care (e.g. with severe disability).
[25] https://www.legis.md/cautare/getResults?doc_id=122127&lang=ro

Administrative Code of the Republic of Moldova #116 (2018) establishes procedure for consideration of petitions of citizens addressed to the relevant authorities for the purpose of ensuring protection of petitioners' rights and legitimate interests.

Labour Code of the Republic of Moldova (March 28, 2003) regulates labor relations and ensures the right of every worker to fair working conditions, including the conditions which meet the requirements of occupational safety and health. Section IX of the Labour Code is dedicated to occupational safety and health.

Law regarding the promotion of employment and unemployment insurance #105 (June 14, 2018) aimed on preventing and mitigating unemployment and its social effects, reduction of unemployment risks and ensuring a high level of employment and adapting to the demands of the labor market.

Law on Occupational Health and Safety # 186-XVI (July 2008) regulates legal relations related to setting of measures to ensure the safety and health of workers at work.

Labour Inspection Law #140-XV (29 June 2001) defines the objectives and powers of the labor inspectorate, its organization, rights, obligations and responsibilities. The labor inspectorate is in particular responsible for monitoring compliance with the provisions of legislative acts relating to employment contracts, working time and rest time, labor discipline, the work of minors and women, protection labor and working conditions.

Government Decision # 629 of 08-08-2017 on approval of the **Code of ethics and deontology of the civil servant with special status within the Ministry of Internal Affairs** establishes ethical and professional values and professional conduct to be shared by these category of personnel. Art. 13 of the Code requires the civil servant to: 1) show a respectful attitude in relations with people; 2) to demonstrate skills in managing conflict situations; 3) to respect the right to privacy, to the inviolability of correspondence and domicile; 4) to respect the principle of the presumption of innocence, ensuring to each person who is the object of the investigation the full exercise of his legal rights; 5) to take into account the specific needs of special categories of the population, such as: children, women, the elderly, people with disabilities. Article 15 of the Code provides that the civil servant with special status does not apply, encourage or tolerate any form of torture, inhuman or degrading treatment. If he becomes aware, by any means, of any similar acts provided, he is obliged to denounce them to his superiors, in writing, being assured of his anonymity. The final provisions of the Code stipulate that violation of the provisions of the Code may lead to disciplinary, civil, contravention or criminal liability.

3.4. Institutional Framework for Regulating Health, Social Welfare, and Labor Safety

The Ministry of Health is the central specialized body of public administration that ensures the implementation of governmental policies in the fields of health, labor, social protection and demography. Ministry of Health is responsible for the organization and regulation of health services provided to individuals and the public, and for ensuring the state surveillance of population health, as well as for managing the social protection programs of the Government of Moldova.

The Ministry of Health is also responsible for providing the legal framework on the management and proper disposal of medical waste generated in the public and private health service sector. This is achieved through developing and approving of sanitary norms, rules, and hygienic specifications.

The Ministry of Health has under its subordination a range of agencies and institutions, which are mandated with responsibilities for implementation of policies promoted by the Ministry. The institutional framework on social protection include the following non-exhaustive list of institutions:

The National Social Insurance House/Casa Naţională de Asigurări Sociale (CNAS) is a central administrative authority subordinated to the Government, with legal personality that administers and manages the public social insurance system. CNAS was established in 2001 based on the Law on the public state social insurance system no. 489-XIV of 08.07.1999. The CNAS is headed by a director general appointed by the Government of the Republic of Moldova and is supervised by a Board of Directors, composed of 12 persons: representatives of the Government, Trade Unions, Employers and the Republican Council of Veterans. CNAS - is the body of the executive power, which implements the state policy in the field of social insurance. Through the public social insurance system, the state guarantees to citizens the right to social protection for retirement, unemployment, illness, disability, etc through payment of pensions, allowances and other social insurance benefits. Under the COVID-19 Emergency Response Project, CNAS will be responsible for managing the payment of benefits: receiving the lists of eligible beneficiaries from social assistance departments at local level, submitting payment requests to the Ministry of Finance, monitoring the cash distribution through designated commercial banks and post offices, and accepting their monthly reports on benefit execution. More specifically, the project disbursements under "Social and Financial Support to Households" sub-component would be linked to the Government's poverty-targeted cash benefit program Ajutor Social and verified achievement of Performance-Based Conditions (PBC). In this respect the COVID-19 Emergency Response Project will rely on the existing benefits payments system managed by the National Social Insurance House and the Government's budget management and reporting systems. The Ajutor Social Program was consolidated and co-financed by WB using the similar financing mechanism under Strengthening the Effectiveness of the Social Safety Net Results-Based Financing Project (P120913) which closed on December 31, 2017. The architecture of the Ajutor Social Program has been assessed by the World Bank during the implementation of that project and has been found to perform with adequate levels of transparency, to function under an adequate system of checks and controls and produce reliable financial and budget execution reports.

The National Health Insurance Company/ Compania Naţională de Asigurări în Medicină (CNAM) is an autonomous state organization of national level, which has legal personality, founded by Government Decision of the Republic of Moldova no. 950 of September 7, 2001. The institution is responsible for financing of most health services, as well as for the quality control and implementation of provided healthcare and the implementation of the Health Insurance regulatory framework. CNAM finances access to an essential package of emergency, primary, and

inpatient services without payment at the point of care. The system also provides universal access to primary health care, for both uninsured and insured patients (including mental health, cancer screening, HIV/AIDS[26], tuberculosis, etc.). Inpatient care is provided at the municipal, district (secondary care) and republican (tertiary care) levels; highly specialized tertiary services are concentrated in Chisinau.

The National Agency for Public Health is the administrative authority subordinated to the Ministry of Health, which has the role to ensure the implementation of policies in the field of national public health.

The National Extraordinary Public Health Commission is responsible for the integrated approach to public health risks / emergencies, the implementation of prevention and management measures, the mobilization of efforts in all sectors and the coordination of activities.

Agency of Medicines and Medical Devices (AMMD) is responsible for authorization of medicines and vaccine, including for surveillance of the quality of medicines and the supervision of the supply of medicines and medical products nationwide. The Government of Moldova has aligned the process of approving COVID-19 vaccines to those recommended by COVAX. Approval by the AMMD will rely on WHO Emergency Use Listing, marketing authorization, and emergency approval of SRAs, including the United States Food and Drug Administration and European Medicines Agency. Expedited regulatory pathways for approval of COVID-19 medical products are in place. Emergency registration is expected to be done within 14 working days of the application submitted and based on confirmation by WHO, while an import authorization can be issued in 4 working days by the AMMD. Vaccines received via donations, the COVAX facility, or procured via UNICEF will not be subject to taxes and import duty. In December 2020, the Government signed a Model Indemnity Agreement to which all manufacturers under COVAX have agreed. Some vaccine manufacturers may also require other protections against product liability claims, including legislative limits on liability or a national no-fault compensation scheme. Under COVAX, a donor-funded and private-insurance-covered no-fault compensation scheme has been established to cover AMC countries. The Ministry of Health will develop the regulatory framework to protect manufacturers from product liability claims, with support from WHO by July 2021.

The National Social Assistance Agency is an administrative authority subordinated to the Ministry of Labour and Social Protection. The Agency's mission is to increase the quality of social assistance provided to the population by implementing state policies in the field of social assistance. In its activity, the Agency exercises the following basic functions: (a) elaboration of the methodological framework for the unitary implementation of the legislation in the field of social assistance; (b) management of the activity of public institutions in which the Ministry of Health exercises the status of founder; (c) facilitating the process of consolidating the professional capacities of the personnel from the social assistance system; and (d) management of the financial

[26] HIV/AIDS: human immunodeficiency virus/acquired immunodeficiency syndrome.

means for financing the programs with special purpose in the field of social assistance and the minimum social services package.

The National Council for Accreditation of Social Service Providers is an administrative authority with the Ministry of Labour and Social Protection, which has the mission to certify the capacity of social service providers, regardless of the type of property, the legal form of organization and administrative subordination and to provide qualitative social services.

The National Council for the Determination of Disability and Capacity of Work has the mission to ensure the fulfilment of the provisions of normative acts in force regarding the determination of disability and capacity of work, having as final objectives the social inclusion of people with disabilities.

Temporary Placement Centers for the elderly, children and people with disabilities (in some localities), and the **Center for Assistance and Protection of victims and potential victims of trafficking in human beings**, that represents institution of social assistance and rehabilitation/recovery from the management of the National Agency for Social Assistance.

The National Employment Agency is the administrative authority subordinated to the Ministry of Labour and Social Protection and has the role to ensure implementation of policies on employment, labor migration and unemployment. The National Employment Agency provides labour market information, employment counselling and career guidance, and administers active and passive labour market schemes, line with the principles of ILO Employment Service Convention (C88), 1948. The organizational and geographical structure ensures the availability of basic employment services, vocational training and access to statutory entitlements throughout the country. Employment services include assistance to unemployed clients (individual and group counselling; profiling and individual employment planning; vocational guidance; and referral to vocational training and public works) and services to employers (short-listing of job candidates and job mediation).

The State Labor Inspectorate is an administrative authority, which is empowered with the right to exercise state control over compliance with legislative acts and other normative acts in the field of work, safety and health at work. The labour inspectorate ensures compliance with legislation and collective agreements with respect to working conditions, wages, labour relations and child labour. Also, it is involved in the training of workers and approves the safety of work equipment and technical devices before these go into production. It also monitors compliance with labour-related legislation within the central and local public administration.

3.5. International Conventions Ratified by Republic of Moldova

Republic of Moldova has signed and ratified many global and regional environmental conventions, multi-lateral agreements, protocols and treaties that stipulate the country's obligations to monitor, assess and report on a number of environmental parameters in Republic of Moldova related to water resources management, atmospheric air pollution and waste management. Some of them listed below are relevant to Emergency COVID-19 Response Project:

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (Ratified on 18th of November, 2008) - an international treaty that was designed to reduce the movements of hazardous waste between nations, and specifically to prevent transfer of hazardous waste from developed to less developed countries. The Convention is also intended to minimize the amount and toxicity of wastes generated, to ensure their environmentally sound management as closely as possible to the source of generation, and to assist less developed countries in environmentally sound management of the hazardous and other wastes they generate.

***Cartagena Protocol on Biosafety (Ratified on 11th of October, 2002*)** - a Protocol to the Convention on Biological Diversity is an international agreement which aims to ensure the safe handling, transportation and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.

***The UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, usually known as Aarhus Convention (Ratified on 7th of April 1999*)** helps member countries to establish rights of the public (individuals and their associations) to receive environmental information that is held by public authorities ("access to environmental information"). This can include information on the state of the environment, but also on policies or measures taken, or on the state of human health and safety where this can be affected by the state of the environment. In addition, public authorities are obliged, under the Convention, to actively disseminate environmental information in their possession. Upon ratification of the convention, the county took up an obligation to ensure citizens' access to justice in environmental matters. The obligation considers provision of a package of guarantees that allows citizens, including civil society, to ask a national court to check whether a public authority has respected the rights and fulfilled the related legal requirements.

Fundamental, Governance and Technical conventions of the International Labor Organization (ILO) covering regulations on employment policy, remuneration, holidays with pay, human resources development, minimum age, freedom of association, etc. as well as those prohibiting forced labor, child labor and discrimination. Moldova ratified 42 ILO Conventions and 1 Protocol, of which 41 are in force. These are related to labour and wage protection, maternity, combating of worst forms of child labour and others. The Republic of Moldova has ratified the Promotional Framework for Occupational Safety and Health Convention (No. 187) in 2010. Other ratified main ILO standards on OSH include the Occupational Safety and Health Convention, 1981 (No. 155) and the Safety and Health in Agriculture Convention, 2001 (no. 184).

Moldova signed on February 6, 2017 in Strasbourg the **Council of Europe Convention on preventing and combating violence against women and domestic violence (Istanbul Convention).** The Parliament approved on October 14, 2021 the ratification of the Istanbul Convention. By ratifying the Convention, the Moldovan authorities duly undertake to prosecute violence against women, allocate resource to ensure the operation of crisis centers, 24/7 hotline, shelters for victims of violence, provide psychological and legal assistance, and other measures. Violence against women during COVID pandemic has been on the rise as reported by CSOs and women activists. Stress, the disruption of social and protective networks, loss of income and decreased access to services all exacerbate the risk of violence for women. Therefore, the issue is particularly relevant for the Emergency COVID-19 Response Project.

3.6. Environmental and Social Standards of the World Bank Relevant for the Project

The Emergency COVID-19 Response Project is required to comply with the World Bank ESF. The ESF sets out the World Bank's commitment to sustainable development, through the Bank Policy and a set of ESSs that are designed to support borrowers' projects with the aim of ending extreme poverty and promoting shared prosperity. The ESSs set out the requirements relating to the identification and assessment of environmental and social risks and impacts associated with projects supported by the Bank through Investment Project Financing. The World Bank believes that the application of these standards, by focusing on the identification and management of environmental and social risks, will support Borrowers in their goal to reduce poverty and increase prosperity in a sustainable manner for the benefit of the environment and their citizens by:

- Supporting Borrowers/Clients/Implementing Agencies in achieving good international practice relating to environmental and social sustainability;
- Assisting borrowers/clients/implementing agencies in fulfilling their national and international environmental and social obligations;
- Enhancing nondiscrimination, transparency, participation, accountability and governance; and
- Enhancing the sustainable development outcomes of projects through ongoing stakeholder engagement.

Of the ten ESSs comprising the ESF, five are relevant to the Moldova Emergency COVID-19 Response project. They establish the standards that the project and its implementing agency (Ministry of Health) will meet through the project life cycle, as follows:

- **ESS 1 - *Assessment and Management of Environmental and Social Risks and Impacts.*** ESS 1 sets out the borrower's responsibilities for assessing, managing and monitoring environmental and social risks and impacts associated with each stage of a project supported by the Bank through Investment Project Financing, in order to achieve environmental and social outcomes consistent with the ESSs.

  The project will have positive environmental and social impacts as it should improve COVID-19 surveillance, monitoring and containment as well as provide targeted support for the more vulnerable households. However, the project could also cause environmental, health and safety risks due to the dangerous nature of the pathogen and reagents and other materials to be used in the project-supported ICUs, laboratories, and quarantine facilities. Other risks, associated with site specific rehabilitation of health facilities, are identified/identifiable and easily to mitigate. To manage these risks, the Ministry of Health , with support from the PIU, will prepare two major instruments:

  (i) An ESMF that will include templates for site specific Environmental and Social Management Plans (ESMP) and Infection Control and Medical Waste Management Plan (ICWMP) so that the ICUs, laboratories, and quarantine facilities to be supported by the Project will apply international best practices in COVID-19 diagnostic testing and other COVID-19 response activities.

- **ESS 2 – *Labor and Working Conditions***. ESS 2 recognizes the importance of employment creation and income generation in the pursuit of poverty reduction and inclusive economic growth. Borrowers can promote sound worker-management relationships and enhance the development benefits of a project by treating workers in the project fairly and providing safe and healthy working conditions. ESS2 applies to project workers including full-time, part-time,

temporary, seasonal and migrant workers.

The project shall be carried out in accordance with the applicable requirements of ESS 2, in a manner acceptable to the Bank, including through, inter alia, implementing adequate occupational health and safety measures (including emergency preparedness and response measures), setting out grievance arrangements for project workers, and incorporating labor requirements into the ESHS specifications of the procurement documents and contracts with contractors and supervising firms.

The project is expected to encompass the following categories of workers: direct workers and contracted workers, Direct workers could be either government civil servants or those deployed as 'technical consultants' by the project. The former will include: health care providers and workers in health care facilities. The latter includes chiefly construction workers involved in the minor civil works.

Civil works contracts will incorporate social and environmental mitigation measures based on the WBG EHS Guidelines and the ESMF; other referenced plans e.g. SEP. All civil works contracts will include industry standard Codes of Conduct that include measures to prevent Gender Based Violence/Sexual Exploitation and Abuse (GBN/SEA). A locally based GRMs specifically for direct and contracted workers will be provided.

- **ESS 3 – *Resource and Efficiency, Pollution Prevention and Management***. ESS 3 recognizes that economic activity and urbanization often generate pollution to air, water, and land, and consume finite resources that may threaten people, ecosystem services and the environment at the local, regional, and global levels.

  Medical wastes and chemical wastes (including water, reagents, infected materials, etc.) from the labs, quarantine, and screening posts to be supported (drugs, supplies and medical equipment) can have impact on the environment and human health. Wastes that may be generated from medical facilities and labs could include liquid contaminated waste, chemicals, and other hazardous materials, and other waste from labs and quarantine and isolation centers including sharps, used in diagnosis and treatment. Each beneficiary medical facility/lab, following the requirements of the ESMF, WHO COVID-19 guidance documents, and other best international practices, will prepare and follow an ICWMP to prevent or minimize such adverse impacts. The ICWMP will mandate that any waste associated with COVID-19 testing or treatment will be incinerated on site whenever possible. It will also contain strict protocols for disinfecting and packing such waste for transportation to the nearest medical waste incinerator if on site destruction is not possible.

- **ESS 4 – *Community Health and Safety***. ESS 4 recognizes that project activities, equipment, and infrastructure can increase community exposure to risks and impacts. In addition, communities that are already subjected to impacts from climate change may also experience an acceleration or intensification of impacts due to project activities.

  Medical wastes and general waste from the labs, health centers, and quarantine and isolation centers have a high potential of carrying micro-organisms that can infect the community at large if they are is not properly disposed of. There is a possibility for the infectious microorganism to be introduced into the environment if not well contained within the laboratory or due to accidents/ emergencies e.g. a fire response or natural phenomena event

(e.g., seismic). Laboratories, quarantine and isolation centers, and screening posts, will thereby have to follow procedures detailed in the ESMF and ICWMP (see ESS 3 above).

The operation of quarantine and isolation centers needs to be implemented in a way that staff, patients, and the wider public follow and are treated in line with international best practice as outlined in WHO guidance for COVID-19 response as above under ESS 1 and ESS 2.

The SEP will also ensure widespread engagement with communities in order to disseminate information related to community health and safety, particularly around social distancing, high risk demographics, self-quarantine, and mandatory quarantine.

The project will mitigate the risk of Sexual Exploitation and Abuse by applying the WHO Code of Ethics and Professional Conduct for all workers in the quarantine facilities as well as the provision of gender-sensitive infrastructure, such as segregated toilets and enough light in quarantine and isolation centers.

The project will also ensure via the above-noted provisions, including stakeholder engagement, that quarantine and isolation centers and screening posts are operated effectively throughout the country, including in remote and border areas, without aggravating potential conflicts between different groups.

In case quarantine and isolation centers are to be protected by security personnel, it will be ensured that the security personnel follow strict rules of engagement and avoid any escalation of the situation, taking into consideration the above-noted needs of quarantined persons as well as the potential stress related to it. For Covid-19 Vaccine Procurement and Deployment, in case military or security personnel is involved, and used in the implementation of Project activities: (a) Adopt and enforce standards, protocols and codes of conduct for the selection and use of security or military personnel, and screen such personnel to verify that they have not engaged in past unlawful or abusive behavior, including sexual exploitation and abuse ("SEA"), sexual harassment ("SH") or excessive use of force; (b) Ensure that such personnel is deployed in accordance with the relevant requirements of ESSs and the ESCP; (c) Ensure that such personnel is adequately instructed and trained, prior to deployment and on a regular basis, on the use of force and appropriate conduct (including in relation to civilian-military engagement, SEA and SH, and other relevant areas), as set out in the, ESMF and the ESCP; (d) Ensure that the stakeholder engagement activities under the Stakeholder Engagement Plan include a communication strategy on the involvement of such personnel under the Project; (e) Ensure that any concerns or grievances regarding the conduct of such personnel are received, monitored, documented (taking into account the need to protect confidentiality), resolved through the Project's grievance mechanism.

- **ESS 10 –** ***Stakeholder Engagement and Information Disclosure***. ESS 10 recognizes the importance of open and transparent engagement between the Borrower and project stakeholders as an essential element of good international practice. Effective stakeholder engagement can improve the environmental and social sustainability of projects, enhance project acceptance, and make a significant contribution to successful project design and implementation.

Considering the serious challenges associated with COVID-19, dissemination of clear messages around social distancing, high risk demographics, self-quarantine, and, when necessary, mandatory quarantine is critical. Meaningful consultation, particularly when public meetings are counter to the aims of the SEP, and disclosure of appropriate information are important for ensuring public health and safety from all perspectives – social, environmental, economic, and medical/ health.

The project's SEP serves the following purposes: (i) stakeholder identification and analysis; (ii) planning engagement modalities viz., effective communication tool for consultations and disclosure; and (iii) enabling platforms for influencing decisions; (iv) defining roles and responsibilities of different actors in implementing the Plan; and (iv) a grievance redress mechanism (GRM).

A detailed mapping of the stakeholders will be done during implementation. Individuals and groups likely to be affected (direct beneficiaries) have been identified.

3.7. The World Bank Group Environmental, Health and Safety Guidelines

The Environmental, Health and Safety (EHS) Guidelines[27] are technical reference documents with general and industry-specific examples of GIIP and are referred to in the ESF. The EHS Guidelines contain the performance levels and measures that are normally acceptable to the World Bank Group, and that are generally considered to be achievable in new facilities at a reasonable cost by using relevant technology. The World Bank Group requires borrowers to apply the relevant levels and/or measures of the EHS Guidelines. When host country regulations differ from the levels and measures presented in the EHS Guidelines, projects will be required to achieve whichever is more stringent. General EHS Guidelines apply to the Moldova Emergency COVID-19 Response Project and most relevant of them are listed below:

EHS 1.1 – Air Emissions and Ambient Air Quality;

EHS 1.3 – Wastewater and Ambient Water Quality;

EHS 1.5 – Hazardous Materials Management;

EHS 1.6 – Waste Management;

EHS 2.3 – Physical Hazards;

EHS 2.4 – Chemical Hazards;

EHS 2.5 – Biological Hazards;

EHS 2.6 – Radiological Hazards;

EHS 2.7 – Personal Protective Equipment;

EHS 2.8 – Special Hazard Environments;

EHS 3.5 – Transportation of Hazardous Materials;

EHS 3.6 – Disease Prevention;

EHS 4.1 – Environment; and

EHS 4.2 – Occupational Health and Safety.

[27] http://documents.worldbank.org/curated/en/157871484635724258/Environmental-health-and-safety-general-guidelines

Additionally, the EHS for Health Care Facilities[28] also applies to the project. The EHS Guidelines for Health Care Facilities include information relevant to the management of EHS issues associated with health care facilities, including general hospitals and small inpatient primary care hospitals, as well as outpatient, assisted living, and hospice facilities. Ancillary facilities may include medical laboratories and research facilities, mortuary centers, blood banks and collection services.

3.8. WHO Guidance

The WHO is maintaining a website specific to the COVID-19 pandemic with up-to-date country specific and general technical guidance[29]. As the situation remains fluid it is critical that those managing both the national response as well as specific health care facilities and programs keep abreast of guidance provided by the WHO and other international best practice. Current technical guidance provided by the WHO includes the following topics, which are being updated regularly:

- Critical preparedness, readiness and response for COVID-19;
- Surveillance, rapid response teams, and case investigation;
- National laboratories;
- Country-level coordination, planning, and monitoring;
- Clinical care;
- Infection prevention and control/WASH[30]
- Serology and early investigation protocols;
- Essential resource planning;
- Guidance for schools, workplaces & institutions;
- Risk communication and community engagement;
- Virus origin / reducing animal-human transmission;
- Points of entry / mass gatherings;
- Naming the coronavirus disease (COVID-19);
- Humanitarian operations, camps, refugees/migrants in non-camps and other fragile settings;
- Health workers; and
- Maintaining Essential Health Services and Systems.

Besides the guidance for governments and states, WHO also recommends public and citizens to comply with the safety measures at home, public areas and workplaces. Those recommendations include application of PPE, sanitizers and suggested models of safe behavior and healthy practice and lifestyle.

Even prior to adopting COVID-19-specific, constantly evolving guidance and recommendations by WHO, the world health body already had had a well-designed guidelines and standard requirements to prepare for and manage pandemic situations worldwide, including specific

[28] https://www.ifc.org/wps/wcm/connect/960ef524-1fa5-4696-8db3-82c60edf5367/Final%2B-%2BHealth%2BCare%2BFacilities.pdf?MOD=AJPERES&CVID=jqeCW2Q&id=1323161961169

[29] https://www.who.int/emergencies/diseases/novel-coronavirus-2019 (accessed on June 28, 2020)

[30] WASH is an acronym for "water, sanitation and hygiene"

chapters for communicable diseases control and preventions. Those to immediate relevance to Emergency COVID-19 Response Project include but are not limited to:

- Safe management of waste from health-care activities[31]. The guideline is designed for state, medical facilities, health-care personnel and waste carrier to advise them about the safe, sustainable and affordable management of medical waste. The guideline aims at reducing health problems and eliminating potential risks to people's health, health-care service provision inevitably create waste that may itself be hazardous to health. The waste produced in the course of health-care activities carries a higher potential for infection spread and injury than any other type of waste. Wherever waste is generated, safe and reliable methods for its handling are therefore essential. Inadequate and inappropriate handling of health-care waste may have serious public health consequences and a significant impact on the environment. Sound management of health-care waste is thus a crucial component of environmental health protection.
- Infection prevention and control (IPC)[32]. IPC related standards and guidelines give direction to followers on the effective application of IPC programs, the safe use of invasive devices, the right infrastructure and resources to achieve good IPC standards, including actions such as hand hygiene at the point of care. Based on systematic reviews, as well as presenting practical country examples, expert consensus guidelines developed by WHO are inherently linked to focusing on implementation and mean that countries and health facilities can prioritize practical actions for improvement. The group of IPC guideline by WHO includes guidelines on:
  - Hand hygiene;
  - Injection safety;
  - Antimicrobial resistance (AMR);
  - Surgical site infections; and
  - Core components of IPC and other interventions.
- Personal Protection Equipment. PPE is most important in preventing transmission of the communicable diseases not only in hospitals, but also through various activities linked to health-care provision: cleaning, waste management and community care related to the outbreak and pandemic situation. In that regard, WHO sets standard requirements and recommendations on PPE[33] and on its rational use[34].
- Also, WHO resources include technical guidance on: (i) laboratory biosafety, (ii) infection prevention and control, (iii) rights, roles and responsibilities of health workers, including key considerations for occupational safety and health, (iv) water, sanitation, hygiene and waste management, (v) quarantine of individuals, (vi) rational use of PPE, (vii) oxygen sources and distribution for COVID-19 treatment centers, (viii) vaccine readiness assessment, (ix) surveillance of adverse events following immunization.

[31] Safe management of waste from health-care activities, second edition 2018: https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf?sequence=1
[32] Infection prevention and control guidelines: https://www.who.int/infection-prevention/publications/en/
[33] WHO standards related to Personal protective equipment: https://www.who.int/medical_devices/priority/COVID_19_PPE/en/
[34] WHO Recommendations about rational use of PPE: https://www.who.int/publications/i/item/rational-use-of-personal-protective-equipment-for-coronavirus-disease-(covid-19)-and-considerations-during-severe-shortages

4. Environmental and Social Baseline

4.1. Environmental Characteristics

Physical Environment

Geographical Location. The Republic of Moldova (RM), covering an area of 33,846 square km, is located in Central Europe, in the northwestern Balkans. The RM's capital city is the municipality of Chisinau (mentioned in the historical records for the first time in 1436) with a population of approximately 820.5 thousand people (NBS, 2017). The RM borders on Ukraine in the North, East and South and on Romania in the West, with the Western borderline going along the river Prut (Figure 1-1).The total length of the RM's national border is 1,389 km, including 939 km of the border with Ukraine and 450 km of the border with Romania.

The RM is situated at longitude 28˚50' east and latitude 47˚ north. The exact location of the extreme points on the RM's territory is as follows: the northernmost point is Naslavcea (latitude 48˚ 21' north and longitude 27˚ 35' east); the southernmost point is Giurgiulesti (latitude 45˚ 28' north and longitude 28˚ 12' east) which is also RM's sole location on the bank of the Danube; the westernmost point is Criva (latitude 48˚ 16' north and longitude 26˚ 30' east); the easternmost point is Palanca (latitude 46˚ 25' north and longitude 30˚ 05' east). The distance between the extreme points is about 350 km from Naslavcea to Giurgiulesti and only 120 km from the West to the East at the latitude of the municipality of Chisinau.

The RM is a Black Sea region country. Its southern border extends almost as far as the Black Sea coast, and the access to the Black Sea is open for RM through the Dniester estuary and the Danube.

Relief. The region between the Prut and the Dniester is a part of the Moldovan Plateau, which starts at the foothills of the Bukovina Mountain Crest and Moldova's Sub-Carpathians in the West and reaches as far as the Dniester in the East. The southwestern part of the Podol Upland extends along the left bank of the Dniester. Hills and flatland areas can be observed next to the upland relief within the framework of those major relief-forming units. The absolute altitudes are within the range of 429 m (Balanesti Hills) and 4 m above the sea level in the Dniester flood land (Palanca).

The relief has contributed to the formation and development of geographic landscapes and ecosystems - next to the other geo-ecological, biotic and socio-human factors. The current geo-ecological complex took shape at the end of the Late Pleistocene Epoch and in the first half of the Holocene (Recent) Epoch. The current biotic complex (flora, fauna, soil) and soils appeared in the second half of the Holocene epoch.

Air and Climate

Air. The air is polluted in the Republic of Moldova by stationary and mobile sources. Currently, in the Republic of Moldova there are 5,866 air polluting enterprises, thermal power plants and small power installations with boilers. Transport is the main source of air pollution, emitting large amounts of hydrocarbons, carbon monoxide, nitrogen dioxide, sulfur dioxide, soot, benz (a) pyrene and lead into the air.

The main challenges in the field of air protection are the following:

- The State Hydrometeorological Service does not have data on recent measurements and in line with EU standards.

- There are exceedances in the Republic of Moldova of limit values set in the EU, in particular for nitrogen dioxide, particulate matter, benzene and benz (a) pyrene.
- Limit values are not approved for PM10 and PM25 pollutants and the values set for some pollutants significantly exceed the regulations used in European countries, while for other pollutants the regulations imposed by the legislation in force are lower, respectively, the requirements of these are stricter than the European ones.
- It is noted that the stationary monitoring stations are from 1970-1978 and are obsolete both morally and physically. Currently, the Republic of Moldova is guided by the Framework Plan for Eastern European countries, according to which it is necessary to create a monitoring network, including for fine PM particles. It should be mentioned that on the territory of the country there are only three monitoring points for PM pollutants (one station in Mateuți village, one in Leova town and one in Chisinau municipality).
- For the purpose of monitoring in any region / part of the country, mobile monitoring stations are used in Europe. Unfortunately, the Republic of Moldova does not have such equipment. Despite complaints from the population about air pollution, State Hydrometeo Service, in the absence of such stations, does not have the opportunity to assess in a timely manner the level of emissions from the existing sources and provide the population with information on the quality of the air they breathe.

As a result of environmental control actions in 2019 by State Ecological Inspectorate, it was found that 5,866 objects with environmental impact are registered in the Republic of Moldova, including 5 of grade I (one) with emissions above 7 253.03 t / year, 20 – of grade II with moderate impact and the majority - with low impact on the air quality. The industrial sector registers 27,070 sources of pollution (emission amount of 9 181.4188 t / year), followed by the transport sector, such as peco stations, passenger service stations, etc., (11 468 sources of pollution), energy sector (5,300 sources of pollution), other sectors (9,998 sources of pollution).

It is worth mentioning that the amount of pollutants emitted into the air at all fixed pollution sources in the current year was estimated at 21867.92 tons per year. From small power plants with boilers, the emission amount constituted 3 795.7206 t / year, of which a good part uses biofuels (pellets, biogas) and gas. According to the reports of the State Ecological Inspectorate in 2019, serious cases of exceeding a limited allowable concentrations were not detected, so no requests for cessation of activities of economic entities were received.

Climate. The climate of the Republic of Moldova is moderately continental, characterized by relatively mild winters with little snow, long warm summers and low humidity. The country is located in the area where the air masses coming from the Atlantic Ocean via Western Europe interact and mix with the air from the extreme continental northeastern regions and the Mediterranean air from the south-west. Two distinctive patterns can be observed regarding the territorial distribution of the climatic features in RM: (i) distinct zoning of the annual rainfall averages which show a decreasing trend from the North to the South; and (ii) the increase by approximately 100 mm of the multiannual rainfall averages in the upland regions depending on the neighboring flatland areas.

The average annual air temperatures vary between 6.3°C (1980) in the North to 12.3°C (2007) in the South (Table 1-1). From 1990 to 2015, the absolute annual temperatures varied from a minimum of

-28.0°C (January 2006) and a maximum of +39.5°C (July 2007). Warm weather lasts about 190 days.

Annual precipitations are decreasing in intensity from North- West to Southeast. In 1960-2015 time series, the average annual precipitations varied between a minimum of 382 mm (2015) and a maximum of 960 mm (2010) in the North; respectively from a minimum of 307 mm (2003) and a maximum of 813 mm (1997) in the South (Table 1-2). The number of days with precipitations (0.1 mm and more) varied from a minimum of 111 (2014-2015) and a maximum of 174 days (1980 and 1987) in the North, respectively from a minimum of 91 (2003) and a maximum of 152 days (1991) in the South.

Climate change. Despite minimal responsible for causing climate change, Moldova is already experiencing climate change impacts with more severe droughts, heatwaves, flooding, and other adverse weather events, such as hail and severe storms.[35] Episodes of drought, including in 2020, have driven fluctuations in economic output. [36] The 2007 drought had negative impacts on 84% of the country's arable land, household food security, and access to water, leading to estimated losses in the agricultural sector of US$ 1 billion. On average, northern Moldova experiences a drought once every ten years, compared to every five years in central Moldova and every three years in the South.[37] In 2008, floods from torrential rains caused US$ 120 million in damage to houses, bridges, and roads and flooded 7,500 hectares of agricultural land.[38] Most climate change scenarios indicate that, in the 21st century, the country may become significantly warmer, with an increase in the average temperature of 2°C to 3°C by 2050.[39] Heat waves will reduce crop productivity, increase extreme weather events, change disease incidence, and lead to a higher spread of pests.

The project location and target beneficiaries have experienced climate and geophysical hazards in the past and are expected to experience these in the future with moderate intensity, frequency, and duration. Among the identified risks, six are considered a high priority: an increased risk of drought and water scarcity; increased heatwave-related deaths; increases in air pollution-related diseases; increased risk of allergic disorders; and an increase in the burden of waterborne and foodborne diseases. Moldova's Third National Communication under the United Nations Framework Convention on Climate Change and the Intended Nationally Determined Contribution towards the achievement of the global goal of the United Nations Framework Convention on Climate Change highlighted the adaptation priorities in the health sector. These priorities include: (a) strengthening disease surveillance systems by including climate-related health outcomes; (b) ensuring improved

[35] https://climateanalytics.org/media/historical_responsibility_report_nov_2015.pdf

[36] Fay, Marianne; Block, Rachel I.; Ebinger, Jane. 2010. Adapting to Climate Change in Eastern Europe and Central Asia. World Bank. © World Bank. https://openknowledge.worldbank.org/handle/10986/2407 License: CC BY 3.0 IGO.

[37] Moldova - Paths to sustained prosperity: a systematic country diagnostic (English). Washington, D.C.: World Bank Group. http://documents.worldbank.org/curated/en/465041475522681625/Moldova-Paths-to-sustained-prosperity-a-systematic-country-diagnostic

[38] USAID. 2017. Climate Risk Profile: Moldova. [online] Available at: <https://www.climatelinks.org/resources/climate-change-risk-profile-moldova#:~:text=Moldova%20is%20highly%20vulnerable%20to,rising%20food%20and%20energy%20prices> [Accessed 17 February 2021].

[39] Sutton, William R.; Srivastava, Jitendra P.; Neumann, James E. 2013. Looking Beyond the Horizon: How Climate Change Impacts and Adaptation Responses Will Reshape Agriculture in Eastern Europe and Central Asia. Directions in development: agriculture and rural development. Washington, DC: World Bank. © World Bank. https://openknowledge.worldbank.org/handle/10986/13119 License: CC BY 3.0 IGO.

access of remote communities and vulnerable groups (e.g., the elderly, obese, and disabled) to healthcare services; (c) enhancing the population's understanding of risk for the emergence of new, unfamiliar diseases and other adverse health impacts; (d) operationalization of "green" standards in health facility infrastructure; and (e) ensuring the prevention, early warning, management and overcoming the impact of extreme weather events, including heatwaves and droughts.

The Additional Financing and investments made under Subcomponent 1.1. seeks to address Moldova's climate vulnerability by contributing to climate change adaptation through new activities. These will leverage the opportunity to invest in sustainable, climate-friendly, energy-efficient cold chain infrastructure, including for transportation, minor works, and storage equipment, including (a) for transportation – improved route planning and electric motorcycles and charging infrastructure; (b) for infrastructure – solar photovoltaic and battery systems, energy-efficient cooling with low global warming potential refrigerants, thermal insulation, solar reflective roofs, and built-in temperature controls; (c) for cold storage equipment – the adoption of low global warming potential refrigerants for solar refrigerators and freezers, cyclopentane insulation, solar direct drive on-site freezers, sterling cycle refrigeration with helium as the coolant for ultra-low freezers, and non-energy consuming coolant packs in shipping units; and (d) for training – to incorporate training content related to the procurement and use of low-carbon equipment and disaster risk management. Safety boxes for disposal of syringes may also constitute an adaptation and mitigation measure by reducing the risk of medical waste exposure during climate-related extreme events, and reducing the requirement for incineration, and thus, greenhouse gas emissions. The total estimate for climate adaptation for these measures is estimated at 20% of Subcomponent 1.5. All the described activities will make the population, health, and social protection systems more resilient to the ongoing impacts and potential emergencies associated with climate change.

Water Resources

Rivers. There are 3621 rivers and water-springs in the Republic of Moldova. All of them form part of the Black Sea basin and can be categorized as follows: the Dniester Basin Rivers, the Prut Basin Rivers and the southern region rivers falling either into the Danube estuary or in the Black Sea coastal salt lakes. The majority of rivers are small. The largest rivers include the Dniester (1,352 km long, including 657 km in the RM, with the annual water debit of approximately 2.4 km^3), Raut (286 km), Cogalnic (243 km, including 125 km in the RM), Bac (155 km), Botna (152 km). The RM's drainage network densities 0.48 km per square kilometer on the average, varying between 0.84 km/ km^2 in the northern regions and 0.12 km/km^2 in the regions on the left bank of the Dniester. The main water sources feeding the rivers are snowfalls and rainfalls, whereas the groundwater plays only a minor role. The majority of precipitations occur in the form of rainfall, whereas snow accounts for as little as 10 per cent of the total precipitations. High water levels are observed in spring due to the melting snow (40-50 per cent of the annual flow). In summer the water levels in rivers - and in particular in small rivers – can rise considerably after storm rainfall, sometimes causing disastrous floods.

Lakes. There are approximately 60 natural lakes in the Republic of Moldova. Most of them are lakes located in the high-water beds of the rivers Prut (Beleu, Rotunda, Fontan) and Dniester (Old Dniester, Cuciurgan). In addition, there are above 3,500 water storage ponds created and maintained for diverse economic purposes (such as irrigation, fishing, recreation, industrial and household needs, protection from floods). Large water-storage reservoirs have been created for

hydropower plants: Costesti–Stinca (735.0 mill. m^3) on the river Prut jointly with Romania; and Dubasari (277.4 mill. m^3) on the Dniester river.

Groundwater. Groundwater has a special role in the surface water balance in the RM. They participate actively in the hydrological cycle as a component of the ground water debit. The distribution of the available ground waters is not even across the country, because their major portion is concentrated in the high-water beds of the Dniester and the Prut. The water supply capacity of the ground water-bearing horizons decreases with the increasing distance to those rivers.

The country has 17 horizons and water systems of various ages and uneven distribution3. Six of these water horizons are more important: the alluvial horizon dating back to the Quaternary Epoch (22 mil m^3), the Middle Sarmatian horizon (110 mil. m3), the Early Sarmatian and the Badenian water system (770 mil. m^3), the Cretaceous (110 mil. m^3), the Late Sarmatian and the Pontian horizon (44 mil m^3). In most water horizons, circa 50 per cent presents potable properties, except for the phreatic horizon – 20-30 per cent. Groundwater reserves are around 1,100 mil m^3, while those approved for economic needs represent circa 255000 m3 per day. About 6,200 artesian wells and circa 250 thousand fountains fed from groundwater wells supply circa 40 per cent of rural population, which provides 1811 thousand m^3/day confirmed groundwater reserves. Of the total national groundwater resources, only 50 per cent can be used for drinking purposes without prior treatment.

Mineral Waters. Currently, in the RM, about 50 types of mineral waters in circa 170 mineral water springs are approved for use and certified, but about half of them (particularly, because fluoride and hydrogen sulphide content exceeds by 10 and respectively 8 times the maximum permitted), are not operating. Of these, circa 25 mineral water springs (Varnita–III, Branesti, Purcari, Edinet-II, Micauti, Cotiujeni, Orhei, Balti-III, Ialoveni, etc.), including therapeutic mineral water springs (Source no. 3 from Gura Cainarului village) are new springs, appreciated because of the last years prospections. Water mineralization levels vary between 1 and 10 g/dm^3. Mineral water springs are typical for the southern and northeastern regions of the country, containing hydrocarbonates and hydrocarbonates-sulfates prevailing the sodium and calcium cations. Their water contains hydrogen sulphide (30-80 mg/dm^3), iodine (17-26 mg/dm^3), bromine (132-139 mg/dm^3) and other chemical elements (lithium, radon, strontium, boron).

Industrial Waters. The industrial ground water available in the RM contains less-common extractable chemical elements, with the waters containing iodine, bromine, strontium, cesium, rubidium, boron and helium being the most widespread. The highest concentration of chemical elements in the water with mineralization levels of 70-100 g/dm^3 is 60 mg/dm^3 for iodine; 360 mg/dm^3 for bromine; 380 mg/dm^3 for strontium; 1.0 mg/dm^3 for cesium; 3 mg/dm^3 for rubidium; and 15.0 ml/dm^3 for helium.

Thermal Waters. Thermal water is common in the high waterbed of the Prut and in the southern regions of the RM. The water temperature is 20-80ºC, and the water debit of the wells is 10-100 m^3 per day.

Sanitation

The Republic of Moldova's water resources are relatively limited compared to other countries in the region. It is the country with the largest water deficit in the region, with about 3,000

m3/capita/year of renewable water resources, of which only 400 m^3/capita/year is formed within the territory of the country. Moldovan water resources largely depend on the volumes of water in the Prut and Dniester rivers, accumulated mostly outside the country. This is of particular importance given that the main source of water supply for the population and for the needs of the economy is surface water, which accounts for 85 per cent of total water consumed. The remaining 15 per cent comes from underground water sources. In these circumstances, measures to prevent pollution, and ensure rational consumption and proper management of water resources are imperative. The relationship with neighboring countries – Ukraine and Romania, with the Republic of Moldova shares the two river basins – and how these water resources is managed across borders are also very important.

The Republic of Moldova faces many challenges in providing sustainable and quality water and sanitation services for all citizens, in particular in rural areas where the population is declining. Despite the progress made by the Republic of Moldova in recent years, it has the largest urban-rural gap and the lowest level of access to water supply and sanitation services in the Danube region.

Thus, according to official data, between 2014 and 2018, public access to water sources gradually increased by 9 percentage points, to 82.1 per cent in 2018. Although investments in water supply systems have mainly been made in rural localities, and the proportion of the rural population with access to water supply sources increased from 56.9 per cent in 2014 to 71.17 percent in 2018, this is still much less than the 97.0 per cent figure in urban areas in 2018.

On the other hand, those with access to public water supply service do not always enjoy drinking water meeting the sanitary norms, as the water supplied through the systems is often not potable. Thus, of the samples taken by the National Public Health Agency in 2017, 54 per cent failed to meet the sanitary-chemical norms. The proportion of the samples not meeting the sanitary-chemical norms reflects a direct link with the extension of water supply systems in rural areas. This is because the water supply for the population in rural localities is mainly sourced from groundwater, which is very often affected by natural or anthropogenic pollution. However, as the budgets of rural localities are quite modest, they cannot afford to invest in water treatment plants, which are expensive and would increase tariffs for water supply services; these are not always affordable for rural population whose incomes are mainly from agricultural activity and are lower than for those living in urban localities.

While access to water supply is generally high at national level, there are significant shortcomings in the share of population with access to public sanitation service. Thus, in 2018, only 29.3 per cent of the stable population in the Republic of Moldova was connected to a centralized sewerage system, including 64.1 per cent in urban localities and only 2.8 per cent in rural localities. There was a small increase in investments in sewerage systems until 2017, followed by a jump of 6.2 percentage points in 2018, mainly due to expansion of the sewerage system in urban localities. In rural areas, the increase was insignificant. Although during this time investments were made in sewerage systems, from both national and external sources, these proved to be ineffective because of the population's refusal to connect to the network. This reluctance is both for economic reasons and because gaps in the legislation, but also because of the low understanding in the population of the need for proper wastewater management.

The studies show that when the population connects to water supply systems, water consumption increases. In the absence of sewage and wastewater treatment solutions, these systems become major sources of water pollution, as is the case of the Republic of Moldova.

In addition to the gap between urban and rural areas, there is a significant difference in the Republic of the Republic of Moldova between the population with access to public water supply service and the population with access to the public sewerage service: this difference of 41.4 per cent in 2018 means there is a very high risk of pollution.

Wastewater is the main source of surface water pollution in the country, a fact recognized and stipulated in the National Development Strategy 'Moldova 2030', which is currently in process of being approved. The Republic of Moldova must focus all its efforts on building and rehabilitating sewerage systems and treatment plants, most of which are dilapidated and obsolete. Statistical data show a slow increase in the volume of wastewater discharged into water basins, with a modest share of wastewater treated according to the regulations in force. Thus, in 2018, of the 677m^3 of wastewater discharged into the emissary, only 123m^3 (18.17 per cent) was sufficiently treated. The rest was partially treated wastewater, often only the mechanical stage, and untreated wastewater.

Proper operation of municipal wastewater treatment plants requires proper management of industrial wastewater, which today is rather ignored. Thus, despite a regulatory framework being in force, oversight of compliance with environmental legislation is too soft, failing to make the business sector accountable and jeopardizing the operation of wastewater treatment processes, which are the responsibility of local public authorities.

Analysis of data on the treatment or pre-treatment of industrial wastewater shows a very modest increase, recorded over recent years, in the proportion of industrial wastewater that is treated.

HCU and ICU considered in the project, are connected to municipal sewage systems, and the treatment of waste waters coming from the operation of HCU and ICU, totally depends from the operations of municipal waste water treatment facilities.

The project will not invest in wastewater management facilities for HCU and ICU which will be covered by the project. The environmental requirements for this aspect should refer to the mandatory connection of HCU and ICU to centralized municipal sewage system or connection to a waste water treatment plant.

Waste Management

Waste management is one of the current problems facing the Republic of Moldova due to its increasing quantity and diversity, as well as its increasingly negative impact on the environment. At the same time, the urban and industrial development of the localities, as well as the general increase of the living standard of the population entails the production of more and more quantities of waste.

The general principles of waste management are concentrated in the waste management hierarchy and apply as an order of priority in waste prevention legislation and policies:

- prevention;
- preparation for reuse;
- recycling;

- other recovery operations, including energy recovery; and
- the elimination.

The application of the waste hierarchy and its observance are mandatory for all subjects involved in waste management, ensuring the prevention of waste generation and the efficient and effective management of waste, so as to reduce its negative effects on the environment.

More information can be found in the Infection Control and Waste Management Plan (ICWMP).

Waste management from medical activity

The producer of medical waste ensures the monitoring of medical waste management system, which includes the implementation of its own waste management plans, the use of appropriate equipment for the treatment of medical waste, waste registration activities and reporting to competent authorities. The Infection Control and Waste Management Plan (ICWMP) contains more explicit information on the management of medical waste and all the relevant information related to this issue.

According to the Sanitary Regulation on the management of waste resulting from medical activity, approved by Government Decision no. 696 of 11.07.2018, each of the hospitals are obliged to have a central space for temporary storage of medical waste. The packaging of waste resulting from medical activity, including hazardous waste, must be carried out in packaging made of materials that allow its disposal with minimal risks to the environment and public health. The packaging in which the collection is made and which comes in direct contact with the hazardous waste resulting from medical activity, is for single use and is disposed of together with the contents.

The central temporary storage area for medical waste shall include the following rooms / areas:

1) receipt and separate temporary storage by type, depending on the waste produced, for: a) non-hazardous waste; b) waste destined for recycling (like paper or plastic); c) cutting-stinging, infectious and anatomopathological waste; d) chemical waste, of cytotoxic / cytostatic drugs, with amalgam; 2) treatment of infectious waste (where relevant); 3) office for the operator (where relevant).

Spaces for the temporary storage of non-hazardous waste until their disposal by sanitation services include, but are not limited to the following: 1) concrete land; 2) containers with the volume that ensures the collection of the amount of waste produced between 2 successive disposals. To reduce the amount of waste, it is advisable to use press containers.

The requirements for the central space for temporary storage of hazardous waste resulting from medical activity include: 1) the floor with a surface resistant to mechanical action, waterproof, smooth and intact, easy to sanitize; 2) adequate drainage system / floor drain for the discharge into the sewerage network of wastewater resulting from sanitation. In the absence of the floor siphon, the sanitation is performed with minimal amounts of water, with disposable cleaning utensils, considered in the end infectious waste; 3) conditions that limit the access of insects, rodents, animals and birds; 4) screens for protection from the action of sunlight; 5) water supply source; 6) lighting and appropriate ventilation installations (at least passive ventilation) to ensure optimal temperatures (prevention of decomposition of organic material, incidents and accidents caused by other hazardous waste); 7) controlled access for authorized personnel; 8) access for units / vehicles that ensure the transport / disposal of waste; 9) conditions for hand hygiene and sanitation of containers for transporting waste and surfaces; 10) technological equipment, furniture, personal

protective equipment, specific equipment for leak management, 11) quantities and necessary assortment of hygienic and disinfection products; 12) autonomous fire signaling and extinguishing systems.

The room for temporary storage points for hazardous chemical waste is marked with appropriate symbols, warning of the nature of the hazard of the chemicals.

A waterproof and resistant bathtub for stored substances is provided for the temporary storage of liquid chemical hazardous waste.

If the tub provided for is missing, then the container for the separate collection of liquid chemical waste shall be placed under the containers in which the hazardous chemical waste is stored.

The room for temporary storage points for hazardous chemical waste is equipped with kits for disposing of liquid waste, personal protective equipment and first aid kits (eye wash, etc.).

At temporary storage points for hazardous chemical waste, the cupboard with shelves for storing waste is divided into several sections, where chemical waste with different characteristics is stored.

Chemical waste with similar hazard characteristics is stored together.

The area of central temporary storage areas for hazardous waste allows the storage of the volume of accumulated waste in the interval between two successive disposals.

The central temporary storage area for hazardous waste is functionally separated from the rest of the construction / subdivisions.

According to the Sanitary Regulation on the management of waste resulting from medical activity, approved by Government Decision no. 696 of 11.07.2018, to ensure safe transportation and disposal to avoid cross contamination, the heads of medical institutions which produce medical waste are expected to monitor the management and registration of medical waste.

According to the List of wastes, the structure of waste from healthcare and related research includes sharp objects, fragments and human organs, including blood vessels and preserved blood; waste, the collection and disposal of which is subject to special measures to prevent infections; chemicals consisting of or containing dangerous substances; cytotoxic or cytostatic drugs; wastes the collection and disposal of which are not subject to special measures for prevention of infections.

The treatment of infectious waste by incineration in facilities, located on the territory of medical institutions is carried out in the districts of Comrat, Telenesti, Calarasi, Ceadir-Lunga, Glodeni, Cimișlia, Drochia, Nisporeni, Ștefan Vodă.

The activity of collecting, transporting and autoclaving medical waste is organized by SRL “UISPAC” (Authorization 005 no.064 / 2015 of 27.10.2015) and SRL “Ecostat” (Authorization 005, no.071 / 2016 of 27.05.2016), the authorizations being issued by the Ministry of Environment.

The pyrolysis treatment of infectious waste is contracted with SRL "Trisumg" from Cahul by some medical institutions from Comrat, Cahul, Vulcanesti, Taraclia, Soldanesti, Ialoveni districts.

The fragments and human organs, formed in hospitals are transported to the Bekkari graves in the respective localities or are buried in cemeteries. The formed chemical waste and expired reagents are handed over for neutralization to CP “Entuziast”, SRL “Eco-Emir”, and the thermometers,

tonometers, used luminescent lamps with mercury content are stored in the rooms of medical institutions.

The management of medical waste remains a problem as long as an efficient waste management system is not established but the management of medical waste will be performed according to the national legislation. Additional details related to medical waste management in the Republic of Moldova are provided in Annex 8.

According to the Order nr. 8 of the Ministry of Agriculture, Regional Development and Environment of the Republic of Moldova from the 29th of March 2019, in order to receive authorization for collection, transportation and elimination of medical waste it is necessary to present the following:

1) for waste collection activities:

a) the origin of the waste;
b) the type and quantity of waste collected;
c) waste collection method (separate, mixed);
d) arrangements, installations and measures for collection, including for environment protection;
e) the destination of the collected waste

2) for waste transport activities:

a) the destination of the transport (for temporary storage, storage and final processing, marketing, recovery, integration into the environment, elimination), with the exact specification of the recipient;
b) types of waste transported, physical condition, quantity;
c) installations, means, endowments, packaging, measures regarding the transport of each type of waste, including environmental protection;
d) necessary transport capacities;
e) the waste transport route;
f) organization of transportation supervision;
g) endowments and measures for intervention in case of accidents and damages in waste transport time;

3) for waste treatment activities:

a) proof that the treatment plant is in accordance with the Program on national waste management and regional waste management programs;
b) description of the location, with reference to water management, with hydrogeological and geological characteristics. This information will be ensured through specialized studies, prepared according to the legal provisions in force;
c) the approval of the state ecological expertise for the project documentation;
d) origin of waste, list, type, composition and quantity of treated waste;
e) for each type of operation - technical and any other requirements, capacity of site concerned;

f) for each type of operation - technology and installations used;
g) procedures and measures, detention facilities and / or neutralization of pollutants resulting from the treatment process, capacity, the efficiency of these installations;
h) emissions of pollutants in the environment, concentration, volume;
i) monitoring and control of operations;
j) closure and subsequent maintenance measures;
k) the proposed methods of prevention and reduction of pollution, including the recovery plan interventions;

4) for waste disposal activities:
a) the document certifying the mining perimeter, issued by the body competent in the field of geology and mineral resources - in the case of placement of waste in basements;
b) the proof issued by the competent body in the field of geology and mineral resources regarding lack of negative impact of waste on groundwater quality;
c) proof of a financial guarantee to ensure that the obligations resulting from the authorization are also fulfilled and the procedures for closing a deposit are respected.

All the waste generated by the vaccination activities of the project, will be also managed according to the existing legislation, and namely according to the Law on Waste 209/2016 and the Sanitary Regulation on the management of waste resulting from medical activity no. 696 of 11.07.2018. More information on medical waste management is included in the Annexes and ICWMP developed as a standalone document at project level.

4.2. Population and Socio-Economic Characteristics

Volatile economic growth, adverse labour market trends and public spending stress have been the main socio-economic characteristics and challenges in Moldova during the past several years. An overview of population, economy and poverty situation is provided below, describing the main economic and social challenges, casual effects on production, employment, vulnerability of groups of population, as well as challenges of the social and healthcare protection systems.

The **population** of Moldova is 2,649,540[40] people (47.9% male and 52.1% female). Roughly, 38% of the population of Moldova live in or around a city. Moldova currently has a flat population growth rate of 0.0% and a total fertility rate of about 1.55 children born to each woman, which is below the replacement rate of 2.1. As of 2019, the population was changing at the rate of -0.28% annually[41]. Around 18.4% of the population is older than 60 years and 2.4% of the population is older than 80 years[42]. Of the top 10 causes of premature death in the Republic of Moldova are relevant co-morbidities for COVID-19 disease (including ischemic heart diseases, stroke, hypertensive heart diseases, lung cancer, colorectal cancer, chronic obstructive pulmonary disease[43]). A large share of the population has cancer (5-year prevalence cases are 32,200) and

[40] https://populationstat.com/moldova/
[41] https://worldpopulationreview.com/countries/moldova-population
[42] Statistical Yearbook of the Republic of Moldova, 2019
[43] http://www.healthdata.org/moldova

lung cancer is the most common form of cancer among men[44]. Given that COVID-19 affects the respiratory system, smoking is an important risk factor and appears to have played a large part in the gender distribution and severity of COVID-19 in China[45]. Thus, it stands to be an aggravating factor for the potential outbreak in Moldova, where 43.6% of men and 5.6% of women smoke[46].

The economy of Moldova, even before the COVID-19 shock, **showed sharp slowdown in the last quarter of 2019**[47]. According to data from the National Bureau of Statistics the Gross Domestic Product (GDP), estimated for the quarter IV of 2020, in nominal value amounted to 56318 million lei current market prices. Compared to the quarter IV 2019, GDP decreased by 3,3% on the gross series and by 4,4% on the seasonally adjusted series. In 2020, the GDP decreased compared to 2019 by 7,0%, on the gross series[48].

The economic lockdown and travel restrictions have led to a **sharp deterioration in activity with a severe drop in disposable income.** A fall in remittances will further depress private consumption and will affect many categories of the population, while the resultant economic downturn will affect the current poor as well as potentially send large numbers of people into poverty.

It is expected that **public revenues will fall considerably**, while health and social expenses and fiscal stimulus will spur expenditures but not enough to compensate for the lost domestic demand due to the COVID-19 crisis. The projected deficit for the baseline scenario is assessed at 5.8 percent, below the official plans as further prioritization of expenditures and financing may be needed. In the second quarter of 2020, the revenues of the national public budget decreased, being by 8.7 percent below the level recorded in the similar period of 2019[49]. On the back of weak domestic demand, lower commodity prices and a higher base effect, disinflationary pressures will prevail against accommodative economic policies, moderate depreciation, supply shocks and poor agricultural yields. All these will affect the population in terms of higher prices, lower food supplies, and lower incomes to care for basic needs such as health, food and education. The absence of savings, loss of remittances, rising prices, and more difficult access to basic goods and food will make the poor very vulnerable. Seeking medical help may be equally difficult for the poor, especially for single parents, families with many children, or families that have members with a disability. Even though government has announced that treatment for COVID-19 will be provided for free, households face other costs when seeking care such as. travel, medicines, caregiving for family members.

The drought has brought agri-producers into the streets in August 2020, demanding support from the Government. While the Government allocated €5.07 million to pay compensations to the registered agri-producers who had suffered from droughts, **poor families who depend on subsistence agriculture are thrown into desperate poverty**.

On the health-system situation side, substantial improvements occurred after 2000 in the Moldova healthcare system, service delivery and access to healthcare facilities. However,

[44]; https://gco.iarc.fr/today/data/factsheets/populations/498-republic-of-moldova-fact-sheets.pdf
[45] Cai, W. 2020. "Sex difference and smoking predisposition in patients with COVID-19." Lancet Respir Med, Doi.org/10.1016/PII. At: https://www.thelancet.com/action/showPdf?pii=S2213-2600%2820%2930117-X
[46]*http://www.euro.who.int/__data/assets/pdf_file/0006/312594/Tobacco-control-fact-sheet-RepofMoldova.pdf?ua=1*
[47] World Bank, "Moldova Economic Update Spring 2020" http://pubdocs.worldbank.org/en/466481588799156228/Moldova-Economic-Update-Spring-2020.pdf
[48] NBS, Press Release of 16 March 2021 https://statistica.gov.md/newsview.php?l=ro&id=6940&idc=168
[49] National Bank of Moldova https://www.bnm.md/en/content/inflation-report-no3-august-2020

Moldova lags behind regional countries as concerns medical staffing, equipment, etc. and for the past decade had registered serious medical brain drain of both young medical professionals and experienced doctors.

The Global Health Security Index published in 2019 highlights key constraints and challenges, deficiency related to rapid response capacity, health system capacity, and detection and reporting, placing Moldova at 78 out of 195 countries. A 2018 Joint External Evaluation (JEE) identified significant vulnerabilities with regards to pandemic preparedness and financing, with particular challenges in the areas of laboratory systems, surveillance and case detection, response coordination, personnel deployment and risk communication. The JEE also highlighted Moldova's critical financing gap in being able to support and field an emergency response. In addition, the recommendations of the JEE point towards the importance of establishing protocols, procedures and capabilities to rapidly expand the country's ability to treat vulnerable patients and introduce measures to stop community transmission. This includes strategies for risk communication, training medical and non-medical workers on relevant protocols, and bolstering routine medical care and emergency treatment capabilities.

In 2016, the Government of Moldova spent approximately US$83.5 per capita on health, with government health expenditure representing around 49% of total health expenditure. Total health expenditure, measured as a percentage of GDP, increased from 5.9% in 2000 to 9% in 2016. Out-of-pocket health spending contributes around 46% of total health expenditure and points to an underlying vulnerability for poorer populations. Since the poor are facing higher constraints related to prices and limited access to basic goods and food, as well as, possibility of unexpected healthcare expenses, these groups stand to be particularly at risk as COVID-19 unfolds.

The health system's resilience is limited and in need of financing in order to ensure that, in a time of crisis and a rapidly unfolding pandemic, it is better positioned to meet the needs of citizens, particularly vulnerable citizens including low-income, disabled, elderly, isolated communities, and Roma communities.

Moldova had registered high Covid infection and death rates among medical and healthcare staff, posing additional risks of the system and capacity to respond to the crisis.

During one year since the first case of COVID-19 which was confirmed in Moldova on March 7, 2020 the number of infected persons as of March 24, 2021 constituted 219 988 confirmed cases and 4661 deaths. Following a peak of 222 cases on April 15, 2020, further increases in case incidence were mitigated by containment measures, including the layered application of physical distancing, testing, contact tracing, and improved sanitation. However, relaxing containment measures and increased social interaction at the beginning of the summer of 2020 contributed to a rise in daily case incidence to a high of 478 cases on June 17, 2020 and another counter-record of 2273 daily case incidence on March 24, 2021[50]. The death counter-record was on March 30 and April 06, 2021. As of April 26, 2021, there were a total of 5745 deaths; a total of 249,385 of Covid cases and 237.934 recovered.

Cold Chain Resources Sufficiency and Management for COVID-19 Vaccine Deployment. An assessment of cold chain capacity has been completed with UNICEF support, which determined that there is adequate capacity to support the first deployment stage. Initial findings indicate that,

[50] https://www.worldometers.info/coronavirus/country/moldova/

at the national level, the country can store about 500,000 vaccine doses at temperatures of -70°C to -80°C, 500,000 vaccine doses at temperatures of -20°C, and 1,000,000 vaccine doses at 2°C to 8°C. World Bank support will be directed towards closing gaps in cold chain equipment and infrastructure in all stages of the national vaccination campaign. The delivery of COVID-19 vaccines will occur in 80 hospitals, 1,400 family doctor centers, and via mobile teams as needed. According to initial assessment, following the procurement of COVID-19 vaccines, the supply chain is as follows: the vaccine is stored at the national vaccine depot in the NAPH as soon as it is received from the supplier, at the required temperature regime (2°C to 8°C, -20°C, or -70°C to -80°C); the vaccine is then transported under isothermal conditions to the regional public health centers, unless storage at -70°C to -80°C is required, in which case, it is transported directly to the health facility; for vaccines distributed to regional public health centers, they are allocated to health facilities in the region; and if necessary, mobile teams are organized at the health facility level for close-to-community vaccination. All health facilities in the country can store vaccines requiring 2°C to 8°C. Vaccines that require the -70°C to -80°C temperature regime will not be stored for more than 120 hours at 2°C to 8°C in the health facility. The National Agency for Public Health is responsible for forecasting the supply of vaccines and incidentals and monitoring supply chain performance. UNICEF is providing technical support for electronic vaccine stock management at the national and regional levels. A simulation of the whole chain, from delivery of vaccines at the airport to service delivery points, has been conducted in January 2021. Additional details on the cold chain analysis is provided in Annex 10.

On the social and labor side, the health crisis has caused a socio-economic crisis, not only due to the loss of human lives, but also due to the consequences of containment measures. The containment measures, including social distancing and stay at-home orders, have forced some businesses to stop or restrict operations. Travel and transport bans, by generating supply-chain disruptions, have limited input availability, worsening the negative supply shock. The effect on labor markets has caused a decline in households' income and consumption, hence triggering a negative demand shock in parallel.

Analysis of national statistics[51] reveals **a reduction in employment in the second quarter of 2020** compared with the same period of 2019. Specifically, the employed population was 21, 5 thousand persons, lower by 8,8% in comparison to the second quarter of 2019 (901, 1 thousand). The share of men was higher than that of women (52,2% men and 47,8% women), and the share of employed persons from the rural area was higher than that of employed persons from the urban area (56,0% in rural area and 44,0% in urban area). This may be linked with the **lockdown affecting more urban businesses compared with rural**.

According to the National Bureau of Statistics, the number of employed persons who stated that their **situation at work was affected due to COVID-19** constituted 200,6 thousand or 24,4% of the total employed population (compared to 33,2 thousand or 4,1% of total employed population in the first quarter of 2020).

[51] National Bureau of Statistics survey "Labour Force in the Republic of Moldova: Employment and unemployment in the 2nd quarter of 2020" https://statistica.gov.md/newsview.php?l=en&idc=168&id=6749&parent=0

As of March 14, 2021 58.6% of confirmed cases of COVID-19 were among females, while 50.7% of deaths were among males.[52]

Poor, vulnerable and disadvantaged population: households from all ethnic groups with children, headed by persons other than parents, families with many children, persons from households employed in agriculture, the elderly, disabled, unemployed, single mothers on maternity leave, persons without education or professional skill are groups of population most vulnerable to insecurity, violence and financial vulnerability. Data from National Bureau of Statistics reveals that Moldovan families spend most of their income for food products, non-food goods and dwelling maintenance. The majority of households cannot ensure a sufficient consumption of products and services. The lowest level of expenditures is registered among the households of self-employed in agriculture and pensioners; these households allocate most of their income for food consumption (about 47% of the total consumption expenditures)[53].

However, the impact of Covid-related restrictions might have affected many groups of population in different ways. A World Bank Report[54] determined that the understanding about vulnerability changed and "many of the new poor are likely to be found in congested urban settings, which can serve as a conduit for the spread of the pandemic. Many of the new poor are likely to be engaged in informal services, construction, and manufacturing, rather than agriculture. These are sectors in which economic activity is most affected by lockdowns and other mobility restrictions as well as continued social distancing".

Families with children tend to be poorer than other groups – the poverty rate for single parents and families with many children is much higher than the average (38.3% and 27.1% respectively compared to 18.6% on average). The Government operated modifications in August 2020[55] planning an indexation twice per year (April 1 and October 1) and a 25% increase in the amount of the GMI from 50% to 75%. This would be a monetary increase of 276.75 lei / per child as social assistance and by 608.85 lei / per child entitlement to aid for the cold period of the year.

Members of poor families with disabilities have increased poverty coefficients (+0.3 for adult with a disability, +0.5 for child with disability, +0.1 for a single adult who has a disability), but given the low GMI their income after Ajutor Social benefit may not even reach subsistence minimum (1,707.4 lei in 2019 for this category).

A rapid survey among Territorial Structures of Social Assistance (27 April - 7 May 2020) identified that families with children of alcoholic parents, families where at least one parent is known to be violent, families with incomes lower than the guaranteed minimum, families with three or more children and families in which a parent lost their job during Covid-19 state of emergency have been hit the hardest by the epidemiological situation and lockdown[56].

[52] The Sex, Gender, and COVID-19 Project. 2021. The COVID-19 Sex-Disaggregated Data Tracker | Global Health 50/50. [online] Available at: <https://globalhealth5050.org/the-sex-gender-and-covid-19-project/the-data-tracker/?explore=country&country=Moldova#search> [Accessed 2 April, 2021].

[53] https://statistica.gov.md/public/files/publicatii_electronice/aspecte_nivelul_trai/Aspecte_nivelul_trai_2019.pdf

[54] Poverty and Shared Prosperity 2020: Reversals of Fortune pahe 170; https://openknowledge.worldbank.org/bitstream/handle/10986/34496/9781464816024.pdf

[55] Decision of the Government # 474 of 08-07-2020 https://www.legis.md/cautare/getResults?doc_id=122127&lang=ro

[56] UNICEF Report July 2020, page 6; source

Thus, poor families with three and more children, non-insured mothers on maternal leave, families with disabled dependents, families depending of subsistence agriculture and the elderly are those in need of targeted support.

Notably, Moldova ranks 107 out of 189 countries and territories as per the Human Development Index (HDI), which measures national progress in health, education and income, losing 10.4% of human development progress due to persisting inequalities. The multidimensional poverty headcount in Moldova is 0.8 percentage points higher than income poverty[57]. This implies that individuals living above the income poverty line still suffer multiple deprivations in health, education and/or standards of living.

Gender inequality and violence against women is linked with stereotypes and social roles attributed to women and men. This affects the position of women in political, economic and public spheres, and increases the incidence of violence against women, including gender segregation. According to a 2019 study[58], the share of those suffering from the most common forms of gender-based violence is twice higher among women in households with persons with disabilities, Roma women, and women of pre-retirement age. In the same study, 17% of women informed they could not afford buying medicine worth 200 lei ($12) for lack of money, and 37% said they did not have enough money. 42% did not go to a doctor even if they needed to and 16% did not visit a doctor because of lack of time or money. The pandemic and related restrictions have aggravated the situation of women. Women struggle with a significantly lower purchasing power, greater pressure because of kindergarten closures and online schooling, and with limited access to services and authorities and to protective measures against COVID-19. Frustration related to health risks, economic loses, uncertainty, restrictions in movement and deprivation, increase violence against women. Due to the measures in response to pandemics, services for prevention and protection of women from violence have been less available due to changed work regimes, lack of information on new modes of access to services, restricted movement or firmer control of perpetrators over women during lockdowns. Access to sexual and reproductive health services have also been rather limited, as well as hotlines, crisis centers, shelters, legal aid, and protection services. There are no national-level estimates of the gender-disaggregated impact of the pandemic on poverty however, before the pandemic women's average monthly earnings were 87% of the average monthly earnings among men. Also, approximately 70% of applicants for the Ajutor Social benefit program were females. Female-headed households have more children (2.33) on average than male households (2.11) and are more likely to be single-parent families. As additional benefits per child are smaller than benefits for adults, households of similar sizes with more children are eligible for smaller benefits. Hence, there is both a higher vulnerability of females to contracting COVID-19 and a greater poverty risk among households led by females.

Females also bear a significant burden of the COVID-19 response within the household, health system, and social services. About 79% of health workers and 87% of social workers in Moldova are female. In line with the WHO SAGE values framework, the prioritization process for COVID-19 vaccination in Moldova has highlighted the importance of preferential access for groups at

[57] http://hdr.undp.org/sites/default/files/hdr2019.pdf
[58] "Unequal Moldova", page 4 https://www.eef.md/media/files/files/unequal-moldova-report-english-web_1278956.pdf

higher risk of infection. The framework also prioritizes those who bear a significant burden of the COVID-19 response, both of which apply to females. In addition to health and social workers, as noted above, the prioritized groups for vaccination are predominantly female in other cases: teachers (75%) and elderly aged 60 years and above (59.9%). In addition to the risk of exposure to COVID-19 during vaccination, the deployment program will involve the use of security forces, which may inadvertently expose females to sexual harassment, exploitation, and abuse; and the disproportionate use of force.

Equitable access to vaccination and the WHO Framework for Allocation & Prioritization of COVID-19 Vaccination. The Framework lists the following potential disadvantaged and vulnerable groups in the case of COVID-19:

- People living in poverty, especially extreme poverty
- Homeless people and those living in informal settlements or urban slums
- Disadvantaged or persecuted ethnic, racial, gender, and religious groups, and sexual minorities and people living with disabilities, including Roma people who are disproportionally affected due to their low standard of living[59]
- Low-income migrant workers, refugees, internally displaced persons, asylum seekers, populations in conflict setting or those affected by humanitarian emergencies, vulnerable migrants in irregular situations, nomadic populations
- Hard to reach population in rural places with poor road infrastructure and thus poor access for ambulance
- Older adults defined by age-based risk
- Older adults in high risk living situations (examples: long term care facility, those unable to physically distance)
- Groups with comorbidities or health states (e.g. pregnancy/lactation) determined to be at significantly higher risk of severe disease or death
- Sociodemographic groups at disproportionately higher risk of severe disease or death
- Social groups unable to physically distance (examples: geographically remote clustered populations, detention facilities, dormitories, military personnel living in tight quarters, refugee camps)
- Groups living in dense urban neighborhoods
- Groups living in multigenerational households.
- Women headed and single parent households.

Moldova has maintained coverage rates of childhood vaccinations exceeding 90%. There are no significant differences between males and females in the probability of receiving a childhood vaccine in Moldova.[60] While COVID-19 vaccination will depend on national immunization systems, priority groups are mostly adults. Moldova does not have nationally representative data on health care use among the elderly, disaggregated by gender, which may indicate access in priority groups. [61] However, on average, empirical research indicates that male and female adults

[59]'The Effects of the COVID-19 Pandemic on the Roma Population', a research performed by the Roma National Center in partnership with UN Women https://moldova.un.org/en/92530-roma-population-affected-disproportionately-covid-19-pandemic

[60] https://researchonline.lshtm.ac.uk/id/eprint/2965139/1/Roma%20vaccination_second_revision.pdf

[61] Tatiana Cojocari, MA, Radu Cupcea, MA, Aging in Moldova: A Country With Orphan Older Adults, The Gerontologist, Volume 58, Issue 5, October 2018, Pages 797–804, *https://doi.org/10.1093/geront/gny055*

are equally likely to forgo essential health care when ill. [62] Males are 1.62 times more likely to report not having health insurance and potentially facing financial barriers to health care use.[63] However, the national immunization program provides all vaccines free of charge such that affordability may not pose a significant barrier to access, regardless of gender.

To ensure all vulnerable groups in Moldova have access to vaccine, under the project a fair, equitable and inclusive vaccine access and allocation is considered. Firstly, the national immunization program provides all vaccines free of charge such that affordability may not pose a significant barrier to access, regardless sociodemographic. Secondly, a National Vaccine Deployment Plan was developed in January 2021 prioritizing population groups vaccine immunization in accordance with recommendations of WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination and WHO Roadmap for prioritizing population groups for vaccines against Covid-19_and Roadmap for prioritizing population groups for vaccines against Covid-19. Thirdly, to assess equitable access to vaccines from a gender perspective, a PDO indicator was introduced to monitor the proportion of females and males in priority groups that have received a COVID-19 vaccination in Moldova.

Vulnerable Children: Poverty and vulnerability of the family and wellbeing/vulnerability of the child are interlinked. According to the Child' Ombudsperson[64], insufficient monthly childcare allowances to cover for a minimum level of child support, lack of protection mechanisms for children left in the care of relatives or other people, multiple deficiencies to care for children with special needs, violence against children, lack of specialists in child's rights within local public administrations are elements that affect certain categories of children. These are children from vulnerable families (large families with three or more children, families depending on subsistence agriculture, families having disabled dependents, single-parent families, children left with caregivers such as elderly grandparents). The pandemic has aggravated the situation of vulnerable children. Lack of a stable income in the family due travel restrictions or closure of the workplace, food insufficiency; limited access to children's education; insufficiency of hygiene make them more vulnerable and unable to cope during the epidemiological situation. According to the specialists of the Territorial Structures of Social Assistance[65], in addition to the categories of children from vulnerable families, street children and children left alone at home due to hospitalization of parents are specifically affected.

Social protection programs cover 62% of the population (compared to 72% in Ukraine and 81% in Romania), with coverage for the bottom quintile reaching almost 80%. Pensions and other social insurance benefits constitute the highest coverage (52% of all population and 53% of the poorest quintile), although the benefits' size is relatively small. Social assistance has much lower coverage: they reach only 12.8% of total population and 27% of the poorest quintile. Inadequate benefit size compromises programs' effectiveness in supporting beneficiaries to rise out of poverty over the long-term. Moldova's expenditure on social assistance remains low compared to the average for the region. Expenditures on social assistance programs stand at about 1% of GDP, while the average in the region is almost double at (1.9% of GDP).

[62] Balabanova, D., McKee, M., Pomerleau, J., Rose, R., & Haerpfer, C. (2004). Health service utilization in the former Soviet Union: evidence from eight countries. Health services research, 39(6p2), 1927-1950.

[63] Richardson, E., Roberts, B., Sava, V., Menon, R., & McKee, M. (2012). Health insurance coverage and health care access in Moldova. Health policy and planning, 27(3), 204-212.

[64] Report of the Ombudsman for Protection of the Child's Rights http://old.ombudsman.md/en/ac_rapoarte

[65] UNICEF Report July 2020, page 6; source

While **social protection is crucial** for many Moldovan families who live under or on the poverty line, **the current design of the Ajutor Social is not suited to provide effective support in deteriorating economic conditions**. The benefit size is not adequate: Ajutor Social payments have a relative incidence (share of the benefit in the overall income of this group) of just 8% for the poorest quintile. Moreover, the program has recently declined both in terms of coverage and nominal budget. Finally, the design of the program is not geared towards supporting vulnerable groups, such as families with more than two children and single parents – in fact, a family of two adults is currently eligible for a higher benefit than a family of an adult and a child . The employment status filter will not permit the inclusion of some of the families recently pushed into poverty, such as returned migrant workers or those informally employed in the past. In this context, changing the design of Ajutor Social to increase the adequacy of support and focusing more on the most vulnerable groups would serve to strengthen its effectiveness in addressing challenges faced by vulnerable populations related to the COVID-19 outbreak.

The assessment of implementation challenges and lessons learned from the parent project and from practices of other countries demonstrates that COVID-19 vaccine deployment require unprecedented efforts to strengthen national supply chains and supportive systems for vaccination. The majority of the countries face implementation challenges deploying vaccines at scale. Also, even in countries that have achieved high immunization coverage rates among children, there may be challenges identifying and reaching high-risk groups for COVID-19, including the aged, health and social workers, and people living with multiple chronic diseases.

Investments in national immunization systems will support improvements across various functions, including in cold chains, communication campaigns, governance mechanisms, transportation infrastructure, data systems, and trained and motivated vaccinators.

5. Potential Environmental and Social Risks and Their Mitigation

5.1. Environmental and Social Risks of the Project

The key types of risks associated with the Original Project are related to: (i) occupational health and safety for medical staff, laboratory staff and communities in due course of detection, transportation of patients/tests/chemicals and reagents, and treatment stages of the COVID-19 cycle; (ii) occupational health and safety related to collection, transportation and disposal of medical waste management; (iii) vulnerable and disadvantaged groups (low-income, disabled, elderly, isolated communities, including potentially Roma communities) encountering obstacles to access facilities and services provided by the project activities; (iv) Handling of quarantining interventions (including dignified treatment of patients; attention to specific, culturally determined concerns of vulnerable groups; and prevention of sexual exploitation and abuse and sexual harassment as well as meeting minimum accommodation and servicing requirements); (v) social tensions that could be exacerbated by the project and community health and safety-related outcomes (especially related to spread of disease and waste management); (vi) social exclusion which is widespread in Moldova due to variance in communities' or individual's ability to pay; (vii) ensuring transparency and equity for financial support to households targeting specifically vulnerable populations.

The overall risk of the Additional Financing for Vaccine Procurement and Deployment is High. The risk associated with sector strategies and policies is rated as High, while the risks in four categories are rated as Substantial, including political and governance, macroeconomic, fiduciary, and environmental and social. While the environmental risks remain substantial, the nature of these risks is different given the new vaccination-related activities, including uncertainties that may require ad hoc decisions and adjustments, occupational and health safety issues related to the handling of vaccine supplies, and additional production of vaccine-related medical waste. The social risks have been assessed to be substantial, due to the broader social risk of inequity in access to vaccines, due to political pressures to provide vaccines to groups that are not prioritized due to need or vulnerability.

Thus, the main environmental risks identified are: (a) Occupational Health and Safety issues related to testing and handling of supplies during vaccination; (b) logistical challenges in transporting vaccines across the country in a timely and safe manner, adhering to the recommended temperature and transportation requirements; (c) production and management of medical healthcare waste; (d) community health and safety issues related to handling, transportation, and disposal of hazardous and infectious healthcare waste associated with vaccination, including sharps and used vaccine vials; and (e) minor environmental impacts—noise and dust emissions—from minor construction work in vaccine storage facilities. These risks are covered by ESS 1, ESS 2, ESS 3, ESS 4, and ESS 10. To mitigate these risks, in September 2020, the Ministry of Health prepared an ESMF, which contains provisions for storing, transporting, and disposing of contaminated medical waste. The document also outlines guidance in line with good international practice and WHO standards on COVID-19 response on limiting viral contagion in healthcare facilities. The ESMF is updated during March-April 2021 to account for the AF-funded activities.

Environmental risks mainly relate to vaccine procurement and deployment, including minor works in vaccine storage facilities.

An Infection Prevention and Control and Waste Management Plan is prepared to reflect evolving procedures for managing waste associated with vaccination.

The social risk is also assessed as being substantial, which is linked with a risk of inequity in vaccines' access due to political pressures to provide vaccines to groups that are not prioritized based on need or vulnerability. Political pressure may exclude the elderly and other vulnerable groups. There may also be traffic and road safety risks to community health and safety that arise during nationwide transportation of vaccines for deployment, including the risk of injuries. Social tensions could be exacerbated by the Project and community health and safety-related outcomes, primarily related to the spread of disease and waste management. The risks associated with the distribution and transport of vaccines are assessed. Traffic and road safety risks associated with the safety of drivers transporting vaccines around the country will be mitigated based on guidance of WHO COVID-19 vaccination: Supply and Logistics Guidance of February 12, 2021[66].

Physical works under the Original COVID-19 Emergency Project include small works such as rehabilitation, renovation, refurbishment, and retrofitting of the existing buildings. No new construction or extension of healthcare or waste management facilities will be financed. Neither will the project involve acquisition of existing public or private facilities. Project activities will not involve land acquisition, physical or economic displacement, or restriction of access to private land and other property.

Project activities will be undertaken by civil servants of Ministry of Health and other state agencies, consultants hired by Ministry of Health , healthcare workers and workers contracted for the delivery of civil works. Staff of the medical institutions will be at risk of contracting infection while working in wards of clinics treating COVID-19 cases, and in laboratories. Other project workers will also be at risk of exposure. Further, construction workers may face modest occupational health and safety hazards typical for small-scale works. It is expected that predominantly local construction companies will perform rehabilitation works under the project. No large numbers of workers will be required at any individual work site. Influx of labor also is not expected.

Delivery of equipment, PPE, test kits and other goods is planned for the selected hospitals, medical laboratories, screening posts, and primary health care facilities quarantine and isolation points, infection treatment centers, ICUs and assisted living facilities. In some health facilities, minor interior works are envisaged to take place. Technical specifications of equipment and PPE as well as designs for installation of ICUs and other specialized facilities will strictly follow WHO guidance and other relevant Good International Industry Practice (GIIP).

The project will not invest into medical waste management systems and infrastructure. However, clinics benefiting from rehabilitation works and delivery of equipment provided by the project will be assisted in improving their infection control and waste management practices as required, especially for HCF in rural areas (plastic bags to manage medical waste, containers) If critical gaps are found in ESMPs/ ICWMPs prepared by HCFs without adequate mitigation measures, the project will hold off supporting such HCFs.

Hospital waste separation, on-site collection, removal and treatment is subject to national regulations, though their implementation faces multiple challenges. Several medical facilities do operate their own incinerators and autoclaves, but their capacity is not always sufficient. No

[66] file:///C:/Users/Eugenia%20Ganea/Downloads/WHO-2019-nCoV-vaccine_deployment-logistics-2021.1-eng%20(2).pdf

municipal incinerators exist for treating the medical waste. There are couple of private companies providing waste management services to medical facilities, but their operation standard in some cases does not meet neither the requirements of the EU directive 2000/76/EC[67] on the incineration of waste nor respective guidelines of WHO. Hazardous medical waste may not be disposed at municipal landfills in difference from the non-hazardous medical waste. The current national waste management policy implies gradual closure of municipal landfills by 2027 and their replacement with the new regional landfills, but it is unlikely to be implemented by then. In 2019, the Government of the Republic of Moldova signed with European Investment Bank the Agreement for the implementation of sound municipal waste management in Moldova with total value of 100 mil EUR. This agreement will address the issues that are related to municipal waste and will not cover hazardous waste.

The authorization of the companies which manage medical waste, is issued by the Environmental Agency, which should monitor that the economic entities are respecting the provisions of the authorizations. The project will identify the needs of the private companies which manage medical waste and build the information capacities of the companies to better manage the medical waste. It will also identify if the existing private companies cover the needs of the whole country, or if there is a need to address specific regions with technical support to better manage COVID-19 pandemic.

Waste resulting from vaccination is classified as infectious and managed according to the Sanitary Regulation on managing waste resulting from the medical activity, approved by Government Decision no. 696/2018. The 2013-2027 national waste management strategy identified the lack of a centralized network for collecting used syringes as a significant hazard in the health sector in Moldova.[68] As per Government Decision no. 696/2018, vaccination teams are required to segregate medical waste at the source and implement appropriate logistics for the collection, storage, transportation, disposal, and neutralization. Non-sharp infectious wastes will be collected in yellow polyethylene bags denoted as containing "biological hazard' with an icon. The Ministry of Health is developing ICWMPs to support the storage, transport, and disposal of medical waste under the original project and vaccine deployment. These plans are consistent with good international practice and WHO standards on COVID-19 response on limiting viral contagion in healthcare facilities.

The project implementation will not imply any transboundary movement of specimens, samples, or any hazardous materials. Only in-country transportation is expected.

If special measures for infection control have to be sustained, stakeholder engagement into the project implementation, including consultation on its environmental and social aspects, may be challenging due to likely restrictions aimed at social/physical distancing and other national regulations. Alternative, non-conventional means of communication will have to be explored and used under such circumstances.

[67] EU directive 2000/76/EC on the incineration of waste: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:l28072

[68] Ministry of Environment. 2021. National Waste Management Strategy of the Republic of Moldova (2013-2027). [online] Available at: <http://serviciilocale.md/public/files/deseuri/2013_01_24_NATIONAL_WASTE_MANAGEMENT_STRATEGY_2013-27_ENG.pdf> [Accessed 17 February 2021].

Importantly, large volumes of personal data and other sensitive information need to be handled in the connection with the management of the COVID-19 outbreak in Republic of Moldova. Process of ensuring the legitimate, appropriate, and proportionate use and processing of mentioned data featured in the national legislation on personal data and overall, regulations of data management, may experience some shortfalls, or call for additional measures to comply with respective laws, and related security and information management systems. There is also a moderate residual risk related to data collection, processing, and privacy during deployment. The identification of priority groups will require access to individually identifiable electronic medical records. Risks to data collection, processing, and privacy may arise from: (a) access to personally identifiable and sensitive information by unauthorized personnel; (b) gaps in regulation on data privacy and protection; and (c) breaches to cybersecurity. There are regulations under the national immunization program that provide adequate guidance for the appropriate use and processing of data, privacy considerations that limit access to essential personnel, and precise institutional arrangements for childhood vaccine delivery. The AF will provide support for software and hardware investments that further mitigate the risk of cybersecurity breaches. These investments may be vulnerable to vendor lock-in that will be mitigated through prior review of relevant tenders by relevant technical experts in the World Bank team. The updated Project Operational Manual also specify mechanisms to ensure personal data protection.

5.2. Risks and Mitigation Measures Established Under the Project

Overall, the project will have positive environmental and social impacts through improved COVID-19 surveillance, monitoring, and containment as well as provide targeted support for vulnerable households.

However, any environmental and social risks identified at this ESMF stage or which are identifiable during project implementation will be mitigated through the relevant ESSs of the World Bank. The PIU will be primarily responsible for supervision and requesting compliance with these standards by all stakeholders, implementing agencies and contractors.

The present ESMF describes how each of the risks will be mitigated and the tools used for that purpose.

More specifically, ESS 1, ESS 2, ESS 3, ESS 4, and ESS 10 which have been determined as relevant for the project, will be used to avoid, minimize or mitigate environmental and social risks. Following these ESSs, Ministry of Health prepared the following environmental and social management instruments:

- **ESS 1 - Assessment and Management of Environmental and Social Risks and Impacts.** The project will have positive environmental and social impacts as it should improve COVID-19 surveillance, monitoring, and containment as well as provide targeted support for the more vulnerable households. However, the project could also cause environmental, health and safety risks due to the dangerous nature of the pathogen and reagents and other materials to be used in the project-supported ICUs, laboratories, and quarantine facilities. To manage these risks, the Ministry of Health prepared the following environmental and social management tools:
    - This ***Environmental and Social Management Framework***, which includes templates for developing site-specific ESMPs (Annex III) and ICWMPs (Annex IV), so that the clinics, laboratories, and quarantine facilities to be supported by the project apply international best

practices in COVID-19 prevention, diagnostic and treatment. The document was reviewed and accepted by the World Bank, disclosed both in country[69] and through the World Bank's external web page[70].

Inclusion of vulnerable and disadvantaged Groups. Empirical evidence and rapid surveys conducted by different institutions reveal that poor, vulnerable and disadvantaged groups such as families with more than two children, single-parent families, mothers on childcare leave, families with disabled dependents, the elderly, families depending on subsistence agriculture, are in specific affected by the existing circumstances. Vulnerable groups within the communities affected by the project will be further confirmed and consulted during project implementation through dedicated means, as appropriate. At this stage, the highest degree of vulnerability is linked with financial poverty, which is further aggravated, especially if infected. The poor are not financially capable to cover the payment for testing, which ranges about $48 and is very high[71] in private laboratories even for the middle-class, as well as treatment costs. Patients in non-critical condition who are treated at home incur treatment costs estimated at a minimum of $100, which can be hardly affordable by poor families. Under **Subcomponent 1.4 Social and Financial Support to Households,** these affected and vulnerable groups will receive targeted support. The project will support the amending of the design of Ajutor Social program to better target these people. Clear eligibility criteria will be developed under this Subcomponent, including detailed descriptions of actions to be taken, approach of selection of such households and beneficiaries. Under Subcomponent 1.5 Vaccine Procurement and Deployment, all vaccines will be provided free of charge.

- The eligibility criteria will be communicated through public media to ensure a transparent process. A communication strategy will be developed and outreach to the target beneficiaries will be ensured through various channels such as TV, written media and direct communication in the local community through local public authorities and Territorial Structures of Social Assistance. The actions set under this Sub-component will include a platform for wide cooperation with civil society organizations and specialized NGOs.
- ***Labor Management Procedure*** is developed as a standalone document. It is developed to (i) respond to the specific health and safety issues posed by COVID-19; and (ii) protect workers' rights as set out in ESS2.
- ***Stakeholder Engagement Plan*** identifies and analyses key stakeholders and describes the process and modalities for sharing information on the project activities, incorporating stakeholder feedback into the Project and reporting and disclosure of project documents. It was prepared in respect of the global prevention efforts and combating the evolving COVID-19 situation. SEP is intended not only to help with the implementation of the community mobilization and behavioral change objectives of the project, but also for suppressing false COVID-19-related information and ensuring equitable access to services.

[69] Link to be provided once available.

[70] Link to be provided once available.

[71] https://www.invitro.md/blog/news/testarea-pentru-virusul-sars-cov-2

The document was reviewed and accepted by the World Bank, disclosed both in country[72] and through the World Bank's external web page[73].

- **ESS 2 – Labor and Working Conditions.** The project will be carried out in accordance with the applicable requirements of ESS 2, in a manner acceptable to the World Bank, including, inter alia, implementing adequate occupational health and safety measures (including emergency preparedness and response measures), setting out grievance arrangements for project workers, and incorporating labor requirements into the ESHS specifications of the procurement documents and contracts with works providers and technical supervision companies.

  The project is expected to encompass the following categories of workers: direct workers and contracted workers. Direct workers could be either government civil servants or those deployed as 'technical consultants' by the project. The former will include health care providers and workers in health care facilities. The latter includes chiefly construction workers involved in the minor civil works. The civil servants will be governed by a set of civil services code and the 'technical consultants' by mutually agreed contracts. The project proposes some small-scale civil works and the expectation is that the majority of labor will be locally hired and hence no large-scale labor influx is envisaged.

  Labour Management Procedures incorporates requirements for ensuring health and safety of project workers. ESMP template, has a section on workers' health and safety requirements.

  Civil works contracts will incorporate social and environmental mitigation measures based on the World Bank Group's Environment Health and Safety Guidelines and the ESMF. All civil works contracts will include industry standard Codes of Conduct that include measures to prevent Gender Based Violence (GBV), including Sexual Exploitation and Abuse (SEA) and Sexual Harassment (SH). Functional grievance mechanisms (GMs), for direct and contracted workers, will be established. Detailed approach on SEA/SH for COVID-19 Projects is described in the Labour Management Procedures. The Labour Management Procedures also contain Code of Conduct to ensure compliance with activities to combat sexual exploitation, abuse and harassment, and a template be used by companies and employers involved in the implementation of Moldova Emergency COVID-19 Response Project (P173776) and Vaccines Additional Financing.

  Mitigation measures for the protection of healthcare workers include clear protocols for treating patients and handling medical waste, disinfectant protocols, which will be included in Infection Control and Medical Waste Management Plan (ICWMP) to be adopted by and then implemented by ECs and laboratories participating in the project. Mitigation measures also include regular testing of healthcare workers, requirements for proper disposal of sharps, along with the environmental health and safety guidelines for staff and necessary Personal Protective Equipment (PPE). The project will also finance PPE and hygiene materials, as well as training on infection prevention and control practices, with a focus on staff providing care to suspected and confirmed cases. It will also provide equipment, drugs and medical supplies, in particular ICU units and beds in designated hospitals, as well as training on COVID-19 treatment and intensive care to respond to the surge in patients requiring admission in ICUs.

[72] Link to be provided once available.

[73] Link to be provided once available.

In line with ESS 2 and Moldovan law, the use of forced labor, child, or conscripted labor is prohibited in the project, including for construction and operation of health care facilities.

- **ESS 3 – Resource and Efficiency, Pollution Prevention and Management**. Medical wastes and chemical wastes (including water, reagents, infected materials, etc.) from the labs, quarantine, and screening posts to be supported (drugs, supplies and medical equipment) can have impact on the environment and human health. Wastes that may be generated from medical facilities and labs could include liquid contaminated waste, chemicals, and other hazardous materials, and other waste from labs and quarantine and isolation centers including sharps, used in diagnosis and treatment. Each beneficiary medical facility/lab, following the requirements of the ESMF to be prepared for the Project, WHO COVID-19 guidance documents, and other best international practices, will prepare and follow an ICWMP to prevent or minimize such adverse impacts. The ICWMP will mandate that any waste associated with COVID-19 testing or treatment will be incinerated on site whenever possible. It will also contain strict protocols for disinfecting and packing such waste for transportation to the nearest medical waste incinerator if on site destruction is not possible.

  The ESMF also include guidance related to transportation and management of samples and medical goods or expired chemical products, as well as small scale rehabilitation activities.

  The site specific ESMPs, to be prepared for rehabilitation of the ICUs in selected hospitals will include procedures for handling construction waste. Facilities with asbestos insulation, pipe lagging, etc. will be excluded from financing under the project.

  In case of basic hand-washing facilities, restrooms or other basic health and hygiene conditions, these will be improved by taking into consideration safe wastewater management (mini septic tanks, etc.). Resources (water, air, etc.) used in health care and quarantine facilities and labs will follow standards and measures in line with State Sanitary Hygienic Service of Ministry of Health and WHO environmental infection control guidelines for medical facilities.

- **ESS 4 – Community Health and Safety.** Medical wastes and general waste from the labs, health centers, and quarantine and isolation centers have a high potential of carrying micro-organisms that can infect the community at large if they are is not properly disposed of. There is a possibility for the infectious microorganism to be introduced into the environment if not well contained within the laboratory or due to accidents/ emergencies e.g. a fire response or natural phenomena event (e.g., seismic). Laboratories, quarantine and isolation centers, and screening posts, will thereby have to follow procedures detailed in the ESMF and ICWMP.

  The operation of quarantine and isolation centers needs to be implemented in a way that staff, patients, and the wider public follow and are treated in line with international best practice as outlined in WHO guidance for COVID-19 response as above under ESS 1 and ESS 2.

  The SEP will also ensure widespread engagement with communities in order to disseminate information related to community health and safety, particularly around social distancing, high risk demographics, self-quarantine, and mandatory quarantine. The project will contribute to dissemination of information on impacts of the lockdown and risks of gender-based violence associated with the quarantine. The training arranged for healthcare workers under Subcomponent 1.2 will also tackle the topic of GBV during the pandemic and how medical staff could support them. WHO recommendations for the medical staff is that if a woman with

suspected or confirmed COVID-19 seeks care because of violence, doctors' response should be the same as for any other survivor. In any circumstances, including during the COVID-19 pandemic, health workers should provide first-line support, using the LIVES approach to help women survivors of violence.

The project will also ensure via the above-noted provisions, including stakeholder engagement, that quarantine and isolation centers and screening posts are operated effectively throughout the country, including in remote and border areas, without aggravating potential conflicts between different groups.

Hiring security personnel under the project is not envisioned at this stage. A stand-alone Security Personnel Management Plan would be required where specific triggers for serious concern are present including:

- Security forces to be deployed to the project are 'implicated in a history of part abuses or inappropriate conduct toward workers or affected communities
- Significant concerns about lack of appropriate training in appropriate conduct and the use of force (and where applicable, firearms)
- Concerns about adequacy of applicable national laws and protocols relevant to deployment of these security forces

Preventative measures are required in ESMPs where security personnel are utilized but risk is screened as low to moderate because:

- security forces to be deployed are not implicated in a history of past abuses
- isolated site-specific incidents are possible but these are preventable with appropriate training, codes of conduct (particularly on SEA/SH), and avenues for grievance redress that have been put in place; security personnel to be deployed provide well understood and established services under contract for project sites and activities without history of past abuse or likelihood of engaging in incidents that cause harm to workers or project-affected communities

In case quarantine and isolation centers are to be protected by security personnel, it will be ensured that the security personnel follow strict rules of engagement and avoid any escalation of the situation, taking into consideration the above-noted needs of quarantined persons as well as the potential stress related to it. In Moldova, where security and/or military personnel had been involved in human development sector activities in the past, no tensions have been reported.

- **ESS 10 – Stakeholder Engagement and Information Disclosure**. The project recognizes the need for effective and inclusive engagement with all of the relevant stakeholders and the population at large. Considering the serious challenges associated with COVID-19, dissemination of clear messages around social distancing, high-risk demographics, self-quarantine and isolation, and, when necessary, mandatory quarantine is critical. Meaningful consultation, particularly when public meetings are counter to the aims of the SEP, and disclosure of appropriate information assume huge significance for ensuring public health and safety from all perspectives – social, environmental and economic. In this backdrop, SEP prepared for the project which serves the following purposes: (i) stakeholder identification and analysis; (ii) planning engagement modalities viz., effective communication tool for

consultations and disclosure; and (iii) enabling platforms for influencing decisions; (iv) defining roles and responsibilities of different actors in implementing the Plan; and (iv) a grievance redress mechanism (GRM).

A detailed mapping of the stakeholders will be done during implementation. Individuals and groups likely to be affected (direct beneficiaries) have been identified. Risk-hot spots on the international borders as well as in-country have been delineated. Mapping of other interested parties such as government agencies/authorities, NGOs and CSOs, and other international agencies have also been completed. Drawing upon their expectations and concerns, a SEP has been prepared by the client and disclosed publicly (put in website where it has been disclosed). SEP will be updated during implementation. The client has also developed and put in place a GRM to enable stakeholders to air their concerns/ comments/ suggestions, if any. However, the existing GRM needs improved procedures to include possibility of anonymous grievances to be raised and addressed, appeal process for unsatisfactory complainants, and provide accessible grievance uptake channels (online and offline, including telephone, text message, email, grievance boxes etc.).

5.3. Risk Mitigation at Planning at the Design Stage

Subproject screening for eligibility and for site-specific risks. PIU will screen each healthcare facility suggested for rehabilitation to ensure that property rights to the building and the land under it are clear and well-documented, that there is no informal private use of the land and/or buildings in the territory of a facility and no land take or any form of involuntary resettlement is required. Environmental and social risks will also be screened for rehabilitation works planned at every facility as per World Bank Group EHS Guidelines, WHO COVID-19 Guidelines, and the screening form contained in Annex I. This will include:

- Review of design to confirm that no large-scale construction is implied: no new construction and no construction and extensions to the existing facilities that would expand environmental footprint of a building;
- Determination of any needed design changes in the facility or its operation such as ICUs, isolation facilities, structural and equipment safety, universal access, nosocomial infection control, medical waste disposal, etc.;
- Confirmation that currently available utilities (power, water, etc.) are permissive for the planned works;
- Confirmation of whether the medical facility will entirely or partially be operated during works or will it be vacant/vacated. Identification of arrangements that need to be in place for ensuring safe operation of the facility in parallel with works if that is needed and possible under the circumstances;
- Determination of whether additional security personnel is required during works and beyond; and
- Determination of whether ESMP needs to be prepared for a given subproject.

Medical waste management and disposal. The PIU will examine medical waste management and disposal practices applied in each beneficiary healthcare facility to determine how they relate to the World Bank Group's EHS Guidelines and current WHO Guidelines for COVID-19. Checking of the existing waste management systems will be conducted using the screening form provided in Annex 1 and will include:

- Identification of current methods of medical waste management and disposal at the healthcare facility;
- Identification of any on-site disinfection/distraction and/or disposal facilities for medical waste including incinerators, pits for burial of medical waste, etc.;
- Identification of removal and final disposal of medical waste from a given healthcare facility, including how material is gathered and stored, routes taken to the disposal facility, and disposal procedures;
- Review of protocols for dealing with medical waste specifically related to infectious diseases like COVID-19;
- Review of training delivered to healthcare workers and other relevant employees of medical facilities for medical waste management and disposal; and
- Identification of whether an ICWMP need to be prepared for a given healthcare facility.

Procuring of goods and supplies. Where the project will include the procurement of goods and supplies (e.g. equipment such as ventilators or PPE or cleaning materials), PIU will develop technical specifications and review those provided by beneficiary healthcare facilities to ensure they are compatible with the WHO guidelines and recommendations and GIIP.

Protecting healthcare workers. The PIU will conduct a review of protocols for protecting healthcare workers from infections disease applied by the given healthcare facility based on current WHO Guidelines (https://www.who.int/medical_devices/priority/COVID_19_PPE/en/) for COVID-19 and the Infection and Prevention Protocol (Annex IV) as well as the ILO guidance on safety measure for employees in the health sector (https://www.ilo.org/sector/Resources/publications/WCMS_741655/lang--en/index.htm). The review will include:

- Determination of whether the training provided to healthcare workers and other employees of the healthcare facility is adequate;
- Determination of whether the staff are trained on how to deal with the remains of those who might die from COVID-19, including those conducting autopsies;
- Determination if adequate stocks of PPE are available on-site; and
- Identification of supply lines for required PPE.

This will be ensured through regular monitoring and site-visits conducted by the PIU Environmental and Social Safeguards staff, using the checklist provided in Annex 5.

Other mitigation measures under the project that might be required include:

- Ensuring a soothing environment so as to avoid panic/conflicts resulting from false rumors and social unrest;
- Assuring proper and quick access to appropriate and timely medical services, antiseptics and PPEs, that is not based on ability to pay or other factors;
- Anticipating and addressing issues resulting from people being kept in quarantine;
- Addressing challenges associated with providing (financial) assistance for vulnerable people and the risk of exclusion.

Since the project will provide funding to address the identified risks and shortcomings it will be important that the Project uses international expertise to achieve international best practices in line with WHO guidelines.

Vaccine readiness and prioritization: The assessment of risks conducted as part of AF preparation by the WB identified that high residual risk reflects results from the vaccine readiness assessment indicating that Moldova needs to develop regulations to protect manufacturers from product liability claims, introducing delays in vaccine procurement. Also, surveys of vaccine hesitancy indicate a high probability of vaccination hesitancy. These risks will be mitigated through technical assistance to develop the required regulations, financing through the AF to support the implementation of the communications strategy, and monitoring vaccine acceptance through biannual surveys. Moldova has conducted an initial vaccine readiness assessment to determine its capacity to procure and deploy safe and effective COVID-19 vaccines to the population. The initial assessment was conducted using the COVID-19 Vaccine Introduction Readiness Assessment Tool (VIRAT) and COVID-19 Vaccine Readiness Assessment Framework (VRAF), referred to as VIRAT-VRAF 2.0. Under the project, the VIRAT-VRAF 2.0 will be updated biannually to capture changes in Moldova's readiness for vaccine deployment and procurement. An indicative action plan that identifies activities that need to be completed within the first six months of deployment under each assessment area of the VIRAT-VRAF 2.0 is provided in the Project Document, including a comprehensive summary of this assessment's initial findings, gaps in readiness and measures to address them.

In a November 2020 survey on behavioral insights on COVID-19, only 31% of the population indicated they would accept a safe and effective COVID-19 vaccine. Biannual surveys will monitor vaccine hesitancy among priority groups and identify potential mitigation measures. The Government is not considering non-voluntary vaccination, and procedures for obtaining written informed consent have been defined.

A multifaceted communications campaign has been developed with tailored content and channels and active disinformation management through social listening, review, and follow-up with exposed groups. The communication campaign will leverage mass media, social media, role models, and healthcare workers. Communication will highlight vaccination stages, priority groups and selection criteria, AEFIs, the Grievance Redress Mechanism (GRM), and how to access providers. The national COVID-19 vaccine deployment plan states that all vaccines will be provided free-of-charge.

Surveillance of Adverse Events Following Immunization: In Moldova, there are protocols for monitoring vaccine safety, including AEFIs, which have successfully reported and managed vaccine safety events in the past, which have been adapted to incorporate COVID-19 vaccines.

Safety monitoring will be the joint responsibility of the NAPH, AMMD, and health facilities. These activities are guided by Order No. 358 of May 12th, 2017; Order No. 752 of June 26th, 2019; and Order No. 1019 of May 11th, 2020, on the Operation of the System for Assessing Causality and Classification of AEFIs. In specific, Order 358 of 12 May 2017 issued by the Ministry of

Health , Labor and Social Protection "On Approving the Regulation on the Performance of Pharmacovigilance Activities established the approval of the following:

1) The Regulation on the Performance of Pharmacovigilance Activities, as per Annex 1 of the respective order;

2) Communication Sheet on Adverse Reactions and/or Lack of Effectiveness of Medicines and Other Medicinal Products as per Annex 2 of the same Order.

3) Communication Sheet on Adverse Reactions to Medicines and Other Medicinal Products "Patient Communicates" as provided by Annex no. 3 of the Order.

2. The holder of the medicine registration certificate, or his official representative, must at all times have at his disposal an appropriately qualified person responsible for pharmacovigilance activities to establish and maintain a system to ensure that all information collected on the safety of medicinal products are accessible to the Medicines and Medical Devices Agency;

3. Chiefs of health facilities, regardless of the legal form of organization and type of ownership:

1) to appoint persons responsible for pharmacovigilance in their health facilities within 1 month from the date of issue of the Order;

2) to ensure the recording and reporting of adverse reactions or the ineffectiveness of medicines and other medicinal products to the Medicines and Medical Devices Agency.

The Ministry of Health Order no. 1019 approves the list of adverse events following immunization to be registered, investigated, and reported, forms for reporting and epidemiological investigation of AEFIs, and the procedures for evaluating the causes and classification of reported AEFIs. Free care will be provided to all individuals experiencing side effects. There are no provisions for monetary compensation.

In December 2020, the Government signed a Model Indemnity Agreement to which all manufacturers supplying vaccines under COVAX have agreed. Under COVAX, a donor-funded and private-insurance-covered no-fault compensation scheme has been established to cover vaccine doses purchased via the COVAX AMC. Some vaccine manufacturers may also require other protections against product liability claims, including legislative limits on liability or a national no-fault compensation scheme. Moldova will need to enter direct indemnification arrangements with these manufacturers. Moldova will also need to develop legislation to provide statutory immunity for manufacturers. However, the country is not considering the establishment of a national no-fault compensation scheme. In place of this, national regulation specifies that state-funded free medical care will be provided to individuals that experience AEFIs. Redress is available to employees that contract COVID-19 within limits proscribed in workman compensation regulation. The adoption of indemnification provisions or any other compensation scheme would have to follow Moldova's national framework.

Use of military or security personnel. As of the date this ESMF is being updated, the engagement of security or military personnel was not being considered for project activities, including

deployment of vaccines. In Moldova, where security and/or military personnel had been involved in human development sector activities in the past, no tensions have been reported between community members, local businesses, sub-contractors and other stakeholders. There have been no reports of security personnel linked with actual or perceived project impacts or perceived behavior of security personnel.

In the context of vaccine deployment in Moldova once vaccines became available, the following observations are descriptive of the situation:

- Small demand for vaccinates due to hesitancy, no shortage, no wide interest;
- No distribution activities or provision of security by peacekeepers, carabineers or police;
- Vaccines are transported from central to local regions using refrigerated trucks without provision of security. These same trucks provide directly to distribution points including in the separatist region with no involvement of security forces;
- Initial shipments during the early Covid emergency lockdowns which involved restrictions on movements of people and businesses did involve use of civil protection (fire and emergency responders) for their manpower and trucks, but did not use public security for vaccine transport or security and this emergency has now been lifted.
- Offices and storage facilities may have guards however these are hired under local arrangements by office managers. They may deploy security sensors and make use of local security patrols.
- Storage and offices are located in towns close to administrative centres.

Considering the nature of the project activities and the minimal use of security monitoring (storage of vaccines and associated equipment), the potential for conflict in and around the project area such as escalation of violence based on grievances and regional protests is estimated as low.

5.4. Risk Mitigation at Construction Stage

No new construction will be supported by the project. Small to medium-scale interior works for rehabilitation, refurbishment or retrofitting of the existing buildings will be undertaken in compliance with site-specific ESMPs. PIU, through its environmental and social consultants, will undertake monitoring of contractors' performance, identify any issues with ESMPs' implementation, recommend corrective action and elevate issues to Ministry of Health in case problems persist. The PIU will also ensure that the site-specific ESMPs are developed, agreed with the Bank, disclosed, discussed with stakeholders and finalized prior to tending of works. ESMPs must be included into the tender packages and later – into the contracts concluded with works providers. Site-specific ESMPs will include:

- Description of site-specific environmental and social risks at construction and operation phases;
- Measures for adequate management of hazardous and non-hazardous construction waste;
- Labor, working conditions, OHS and GBV/SEA/SH risks; and
- Plan for monitoring of ESMP implementation.

Construction waste will be managed by the municipal waste company.

5.5. Risk Mitigation at Operational Stage, including Vaccination Campaign

Best practice in avoiding or minimizing the spread of infectious diseases, specifically with regard to cross-infection between healthcare facilities and the community, is to implement 'cradle-to-grave' management for infection control. The details of this will differ, depending on the design of the subprojects and the quality of the existing facilities, assets and management systems. Following an assessment of risks along each link of the chain, details of the procedures to be implemented to manage infection control and waste management will be set out in the ICWMPs. If a project beneficiary facility has existing facilities and procedures, these may be enhanced as required. Annex IV carries a template for developing ICWMPs. Typical aspects to be covered include:

- Delivery and storage of goods, including samples, pharmaceuticals, vaccines, reagents and other hazardous materials;
- Healthcare treatment practices, including sharps management, provision and use of PPE, appropriate cleaning procedures, testing for COVID-19, and transportation of samples to testing facilities, health and safety procedures to protect workers and the community.;
- Waste management procedures that align with WHO guidance on Safe Management of Wastes from Healthcare Activities, including with respect to:
  - Waste generation, minimization, reuse and recycling;
  - Waste segregation at the point of care, packaging, collection, storage and transport;
  - Suitability and capacity of onsite disinfection and waste handling equipment such as autoclave. Onsite treatment facilities may include small-scale incinerator and wastewater treatment works. Their adequacy and compliance should be assessed, and proper measures proposed as necessary;
  - Suitability and capacity of off-site disposal facilities, where healthcare wastes will be transported and disposed off-site. The adequacy and compliance with transport and disposal regulations and licensing for the transport vehicles and the offsite disposal facilities should be assessed.
- OHS, labor and working conditions, GBV/SEA/SH, gender and disability.

Other key social issues that are considered during the vaccination stage include the following:

- Ensuring the vaccines reach out to disadvantaged and vulnerable groups after identifying their barriers to access. Since the national immunization program provides all vaccines for free, affordability is not likely to not pose a t barrier to access immunization.
- Stakeholder engagement is key to communicating the principles on fair, equitable and inclusive access and allocation of vaccines, reaching out to disadvantaged and vulnerable groups, overcoming demand-side barriers to access (such as mistrust of vaccines, stigma, cultural hesitancy), and creating accountability against misallocation, discrimination and corruption.

Stakeholder engagement included consultations with various stakeholders, held on February 26, 2021. Due to restrictions in social gatherings, consultations were conducted virtually, convening more than 60 participants who represented civil society organizations active in the social and environmental protection field, national Workers' organization, national Employers' organization,

relevant state agencies and the community of healthcare institutions. The consultation were also aimed at:

- seeking insight from Community representatives related to the local settings so that they can act as the primary liaison between the project and their established networks,
- sharing with the public the project's approach to comply with Environmental and Social Standards, seeking feedback and comments from stakeholders related to the project interventions and required improvements, including related to grievance mechanisms;
- seeking feedback and comments from stakeholders related to the project interventions and required improvements, including related to grievance mechanisms.

Project activities under the Additional Financing will sustain two-way communication with citizens, communities, and civil society established under the original project and PEF Grant. The SEP has expanded mechanisms for messaging to communities and receiving feedback, through digital and traditional platforms, including: (a) needs assessments for activity planning; and (b) just-in-time messaging and feedback through online, virtual, or face-to-face consultative events and portals. Additional measures have been introduced to ensure the involvement of at-risk groups for COVID-19, including the aged, people living with chronic diseases, female-headed households, social workers, and other vulnerable groups. The institutional GRM under the Ministry of Health for the Health Transformation Project collects and respond to complaints.

Feedback will also be received at the local level through facilities, as discussed in the consultation meeting of 26 February 2021. The project is engaged with civil society organizations to support outreach and community engagement to enhance transparency and accountability. A beneficiary feedback indicator in the results framework measures the effectiveness of the community engagement platform of activity.

5.6. Risk Mitigation at Decommissioning Stage

In response to the surge of COVID-19 testing and treatment, temporary care facilities may be established, which could shortly thereafter be decommissioned. If this becomes relevant during the project life, environmental and social risks associated with the decommissioning of these temporary facilities will be considered and planned in accordance of the good international practice. Typical set of mitigation measures would include disposal of various types of waste, disinfection and site reinstatement.

A summary of risks and mitigation measures is presented in the table below.

Table 1. Summary of Environmental and Social Risk Assessment and Proposed Mitigation

Table 1. Summary of Environmental and Social Risk Assessment and Proposed Mitigation Measures			
Name of the component, sub-component	**Description of activities**	**Preliminary E&S risk & impact assessment**	**Mitigation measures, monitoring and responsibilities**
Component 1 – Emergency COVID-19 Response			
Subcomponent 1.1: Case Confirmation (EUR 3.06 million) will finance medical supplies and equipment to support strengthening disease surveillance systems and the capacity of selected public health laboratories to confirm cases **Subcomponent 1.2: Health System Strengthening (EUR 30.0 million) will finance the strengthening of public health facilities** **Subcomponent 1.3: Communication Preparedness (EUR 0.3 million)**			
Medical equipment Laboratory equipment Protective equipment Disinfection supplies Diagnostic supplies Various equipment	Procurement and supply of: • PPE • hygiene materials, • COVID-19 test kits, • laboratory reagents, • polymerase chain reaction equipment, • specimen transport kits, • equipment and medical supplies • light vehicles for safe and rapid transportation of samples	In the **planning and design phase** the key environmental and social risks are related to: (a) Procurement of inadequate goods and supplies (b) Location, type and scale of healthcare facilities and associated waste management facilities, including waste transport routes. (c) Proper design and functional layout of healthcare facilities. (d) Lack of communication approach and strategy, which can raise concern, speculations and misinformation among the public. In case of minor civil works, the	(a) **Procurement**. The PIU shall ensure that the required technical specifications are met in accordance with WHO guidelines and GIIP. This will involve following: • Development of technical specifications for equipment and PPE for healthcare workers and non-medical staff in healthcare facilities according to WHO interim guidance on rational use of PPE for coronavirus disease 2019. • Implementation of legally prescribed procurement procedures in accordance with the relevant Law on Public Procurement • Distribution of medical equipment and other goods and supplies ensuring it goes where it is needed most. (b) **Location, type and scale of healthcare facilities**. PIU shall screen all HCFs where equipment will be distributed for: • *Location of facilities*: the environmental and social assessment should examine nearby sensitive social receptors such as a residential area or school and availability of municipal services such as public water supply, sewage and waste collection services at the location. • *Type and scale of facilities*: The assessment should identify and examine the salient characteristics and carrying/disposal capacity of a targeted facility. The assessment should consider the waste processing and

		impacts in the **construction phase** are related to: (e) Noise emissions and waste from minor construction / refurbishment of ICUs. In the **operational stage** the impacts are related to: (f) Inappropriate management of medical waste that can impact human health and environment. (g) Insufficient OHS protection of health workers that can cause increasing number of COVID19 cases among the health workers (h) Poor response to containment of COVID19, which can result in increase, spread of the disease inside and outside the HCFs. (i) No access to health care services and facilities for marginalized and vulnerable social groups, inaccessibility of	transportation arrangements, operational procedures and working practices, and the required capacity of the type of disposal facility needed for the volume of the wastes generated. For example: a general hospital, a high-level biosafety laboratory for coronavirus testing; a temporary hospital or quarantine area, a pyrolytic incinerator or a hazardous waste landfill for medical waste disposal. (c)**Proper design and functionality** may involve several aspects: i) structural and equipment safety, universal access[74]; ii) nosocomial infection control[75]; iii) waste segregation, storage and processing, exclusion criteria under this project establishing ICU in facilities with asbestos roof, PIU shall ensure that the design of ICUs refurbishment shall meet National guidelines for IPC in healthcare facilities taking into account guidance from WHO and/or CDC on COVID-19: (i) WHO guidance for Severe Acute Respiratory Infections Treatment Centre; (ii) WHO interim guidance on infection prevention and control during health care when novel coronavirus (nCov) infection is suspected; (iii) WHO interim guidance Water, sanitation, hygiene, and waste management for the COVID-19 virus; (iv) WHO interim practical manual on Improving infection prevention and control at the health facility; (v) CDC Guideline on preventing transmission of infectious agents in healthcare settings; (vi) CDC Guidelines for environmental infection control in health-care facilities; (d) **Communication approach and strategy:** Implement Stakeholder Engagement Plan (SEP) prepared for the Project; implement communication plan and outreach strategy (e)**Civil works.** PIU shall ensure that all ICU refurbishment work done at the HCFs under the project will be carried out in compliance with a site-specific ESMP based on the template attached to this ESMF. The site-specific ESMP will include:

[74] Refer to ESS 4 Community Health and Safety

[75] Nosocomial infection can be descried as an infection acquired in hospital by a patient who was admitted for a reason other than that infection. Also called „hospital acquired infection".

		facilities and services designed to combat the disease, in a way that undermines the central objectives of the project. (j) Lack of information and stakeholder engagement which may lead to panic and social problems. In the **decommissioning phase** impact are related to: (k) In this phase, temporary care facilities may be established, which could shortly thereafter be decommissioned. If this becomes relevant during the project life, environmental and social risks associated with the decommissioning of these temporary facilities will be considered and planned in accordance of the good international practice. Typical set of mitigation measures would include disposal of various types of waste, disinfection and site reinstatement.	• Environmental risks and issues such as resource efficiency and material supply • Construction related solid wastes, wastewater, noise, dust and emission management • Hazardous materials management • Occupational Health and Safety (OHS) issues • Security personnel management, • Labor and working conditions. The ESMP will form part of the Contract and the ESMF will be part of the bidding document. The Borrower will require the contractor to follow Labor management and working conditions as defined in the "Labor Management Procedures" (LMP), developed as a standalone document for the project. (f)**Waste management practices.** PIU will lead the work to ensure the following: • Each HCF is operated in accordance with the ICWMP prepared for the project (Annex IV) • Waste segregation, packaging, collection, storage disposal, and transport is conducted in compliance with the national legislation, ICWMP and WHO COVID-19 Guidelines • Onsite waste management and disposal will be reviewed regularly and training on protocols contained in the ICWMP conducted on a monthly basis • The PIU will audit any off-site waste disposal required on a monthly basis and institute any remedial measures required to ensure compliance, and • Waste generation, minimization, reuse and recycling are practiced where practical in the COVID-19 context. (g) **Protecting of healthcare workers.** Ministry of Health and HCFs shall ensure the following: • Regular delivery and proper storage of goods, including samples, pharmaceuticals, disinfectant, reagents, other hazardous materials, PPEs, etc.; • Ensure protocols for regular disinfection of public spaces, wards, ICUs, equipment, tools, and waste are in place and followed;

			• Ensure hand washing and other sanitary stations are always supplied with clean water, soap, and disinfectant; • Ensure equipment such as autoclaves are in working order; and • Provide regular testing to healthcare workers routinely in contact with COVID-19 patients. • Ensure that labor conditions for healthcare workers are in line with LMP • Ensure that healthcare workers have access to the HCF grievance mechanism. Refer to LMP for issues related to raising concern about workplace health and safety. (h) **Containment of COVID-19.** PIU and HCFs shall ensure the following: • Quarantine procedures for COVID-19 patients are maintained; • Patients in quarantine are not discriminated due to socioeconomic status, level of education, gender, disabilities and any other vulnerabilities. • When practical, COVID-19 patients are given access to phone or other means of contact with family and friends to lessen the isolation of quarantine; • Patients in quarantine have access to development and project related information and should be able to take part in consultation through appropriate means • The public is regularly updated on the situation and reminded of protocols to prevent the spread of COVID-19; and • Members of the general public (family and friends) who have been exposed to confirmed COVID-19 patients are tested when practical. WHO quarantine guidelines can be found at: https://apps.who.int/iris/rest/bitstreams/1272428/retrieve For detailed HCF infection and prevention control protocol are provided in the Annexes V and while WASH protocol guidelines are available from WHO at https://www.who.int/publications/i/item/water

			-sanitation-hygiene-and-waste-management-for-covid-19-technical-brief-03-march-2020 (i) **Vulnerable groups access to health care services and facilities:** • PIUs and HCFs shall commit to the provision of services and supplies to all people, regardless of their social status based on the urgency of the need, • Make information available to health service providers on where SEA/SH psychosocial support and emergency medical services can be accessed; • Awareness about and access to GRM. (j) **Stakeholder *Engagement and Grievance Mechanism:*** • Continued engagement with stakeholders on the operation of the HCF and other project related activities as per the SEP; • Information dissemination/awareness as per the "Risk communication and community engagement strategies for COVID-19 in RS" and "Risk communication, community engagement for specific communities"; • Awareness about and access to grievance mechanism. (k) **Deactivation *of any temporary healthcare facilities or hospital waste management facilities*** after the outbreak is declared, shall be done in accordance with regulatory deactivation procedures and international best practices. Annex **Error! Reference source not found.** presents guidance on due mitigation measures which will be covered under the sub-project specific ESMPs that would be developed.
Subcomponent 1.4: Social and Financial Support to Households (EUR 21.9 million)			
Cash support Household support Strengthen support for families with children	strengthen support for families with children by changing the adult equivalency formula (increasing the coefficient for children)	In the **planning and design stage**, a key social risk is related to: (l) Exclusion of marginalized and vulnerable social groups from social	(l) The **Project** will engage with support for strengthening the social protection for the poor by amending the design of the Ajutor Social program so that it is better able to target vulnerable populations that may be adversely affected by COVID-19. • Use GMI threshold both to determine eligibility, filtering out families with incomes

Amending the design of the Ajutor Social program	the income eligibility threshold (GMI) for all beneficiaries will be temporarily increased by 23 percent	protection assistance In the **operation phase** the impact is related to: (m) Marginalized and vulnerable social groups are unable to access social protection services in a way that undermines the central objectives of the project. (n) Cash transfers can affect household power dynamics, which can exacerbate or otherwise influence dynamic of incidents of GBV/SEA/SH. Intimate partner violence can also be exacerbated by limited movement and social opportunities for men due to job loss.	higher than GMI per adult equivalent, and to determine the benefit size, • Remote (telephone/video calls) assessment to conduct rapid need; • automatically extend eligibility for families that are up for re-certification, • accept remote applications (e.g., by phone), and • replace income verification documents with the applicant's declaration. • In-home visits to verify eligibility for families that are subject to such checks will also be cancelled for the period of emergency. (m) To mitigate this risk: • Clear eligibility criteria will be developed under this Subcomponent, including detailed descriptions of actions to be taken, approach of selection of such households and beneficiaries. • The eligibility criteria will be communicated through public media to ensure a transparent process. • A communication strategy will be developed and outreach to the target beneficiaries will be ensured through various channels such as TV, written media and direct communication in the local community through local public authorities and Territorial Structures of Social Assistance. • Facilitate the setting of a platform for wide cooperation with civil society organizations and specialized NGOs. (n) To mitigate the GBV related risks, the project will take the following steps: • Ensuring an environment for stakeholders' cooperation, including through involving CSOs and other professionals to expand support, including psychological counselling for those in need; • Enhancing the work of multidisciplinary teams that are active in the majority of localities throughout the country and referral of GBV victims to specialized support; • Handling of quarantining interventions (including dignified treatment of patients; attention to specific, culturally determined concerns of vulnerable groups; and prevention of

			sexual exploitation and abuse and sexual harassment; • Implementing effective and inclusive outreach program encompassing stakeholder engagement throughout the project cycle
Subcomponent 1.5: Subcomponent 1.5: Vaccine Procurement and Deployment (EUR 24.8 million)			
		Political pressures and different interpretations of standards creating pressure for authorities to purchase vaccines before being appropriately certified	To mitigate this risk: • A Vaccine Delivery and Distribution Manual for effective vaccine delivery and vaccination implementation will be adapted from the national COVID-19 vaccination plan, adopted, and included as an annex to the updated project operational manual • Financing from this AF will only be used for vaccines that meet the approved standard
		Delays in vaccine procurement through inability to protect manufacturers from product liability claims	The risk will be mitigated through: The Ministry of Health will develop the regulatory framework to protect manufacturers from product liability claims, with support from WHO by July 2021.
		Social tensions exacerbated by the community health and safety-related outcomes, by authorities' ability to ensure compliance with the targeting of the vaccines to priority populations and avoidance of elite capture of vaccine doses	The risk will be mitigated through: • Transparent and public communication of priority groups in the national COVID-19 vaccine deployment plan and selected according to the WHO SAGE values framework • Deployment to vulnerable groups in the second and third deployment stages • Monitoring the vaccine deployment plan's implementation to track compliance with the procedures in the national COVID-19 deployment plan and Order No. 93 of 05 Feb. 2021[76]
		High probability of vaccination hesitancy, as identified by surveys of vaccine hesitancy	The risk will be mitigated through: • Hiring of a Communications Specialist • The implementation of the communications strategy and monitoring vaccine acceptance through biannual surveys; • Stakeholder engagement and considerations for simple, accurate, accessible and culturally appropriate information dissemination;

[76] Order No. 93 of 5 Feb. 2021 on Implementation of National Vaccine Deployment Plan and relevant instructions https://msmps.gov.md/wp-content/uploads/2021/02/Ordin-nr.-93-din-05.02.2021-Cu-privire-la-implementarea-Planului-national-de-imunizare-anti-Covid-19-1.pdf

			combating misinformation; responding to grievances. The risk will be mitigated through: • Applying existing regulations under the national immunization program that provide adequate guidance for the appropriate use and processing of data, privacy considerations that limit access to essential personnel, and precise institutional arrangements for childhood vaccine delivery. • The AF will provide support for software and hardware investments that further mitigate the risk of cybersecurity breaches; • The updated Project Operational Manual specifying mechanisms to ensure personal data protection.
		Social risks related to data collection, processing, and privacy which may arise from: (a) access to personally identifiable and sensitive information by unauthorized personnel; (b) gaps in regulation on data privacy and protection; and (c) breaches to cybersecurity	The risk will be mitigated through: Modifying the ongoing communications campaign to target better female-headed households with information on accessing the Ajutor Social Program benefits. Raise awareness and encourage to contact the call-line 0 8008 8008
		Risks associated with gender-based violence, sexual abuse, exploitation, and harassment SEA/SH increase in project area (e.g. requests for sexual favors to receive vaccinations)	The project will guard against gender-based violence risks by introducing a code of conduct, which will clarify personnel's obligations. Provide information to potential beneficiaries on eligibility criteria and GM process via various media (radio, SMS, television, online, posters) Work with local NGOs to provide social services for affected beneficiaries, as well as assistance to register The project will monitor the implementation fidelity and impact of the above activities via PDO indicators and IRIs as follows: 1) To assess equitable access to vaccines, a PDO indicator will be introduced to monitor the proportion of females and males in priority groups that have received a COVID-19 vaccination in Moldova. 2) To monitor the implications of support for social assistance, two new gender-disaggregated IRIs will monitor the percentage of applicants

			who have benefited from the Ajutor Social Program and the average benefit for households with a female versus male applicant. 3) To track the implementation of activities to mitigate exposure to gender-based violence, a new IRI will monitor the percentage of workers associated with the project who have participated in an information session on the code of conduct.
		Capacity of the Borrower to monitor adverse events following immunization (AEFI) in line with WHO guidelines	• The risk is mitigated through Ministry of Health adopting relevant policy measures through Order No. 1019 dated 05 November 2020 regarding the functioning of the system for causality evaluation and classification of adverse events following immunization (AEFI) aimed at aligning the monitoring of AEFI with WHO Guidelines and relevant standard COVID-19 AEFI reporting form
		Environmental risks arising from medical waste associated with vaccination	The risk is mitigated through: • Developing an Infection Prevention and Control and Waste Management Plan at project level, which will reflect evolving procedures for managing waste associated with vaccination
		Environmental risks associated with works in vaccine storage facilities.	• The risk will be mitigated through project investing in sustainable, climate-friendly, energy-efficient cold chain infrastructure, including for transportation, minor works, and storage equipment, including (a) for transportation – improved route planning and electric motorcycles and charging infrastructure; (b) for infrastructure – solar photovoltaic and battery systems, energy-efficient cooling with low global warming potential refrigerants, thermal insulation, solar reflective roofs, and built-in temperature controls; (c) for cold storage equipment – the adoption of low global warming potential refrigerants for solar refrigerators and freezers, cyclopentane insulation, solar direct drive on-site freezers, sterling cycle refrigeration with helium as the coolant for ultra-low freezers, and non-energy consuming coolant packs in shipping units; and (d) for training – to incorporate training content related to the procurement and use of low-carbon equipment and disaster risk management. Conduct cold-chain analysis (see Annex 11)

		Failure to store and handle vaccines properly, which can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease	Design and establish or improve vaccine cold chain temperature monitoring plan. Comply with WHO guidance on temperature monitoring[77] and CDC Vaccine storage and Handling toolkit[78]
Component 2 – Implementation Management and Monitoring and Evaluation (EUR0.6 million)			
	• overall administration of the project (including procurement and financial management) • regular monitoring and reporting of project implementation • recruitment of additional staff/consultants if needed. • capacity building through training in participatory M&E at all administrative levels and at the regional level, • joint learning across and within entities, • evaluation workshops, and development of an action plan for M&E and replication of successful models	In the **operation phase** the impact is related to: (o) labor management risks relevant for the engagement of personnel on the project, (p) occupational and health and safety issues related to spreading of COVID19 during capacity building and workshop activities and (q) inadequate stakeholder engagement	(o) Implementation of LMP which was developed as standalone document for Vaccine Additional Financing (Procurement and Deployment) (p) Assess the risk using WHO Guidance for risk assessment for generic events available at https://www.who.int/publications/i/item/10665-333185. Ensure that all recommendations from health care institutions are followed, ensure practicing physical distancing and use of PPE. (q) Implementation of SEP, Communication and Outreach Strategy developed for this Project, including implementation of the communications strategy and monitoring vaccine acceptance through biannual surveys.

[77] https://apps.who.int/iris/bitstream/handle/10665/183583/WHO_IVB_15.04_eng.pdf;jsessionid=9F079AFFA760DBD35C08B13930268B01?sequence=1

[78] https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

6. Procedures to Address Environmental and Social Issues

Ministry of Health is responsible for the overall implementation of the project through the PIU. The PIU will be responsible for day-to-day project management and support, ensuring that project implementation is compliant with the World Bank's ESF - particularly, with the relevant ESSs; the World Bank Group's EHS Guidelines; WHO COVID-19 Guidelines; and this ESMF. The PIU will be adequately staffed and maintained throughout the project life.

The process of implementation of this ESMF includes **the following activities**, to be undertaken by the PIU working closely with the project beneficiary healthcare facilities:

6.1. Screening

All activities undertaken by the project will be screened using the form found in Annex 1 in order to exclude ineligible and high-risk activities, identify potential environmental and social issues, and classify the environmental and social risks. Copies of each of these screening forms will be kept at the PIU. The PIU's quarterly report to the World Bank will include copies of each screening undertaken during the subject quarter.

The PIU and the project beneficiary healthcare facilities will prepare and implement the necessary environmental and social instruments and procedures for each activity financed under the project (in Romanian and English languages). The scope of this Emergency COVID-19 Response Project and AF requires the following three types of environmental and social instruments that will guide the implementation of environmental and social mitigation measures and related procedures:

6.2. Environmental and Social Management Plans (ESMPs)

After the screening, ESMPs, based on the sample found in Annex 2, Contractors will develop site-specific ESMPs for any small-scale works to be conducted in healthcare facilities. The ESMP shall be site-specific, and proportionate and relevant to the hazards and risks associated with the particular activity and will be implemented by the health facility and contractors. The ESMP template provided in the Annex of this ESMF identifies potential environmental, social, health and safety issues associated with the construction and operation of healthcare facilities in response to COVID-19. The site-specific ESMP should set out appropriate measures for infection control and waste management during operation of the relevant healthcare facility.

Preventative measures are required in ESMPs where security personnel are utilized but risk is considered low to moderate (see page 61). These include:

Ensure that the ESMP describes protocols for selection and use of security forces

Ensure that the ESMP includes a Code of Conduct addressing the use of appropriate force and on Sexual Exploitation and Abuse / Sexual Harassment (SEA/SH)

Provide training on use of appropriate force and code of conduct prior to deployment

Include a communications strategy in stakeholder engagement activities

Update the project GRM procedure to accommodate grievances related to involvement of security personnel under the project

Where the specific triggers for serious concern are present (see page 61) prepare a stand-alone security personnel management plan

The ESMP requirements will be included in the bidding documents and contracts for the provision of civil works and works supervision services, thus binding contractors to comply with project standards and requirements.

6.3. Infection Control and Waste Management Plan (ICWMPs)

Every beneficiary healthcare facility will prepare and implement an ICWMP, based on the template found in Annex 3.

A project-level ICWMP is developed by the Ministry of Health to support the storage, transport, and disposal of medical waste under the original project and vaccine deployment. These plans are consistent with good international practice and WHO standards on COVID-19 response on limiting viral contagion in healthcare facilities.

The ICWMP covers environmental and social infections control measures and procedures for the safe handling, storage, and processing of COVID-19 waste materials in order to prevent, minimize, and control environmental and social impacts during the operation of project-supported HCUs and ICUs. The ICWMP sets a procedure on how to develop a site specific ICWMP for HCUs and ICUs involved in the project. A site specific ICWMP is developed by the HCU or ICU representative delegated by the HCU to oversee the management of infectious medical waste, basing on the template for the development of ICWMP and under the guidance of the Environmental specialist and Waste Management Expert of the project, who advise the representative of the HCU on the accuracy of the presented information. The last draft of the ICWMP is reviewed by the Environmental Specialist and is approved by the Director of the HCU.

6.4. Stakeholder Engagement Plan (SEP)

The Ministry of Health prepared a SEP for the project and it is applicable to all project-financed activities. It is an important reference for stakeholder outreach, communication, public awareness, operation of GRM and other information channels. The Stakeholder Engagement Plan was disclosed on the Ministry of Health's website on March 30, 2020, and November 11, 2020, respectively.[79] The SEP was updated in January 2021 to reflect changes in the project related to

[79] Ministerul Sănătății, Muncii și Protecţiei Sociale. 2021. Ministerul Sănătății, Muncii și Protecţiei Sociale - MSMPS. [online] Available at: <https://msmps.gov.md/> [Accessed 17 February 2021].

the new activity and Subcomponent on vaccine procurement and deployment. The updated SEP was disclosed on March 2, 2021 on the website of the Ministry of Health.

The SEP outlines the principles for stakeholder engagement including:

- *Openness and life-cycle approach*: conducting public consultations for the project(s) will be arranged during the whole life-cycle, carried out in an open manner, free of external manipulation, interference, coercion or intimidation;
- *Informed participation and feedback*: information will be provided to and widely distributed among all stakeholders in an appropriate format; opportunities are provided for communicating stakeholders' feedback, for analyzing and addressing comments and concerns;
- *Inclusiveness and sensitivity*: stakeholder identification is undertaken to support better communications and build effective relationships. The participation process for the project is inclusive. All stakeholders at all times are encouraged to be involved in the consultation process. Sensitivity to stakeholders' needs is the key principle underlying the selection of engagement methods. Special attention is given to vulnerable groups, in particular women, youth, elderly, persons with disabilities, displaced persons, those with underlying health issues, and the cultural sensitivities of diverse ethnic groups.
- *Flexibility*: if social distancing inhibits traditional forms of engagement, the methodology should adapt to other forms of engagement, including various forms of internet communication.

The Project will implement an effective communication and outreach campaign as a mitigation measure to reach out the potentially excluded vulnerable and disadvantaged groups, and avoid the elite capture in obtaining vaccine in Rayons (districts) and local public administrations. The communication approach will focus on:

- Transparent and public communication of priority groups in the national COVID-19 vaccine deployment plan and selected according to the WHO SAGE values framework;
- Deployment to vulnerable groups in the second and third deployment stages;
- Monitoring the vaccine deployment plan's implementation to track compliance with the procedures in the national COVID-19 deployment plan and Order No. 93 of 05 Feb. 2021.

6.5. Consultation and Disclosure

Consultations for the project were conducted only through virtual platforms and remotely, given the need for social distancing during the COVID-19 pandemic. The most recent consultation meeting was held via Zoom on February 26, 2021 and convened over 60 participants including civil society organizations from the social and environmental sphere, the social partners representing the national employers' organization and workers' organization, governmental agencies with mandate in health, including the National Agency for Public Health and other

specialized agencies like labour inspection, etc.

The PIU and the beneficiary healthcare facilities will identify key stakeholders for each of the three instruments and organize consultations via virtual platforms and email as may be needed in future too.

All instruments are disclosed and will be disclosed in future too through the web pages of Ministry of Health and the beneficiary healthcare facilities, with print copies also available, on demand, at both. These documents will also be disclosed through the external web page of the World Bank.

Review and Approval – environmental and social management instruments will be prepared by the beneficiary healthcare facilities with the support of PIU and reviewed and cleared by the World Bank.

Implementation – the individual beneficiary healthcare facilities will be responsible for the implementation of the environmental and social management instruments. The PIU will provide implementation support and supervision.

PIU will be responsible for Environmental and Social Screening of project activities and monitoring of implementation of environmental and social management instruments.

Beneficiary healthcare facilities and construction contractors will ensure development of environmental and social management instruments such as ESMPs, ICWMPs, Occupational Health and safety procedures, Code of Conduct, GRM in compliance with WB ESF and ESMF of Moldova Emergency COVID-19 Response Project.

PIU will provide guidance and support in elaboration of mentioned instruments. The relevant provisions and requirements will be included in contracts with vendors such as construction companies involved in the small scale rehabilitation works in ICUs.

Monitoring and Reporting – there will be two types of reports: monthly reports from the beneficiary healthcare facilities to the PIU and quarterly reports from the PIU to the World Bank.

- ***Monthly Reports*** - individual HCFs will prepare monthly reports to the PIU on each activity being undertaken. These reports will include progress on any on-going small works, statistics related to the implementation of the ICWMP, statistics related to local hotlines, any grievances received via the GRM and information on their resolution, and any other relevant information.
- ***Quarterly Reports*** – the PIU will submit an overall report of project implementation to the Bank every quarter the project is active. These reports will include statistics on national project implementation; a summary of grievances received and their resolution, a summary of activities for each individual beneficiary healthcare facility and copies of screenings and site-specific instruments prepared during the subject quarter. Quarterly reports will be integrated into Ministry of Health ’s general project progress reporting to the World Bank.

Infection Control and Waste Management - The PIU and project beneficiary healthcare facilities are responsible for implementing actions to prevent the spread of COVID-19 and ensure proper treatment of medical waste at all stages of project operations. The two main instruments to

be used - ESMP and ICWMP - are described above and further outlined in Annexes 2 and 3. Key principles, included in those instruments, that are to be maintained by the project throughout implementation include the following:

- Covering in ICWMP environmental and social infections control measures and procedures for the safe handling, storage, and processing of COVID-19 waste materials in order to prevent, minimize, and control environmental and social impacts during the operation of project-supported HCUs and ICUs.
- Ensuring occupational health and safety standards for workers. The ESMP and ICWMP should address applicable elements of occupational health and safety management as described in the World Bank Group ESH Guidelines. Each instrument should identify specific potential occupational hazards, including those related to the COVID-19 pathogen. The ICWMP specifically will deal with the ensuring adequate facilities for handwashing, cleaning and decontamination procedures, use of PPEs, and disposal of medical waste.
- Requirements for handling dead bodies. The WHO Guidelines include guidance on the management of dead bodies in the COVID-19 context80. Healthcare workers, mortuary staff, and others handling bodies should apply standard precaution including hand hygiene before and after interaction with the body, and the environment; and use appropriate PPE according to the level of interaction with the body, including a gown and gloves. If there is a risk of splashes from the body fluids or secretions, personnel should use facial protection, including the use of face shield or goggles and medical masks.
- Safe handling of medical waste and sharps disposal. The ICWMP should contain detailed instructions on handling medical waste at a given facility. Medical waste, including any waste suspected to contain pathogens should be segregated and marked “infectious” with international infectious symbol in a strong, leak proof plastic bag, or a container capable of being autoclaved. Medical waste should be sterilized via chemical disinfection, wet thermal treatment (i.e. autoclave), microwave irradiation, or incineration prior to disposal. Sharps, including needles, scalpels, blades, knives, infusion sets, saws, broken glass, and nails etc. should be segregated in a rigid, impermeable, puncture-proof container (e.g. steel or hard plastic) container for sterilization and disposal in accordance with the guidelines. Additionally, needles and syringes should undergo mechanical mutilation (e.g. milling or crushing) prior to treatment, particularly chemical, wet thermal treatment, and microwave irradiation.
- Personal Protective Equipment. In addition to the World Bank Group EHS Guidelines on PPEs, the WHO has published guidelines on the rational use of PPEs during the COVID-19 pandemic81, which highlight the issues faced by the global shortage of PPEs. The ICWMP will take these guidelines into account and ensure that healthcare workers involved in the critical care of COVID-19 patients have the necessary means for adequate protection and that patients, particularly those who do not require hospitalization, understand their responsibilities for obtaining and wearing relevant PPEs when around others.

Labor Management – The project is expected to include direct workers and contracted

[80] https://apps.who.int/iris/bitstream/handle/10665/331538/WHO-COVID-19-lPC_DBMgmt-2020.1-eng.pdf
[81] https://apps.who.int/iris/bitstream/handle/10665/331695/WHO-2019-nCov-IPC_PPE_use-2020.3-eng.pdf

workers.

Direct workers are either government civil servants or those deployed as 'technical consultants' by the project. The former will include health care providers and workers in health care facilities. The civil servants will be governed by a set of civil services code and the 'technical consultants' by mutually agreed contracts. **Contracted workers** include chiefly construction workers involved in the minor civil works. The project proposes some small-scale civil works and the expectation is that the majority of labor will be locally hired and hence no large-scale labor influx is envisaged. Workers of companies involved in the provision of medical supplies, PPE, chemicals, reagents, disinfectants, basic care and hygiene packages, etc. fall under the category of contracted work.

The LMP, prepared for the project in line with the ESS 2 and the national legislation of Republic of Moldova, was updated as a standalone document for the Vaccine Deployment Additional Financing in April 2021. The ESMP template for the works attached to the ESMF, contains a section on worker health and safety requirements. PIU will be responsible for ensuring that (i) every individual providing works or consultant services holds a formal valid contract; (ii) the contracted construction companies have Code of Conduct and ESHS plans in place and follow them; and (iii) every project worker has access to project GRM or contractor's GRM for raising concerns and complaints.

7. Public Consultation and Disclosure

According to the WB ESF, the borrower through the Project implementing entities, should ensure the open dialogues, public consultations, timely and full access to information related to the Project activities. Accordingly, the draft ESMF is disclosed on Ministry of Health website both in Romanian and English and be made available for feedback from any interested parties/individuals, civil society organizations, labor organizations and environmental professionals through different network channels and e-mail with advance notice before disclosure. Due to the recent regulations in the country related to the Covid-19 pandemic, the process of public consultation and disclosure of the present ESMF will be guided by the World Bank Technical Note: Public Consultations and Stakeholder Engagement in WB-supported operations when there are constraints on conducting public meetings. The day before the public consultation, interested parties will be sent reminders and provided with the link of virtual conference meeting. The minutes of the public consultation meeting will be annexed to this ESMF.

The Final ESMF cleared by the World Bank is disclosed on the official websites of Ministry of Health and the World Bank.

8. Stakeholder Engagement

A Stakeholder Engagement Plan (SEP) for Moldova Emergency COVID-19 Project has been prepared according to Environmental and Social Standard ESS 10 on "Stakeholder Engagement and Information Disclosure" under the World Bank's Environment and Social Framework (ESF). SEP includes Stakeholder Engagement Program to provide stakeholders with timely, relevant, understandable, and accessible information and consult with them in a culturally appropriate manner, which is free of manipulation, interference, coercion, discrimination and intimidation. The SEP was updated in course of project implementation to reflect changes and new circumstances. The most recent version, cleared with the WB was updated in February 2021 and available on the website of the Ministry of Health [82].

The PIU and the Ministry of Health had conducted a Stakeholder Consultation on February 26, 2021, which discussed the project activities, environmental and social risks and mitigation measures, approach to addressing grievances and way forward to improve the existing Grievance Redress Mechanism to receive and address concerns emerging during implementation in a transparent and accountable manner, required improvements to the local settings so that stakeholders and representatives of local communities could act as the primary liaison between the project and their established networks.

The SEP defines a program for stakeholder engagement, including public information disclosure and consultation, throughout the entire project cycle. The SEP outlines the ways in which the project team will communicate with stakeholders and includes a mechanism by which people can raise concerns, provide feedback, or make grievances about project and any activities related to the project. The involvement of the local population is essential to the success of the project in order to ensure smooth collaboration between project staff and local communities and to minimize and mitigate environmental and social risks related to the proposed project activities. In the context

[82] https://msmps.gov.md/informatie-de-interes-public/proiectul-bancii-mondiale-raspuns-de-urgenta-la-covid-19-in-republica-moldova/documente/

of infectious diseases, broad, culturally appropriate, and adapted awareness raising activities are particularly important to properly sensitize the communities to the risks related to infectious diseases and means of prevention.

9. Grievance Redress Mechanism

9.1. Objective of the GRM System

The objective of the GRM is to serve as an effective tool for early identification, assessment and resolution of grievances, serving as a project risk management mechanism and strengthening accountability to beneficiaries. The GRM serves as feedback mechanism that can improve project impact and mitigate the undesirable ones. The GRM mechanism will be available to project stakeholders and other affected parties to submit questions, comments, suggestions and/or complaints and provide any form of feedback on all project-funded activities.

The PIU will strengthen the existing institutional grievance mechanisms under the Ministry of Health to address all complaints and requests related to project implementation and will adapt them to the COVID-19 circumstances in line with epidemiological measures and recommendations issued at the given time, and the ESS10 requirements. A consultation meeting with stakeholders and healthcare institutions was held on Feb. 26 2021, which discussed way forward to enhance the existing grievance redress mechanism, All the communication by the Ministry of Health and the relevant agencies will highlight vaccination stages, priority groups and selection criteria, AEFIs, the Grievance Redress Mechanism (GRM), AEFI will be reported[8384] in accordance with instructions specified in "Order No. 1019 dated 05 November 2020 Regarding the functioning of the system for causality evaluation and classification of adverse events following immunization (AEFI)".

At present, the institutional arrangements[85] allow to receive grievances online, via email, telephone and fax, written complaints sent by landmail, in personal delivery to the physical address of the Ministry of Health. The existing setup will be strengthen to include complaint boxes for anonymous grievances, which will be placed in healthcare institutions and other places. During project implementation, additional channels may identified through communication with petitioners.

9.2. Principles of the GRM System

- All complainants will be treated with courtesy, equally and fairly and no discrimination will be allowed;
- All complaints will be treated seriously, regardless of the channel of transmission and form of communication and be registered in a designated logbook, documented and responded in writing;
- The timeframes indicated will be observed and the complainant will be notified if more time

[83] https://vaccinare.gov.md/questions

[84] https://msmps.gov.md/wp-content/uploads/2021/02/Ordin-nr.-93-din-05.02.2021-Cu-privire-la-implementarea-Planului-national-de-imunizare-anti-Covid-19-1.pdf

[85] https://msmps.gov.md/contacte/petitii-online/

is required to address the particular grievance;
- All complainants, if needed, will receive guidance in making and filing their complaint; and
- All complaints will be dealt with confidentiality.

9.3. GRM Process

Channel of Submission

The following channels will be used through which citizens/beneficiaries/Project Affected Persons (PAPs) and patients in healthcare units can make complaints/suggestions/compliments regarding project-funded activities:

1. By Email: secretariat@msmps.gov.md;
2. Online at https://msmps.gov.md/en/contacte/online-petitions/;
3. In writing: str. Vasile Alecsandri, 2; MD-2009, mun. Chișinău ;
4. Dedicated phone number: +373 22 268 824;
5. Green-Line 022 721 010 / 0 80071010 ;
6. By fax: 022 268-816 ;
7. Other: verbal complaints addressed to project staff at the ministry which should be recorded in writing by the receiver;
8. Grievance boxes will be placed in medical/health institutions supported by the project, to collect grievances that may be raised for adequacy of medical treatment received (or not received)/ provided (or not provided) by HCWs;
9. Grievance boxes will be placed in hostels or residential places where medical staff is accommodated, such as NGO "AVE Copiii" [86] for receipt of grievances from medical staff. At the same time, healthcare workers can consider submitting an appeal to the competent inspection authority and/or initiate a lawsuit before the competent court. Information about the GRM will be available on notice boards of healthcare units and provided at induction trainings.

The above GRM are not a substitute for law courts and shall not interfere with access to other judicial or administrative legal remedies provided by Moldova laws or replace grievance mechanisms that already exist under collective agreements. The GRM template is provided in the Annex 6 of this document.

9.4. Receipt and Referral

The person receiving the complaint will complete the grievance form provided in the annex, or the complainant can fill the form himself/herself and submit it to one of the addresses above.

[86] https://avecopiii.md/campania-ajuta-ne-sa-i-protejam/

The dedicated GRM Officer in the MOH will register the grievance in the Grievance Log and inform the complainant of the timeframe he/she is expected to receive a response. When making a grievance, the complainant should provide the following details: (a) the essence of the grievance, what was done in non-compliance to existing processes? (b) How the complainant is affected by the situation; (c) relevant details, such as time, date, place, names of individuals; (d) supporting documentation; (e) expected remedy needed to correct the situation.

Then the GRM officer will refer the case to the Project Director.

Within two business days, the Project Director will determine which person/department should be responsible to investigate the complaint, whether the complaint requires an investigation or not and the timeframe to resolve it. The Project Director should ensure that there is no conflict of interest involved for the investigating officer. The length of the investigation process depends on the complexity of the case. However, all complainants should receive feedback on the status of their grievance within ten business days.

9.5. Investigation

The person/department responsible for investigating the complaint will collect and review all the facts related to the grievance within 10 days. The process may include meetings with the person who filed the grievance (if willing to meet) and those who can facilitate the resolution. The deadline for investigating the complaint may be extended to 20 working days by the Project Director, and the complainant is to be informed about this fact within 2 working days, whether:

- additional consultations are needed to provide response to the complaint;
- the complaint refers to a complex volume of information and it is necessary to study additional materials for the response.

After the investigation is finalized, the proposed response will be presented to the GRM/ES Officer and Project Director. The GRM Officer will record the proposed action in the Registry of Grievances in the section that describes the suggested action.

9.6. Response to the Complainant

The complainant will be informed about the results of verification via letter, email or by post, as received. The response shall be based on the materials of the investigation and, if appropriate, shall contain references to the national legislation. The GRM officer will seek feedback whether the proposed actions are deemed satisfactory and will record the response in the corresponding section of the grievance form.

9.7. Right to Appeal

If the complainant is not satisfied with the response, one more attempt will be made to clarify the rationale for the proposed action by the GRM staff, Project Coordinator and the investigating person/department and other relevant personnel may be involved in the appeals process. A final decision will be taken following the appeal meeting. If the response remains unsatisfactory to the complainant, he/she/they may resort to raising their grievances outside the project GRM system.

9.8. Grievance Log

Grievances submitted through the channels listed above will be collected by the PIU staff and aggregated in the project Grievance Log. A grievance log will be maintained to ensure that each complaint has an individual reference number and is appropriately tracked, and recorded actions are completed. When receiving feedback, including grievances, the following is defined:

- Type of appeal;
- Category of appeal;
- People responsible for the examination and execution of the appeal;
- Deadline of resolving the appeal; and
- Agreed action plan.

The log should contain the following information:

- Name of the project affected person, his/her location and details of his / her complaint;
- Date of reporting by the complaint;
- Details of corrective action proposed, name of the approval authority;
- Date when the proposed corrective action was sent to the complainant (if appropriate); and
- Details of the Grievance Committee meeting (if appropriate).

9.9. Monitoring and Reporting

During implementation, the PIU team will prepare brief monthly reports on E&S performance which will include updates on SEP implementation and describe the nature of grievances received, status of resolution and other relevant details. These monthly reports will be used to prepare the semi-annual and annual aggregate reports that will be used to inform the MHLSP and the World Bank teams as well as to project stakeholders via publication on the Ministry of Health website and via individual stakeholder meetings. The PIU will monitor the following GRM-related set of indicators:

- Number of grievances received by category of complaint, gender and channel of transmission;
- Number of cases resolved satisfactorily/unsatisfactorily for the complainant and under consideration;
- Time taken to resolve complaints (within established timeframe, exceeded the timeframe);
- Any issues faced with the procedures/staffing or use;
- Factors that may be affecting the use of the GRM/beneficiary feedback system; and
- Any corrective measures suggested/adopted.

10. Institutional Arrangements, Responsibilities and Capacity Building

10.1. Overall responsibilities of entities involved in the implementation of the project

Institutional and implementation arrangements build upon existing structures and systems as far as possible. More specifically, the Project Implementation Unit (PIU) of the ongoing Health Transformation Project in Moldova will implement the activities of this project, including Additional Financing for Vaccine Procurement and Deployment. Working with the current PIU in the Ministry of Health is expected to enhance the likelihood of successful implementation of project activities and speedy disbursement to achieve desired outcomes. The PIU has extensive experience in the World Bank's fiduciary and implementation procedures as it has worked for the Health Transformation Project for several years. The PIU consists of a team of consultants including a Project Coordinator&Procurement Specialist, Financial Management Specialist. To strengthen the PIU's capacity, additional staff were contracted, such as Social Protection Specialist, who supports the implementation of activities related to Subcomponent 1.4., a Civil Works Engineer, Environmental Consultant, Social Safeguards Consultant. To support activities under AF Vaccine Procurement and Deployment, a Communication Specialist was hired and a Waste Management Specialist is being hired. Additional technical and other expertise will be outsourced to enhance existing capacities of the PIU as may be required.

A Project Operational Manual (POM) was developed and approved in June 2020 describing the roles, responsibilities, and processes under the project. The Project Operational Manual was updated in August 2021 to reflect the AF for Vaccine procurement and deployment.

Thus, the PIU will be responsible for managing project implementation, including leading the procurement of medical supplies and equipment and contracting the civil works for facility refurbishment. In more details, the PIU will have the responsibility to lead the implementation of all activities under:

Component 1 Emergency COVID-19 Response and its Subcomponent 1.1: Case Confirmation (strengthening diseases surveillance systems and the capacity of the selected public health laboratories to confirm cases by financing medical supplies and equipment); Subcomponent 1.2 on strengthening of public health facilities to provide critical care to COVID-19 patients (will support interior minor refurbishment to remodel ICUs and increase the availability of isolation rooms, and will also finance ambulances to support urgent transportation of patients); Subcomponent 1.3 which will support information and communication activities to increase the attention and commitment of government, private sector, and civil society to the COVID-19 pandemic, and to raise awareness, knowledge and understanding among the general population. Subcomponent 1.4: Social and Financial Support to Households which will support the providing social and financial support to households through, among other things: (a) supporting reforms to Ajutor Social, and; (b) financing cash transfers and Subcomponent 1.5 Vaccine Procurement and

Deployment under the AF, which will finance the procurement of vaccines in line with the national COVID-19 vaccine deployment plan in stages two and three. Some other activities, such as trainings may be outsourced to third parties through contractual agreements acceptable to the WB.

The PIU will have the responsibility for contracting the necessary work and implementation of activities under the above listed components/subcomponents. Upon the Ministry of Health's request, the WB will provide bank facilitated procurement to proactively assist in accessing existing supply chains. Once the suppliers are identified, the World Bank could support with negotiating prices and other contract conditions.

The Ministry of Health as implementing agency will remain fully responsible for signing and entering into contracts and implementation, including assuring relevant logistics with suppliers such as arranging the necessary freight/shipment of the goods to their destination, receiving and inspecting the goods and paying the suppliers, with the option of using the World Bank's system of making direct payment to the contractors or suppliers or consultants on behalf of the Borrower from the proceeds of the financing, in accordance with the terms of the Financing Agreement. The World Bank could provide, if needed, hands-on support to Borrowers in contracting to outsource logistics. Bank facilitate payment to access available supplies may include aggregating demand across participating countries, whenever possible, extensive market engagement to identify suppliers from the private sector and UN Agencies.

The Ministry of Health is also responsible for the national COVID-19 vaccination program's overall governance and will facilitate the program's alignment of activities under the project. The Ministry of Health is also responsible for developing a project report at the end of each calendar semester. A Vaccine Delivery and Distribution Manual for effective vaccine delivery and vaccination implementation was adapted from the national COVID-19 vaccination plan, adopted, and included as an annex to the updated project operational manual. To support the implementation of additional activities to manage environmental and social risks, the PIU hired communications and is expected to also hire a medical waste management expert. Given the satisfactory pace and quality of implementing the original project and proactive mitigation of challenges, the institutional arrangements will not be changed.

The National Social Insurance House: Institutional arrangements for Subcomponent 1.4 "Social and Financial Support to Households", provide that Casa Nationala de Asigurari Sociale (CNAS) / National Social Insurance House will be responsible for managing the payment of benefits: receiving the lists of eligible beneficiaries from social assistance departments at local level, submitting payment requests to the Ministry of Finance, monitoring the cash distribution through designated commercial banks and post offices, and accepting their monthly reports on benefit execution. The project disbursements under "Social and Financial Support to Households" sub-component would be linked to the Government's poverty-targeted cash benefit program Ajutor Social and verified achievement of Performance-Based Conditions (PBC).

State Treasury under the Ministry of Finance: the financial reporting system of the State Treasury and National Social Insurance House will regularly monitor and report on budget estimates and actual expenditures for the allowances of the Ajutor Social Program. This monitoring will give the Project the opportunity to rely on the national fiduciary system for Project's financial management and disbursement. Disbursement-based reports will include reports on the allowances of the Ajutor Social Program prepared by NSIH and will describe the initial balances, the amounts calculated and transferred, the amounts reimbursed back to NSIH, the closing balances by districts.

Responsibility for monitoring during construction: the Civil Works Engineer hired in the PIU team will lead the monitoring and supervision activity during construction.

Project reporting responsibilities: the PIU will prepare project progress reports (technical, financial and procurement) and an annual work plan with inputs from the Ministry of Health .

10.2. Staffing and Capacity Building for Effective Infection Control and Waste Management

Effective infection control and waste management will have both professional and auxiliary staffs that are required for the continuous and proper operation of the respective facilities. The HCFs will designate on a full-time or on surge basis necessary personnel, which will operate in line with the relevant Health Norms and Standards Guidelines.

However, its noted that all critical staff right from the head of the respective facility, the heads of departments or sections and all staff working in the quarantine centers in the target rayons or the PoEs, isolation and treatment centers, the laboratories and blood services as well as in all other facility service areas, will be responsible for the waste they produce and ensure that appropriate standard precautions are adhered to. Among them not mentioned earlier include:

- Head of Hospital
- Heads of Hospital Departments
- Chief Pharmacist
- Radiation Officer
- Matron/Senior Nursing Officer
- Housekeeping in-charge
- Hospital Manager
- Hospital Engineer
- Supplies officer: supply chain management
- Financial Controller
- Rayon Public Health officer
- Hotel Manager / Isolation / Quarantine Centers Manager,
- Waste Handlers, and
- Incinerator Operator

10.2.1 Head of Healthcare facilities

Head of Hospital (Medical superintendents /health facility in-charge/ Healthcare Administrator) do supervise the everyday operations of healthcare facilities. They focus on improving the quality of patient care by ensuring the facilities are well-staffed, finance well-managed and general management of the facility. Some of the specific roles include:

• Establish a waste-management team to oversee the preparation of specific HCF ICWMP and monitor its implementation,
• Ensuring adequate financial resources allocated to fully implement specific ICWMP,
• Designate a waste-management officer to supervise and implement the ICWMP in the HCF
• Obtain and be familiar with national waste management policies and set regular (e.g. annual) review dates for the facility HCWM policy.
• Ensure adequate training for staff and designate the staff responsible for coordinating and implementing training courses on IPC and Healthcare waste management and emergency response procedures,
• Provide measures in place to prevent health-care waste from causing environmental pollution or adverse effects on human health;
• Ensure health care waste management system in the HCF is managed according to the national regulations; ensuring that health-care waste is adequately segregated and safely packed, especially in the case of sharps which should be packed in puncture-proof containers; and ensure that bags or containers of health-care waste are handled only by those officially licensed to transport and/or dispose of such waste.

10.2.2 Departmental Managers

The departmental managers should:

• Develop a facility HCWM plan (goal, budget, personnel, roles, supervision, training, reporting). Allocate adequate financial and human resources to implement the plan including up to final disposal.
• Ensure adequate supply of safety boxes, bins, bin liners and PPE.
• Develop a protocol for management of needle-stick injury.
• Advocate for health worker safety.
• Provide supportive supervision in HCWM.

10.2.3 Rayon Waste Management Officer (RWMO)

All Rayon Public Health Officers (RPHO) should designate a rayon waste management officer in charge of rayon waste management; to map out and document all health care facilities in the rayon indicating waste management gaps, recommend actions as well implementations of the actions. The RPHO will be responsible for monitoring of the healthcare waste management system at respective rayons. It is therefore essential that the RPHO has direct access to the implementing

facilities and reports directly to the PMT. He or she is responsible for the rayon hospitals waste management officers stationed in health facilities.
At service level, the Waste Management Officer based at the facilities should:
▪ Ensure the day-to-day operation and monitoring of the waste-management system
▪ Supervise waste handlers and waste management staff;
▪ Liaise with the department heads to make sure that their staff are carrying out waste-related tasks properly;
▪ Ensure availability of waste management equipment;
▪ Monitor performance indicators and ensure reports are developed on the implementation of ICWMP.
▪ Manage healthcare waste management budget;
▪ Organize staff training and information.
▪ Document, report and review any reported incidents concerning the handling of health-care waste in liaison with the infection-control department.
• Liaise with the Supplies Department to ensure that an appropriate range of coded bags and containers for health-care waste, protective clothing, and collection trolleys are available at all times;
• Be responsible for installing and maintaining waste treatment and storage facilities and handling equipment to comply with the specifications of environmental standards;
• Be responsible for coordinating maintenance and repair of waste treatment facilities; and
• Develop maintenance standards for waste management equipment. It is normal that most equipment requires preventive maintenance especially the incinerator, autoclave or the microwave.

10.2.4 Infection Control Officer

The responsibilities for the Infectious Control Officer include:
▪ Liaise with the waste-management officer
▪ Provide advice about the control of infection, and the standards of the waste treatment and disposal system.
▪ Identify training requirements according to staff grade and occupation
▪ Organize and supervise staff training courses on the infection risks from poor waste management
▪ Liaise with the department heads and the hospital manager to coordinate training.
▪ May also have overall responsibility for chemical disinfection, the safe management of chemical stores, and minimizing chemical waste creation.

10.2.5 Chief Pharmacist/Radiation Officer

The responsibilities include:
Minimizations/management of wastes from their departments, including:
• Advise on pharmaceutical/radioactive waste treatment and disposal;

• Stay up to date on minimization, proper treatment and safe disposal of pharmaceutical/radioactive wastes,
• Coordinate monitoring of pharmaceutical/radioactive waste, ensure personnel in their departments receive adequate training,
• The chief pharmacist also has the special responsibility of ensuring that genotoxic products are used safely, and that genotoxic waste is managed safely according to the regulations.
• The radiation officer must also ensure that additional regulations on the storage and safeguarding of radioactive wastes are strictly followed.

10.2.6 Procurement Officer Responsibilities

• Liaise with the Environment Expert / officer to ensure a continuous supply of the healthcare waste management commodities (plastic bags and containers of the right quality, spare parts for onsite health-care waste-treatment equipment).
• Investigate the possibility of purchasing environmentally friendly products e.g.:

- PVC–free products
- Mercury free equipment
- Recycled materials
- LEDS

10.2.7 Hospital Engineer

▪ Installing and maintaining waste-storage facilities and handling equipment.
▪ Accountable for adequate operation and maintenance of any on-site waste treatment equipment
▪ Responsible for ensuring that the staff operating on-site waste-treatment facilities are trained in their operation and maintenance.

5.2.8 Waste Handlers

Waste handlers have principal duties and responsibilities: the waste handler is responsible for collecting, segregating, labelling, temporal storage, transporting, infectious waste and other medical waste in accordance with relevant healthcare facilities, isolation / quarantine areas, and blood transfusion centers approve procedures and regulatory requirements. Specific roles include:
• Collects, separates, contains, labels and transports solid waste, medical waste & recyclable goods from generation points to specified collection location and incinerator
• Tracking and maintaining records of wastes generated from each health facilities/quarantine/isolation centers and laboratories
• Empties, relines, & cleans solid & medical waste containers according to procedures
• Segregates waste for containment prior to transporting off-site for incineration
• Separates, contains, seals, labels, weighs, & stores high-risk infectious (red bag) waste to be incinerated
• Cleans and disinfects medical waste carts
• Maintains waste area facility in a clean and orderly condition; sweeps and cleans area at the end of each shift,

• Assures safe working conditions at all times as designated by the SOP; utilizes safety equipment and/or protective equipment as directed (i.e. safety gloves and eye protection), follows defined safety procedures, and
• Follow waste management procedure during waste handling transportation, storage, treatment and disposal including infection control.

10.2.9 Incinerator Operator

An incinerator operator is a skilled attendant assigned the duties of ensuring that the waste has been properly treated through incineration and the ash properly disposed. The operator should always be provided with the minimum required personal protective equipment (PPE) and ensure appropriate use, the equipment is maintained and kept clean. The PPE should be properly maintained, kept clean and not taken home; it must remain at the health facility to avoid possible spread of infection to the community.
The incinerator operator should:
1. Follow the incinerator operations procedure.
2. Use protective equipment when handling waste.
3. Ensure an adequate supply of fuel is available.
4. Record the weight and type of waste received.
5. Follow the regular maintenance schedule for incinerator operation.
The operator should at minimum have the following PPEs for use:
i. Gloves: Always wear gloves when handling health care waste.
ii. Boots: Safety boots or leather shoes provide extra protection to the feet from injury by sharps or heavy items that may accidentally fall. Boots must be kept clean.
iii. Overalls: Overalls should be worn at all times.
iv. Aprons: Heat-resistant aprons should be worn when operating the incinerator.
v. Goggles: Clear, heat-resistant goggles can protect the eyes from accidental splashes or other injury.
vi. Nose and Mouth respirators / mask (N95), and
vii. Helmet: Helmets protect the head from injury and should be worn at all times during the incineration process.

10.2.10 Laboratory Manager

The laboratory manager is responsible for ensuring appropriate laboratory techniques, safety procedures, and hazards associated with handling biohazards and associated wastes are appropriately implemented. Responsibilities of the Laboratory Manager in regard to health care waste include:
• Accept direct responsibility for the health and safety of those working with bio-hazardous materials and/or select agents and toxins associated with COVID 19,
• Adhere to approved emergency plans for handling accidental spills and personnel contamination,

• Ensure compliance by laboratory personnel with relevant regulations, guidelines, and policies,
• Ensure all appropriate personal protective equipment is provided and used. Ensure proper training, including refresher training, and instruction for laboratory personnel in safe practices and protocols, including, at a minimum, training in aseptic techniques and characteristics of the material(s) used.
• Tracking and maintaining records of wastes generated from laboratory.
• Ensuring that individuals working in the facility are experienced and proficient in handling the biological agents at the appropriate level of containment.
• Ensure compliance by waste handler, waste water treatment and incinerator personnel with relevant regulations, guidelines, and policies of infection control and waste management.
• Ensure that all the relevant staff including; waste handler, waste water treatment plant and incinerator personnel are adequately trained in waste management and risk management in waste water treatment plant and incinerator facility respectively.

10.2.11 Medical Waste Autoclave / Microwave Operators

▪ Follow the equipment's operations procedure.
▪ Use protective equipment when handling waste.
▪ Monitoring and timely report on fuel use and supply status.
▪ Record the weight and type of waste received.
▪ Follow a regular maintenance schedule and quality assurance testing procedures.
▪ Ensure treated waste is safely transported to a collection point for final disposal.

10.2.12 Healthcare Facility cleaners

Under the supervision of the facility waste management and environmental / IPC officer, these individuals perform different washing and cleaning activities within and outside the main Quarantine, Isolation and Treatment centers, Blood services and Laboratories these include
• Cleans laboratory equipment, such as glassware, metal instruments, sinks, tables, and test panels, using solvents, brushes, and rags
• Mixes water and detergents or acids in container to prepare cleaning solution according to specifications.
• Washes, rinses, and dries glassware and instruments, using water, acetone bath, and cloth or hot-air drier.
• Scrubs walls, floors, shelves, tables, and sinks, using cleaning solution and brush.
• May sterilize glassware and instruments, using autoclave.
• The HCF cleaners should be provided with the minimum required PPE (medical mask, gown, heavy duty gloves, boots or closed shoes) according to the WHO guidelines on Covid-19 Personal Protective Equipment (PPE) for Healthcare Workers.

10.2.13 Other COVID-19 Healthcare Service Providers

When a hotel, institution, stadium, PoE is selected as a quarantine / isolation area for COVID -19 cases, the in charge of the facility becomes the manager to ensure compliance with health and safety legislation and licensing laws. At the same time the facility is assigned a qualified medical doctor who will be monitoring of the implementation of the infection preventive measures for the

people in the quarantine centers. He/she takes the overall responsibility, leads an intra-departmental team and regularly reviews issues and performance of the infection control and waste management practices at the facility including but not limited to:

- Follow and implement waste management policies;
- Follow the colour-coded waste segregation system while carrying out waste segregation;
- Safely contain sharps in a safety box;
- Provide on-the-job training for new staff with regard to ICWMP; and
- Ensure sound treatment and disposal of waste generated in the facility.

10.2.14 Health Care Waste Treatment and Disposal Facilities staff

Healthcare waste treatment and disposal Facilities (those separate from a HCF but providing services to HCF) are essential in the managing healthcare waste for the healthcare facilities without waste treatment and disposal options. Key elements in improving health-care waste management are:

• Timely waste collection, treatment and disposal of the generated healthcare waste, raising awareness of the risks related to health-care waste, and of safe practices including (i) safety and health hazards (ii) aesthetic damage (iii) environmental issues and pollution,

• Train their respective clients (health facilities) in appropriate healthcare waste segregation, collection and storage practices,

• Developing strategies and systems along with strong oversight and regulation to incrementally improve waste segregation, transportation, destruction and disposal practices with the ultimate aim of complying with Waste Management Regulations and international standards (WHO guidelines on healthcare waste management);

• Where feasible, favoring the safe and environmentally sound treatment of hazardous health care wastes (e.g. by autoclaving, microwaving, steam treatment integrated with internal mixing, and chemical treatment) over medical waste incineration;

• Building a comprehensive system, addressing responsibilities, resource allocation, handling and disposal;

• Selecting safe and environmentally-friendly management options, to protect workers at the waste treatment facilities involved in the treating or disposing of waste.

10.3. Institutional Arrangements and Responsibilities for Implementation of Provisions of the ESMF

The main environmental risks are related to include: (a) occupational health and safety for medical staff, laboratory staff and communities in the course of detection, transportation of patients/tests/chemicals and reagents, and treatment stages of the COVID-19 cycle; and (b) occupational health and safety related to collection, transportation and disposal of medical waste management. To mitigate these risks the Ministry of Health prepared the present Environmental and Social Management Framework (ESMF). In addition to the ESMF, the client will implement the activities listed in the Environmental and Social Commitment Plan (ESCP).

The management of environmental and social risks and impacts related to COVID-19 activities under the project will be carried out in accordance with the World Bank Environmental and Social Framework (ESF), effective October 1, 2018. The Ministry of Health as implementing agency for the project and the PIU will ensure compliance with provisions of the present ESMF. The MINISTRY OF HEALTH will request compliance of all contractors and subcontractors with provisions set in this ESMF.

A part-time Environmental Specialist and part-time Social Safeguard Specialist were hired in August 2020, who will lead the implementation of the present ESMF and related activities.

10.4. Institutional arrangements and Responsibilities for Implementing Stakeholder Engagement and Communication Activities

The PIU and the MoH will be responsible for implementing stakeholder engagement activities. The Communication Specialist and Social Safeguards Specialist and the Environmental Specialist with support from the MoH Public Relations Department will be responsible for activities undertaken within the framework of the SEP.

10.5. Institutional Arrangements and Responsibilities for the Implementation of Vaccine Deployment

The list of national and international authorities, as well as their tasks and responsibilities with regard to the implementation of the COVID-19 vaccination, includes but is not limited to the following:

Table 3. Authorities and Responsibilities

Authorities	**Activities**
Government NEPHC	Coordinates activities, mobilizes and allocates funds.
Ministry of Health (MoH)	Ensures the operational process of approving the coordination, information and communication activities.
Ministry of Finance (MoF)	Allocates funds for vaccine and necessary equipment supplies.
National Agency for Public Health (NAPH)	Ensures the planning, importation, organization and distribution of the vaccine. Monitors the immunization process and its safety.

Agency for Medicines and Medical Devices (AMMD)	Ensures the vaccine authorization process. Issues import authorization. Pharmacovigilance.
Customs Service (CS)	Ensures customs clearance of vaccines.
Centre for Centralized Public Procurement in Health (CAPCS)	Ensures the purchase of medical devices and equipment necessary for the immunization process.
National Health Insurance Company (NHIC)	Ensures the regular financing of healthcare facilities in order to procure the necessary equipment for the immunization sessions; protective equipment. Allocates additional resources for the procurement of vaccine or equipment, within the means of available compulsory health insurance funds.
Healthcare facilities (HCF)	Select, inform and recruit target population groups for vaccination, organization of immunization sessions. Report immunization data and adverse events.
International partners (GAVI, WHO, UNICEF)	Ensure technical and methodological support.
International donors (Word Bank, EU etc.)	Financial support.

The effective implementation is based on the close collaboration and cooperation of a number of ministries, services, organizations and institutions under the auspices and in partnership with MHLSP:

1) Public, private, departmental healthcare and long-term residential facilities.
2) NAPH and territorial subdivisions.
3) "Nicolae Testemitanu" State University of Medicine and Pharmacy.
4) NHIC and its territorial subdivisions.
5) Local public administration authorities.
6) Education and early education facilities.
7) Coordinating Council for the implementation of the National Immunization Program.
8) National Advisory Committee of Experts on Immunization

Also, development partners have important roles in the support roles in deployment of vaccines are the following:

WHO
The WHO is providing technical support for the development of a national vaccine deployment plan; a regulatory framework for approval and import of COVID-19 vaccines; the mapping of service delivery platforms; microplanning for priority groups; protocols for infection prevention and control; training of health workers; the development of a monitoring and surveillance framework; the operationalization of a framework for safety surveillance; and the development of a crisis communication plan.
UNICEF
UNICEF supports the assessment of cold chain capacity, developing standard operating procedures for collection and disposal of medical waste, and developing a demand generation plan to increase vaccine acceptance.
Gavi and Global Fund
Gavi and Global Fund provide catalytic support towards cold chain equipment needs at the national and regional levels.
COVAX Facility
The COVAX Facility will finance OVID-19 vaccines for the first 20% of the population.
IDA
IDA will provide COVID-19 vaccines to cover 30% of the population and technical and financial support for vaccine deployment for 50% of the population, including planning and management, supply and distribution, program delivery, and supporting systems and infrastructure.

10.6. ESMF Monitoring, Evaluation and Reporting Arrangements

Monitoring and evaluation (M&E) activities will be the responsibility of the PIU. The PIU will (a) monitor project implementation; (b) collect data and information related to the PDO and intermediate indicators; and (c) prepare progress reports by coordinating with related departments at Ministry of Health . Progress reports will cover compliance with the planned project activities, the updated Procurement Plan, progress on the achievement of indicators as defined in the Results Framework; and progress on the Environmental and Social Framework (ESF). These reports will be submitted to the World Bank, by the PIU on a semi-annual basis.

The activities and disbursements for subcomponent 1.4 will be tracked through the monthly payroll disbursed to Ajutor Social recipients by the National Social Insurance House. The NSIH collects the data from the local welfare offices that process applications, verifies the data, and transfers funds to recipients' accounts in designated banks . The NSIH will send the report on the transfers made to Ajutor Social recipients to the MINISTRY OF HEALTH and the Ministry of Finance. The MINISTRY OF HEALTH will verify the DLIs under this project.

10.7. Training and Capacity Building Needs

Under the Original Project, capacity building and training is foreseen for health professionals and other personnel involved in Project implementation. Training activities are foreseen for such personnel throughout Project implementation, and will be organized by the PIU and professionals experienced in the relevant topics.

The key training for medical and non-medical professionals are related to:

- training on infection prevention and control (IPC) practices to mitigate potential shortages of staff who are able to provide care to suspected and confirmed cases. The training will be with a focus on staff providing care to suspected and confirmed cases. The training on IPC will improve the capacity of the system to limit spread in health facilities of the current infection and possible future outbreaks;
- training medical and non-medical workers on relevant protocols, and bolstering routine medical care and emergency treatment capabilities;
- training on COVID-19 treatment and intensive care to respond to the surge in patients requiring admission in ICUs;
- training in critical care to ensure the capacity of staff to use equipment for severe COVID patients and other patients requiring intensive care.

Training topics also include:

- Training as per the WHO Country & Technical Guidance - Coronavirus disease (COVID-19) https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance including but not limited to:
  - COVID-19 Infection Prevention and Control Recommendations
  - Laboratory biosafety guidance related to the COVID-19
  - Specimen collection and shipment
  - Standard precautions for COVID-19 patients
  - Risk communication and community engagement
  - Establishment of quarantine
- Training topics as per the WHO Guidelines on Safe Management of Wastes from Health-Care Activities https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf;jsessionid=EE45FF4B510A5297A7DFF6030A3BED25?sequence=1
- Entity Sanitary Regulations and Norms

Additional capacity building activities during the project implementation may include:

- Capacity building for relevant staff in local public administrations: training on how to facilitate community-level outreach to vulnerable groups.
- Capacity building for designated staff in the Ministry of Health: training on how to assist the grievance applicant at all stages of his grievance and ensure that his/her grievance is properly handled, as well as training on outreach, non-discriminatory services delivery, etc.
- Capacity building of all relevant staff (including staff of centers social care) involved in GRM: training and provision of relevant information and expertise to provide phone consultations and receive feedback
- Capacity building of social assistants engaged in providing support through the Ajutorul Social Program
- Capacity building of medical waste collection and disposal workers: training on OHS measures, training on health and safety and practical aspects of health care waste management including waste prevention, separate collection, handling and disposal, PPE, waste management plans, safe waste transfer vehicles for rural health facilities;
- Capacity building of traditional media and journalists: training and communication to improve knowledge and techniques to arrange for media coverage of COVID-19 related emergency response procedures.

For deployment of the vaccine campaign, initial training of 673 health workers to be involved in vaccine delivery was conducted on January 13-15, 2021, led by NAPH and the Nicolae Testemitanu Medical University, with technical support from WHO and UNICEF. NITAG and the Ministry of Health review all training materials. Procedures have been instituted to prevent and control infection spread, including separate COVID-19 vaccination days, ventilation for waiting areas, temperature checks, protective masks, personal hygiene, and observing the one-meter distancing requirement. Where surge capacity is required, medical students will be trained to undertake vaccination.

Under the Additional Financing for Vaccine Procurement and Deployment training is foreseen as follows:

- Training and incentives for vaccinators; Vaccinator training will be held on a rolling basis, via face-to-face with facilitation and online through self-study;
- Personnel training in IT and data skills to support the management of the COVID-19 vaccine deployment campaign.

11. Annexes

Annex 1. Screening Form for Potential Environmental and Social Issues

This form is to be used by the Project Implementation Unit (PIU) to screen for the potential environmental and social risks and impacts of a proposed subproject. It will help the PIU in identifying the relevant Environmental and Social Standards (ESS), establishing an appropriate E&S risk rating for these subprojects and specifying the type of environmental and social assessment required, including specific instruments/plans. Use of this form will allow the PIU to form an initial view of the potential risks and impacts of a subproject***. It is not a substitute for project-specific E&S assessments or specific mitigation plans.***

A note on *Considerations and Tools for E&S Screening and Risk Rating* is included in this Annex to assist the process.

Subproject Name	
Subproject Location	
Subproject Proponent	
Estimated Investment	
Start/Completion Date	

Questions	**Answer**			**ESS relevance**	**Due diligence / Actions**
	Yes	**No**	**N/A**		
Does the subproject involve civil works including new construction, expansion, upgrading or rehabilitation of healthcare facilities and/or waste management facilities?				ESS1	ESIA/ESMP, SEP
Does the subproject involve land acquisition and/or restrictions on land use?				ESS5	- No subproject or activity will entail land acquisition under this project, and RAP is not to be prepared
Does the subproject involve acquisition of assets for quarantine, isolation or medical treatment purposes?				ESS5	Not eligible for financing

Questions	Answer			ESS relevance	Due diligence / Actions
	Yes	No	N/A		
Is the subproject associated with any external waste management facilities such as a sanitary landfill, incinerator, or wastewater treatment plant for healthcare waste disposal?				ESS3	ESIA/ESMP, SEP
Is there a sound regulatory framework and institutional capacity in place for healthcare facility infection control and healthcare waste management?				ESS1	ESIA/ESMP, SEP
Does the subproject have an adequate system in place (capacity, processes and management) to address waste?					
Does the subproject involve recruitment of workers including direct, contracted, primary supply, and/or community workers?				ESS2	LMP, SEP
Does the subproject have appropriate OHS procedures in place, and an adequate supply of PPE (where necessary)?					
Does the subproject have a GRM in place, to which all workers have access, designed to respond quickly and effectively?					
Does the subproject involve transboundary transportation (including Potentially infected specimens may be transported from healthcare facilities to testing laboratories, and transboundary) of specimen, samples, infectious and hazardous materials?				ESS3	ESIA/ESMP, SEP
Does the subproject involve use of security or military personnel during construction and/or operation of healthcare facilities and related activities?				ESS4	ESIA/ESMP, SEP
Is the subproject located within or in the vicinity of any ecologically sensitive areas?				ESS6	ESIA/ESMP, SEP
Is the subproject located within or in the vicinity of any known cultural heritage sites?				ESS8	ESIA/ESMP, SEP
Does the project area present considerable Gender-Based Violence (GBV) and Sexual Exploitation and Abuse (SEA) risk?				ESS1	ESIA/ESMP, SEP
Does the subproject carry the risk that disadvantaged and vulnerable groups may have unequitable access to project benefits?				ESS1	ESIA/ESMP, SEP

Questions	Answer			ESS relevance	Due diligence / Actions
	Yes	**No**	**N/A**		
Is there any territorial dispute between two or more countries in the subproject and its ancillary aspects and related activities?				*OP7.60 Projects in Disputed Areas*	Governments concerned agree
Will the subproject and related activities involve the use or potential pollution of, or be in international waterways[87]?				*OP7.50 Projects on International Waterways*	Notification (or exceptions)

Conclusions:

1. **Proposed Environmental and Social Risk Ratings (High, Substantial, Moderate or Low). Provide Justifications.**
2. **Proposed E&S Management Plans/ Instruments.**

[87] International waterways include any river, canal, lake or similar body of water that forms a boundary between, or any river or surface water that flows through two or more states.

Annex 2. Guidance for E&S Screening and Risk Rating for a COVID-19 Response Project

INFECTION CONTROL: CONSIDERATIONS AND TOOLS TO ASSIST IN E&S SCREENING AND RISK RATING:

In the context of global COVID-19 outbreak, many countries have adopted a containment strategy that includes extensive testing, quarantine, isolation and treatment either in a medical facility or at home.

A COVID-19 response project may include the following activities:

- construction of and/or operational support to medical laboratories, quarantine and isolation centers at multiple locations and in different forms, and infection treatment centers in existing healthcare facilities;
- procurement and delivery of medical supplies, vaccines, equipment and materials, such as reagents, chemicals, and Personal Protective Equipment (PPEs);
- mass deployment of a safe and effective vaccine
- transportation of potentially infected specimens from healthcare facilities to testing laboratories;
- construction, expansion or enhancing healthcare waste and wastewater facilities;
- training of medical workers and volunteers; and
- community engagement and communication.

1. Screening E&S Risks of Medical laboratories

Many COVID-19 projects include capacity building and operational support to existing medical laboratories. It is important that such laboratories have in place procedures relevant to appropriate biosafety practices. WHO advises that non-propagative diagnostic work can be conducted in a Biosafety Level 2 (BSL-2) laboratory, while propagative work should be conducted at a BSL-3 laboratory? Patient specimens should be transported as Category B infectious substance (UN3373), while viral cultures or isolates should be transported as Category A "Infectious substance, affecting humans" (UN2814).The process for assessing the biosafety level of a medical laboratory (including management of the laboratory operations and the transportation of specimens) should consider both biosafety and general safety risks. OHS of workers in the laboratory and potential community exposure to the virus should be considered.

The following documents provide further guidance on screening of the E&S risks associated with a medical laboratory. They also provide information for assessing and managing the risks.

- WHO; Prioritized Laboratory Testing Strategy According to 4Cs Transmission Scenarios
- WHO Covid-19 Technical Guidance: Laboratory testing for 2019-nCoV in humans
- WHO Laboratory Biosafety Manual, 3rd edition
- USCDC, EPA, DOT, *et al*; Managing Solid Waste Contaminated with a Category A Infectious Substance (August 2019).

2. Screening E&S Risks of Quarantine and Isolation Centers

According to WHO:

- **Quarantine** is the restriction of activities of or the separation of persons *who are not ill but who may have been exposed to* an infectious agent or disease, with the objective of monitoring their symptoms and ensuring the early detection of cases.
- **Isolation** is the separation of *ill or infected persons* from others to prevent the spread of infection or contamination.

Many COVID-19 projects include construction, renovation and equipping of quarantine and isolation centers at Point of Entry (POE), in urban and in remote areas. There may also be circumstances where tents are used for quarantine or isolation. Public or private facilities such as a stadium or hotel may also be acquired for this purpose.

In screening for E&S risks associated with quarantine and isolation, the following may be considered:

- contextual risks such as conflicts and presence or influx of refugees;
- construction and decommissioning related risks;
- land or asset acquisition;
- use of security personnel or military forces;
- availability of minimum requirements of food, fuel, water, hygiene;
- whether infection prevention and control, and monitoring of quarantined persons can be carried out effectively; and
- whether adequate systems are in place for waste and wastewater management.

- provision of accurate information to ill, infected or exposed persons in a simple, accessible and culturally appropriate manner

The following documents provide further guidance regarding quarantine of persons.

- WHO; Considerations for quarantine of individuals in the context of containment for coronavirus disease (COVID-19)
- WHO; Key considerations for repatriation and quarantine of travelers in relation to the outbreak of novel coronavirus 2019-nCoV
- WHO; Preparedness, prevention and control of coronavirus disease (COVID-19) for refugees and migrants in non-camp settings.

3. Screening E&S Risks of Treatment Centers and for Deployment of Vaccines

WHO has published a manual that provides recommendations, technical guidance, standards and minimum requirements for setting up and operating severe acute respiratory infection (SARI) treatment centers in low- and middle-income countries and limited-resource settings, including the standards needed to repurpose an existing building into a SARI treatment center, and specifically for acute respiratory infections that have the potential for rapid spread and may cause epidemics or pandemics.

- WHO Severe Acute Respiratory Infections Treatment Centre
- WHO Covid-19 Technical Guidance: Infection prevention and control / WASH
- WBG EHS Guidelines for Healthcare Facilities.

- WHO: Diagnostics, therapeutics, vaccine readiness, and other health products for COVID-19
-

4. Screening E&S Risks Relating to Labor and Working Conditions

A COVID-19 project may include different types of workers. In addition to regular medical workers and laboratory workers who would normally be classified as direct workers, the project may include contracted workers to carry out construction and community workers or community volunteers) to provide clinical support, contact tracing, and data collection, and other support or work that they wish to volunteer. The size of the workforce engaged could be considerable. Risks for such a workforce will range from occupational health and safety to types of contracts and terms and conditions of employment. Further details relevant to labor and working conditions for COVID-19 projects are discussed in the LMP template for COVID-19.

Annex 3. Environmental and Social Management Plan (ESMP) Template

Introduction

The Borrower will need to develop an Environmental and Social Management Plan (ESMP), setting out how the environmental and social risks and impacts will be managed through the project lifecycle. This ESMP template includes several matrices identifying key risks and setting out suggested E&S mitigation measures. The Borrower can use the matrices to assist in identifying risks and possible mitigations.

The ESMP should also include other key elements relevant to delivery of the project, such as institutional arrangements, plans for capacity building and training plan, and background information. The Borrower may incorporate relevant sections of the ESMF into the ESMP, with necessary updates.

The matrices illustrate the importance of considering lifecycle management of E&S risks, including during the different phases of the project identified in the ESMF: planning and design, construction, operations and decommissioning.

The issues and risks identified in the matrix are based on current COVID-19 response and experience of other Bank financed healthcare sector projects. The Borrower should review and add to them during the environmental and social assessment of a subproject.

The WBG EHS Guidelines, WHO technical guidance documents and other GIIPs set out in detail many mitigation measures and good practices and can be used by the Borrower to develop the ESMP. Proper stakeholder engagement should be conducted in determining the mitigation measures, including close involvement of medical and healthcare waste management professionals.

The Infection Control and Waste Management Plan forms part of the ESMP. The ESMP should identify other specific E&S management tools/instruments, such as the Stakeholder Engagement Plan (SEP), labor management procedures (LMP), and/or Medical Waste Management Plan.

Table 1.
Environmental and Social Risks and Mitigation Measures during Planning and Design Stage

Key Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
Identify the type, location and scale of healthcare facilities (HCF) or facilities to be used for deployment of vaccines					
Identify the need for new construction, expansion, upgrading and/or rehabilitation					
Identify the needs for ancillary works and associated facilities, such as access roads, construction materials, supplies of water and power, sewage system					
Identify the needs for acquisition of land and assets (e.g. acquiring existing assets such as hostel, stadium to hold potential patients)					

Identify onsite and offsite waste management facilities, and waste transportation routes and service providers	Inadequate facilities and processes for treatment of waste	• Estimate potential waste streams including sharps and vaccine program wastes • Consider the capacity of existing facilities, and plan to increase capacity, if necessary, through construction, expansion etc. • Specify that the design of the facility considers the collection, segregation, transport and treatment of the anticipated volumes and types of healthcare wastes • Require that receptacles for waste should be sized appropriately for the waste volumes generated, and color coded and labeled according to the types of waste to be deposited. • Develop appropriate protocols for the collection of waste and transportation to storage/disposal areas in accordance with WHO guidance. Design training for staff in the segregation of wastes at the time of use.			
Identify needs for transboundary movement of samples, vaccines, specimen, reagent, and other hazardous materials					
Identify needs for workforce and type of project workers		• Identify numbers and types of workers • Consider accommodation and measures to minimize cross infection • Use the COVID-19 LMP template to identify possible mitigation measures			

Identify needs for using security personnel during construction and/or operation of HCF		• Describe protocols for selection and use • Include a Code of Conduct on use of appropriate force and SEA/SH • Provide training prior to deployment • Include a communications strategy in stakeholder engagement activities • Update the project GRM procedure to accommodate grievances related to involvement of security personnel under the project • Where the specific triggers for serious concern are present (see page 61) prepare a stand-alone security personnel management plan			
HCF design – general	• Structural safety risk; • Functional layout and engineering control for nosocomial infection				
HCF design - considerations for differentiated treatment for groups of higher sensitivity or vulnerable (the elderly, those with preexisting conditions, or the very young) and those with disabilities	Some groups may have difficulty accessing health facilities				

Design of facility should reflect specific treatment requirements, including triage, isolation or quarantine		• The design, set up and management of will take into account the advice provided by WHO guidance for Severe Acute Respiratory Infections Treatment Center. • Hand washing facilities should be provided at the entrances to health care facilities in line with WHO Recommendations to Member States to Improve Hygiene Practices. • Isolation rooms should be provided and used at medical facilities for patients with possible or confirmed COVID-19. • Isolation rooms should: ➢ be single rooms with attached bathrooms (or with a dedicated commode); ➢ ideally be under negative pressure (neutral pressure may be used, but positive pressure rooms should be avoided); ➢ be sited away from busy areas or close to vulnerable or high-risk patients, to minimize chances of infection spread; ➢ have dedicated equipment (for example blood pressure machine, peak flow meter and stethoscope ➢ have signs on doors to control entry to the room, with the door kept closed; ➢ have an ante-room for staff to put on and take off PPE and to			

		wash/decontaminate before and after providing treatment.			
Design to consider mortuary arrangements	Insufficient capacity Spread of infection	• Include adequate mortuary arrangements in the design • See WHO Infection Prevention and Control for the safe management of a dead body in the context of COVID-19)			
Identify the needs for an effective communication campaign on vaccination, including tailored outreach to different groups (including disadvantaged or vulnerable groups), with different partners					
Assess the capacity of the Borrower to establish effective vaccine cold chain temperature monitoring	Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease	➢ Support the Borrower to design and establish or improve vaccine cold chain temperature monitoring plan. ➢ See WHO guidance on temperature monitoring[88] and CDC Vaccine storage and Handling toolkit[89]			

[88] https://apps.who.int/iris/bitstream/handle/10665/183583/WHO_IVB_15.04_eng.pdf;jsessionid=9F079AFFA760DBD35C08B13930268B01?sequence=1

[89] https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

Assess the capacity of the Borrower to monitor adverse events following immunization (AEFI) in line with WHO guidelines	Insufficient capacity for ensuring immunization safety through detecting, reporting, investigating and responding to AEFI.	➢ Support the Borrower to design and establish or improve surveillance system of AEFI. ➢ See WHO Global manual of surveillance of adverse events following immunization[90].			

[90] https://www.who.int/vaccine_safety/publications/Global_Manual_revised_12102015.pdf?ua=1

Table 2.
Environmental and Social Risks and Mitigation Measures during Construction Stage

Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
Clearing of vegetation and trees; Construction activities near ecologically sensitive areas/spots	- Impacts on natural habitats, ecological resources and biodiversity				
General construction activities Foundation excavation; borehole digging	- Impacts on soils and groundwater; - Geological risks				
General construction activities	- Resource efficiency issues, including raw materials, water and energy use; - Materials supply				
General construction activities – general pollution management	- Construction solid waste; - Construction wastewater; - Nosie; - Vibration; - Dust;				

Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
	- Air emissions from construction equipment				
General construction activities – hazardous waste management	- Fuel, oils, lubricant				
General construction activities – Labor issues	- Workers coming from infected areas - Co-workers becoming infected - Workers introducing infection into community/general public	- Refer to COVID-19 LMP - Consider ways to minimize/control movement in and out of construction areas/site. - If workers are accommodated on site require them to minimize contact with people outside the construction area/site or prohibit them from leaving the area/site for the duration of their contract - Implement procedures to confirm workers are fit for work before they start work, paying special to workers with underlying health issues or who may be otherwise at risk - Check and record temperatures of workers and other people entering the construction area/site or require self-reporting prior to or on entering - Provide daily briefings to workers prior to commencing work, focusing on COVID-19 specific considerations including cough etiquette, hand hygiene and distancing measures. - Require workers to self-monitor for possible symptoms (fever, cough) and to			

Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
		report to their supervisor if they have symptoms or are feeling unwell - Prevent a worker from an affected area or who has been in contact with an infected person from entering the construction area/site for 14 days Preventing a sick worker from entering the construction area/site, referring them to local health facilities if necessary or requiring them to isolate at home for 14 days			
General construction activities – Occupational Health and Safety (OHS)					
General construction activities – traffic and road safety					
General construction activities – security personnel		• Describe protocols for selection/ use • Include a Code of Conduct on use of appropriate force and SEA/SH • Provide training prior to deployment • Include a communications strategy • Update the project GRM procedure to accommodate grievances related to involvement of security personnel • Where the specific triggers for serious concern are present (see page 61) prepare a stand-alone security personnel management plan			

Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
General construction activities – land and asset	Acquisition of land and assets				
General construction activities	GBV/SEA issues				
General construction activities – cultural heritage	Cultural heritage	Chance-finds procedure			
General construction activities – emergency preparedness and response					
Construction activities related to onsite waste management facilities, including temporary storage, incinerator, sewerage system and wastewater treatment works					
Construction activities related to demolition of existing structures or facilities (if needed)					
To be expanded					

Table 3.
Environmental and Social Risks and Mitigation Measures during Operational Stage

Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
General HCF operation – Environment	General wastes, wastewater and air emissions				
General HCF operation – OHS issues	- Physical hazards; - Electrical and explosive hazards; - Fire; - Chemical use; - Ergonomic hazard; - Radioactive hazard				
HCF operation – Labor issue					
HCF operation - considerations for differentiated treatment for groups with different needs (e.g. the elderly, those with preexisting conditions, the very young, people with disabilities)					

Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
HCF operation – cleaning		● Provide cleaning staff with adequate cleaning equipment, materials and disinfectant. ● Review general cleaning systems, training cleaning staff on appropriate cleaning procedures and appropriate frequency in high use or high-risk areas. ● Where cleaners will be required to clean areas that have been or are suspected to have been contaminated with COVID-19, provide appropriate PPE: gowns or aprons, gloves, eye protection (masks, goggles or face screens) and boots or closed work shoes. If appropriate PPE is not available, provide best available alternatives. ● Train cleaners in proper hygiene (including handwashing) prior to, during and after conducting cleaning activities; how to safely use PPE (where required); in waste control (including for used PPE and cleaning materials).			
HCF operation - Infection control and waste management plan					
Mass vaccination program involving deployment of vaccines from many facilities (not just HCF), vehicles and locations	Mass vaccination provides a vector for the spread of disease	Develop infection control and waste management plan for vaccination program to consider the use of non-HCF for deployment			

Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
Waste minimization, reuse and recycling	Use of incinerators results in emission of dioxins, furans and particulate matter	▯ Where possible avoid the use of incinerators. ▯ If small-scale incineration is the only option, this should be done using best practices, and plans should be in place to transition to alternative treatment as soon as practicable (such as steam treatment prior to disposal with sterile/non-infectious shredded waste and disposed of in suitable waste facilities). ▯ Do not use single-chamber, drum and brick incinerators. ▯ If small-scale incinerators are used, adopt best practices to minimize operational impacts.			
Delivery and storage of specimen, samples, reagents, pharmaceuticals and medical supplies					
Storage and handling of specimen, samples, reagents, and infectious materials					
Procurement, delivery and set up of equipment for the storage and handling of vaccines and associated medical equipment	Surfaces of imported materials may be contaminated and handling and processing	Technical specifications for procuring equipment should require good hygiene practices in line with WHO technical guidance to be observed when preparing the procured goods.			

Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
	may result in spread of COVID-19	Check national and WHO technical guidance for latest information regarding transmission of COVID on packaging prior to finalization of working protocols at facilities receiving procured goods and update working methods as necessary.			
Transport of goods or supplies, including the delivery, storage and handling of vaccine, specimen, samples, reagents, pharmaceuticals and medical supplies	COVID-19 is spread by drivers during the transport and distribution of goods or supplies. Traffic accidents occur during transportation of goods	Good hygiene and cleaning protocols should be applied. During the transport, truck drivers should be required to wash hands frequently and /or be provided with hand sanitizer, and taught how to use it. Measures to minimize impacts during transportation, including hazardous materials can be found in the EHSGs.			
Waste segregation, packaging, color coding and labeling					
Onsite collection and transport					
Waste storage					
Onsite waste treatment and disposal					
Waste transportation to and disposal in offsite					

Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
treatment and disposal facilities					
Transportation and disposal at offsite waste management facilities					
HCF operation – transboundary movement of specimen, vaccine, samples, reagents, medical equipment, and infectious or hazardous materials					
Operation of acquired assets for holding potential COVID-19 patients					
Emergency events	- Spillage; - Occupational exposure to infectious disease; - Exposure to radiation; - Accidental releases of infectious or hazardous substances to the environment;	Emergency Response Plan			

Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
	- Medical equipment failure; - Failure of solid waste and wastewater treatment facilities - Fire; - Other emergent events				
Mortuary arrangements	- Arrangements are insufficient - Processes are insufficient	Implement good infection control practices (see WHO Infection Prevention and Control for the safe management of a dead body in the context of COVID-19) Use mortuaries and body bags, together with appropriate safeguards during funerals (see WHO Practical considerations and recommendations for religious leaders and faith-based communities in the context of COVID-19)			
	-				
Vaccination campaign - considerations for communication and outreach for	-				

Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
disadvantaged or vulnerable groups					
Stakeholder engagement – considerations for simple, accurate, accessible and culturally appropriate information dissemination; combating misinformation; responding to grievances	-				
Targeting of beneficiaries is not done in a fair, equitable and inclusive manner	- Lack of transparency about the vaccination program	Outreach/communication tools to make potential beneficiaries aware of the eligibility criteria, principles and methods used for targeting Ensure project includes a functional Grievance Mechanism			
	- Poorest / most needy households are left out	See above. Clear, transparent and unambiguous eligibility criteria Use good quality Government data combined with geographical targeting - Use local community structures to identify and select beneficiaries, based on inclusive consultations			

Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
	- Lack of diversity and inclusion in vaccination program, resulting in inadequate benefits for other vulnerable groups	Ensure women participate in the program and, where possible, give preference to women within households as transferees Work with community representatives/NGOs so that vulnerable groups such as unaccompanied children, youth, Sexual Exploitation and Abuse/Sexual Harassment (SEA/SH) survivors, Indigenous Peoples, LGBTI communities, refugees, internally displaced peoples, etc. are included in project activities and benefits			
	- SEA/SH increase in project area (e.g. requests for sexual favors to receive vaccinations)	Consultations to discuss process for identifying vaccination prioritization Grievance Mechanism (GM) to be established as soon as possible to handle complaints Provide information to potential beneficiaries on eligibility criteria and GM process via various media (radio, SMS, television, online, posters) Work with local NGOs to provide social services for affected beneficiaries, as well as assistance to register			

Table 4.
Environmental and Social Risks and Mitigation Measures during Decommissioning

Key Activities	Potential E&S Risks and Impacts	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
Decommissioning of interim HCF					
Decommissioning of medical equipment					
Regular decommissioning					
To be expanded					

Annex 4. Infection Control and Waste Management Plan (ICWMP) Template

The project-level ICWMP covers environmental and social infections control measures and procedures for the safe handling, storage, and processing of COVID-19 waste materials in order to prevent, minimize, and control environmental and social impacts during the operation of project-supported HCUs and ICUs. The project-level ICWMP provides instructions on the development of site specific ICWMPs for HCUs and ICUs involved in the project. It also contains detailed instructions on how to manage various types of waste resulted from COVID-19 pandemics. The template for site specific ICWMP contains the following information:

1. Introduction

1.1 Describe the project context and components;

1.2 Describe the targeted healthcare facility (HCF):

- Type: E.g. general hospital, clinics, inpatient/outpatient facility, medical laboratory, quarantine or isolation centers;
- *Special type of HCF in response to COVID-19: E.g. existing assets may be acquired to hold yet-to-confirm cases for medical observation or isolation;*
- Functions and requirement for the level infection control, e.g. biosafety levels;
- Location and associated facilities, including access, water supply, power supply;
- Capacity: beds;

1.3 Describe the design requirements of the HCF, which may include specifications for general design and safety, separation of wards, heating, ventilation and air conditioning (HVAC), autoclave, and waste management facilities.

2. Infection Control and Waste Management

2.1 Overview of infection control and waste management in the HCF:

- Type, source and volume of healthcare waste (HCW) generated in the HCF, including solid, liquid and air emissions (if significant);
- Classify and quantify the HCW (infectious waste, pathological waste, sharps, liquid and non-hazardous) following WBG EHS Guidelines for Healthcare Facilities and pertaining GIIP;
- *Given the infectious nature of the novel coronavirus, some wastes that are traditionally classified as non-hazardous may be considered hazardous. It's likely the volume of waste will increase considerably given the number of admitted patients during COVID-19 outbreak. Special attention should be given to the identification, classification and quantification of the healthcare wastes;*
- Describe the healthcare waste management system in the HCF, including material delivery, waste generation, handling, disinfection and sterilization, collection, storage, transport, and disposal and treatment works;
- Provide a flow chart of waste streams in the HCF if available;
- Describe applicable performance levels and/or standards; and
- Describe institutional arrangement, roles and responsibilities in the HCF for infection control and waste management.

2.2 Management Measures

- Waste minimization, reuse and recycling: HCF should consider practices and procedures to minimize waste generation, without sacrificing patient hygiene and safety considerations.
- Delivery and storage of specimen, samples, reagents, pharmaceuticals and medical supplies: HCF should adopt practice and procedures to minimize risks associated with delivering, receiving and storage of hazardous medical goods.
- Waste segregation, packaging, color coding and labeling: HCF should strictly conduct waste segregation at the point of generation. Internationally adopted method for packaging, color coding and labeling the wastes should be followed.
- Onsite collection and transport: HCF should adopt practices and procedures to timely remove properly packaged and labelled wastes using designated trolleys/carts and routes. Disinfection of pertaining tools and spaces should be routinely conducted. Hygiene and safety of involved supporting medical workers such as cleaners should be ensured.
- Waste storage: an HCF should have multiple waste storage areas designed for different types of wastes. Their functions and sizes are determined at design stage. Proper maintenance and disinfection of the storage areas should be carried out. Existing reports suggest that during the COVID-19 outbreak, infectious wastes should be removed from HCF's storage area for disposal within 24 hours.
- Onsite waste treatment and disposal (e.g. an incinerator): Many HCFs have their own waste incineration facilities installed onsite. Due diligence of an existing incinerator should be conducted to examine its technical adequacy, process capacity, performance record, and operator's capacity. In case any gaps are discovered, corrective measures should be recommended. For new HCF financed by the project, waste disposal facilities should be integrated into the overall design and ESIA developed. Good design, operational practices and internationally adopted emission standards for healthcare waste incinerators can be found in pertaining EHS Guidelines and GIIP.
- Transportation and disposal at offsite waste management facilities: Not all HCF has adequate or well-performed incinerator onsite. Not all healthcare wastes are suitable for incineration. An onsite incinerator produces residuals after incineration. Hence offsite waste disposal facilities provided by local government or the private sector are probably needed. These offsite waste management facilities may include incinerators, hazardous wastes landfill. In the same vein, due diligence of such external waste management facilities should be conducted to examine its technical adequacy, process capacity, performance record, and operator's capacity. In case any gaps are discovered, corrective measures should be recommended and agreed with the government or the private sector operators.
- Wastewater treatment: HCF wastewater is related to hazardous waste management practices. Proper waste segregation and handling as discussed above should be conducted to minimize entry of solid waste into the wastewater stream. In case wastewater is discharged into municipal sewer sewerage system, the HCF should ensure that wastewater effluent comply with all applicable permits and standards, and the municipal wastewater treatment plant (WWTP) is capable of handling the type of effluent discharged. In cases where municipal sewage system is not in place, HCF should build and properly operate onsite primary and secondary wastewater treatment works, including disinfection. Residuals of the onsite wastewater treatment works, such as sludge, should be properly disposed of as well. There're also cases

where HCF wastewater is transported by trucks to a municipal wastewater treatment plant for treatment. Requirements on safe transportation, due diligence of WWTP in terms of its capacity and performance should be conducted.

More information on health care waste management in the Republic of Moldova is available in Annex 8.

3. Emergency Preparedness and Response

Emergency incidents occurring in a HCF may include spillage, occupational exposure to infectious materials or radiation, accidental releases of infectious or hazardous substances to the environment, medical equipment failure, failure of solid waste and wastewater treatment facilities, and fire. These emergency events are likely to seriously affect medical workers, communities, the HCF's operation and the environment.

Thus, an Emergency Response Plan (ERP) that is commensurate with the risk levels is recommended to be developed. The key elements of an ERP are defined in ESS 4 Community Health and Safety (para. 21).

4. Institutional Arrangement and Capacity Building

A clearly defined institutional arrangement, roles and responsibilities should be included. A training plan with recurring training programs should be developed. The following aspects are recommended:

- Define roles and responsibilities along each link of the chain along the cradle-to-crave infection control and waste management process;
- Ensure adequate and qualified staff are in place, including those in charge of infection control and biosafety and waste management facility operation;
- Stress the chief of a HCF takes overall responsibility for infection control and waste management;
- Involve all relevant departments in a HCF, and build an intra-departmental team to manage, coordinate and regularly review issues and performance;
- Establish an information management system to track and record the waste streams in HCF; and
- Capacity building and training should involve medical workers, waste management workers and cleaners. Third-party waste management service providers should be provided with relevant training as well.

5. Monitoring and Reporting

Many HCFs in developing countries face the challenge of inadequate monitoring and records of healthcare waste streams. HCF should establish an information management system to track and record the waste streams from the point of generation, segregation, packaging, temporary storage, transport carts/vehicles, to treatment facilities. The HCF is encouraged to develop an IT based information management system should their technical and financial capacity allow.

As discussed above, the HCF chief takes overall responsibility, leads an intra-departmental team and regularly reviews issues and performance of the infection control and waste management practices in the HCF. Internal reporting and filing systems should be in place.

Externally, reporting should be conducted per government and World Bank requirements.

Table ICWMP

Activities	Potential E&S Issues and Risks	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
General HCF operation – Environment	General wastes, wastewater and air emissions				
General HCF operation – OHS issues	- Physical hazards; - Electrical and explosive hazards; - Fire; - Chemical use; - Ergonomic hazard; - Radioactive hazard.				
HCF operation - Infection control and waste management plan					
Waste minimization, reuse and recycling					
Delivery and storage of specimen, samples, reagents, pharmaceuticals and medical supplies					
Storage and handling of specimen, samples, reagents,					

Activities	Potential E&S Issues and Risks	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
and infectious materials					
Waste segregation, packaging, color coding and labeling					
Onsite collection and transport					
Waste storage					
Onsite waste treatment and disposal					
Waste transportation to and disposal in offsite treatment and disposal facilities					
HCF operation – transboundary movement of specimen, samples, reagents, medical equipment, and infectious materials					
Emergency events	- Spillage; - Occupational exposure to infectious; - Exposure to radiation;	Emergency response plan			

Activities	Potential E&S Issues and Risks	Proposed Mitigation Measures	Responsibilities	Timeline	Budget (source)
	- Accidental releases of infectious or hazardous substances to the environment; - Medical equipment failure; - Failure of solid waste and wastewater treatment facilities; - Fire; - Other emergent events.				
Operation of acquired assets for holding potential COVID-19 patients					
To be expanded					

Annex 5. Field Environmental and Social Monitoring Checklist

Site location (name of healthcare facility and its address)					
Name of civil works contractor					
Name of PIU monitor visiting the site					
Date of site visit					
Status of civil works (briefly describe types of works underway in the report period)					
Number of contracted workers on site during the report period					
Number of workers grievances received in reporting period / number of open workers grievances at the moment /number of workers closed grievances at the moment					
Number of community grievances received in reporting period/number of open community grievances at the moment/number of closed community grievances at the moment					
Documents and activities to be examined	Status				Comments
	Yes	Partly	No	N/A	
Contractor holds license for extraction of natural construction materials					
Contractor holds permit for operating concrete/asphalt plant					
Contractor holds agreement for final disposal of construction waste					`
Contractor holds agreement with service provider for removal of household waste from site					
Work site is fenced, and adequate warning signs installed					
Works do not impede pedestrian access and motor traffic, or temporary alternative access is provided					
Working hours are observed					
Works to not disrupt or cause nuisance to operation of the healthcare facility within which they are undertaken					
Construction machinery and equipment is in standard technical condition (no excessive exhaust and noise, no leakage of fuels and lubricants)					

Construction materials and waste are transported under the covered hood					
Adequate dust control measures are applied					
Contractor's camp or work base is fenced; sites for temporary storage of waste and for vehicle/equipment servicing are designated					
Contractor's camp is supplied with water and sanitation is provided					
Contractor's camp or work base is equipped with first medical aid and fire-fighting kits					
Workers wear uniforms and protective gear adequate for technological processes (gloves, helmets, respirators, eyeglasses, etc.)					
Construction waste is being disposed exclusively in the designated locations					
Upon completion of physical activity on site, the site and contractor's camp/base cleared of any remaining left-over from works and harmonized with surrounding landscape					
All contracted workers have an employment contract or engagement agreement in writing					
All contracted workers are paid at least once a month					
No contracted workers worked over 8 hours a day, 40 hours a week without an overtime pay					
All contracted workers had a regular daily and weekly rest					
OHS-related training program conducted for contracted workers within the report period.					
Contracted workers involved in accidents at work resulting in injuries or fatalities.					
Contracted workers reported on cases of discrimination, harassment, sexual harassment or non-compliance with law					

Annex 6. Grievance Redress Mechanism Template

Grievance Redress Mechanism Template

Designation (entered by the contractor/HCF)	
First name and Surname (not obligatory) *Please indicate with an X* [...] I would like to lodge a complaint anonymously […] Please do not disclose my identity without my consent	
Contact data Signify the desired manner of contact (by mail, phone, email)	[…] By mail: *Provide an address for mail delivery.* _____ _____ […] By phone: _____ […] By email: _____
Description of event to which the complaint relates	What occurred? Where did it happen? To which person did it happen? What came out as a consequence of the problem?
Date of the event/complaint	
	[…] Event that occurred once/complaint (date _____) […] It occurred more than once (how many times? _____) […] Ongoing (a problem that currently exists)
What would you want to be undertaken?	

Signature: _____ Date: _____

Annex 7. Medical waste management in the Republic of Moldova

1. Collection of dangerous medical waste

Medical waste and household waste, generated by medical institutions in the process of diagnosis and treatment of patients with pneumonia and patients suspected of Covid-19, should be collected according to the classification of medical waste. In the Republic of Moldova, the classification of medical waste can be found in the annex to the Sanitary Regulation on the management of the resulting waste from medical activity. The collection of medical waste by categories minimizes the risk of infection and guarantees the safety of human health.

2. Packaging of dangerous medical waste

2.1 Specifics of packaging for dangerous medical waste

It is recommended that infectious medical waste be packaged in strict accordance with legal standards and provisions, using packaging bags, containers and warning symbols specific to medical waste and then placed in special packaging boxes or containers of single use. Hazardous waste resulting from medical activity is packaged and labeled in compliance with the conditions of the above mentioned Sanitary Regulation and in accordance with national legislation on classification, labeling and packaging of substances and mixtures and in accordance with international treaties to which the Republic of Moldova is a party. It should contain the following:

- degree of toxicity;
- full name of the waste;
- their state of aggregation;
- color, smell, flammable and explosive properties;
- type of packaging;
- the name of the technological process from which they resulted;
- special behavioral requirements in normal conditions and in exceptional situations;
- the address of the enterprise or organization where they were produced.

According to the Sanitary Regulation on the management of medical waste, the packaging in which the separate collection is made and which comes in direct contact with the hazardous waste resulting from the medical activity is for single use and is disposed of with the contents. Cutting-edge, anatomopathological and infectious waste, identified by codes 18 01 01, 18 01 02 and 18 01 03 * in the List of wastes and the Annex to this Sanitary Regulation shall be packed in yellow bags. For separate collection of non-sharp infectious waste, cardboard boxes provided with yellow polyethylene bags or yellow-marked polyethylene bags shall be used. Bags for the storage of hazardous / infectious medical waste must meet the following conditions:

a. be made of high density plastic with high mechanical strength;
b. close easily and securely;
c. the thickness of plastic from which the bag is made should be between 50-70μm,
d. the heat seals should be continuous, resistant and not allow liquid to leak.

When choosing the size of the bag, the amount of waste produced is taken into account in the interval between two successive waste disposals. The height of the bag for the storage of hazardous / infectious waste identified by code 18 01 03 * in the List of wastes and the Annex to the sanitary regulations in question must exceed the height of the bin, so that the part of the bag passing over its upper edge can allow the bag to be closed and transported safely. The degree of filling of the bag for the storage of hazardous / infectious waste must not exceed three quarters of its volume. For the packaging of waste resulting from medical activity is prohibited the use of other categories of packaging that do not present documents confirming the suitability of the product for use (certificates, reports), including the chemical composition of the material from which the packaging is made in accordance with Law no. 209 of July 29, 2016 and the Sanitary Regulations. Therefore, it is allowed only the use of packaging that meets the requirements of art. 55 para. (3) of Law no.09 of July 29, 2016 on waste and the sanitary regulation.

2.2 Labelling of packaging for dangerous medical waste

Both the boxes provided inside with polyethylene bags and the bags in question are to be marked and labeled in Romanian with the following information:

- the category of waste collected;
- the “Biological hazard” icon;
- capacity of the container (l or kg);
- how to use it;
- the marking line of the maximum filling level;
- the date of starting the use of the container in the section / subdivision;
- the name of the institution and the section / subdivision that used the container;
- the person responsible for their management / use;
- date of final filling.

When the bag is not placed in a cardboard box to ensure mechanical strength, for the storage of hazardous / infectious waste identified by code 18 01 03 * in the List of wastes and the annex to the Sanitary Regulation, the bag must be placed in the bin with lid and pedal or in bag holder, equipped with lid. The bins, also fitted with a pedal and lid, must be marked with the "Biological hazard" icon.

2.3 Temporary storage of dangerous medical waste

In each medical institution is organized a central space for temporary storage of waste resulting from medical activity. Hazardous waste produced in the subdivisions of medical institutions, prior to transportation to the central temporary storage space, may be placed in a space intended for storing cleaning equipment / dirty linen.

2.3.1 Properties of containers for storage of dangerous medical waste

Temporary storage of infectious, stinging and pathological waste identified by code 18 01 01, 18 01 02, 10 01 03 * in the list of wastes and in the Annex to the Sanitary Regulation takes place in mobile containers with rigid walls. According to the law of the Republic of Moldova, mobile containers intended for the temporary storage of hazardous medical waste must be:

a) marked with yellow, on which the icon "Biological hazard" is fixed and inscribed with the specification "Pathological waste" (where relevant);
b) made of materials resistant to mechanical actions, easily washable and resistant to the action of disinfectant solutions;
c) secured, with the possibility of being sealed, provided with a fastening system adapted to the automatic collection system by the transport vehicle or adapted to the emptying system in the waste treatment installation;
d) the size of the containers ensures the taking over of the entire quantity of waste produced in the interval between two successive disposals. These containers do not contain unpackaged hazardous waste (bulk) or waste assimilated to municipal waste.

2.3.2 Timeline of temporary storage of dangerous medical waste

The duration of temporary storage of hazardous waste resulting from medical activity must be as short as possible, and during the temporary storage the hygiene rules in force must be observed. For sharp, anatomopathological and infectious waste identified by codes 18 01 01, 18 01 02 and 18 01 03 * in the list of wastes and in the Annex to the Sanitary Regulation, the duration of temporary storage in the medical institution shall not exceed 48 hours, except the situation in which the waste is stored in a location provided with a cooling system that constantly ensures a temperature of + 4ºC - + 8ºC, in which case the storage duration is a maximum of 7 days. Unlike the legal provisions of the Republic of Moldova, China's Guide to Medical Waste Management Caused by COVID-19 stipulates that medical and health institutions may implement temporary storage of infectious medical waste generated by coronavirus for a period not exceeding 24 hours. At the same time, the Guide stipulates the obligation to disinfect the storage space according to the method and frequency indicated by the competent health service, and the washing liquid from the storage space must be discharged into the medical disinfection and wastewater treatment system of medical and health institutions for treatment.

2.3.3 Characteristics of storage placement for dangerous medical waste

The temporary storage site must have an automatic temperature monitoring and recording system, which is checked periodically. Cardboard boxes intended for the collection of hazardous medical waste are to be stored temporarily on dry surfaces, protected from rainwater and must be transported without leakage. Requirements for the central storage space for temporary storage of medical waste include:

1. the floor with a surface resistant to mechanical action, waterproof, smooth and intact, easy to sanitize;
2. adequate drainage system / floor drain for the discharge into the sewerage network of wastewater resulting from sanitation. In the absence of the floor siphon, the sanitation is performed with minimal amounts of water, with disposable cleaning utilities, considered, in the end, infectious waste;
3. conditions restricting the access of insects, rodents, animals and birds;
4. screens for protection from the action of the sun's rays;
5. water supply source;
6. appropriate lighting systems and ventilation installations (at least passive ventilation) to ensure optimum temperatures (prevention of decomposition of organic matter, accidents caused by other hazardous waste);
7. controlled access for authorized personnel;
8. access for units / vehicles that ensure the transport / disposal of waste;
9. conditions for hand hygiene and sanitation of containers for transporting waste and surfaces;
10. technological equipment, furniture, personal protective equipment, specific equipment for leak management,
11. quantities and assortment of sanitary and disinfection products required;
12. autonomous signaling and fire-fighting systems.

It is forbidden to operate the central storage facilities for temporary storage of waste resulting from medical activity on sites located outside medical institutions, or which do not belong to economic operators who carry out operations of treatment or disposal of waste resulting from medical activity.

2.4 Transportation of dangerous medical waste

The transportation of waste resulting from medical activity, including hazardous waste, to the place of treatment or disposal is carried out in compliance with the provisions on environmental protection and public health stipulated in Article 4 of Law no. 209 of July 29, 2016 on waste.

2.4.1 Transportation of dangerous medical waste inside the sanitary-medical institutions

The transport of hazardous waste inside medical institutions is carried out on a separate circuit from that of patients and visitors. Hazardous and non-hazardous waste is transported separately. The waste resulting from the medical activity is transported inside the medical-sanitary institution

with the help of special carts and mobile containers. Mobile trolleys and containers used in medical institutions are cleaned and disinfected after each use, in the place where they are unloaded, using biocidal products registered in the Republic of Moldova.

2.4.2 Transportation of dangerous medical waste outside the sanitary-medical institutions

Hazardous and non-hazardous waste from medical activity is handed over by the producing institution to the authorized economic operators, in accordance with art. 25 of Law no. 209 of July 29, 2016 on waste by the authorities empowered by art. 24 of the mentioned law on the basis of a contract. In the situation where a medical institution is located in several buildings situated in different places, the transportation of waste resulting from medical activity is done through economic operators providing services, contracted by the medical institution. The transport of hazardous waste, resulting from medical activity, on public roads to the place of treatment or disposal and their transfer for final disposal abroad, is carried out in accordance with the requirements established in art. 44 and 64 of Law no. 209 of July 29, 2016 on Waste, the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), to which the Republic of Moldova acceded by Parliament Decision no. 44-XIV of 4 June 1998, and the Regulation on Road Transport of Dangerous Goods, approved by Government Decision no. 589 of July 24, 2017.

From the above, we can emphasize that the rules for the transport of hazardous / infectious waste are of a general nature. However, given that the situation created by the spread of coronavirus is a specific one, these rules need to be adapted to the new conditions in order to increase their efficiency. If we refer to China's Guide to Medical Waste Management Caused by COVID-19, we see that transportation rules are much stricter and more complex. Thus, it stipulates that for the transport of infectious medical waste generated in the process of prevention and control of COVID-2019, vehicles specially designed only for the given category of waste will be used. In the process of medical waste transfer, the electronic transfer form can be used depending on the real local situation. Prior to the transfer, the route and requirements for the transfer are established. Transport routes should avoid densely populated areas as much as possible, and rush hours should be avoided for transport. Medical waste must be transferred to disposal facilities within 48 hours. Transport vehicles shall be disinfected in accordance with the method and frequency indicated by the competent health service after each unloading.

2.5 Elimination of dangerous medical waste

The processes and methods used for the treatment and disposal of waste resulting from medical activity must not endanger public health and the environment and must comply with the following requirements:

a. They must not present a danger to water, air, soil, fauna or vegetation;

b. does not have a negative impact on the health of the population in the neighboring residential areas;
c. does not produce noise pollution and unpleasant odor; d. does not affect landscapes or protected areas. When choosing the treatment method, the type of waste, environmental and safety factors, technological capabilities and the provisions of Law no. 209 of July 29, 2016 on waste and of the present Sanitary Regulation on waste management resulting from medical activity are taken into account.

2.5.1 Treatment of infectious / dangerous medical waste depending on technological capacities of medical institution

The treatment of hazardous waste depending on the technological capacities of medical institutions can be:

a) outsourced treatment - by handing over, based on the service contract, to authorized economic operators, in accordance with art. 25 of Law no. 209 of July 29, 2016 on waste, by the authorities empowered by art. 24 of the mentioned law for the treatment of waste resulting from medical activity by types of waste. Exceptions are waste, the collection and disposal of which are subject to special measures for the prevention of infections identified by code 18 01 03 * in the Annex to the Sanitary Regulation, produced in microbiological laboratories and / or from patients with highly contagious communicable diseases, which require treatment at the source of generation.
b) Internal treatment - medical institutions equipped with waste shredding equipment and their own thermal decontamination installations, can treat the cutting-stinging and infectious waste identified with codes 18 01 01 and 18 01 03 * in the List of wastes and in the annexes of the Sanitary Regulations.

2.5.2 Specifics and methods of elimination of dangerous medical waste

For the treatment of cutting, stinging and infectious waste identified with codes 18 01 01 and 18 01 03 * in the List of wastes and in the annex to the Sanitary Regulation, autoclaves with the following activity principles are used: • Gravitational; • pre-vacuum or autoclave; • other advanced technologies. The validation of the autoclaving process of cutting-stinging and infectious waste is performed each time by applying chemical and periodic indicators (weekly or every 40 hours of use) biologically, but not limited to those listed. At the same time, the treatment of sharp-stinging and infectious waste ensures the reduction of the level of microbial inactivation. Chemical disinfection of infectious waste is allowed only for liquid waste (blood, urine, faeces and vomit, etc.).

2.6 Disposal of dangerous medical waste

The disposal of hazardous waste resulting from medical activity is carried out in accordance with the regulations specific to each category of waste, in accordance with the disposal operations stipulated in Annex no. 1 to Law no. 209 of July 29, 2016 on waste. The disposal methods used must ensure the rapid and complete destruction of factors potentially harmful to the environment and the health of the population.

2.6.1 Methods of disposal of dangerous medical waste

The legislation of the Republic of Moldova provides several ways of final disposal of hazardous / infectious waste, resulting from medical activity, depending on the category of waste:
a. Incineration - anatomopathological waste (fragments and human organs, including blood vessels and preserved blood); chemical wastes consisting of or containing dangerous substances; cytotoxic and cytostatic drugs.
Emissions to air and water from waste incineration plants resulting from medical activity shall not exceed the emission limit values established by environmental legislation and international treaties to which the Republic of Moldova is a party. Sedimentary residues from the cleaning of boilers, filters, ducts and chimneys of incineration plants, being very dangerous, need to be disposed of in special places intended for the burial of hazardous waste.
b. Storage - waste whose collection and disposal are subject to special measures to prevent infections; cutting waste. They are stored in the authorized hazardous waste landfill after mandatory treatment.

Annex 8. Order No. 1019 dated 05 November 2020 Regarding the functioning of the system for causality evaluation and classification of adverse events following immunization (AEFI)

Ministry of Health , Labor and Social Protection of the Republic of Moldova

For the purpose of evaluating the causality relation and classifying the adverse events following immunization (AEFI), to monitor and ensure the quality of vaccination products and immunization services, observing the recommendations of the World Health Organization and the provisions of the Guide on Supervision of Adverse Events Following Immunization, approved via the Order of the MHLSP No. 752 of 26 June 2019, based on the Regulation on Organization and Operation of the Ministry of Health , Labor and Social Protection, structure and limit-number of personnel in its central apparatus, approved via Government Decision No. 694 of 30 August 2017,

ORDER:

1. To approve:
   1) The list of adverse events following immunization, which are to be registered, investigated and reported according to Annex No. 1.
   2) The form for reporting adverse events following immunization (AEFI), according to Annex No. 2.
   3) The form for nominal record-keeping of adverse events following immunization (AEFI), according to Annex No. 3.
   4) The form for epidemiological inquiry of the AEFI, according to Annex No. 4.
   5) Nominal composition and the Regulation of the Commission for evaluation of causality and classification of AEFI, according to Annex No. 5.
2. The providers of primary healthcare, inpatient healthcare, emergency healthcare services, regardless of the type of ownership and legal organization form, the Head of the General Social and Health Assistance Division of Chisinau Municipality Council, Head of Health Service under Balti Mayoralty, Director of Health and Social Protection Division of ATU Gagauzia will organize and ensure:

   1) Identification of cases and clusters of AEFI, being guided by the list of adverse events following immunization, which are to be registered, investigated and reported (Annex No. 1), provision of medical assistance to patients with AEFI, nominal record-keeping of cases (annex No. 3), conclusions of the AEFI reporting form (Annex No. 2) and sending it to the territorial PHC.

   2) Submission to the MHLSP, not later than 24 hours (one working day), of an extraordinary report regarding the case (cases) of AEFI, being guided by the envisaged form (Annex No. 2) in the following cases of AEFI:

   - ✓ death;
   - ✓ group of cases;
   - ✓ petition (information) about a severe case of AEFI;
   - ✓ “notorious” AEFI case in the society (information present in mass-media, on social media).

3) Collection of relevant sample for lab investigation of AEFI cases.

4) Delegation of requested specialists and submission of necessary medical documentation for investigating AEFI cases.

3. The territorial subdivisions of the National Public Health Agency will organize and ensure the carrying out of all the activities envisaged in p. 4.1.2 of the Guide on Supervision of Adverse Events Following Immunization, approved via the Order of the MHLSP No. 752 of 26 June 2019.
4. The National Public Health Agency will organized at the national level and will ensure the carrying out of all activities envisaged in p. 4.1.3. of the Guide on Supervision of Adverse Events Following Immunization, approved via the Order of the MHLSP No. 752 of 26 June 2019 in collaboration with the Medicines and Medical Devices Agency.
5. The heads of the State University of Medicine and Pharmacy "Nicolae Testemitanu", PMSI Institute of Mother and Child, Medicines and Medical Devices Agency, Phtysiopneumology Institute "Chiril Draganiuc", health authorities from Bender and Tiraspol municipalities, will ensure the co-optation of specialists for activities within the Commission for evaluation of causality and classification of AEFI in line with the approved regulation.
6. Control over the enforcement of the present order shall be attribute to Marina Golovaci and Constantin Rimis, State Secretaries.

Minister

Viorica Dumbraveanu

Annex No. 1 to the Order of the MHLSP No. 1019 dated 05 November 2020

List of adverse events following immunization, which are to be registered, investigated and reported

No.	AEFI	Standard case definition	Interval of occurrence after vaccination	Vaccine
1	**2**	**3**	**4**	**5**
1.0	**Local reactions at the injection place or associated directly with injection place**			
1.1	Sterile abscess	Small formation at the injection place with fluctuant or drained content. Infiltration implies inflammation signs: - local hyperemia - edema - pain The abscess may be accompanied by increase of body temperature	0-7 days	All injectable vaccines
1.2	Bacteria abscess	Visible infection, lesion with fluctuations of soft tissues: pus, inflammation signs, fever, positive bacteria cultures or prevalence of neutrophils. The absence of one or more of these characteristics does not exclude the possibility of "bacteria abscess"	0-7 days	All injectable vaccines
1.3	Cold abscess	Formation with tumefaction aspect with/without change of skin color on it; painless when touched, fluctuations may be noted in the center; it is frequently accompanied by reactive increase of axillary lymph nodes. It is possible to open it spontaneously and excise it.	From 2 weeks to 8 months	BCG
1.4	Ulcer	Lesion of skin and subcutaneous adipose tissue. The size is 10 mm in diameter (edges are undermined, surrounding infiltration is poorly expresses, the base may be covered with pus secretion)	From 2 weeks to 6 months	BCG

1.5	Keloid scar	Elevated dense formation with a size from 10 mm of the scar; it is round, elliptic, sometimes stellate. Smooth, shiny surface. The color is from light pink to brownish. May be accompanied by an itching feeling, sting or possibly pain.	After 1 year	BCG
1.6	Post-injection infiltration and hyperemia	Hyperemia and edema, which get extended from the injection place and has one or more of the following characteristics: - edema is extended beyond the nearest joint - pain, redness and edema last for more than 3 days and induce patient's agitation; - needs hospitalization. Smaller intensity local reactions are considered to be ordinary, and usually pass within 3 days and should not be registered and reported	0-7 days	All injectable vaccines
1.7	Phlegmon	Acute diffuse purulent inflammation of the subcutaneous tissue; unlike the abscess, it has no clear limits.	0-7 days	All injectable vaccines
2.0	**Systemic reactions**			
2.1	Fever	Increase of body temperature (based on axillary temperature) is qualified as: • moderate fever: 38.5-39.5°C, two or more days; • severe fever: 39.5°C and more	Up to 3 days after inactivated vaccines and up to 30 days after live vaccine	All
2.2	Persistent inconsolable crying	Crying with yelling for 3 or more hours.	0-72 hours	Vaccine with cellular pertussis component
			5-30 days	MMR
			5-42 days	Vaccine against chicken pox
2.3	Hypotonic-hyporesponsive episode	It has a sudden onset, appearing after vaccination and lasting from one minute up to several hours in children under 10 years	From 3-4 hours up to 48 hours after vaccination	In general, DTP, DTP+Hib+HBV, other more rare

		old. All the below signs should be present: - poor muscle tone; - decreased response reactions (sensory hyposensitivity) or lack of reactions, inclusively; - transitory disorders or loss of consciousness; - absence of visual contact/transitory amnesia - pale skin or cyanosis		
2.4	Lymphadenopathy	Increase of the lymph nodes, without inflammation signs	0-7 days	Inactivated vaccine
			5-30 days	MMR
			5-42 days	Vaccine against chicken pox
2.5	Regional lymphadenitis	Inflammation of at least one lymph node from 100 mm in diameter or more. Ordinary localization – left axillary region, it is possible for other lymph nodes to get inflamed: supraclavicular and/or subclavian, cervical, and in shoulder's region.	From 2 weeks up to 6 months	BCG
2.6	Parotiditis	Increase in volume of salivary parotid glands	5-30 days	MMR, urlian
2.7	Orchitis	Inflammation of testicles in boys	5-30 days	MMR, urlian
2.8	Exanthem	Widespread, diffuse and polymorphic rash	0-7 days	Inactivated vaccines
			0-30 days	MMR, BCG
			0-42 days	Vaccine against chicken pox
2.9	Vomit and/or diarrhea	• Vomit and/or severe diarrhea, accompanied by dehydration and/or other common signs which represent a danger for life • Diarrhea lasting for 14 or more days	0-72 hours	Inactivated vaccines
			0-7 days	Vaccine against rotavirus
3.0	**Allergic reactions**			
3.1	Anaphylaxis (including	The syndrome may endanger life, it has a sudden onset and rapid intensification of signs	Up to 24 hours (usually	All vaccines

	anaphylactic shock)	and symptoms, **involving more (>2) systems and organs**, and namely: • **skin** – hyperemia of face, rash (urtication), Quincke edema (edema on face/edema on body surface); • **respiratory organs** – persistent cough, wheezing (bronchospasm), stridor, laryngeal edema; • **gastrointestinal system** – nausea, stomach pains; • **cardiovascular system** – hypertension, weak pulse or absent pulse in peripheral vessels • **extreme episode** – shock	during the first hour after vaccination)	
3.2	Other severe allergic reactions (Steven-Johnson syndrome, Lyell syndrome, and other)	Systemic severe allergic reaction which involves skin and mucous membranes (most frequently of the mouth and eyes)	0-48 hours (usually in the first 5-6 hours after vaccination)	All vaccines
4.0	**Neurologic reactions**			
4.1	Seizures	Generalized seizures, which are not accompanied by focal neurological signs or symptoms: • febrile seizures – the temperature of the body increased to over +38.5°C (axillary); • afebrile seizures – temperature of the body is normal	0-72 hours	Inactivated vaccines
			5-30 days	MMR
			5-42 days	Vaccine against chicken pox
4.2	Encephalopathy	Acute and severe neurological affection expressed by the following conditions: • seizures; • pronounced behavioral change during the day and over a longer period, • change of consciousness	0-42 hours	Inactivated vaccines
			5-30 days	MMR
			5-42 days	Vaccine against chicken pox

4.3	Encephalitis	Acute and severe neurological affection expressed through cerebral and focal neurological disorders, seizures, change of consciousness and/or apparent behavior change lasting one or more days.	0-42 hours	Inactivated vaccines
			5-30 days	MMR
			5-42 days	Vaccine against chicken pox
4.4	Disseminated acute encephalomyelitis	Inflammatory demyelinating disease of the central nervous system, characterized by an acute or under-acute evolution	0-42 hours	Inactivated vaccines
			5-30 days	MMR
			5-42 days	Vaccine against chicken pox
4.5	Subacute sclerosing panencephalitis SSPE	Acute progressive inflammatory disease of the brain. General cerebral disorders, neurologic disorders with loss of cognitive functions	1-3 years	Vaccine with measles component
4.6	Meningitis	Severe acute disease, with fever, with symptoms of cerebral lesions, with positive meningeal signs and modification of characteristics of the cerebrospinal fluid, confirmed by lab tests.	0-15 days	Inactivated vaccines
			5-30 days	Vaccine with urlian component
			5-42 days	Vaccine against chicken pox
4.7	Acute flaccid paralysis associated with live attenuated polio vaccine	Acute onset of flaccid paralysis and locomotor neurological disorders in the context of poliomyelitis diagnostic when isolating the vaccine virus and absence of the wild virus in faeces samples. Affection of spinal and bulbar neurons, identified based on electromyography tests. It lasts for over 60 days since the onset of the disease.	5-30 days	Persons who were vaccinated with VPO
			5-75 days	The person who has contacted with persons who were vaccinated with VPO
4.8	Guillain-Barre Syndrome	Acute, flaccid paralyses expressed through polyradiculo-neuropathy, quadriplegia, pain	0-8 weeks	Live vaccines
4.9	Anesthesia or paresthesia	Constant feeling of numbness, pricks, and moderate pain in limbs, limitation of active movements for 3 or more days.	0-15 days	Inactivated vaccines
			5-30 days	MMR
			5-42 days	Against chicken pox

4.10	Brachial plexus neuritis	Pain, limitation of active movements in the superior part of limbs, on the side where the vaccine was performed	2-28 days	Vaccines containing tetanus toxoid
4.11	Neuritis of the facial nerve (Bell paralysis)	Inflammation of the nerve, which irritated facial muscles on one side of the face. As a result, decrease (paresis) or complete absence (paralysis) of face movements and face asymmetry	0-3 months	Live vaccines
5.0	**Other**			
5.1	Toxic shock syndrome (TSS)	Sudden increase of body temperature, worsening of general condition, vomiting and watery stool, decrease of blood pressure in several hours after vaccine administration	24-48 hours	All injectable vaccines
5.2	Sepsis	Sudden onset of severe generalized disease, caused by bacteria infection and confirmed (if possible) by blood culture with positive result	Up to 7 days	All injectable vaccines
5.3	Psychogenic disorders	Reactions associated with stress and anxiety: • faint (syncope) • other psychogenic disorders caused by panic, with presence or absence of hyperventilation syndrome These reactions are sometimes accompanied by tonic-clonic seizure (see the table "Differential diagnosis of anaphylaxis, vasovagal syncope and reactions to stress, associated with immunization"*)	Before, during or immediately after the injection	All injectable vaccines
5.4	Arthritis	Persistent pain (10 and more days) in joints, frequently the small peripheral joints being affected	0-30 days	Inactivate vaccines
			5-30 days	Vaccine with rubella component
			5-42 days	Vaccine against chicken pox

5.5	Disseminated BCG infections	Generalized and persistent infection (uveitis, lupus eritematos), which occurs after the administration of the BCG vaccine and which is confirmed by identification of Mycobacterium bovis strain. Usually in immune-compromised persons	1-12 months	BCG
5.6	Osteitis (osteomyelitis)	Specific inflammation of bone tissue confirmed through identification of Mycobacterium bovis strain	3-36 months	BCG
5.7	Post-BCG syndrome	Clinical expression of a syndrome which occurs shortly after administration of the BCG vaccine, mainly being of allergic nature: erythema nodosum, ring granuloma, skin rash, etc.	Up to 1 year	BCG
5.8	Thrombocytopenic purpura	Hemorrhagic rash, bleeding of oral and nasal mucosa. Hematuria. Thrombocytopenia confirmed through lab tests.	12-35 days	Vaccine with measles component
5.9	Intestinal invagination	Stomach pain, repeated vomit, lack of stool, with clinical and imaging conformation	0-42 days	Vaccine against rotavirus
5.10	Other severe AEFI	• death • endangered life • needs medical intervention to prevent disorders or reversible damages • needs hospitalization or prolongation of patient's hospitalization • lead to total or partial loss of workability or induce disability • there are congenital anomalies/congenital pathologies	30 days	All vaccines

Annex No. 2 to the Order of the MHLSP No. 1019 dated 05 November 2020

Ministry of Health , Labor and Social Protection of the Republic of Moldova

Name of institution _____

Medical Documentation / Form no. 064/e

Approved by the MHLSP no. --- of ----- 2020

Form for reporting adverse events following immunization (AEFI)

Identification Number of the registered AEFI _____

Confidentiality of identification data mentioned in this form will be observed.

Name and surname of the patient: _____ *Name and surname of reporting person: _____

Date of birth (DD/MM/YYYY): _____

_____

Sex: □M □F

*Institution/function/department/address of reporting

Personal code of the patient: _____ person:

_____

Address of the patient: _____ *Telephone

_____

Telephone: _____ *Email

_____

Email: _____ *Reporting date (DD/MM/YYYY):

_____

Name of the medical institution where the vaccination was performed:

_____

_____

_____

Vaccine						Solvent		
**Name of vaccine administrated, name of producer, country of*	**Vaccination date*	**Vaccination time*	*Order number of the performed dose (for instance,*	**Lot number*	**Validity period*	**Lot number*	**Validity period*	*Date and time of vaccine reconstitution*

origin of the vaccine			*the first, the second, etc.)*					

AEFI subject to registration, according to the list (Annex 1): Date and time of AEFI onset (DD/MM/YYYY): ___ / ___ /_____ □hour □minutes Was the patient hospitalized? □ Yes □ No Date when the patient requested medical assistance DD/LL/YYYY: ___ / ___/ _____ Hospitalization date: DD/LL/YYYY ___ / ___ / _____	Describe se AEFI (clinical signs and symptoms, time, date, hour of onset), presumptive diagnosis, provided assistance. ***If necessary, use an additional page***.

Is the case a severe one? Yes /No
If Yes: □ Hospitalization; □ Danger for life; □ Disability; □ Congenital anomaly; □ Death

End of the AEFI
Got recovered □; In process of recovery □; Got recovered with residual effects □; Condition without dynamics □□; It is not known □; Passed away □;
If dead, indicated the date of death (DD/MM/YYYY): __ / __ / _____ Was autopsy performed?: □ Yes □ No □ It is not known

Previous medical anamnesis (including incurred diseases, episodes of similar reaction or other allergies), simultaneously taken medicines, and other relevant information (e.g. other cases). ***If necessary, use an additional page***:

It is filled in at the level of the territorial PHC:

Is an investigation necessary? □ Yes □□ No	If yes, indicate the date planned for investigation (DD/MM/YYYY): ___ / ___ / _____

It is filled in at the national level:

Date when the message was received at the NPHA (DD/MM/YYYY) ___ / ___ /_____	Single number of AEFI identification:

Comments:

_____

_____

****It is mandatory to fill in these fields***

Annex No. 3 to the Order of the MHLSP No. 1019 dated 05 November 2020

Ministry of Health , Labor and Social Protection of the Republic of Moldova

Name of institution _____

Medical Documentation / Form no. 064-1/e

Approved by the MHLSP no. --- of ----- 2020

Form for nominal record-keeping of adverse events following immunization (AEFI)

Epidemiological number	Name, surname, identification code of the patient	Date of birth (dd/mm/yyyy(	Patient' s domicile Locality/city/district	Medical institution in which immunization was performed	Immunization date (dd/mm/yyyy) time	Reaction (according to the list with AEFI which are to be	Type of reaction (code) (1) minor (2) severe/serious (3)	End: (1) got recovered, (2) disability, (3) death, (4) it is	Suspected vaccine: name, producer, order number of the	No. of the vaccine lot and validity period	No. of the solvent loot and validity period	Time interval between the moment the vaccine was	Date of AEFI report reception (dd/mm/yyyy)	Was there any investigation performed? (if yes. Indicate the	Final classification (code)*	Date the epidemiological investigation was finished
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**

Annex 9. Extracts from the Moldova national legislation related to health protections and reporting of adverse effects following immunization

Constitution of the Republic of Moldova:

Article 36
Right to health protection

(1) The right to health protection is guaranteed.

(2) The minimum health insurance provided by the State shall be free of charge.

(3) The structure of the national health security system and the means aimed at protecting the physical and mental health of the individual shall be provided for by organic law.

Civil Code of the Republic of Moldova:

Article 1400. Scope of section

(1) The provisions of the respective section shall apply to contracts in which one party (provider of treatment services) commits to provide medical treatment to the other party (patient).

(2) The provisions of this section shall be applied accordingly to contracts through which the treatment services' provider commits to provide any other service for the purpose of changing the physical or mental condition of the person.

(3) In cases when not being a contracting party, the patient shall be considered to be a third party whom the contract empowers with rights related to the obligations of the treatment services' provider has according to this section.

Article 1401. Preliminary examination

In so far as this is reasonably necessary to provide the service, the treatment services' provider shall:

a) ask the patient about his health condition, symptoms, incurred diseases, previous treatments or other current treatments, as well as about the treatment preferences and priorities;

b) perform necessary tests to diagnose the patient's health condition;

c) consult any other treatment services' providers involved in patient's treatment.

Article 1402. Duties regarding tools, medicines, materials, installations and premises

(1) The provider of treatment services shall use tools, medicines, materials, installations and premises which have at least the quality which is requested within an accepted and prudent professional practice, that complies with the legal provisions in force, and which are adequate for achieving the specific goal for which they will be used.

(2) Any clause which derogates from the provisions of the present article in the detriment of the patient shall be null and void.

Article 1403. Duty of competence and prudence

(1) Based on the duty of competence and prudence, the treatment services' provider shall in particular provide the patient with a level of competence and prudence that a reasonable treatment services' provider would offer in similar circumstances.

(2) If he lacks experience or competence for treating the patient with the necessary level of competence and prudence, the treatment services' provider shall send the patient to another treatment services' provider who is able to offer the respective level of competence and prudence.

(3) Any clause that derogates from the provisions of the present article in the detriment of the patient shall be null and void.

Article 1404. Duty to inform

(1) To offer the patient a free choice of treatment, the treatment services' provider shall inform him in particular about the following:

a) patient's current health condition;

b) nature of suggested treatment;

c) advantages of suggested treatment;

d) risks of suggested treatment;

e) alternatives for suggested treatment, as well as its advantages and risks as compared to those of the suggested treatment; and

f) consequences if treatment is not taken.

(2) In any circumstances, the treatment services' provider shall inform the patient about any risk or alternative which could reasonably influence the decision of the patient to accept or refuse the suggested treatment. It is presumed that a risk may influence reasonably the decision if its materialization would provoke a serious damage to the patient. Unless otherwise provided, the provisions of section 5 regarding the duty to inform shall be applied correspondingly.

(3) The information shall be provided to the patient in a comprehensible manner for him.

Article 1405. Duty to inform in case of treatment which is not necessary or experimental treatment

(1) If the treatment is not necessary to maintain or improve patient's health, the treatment services' provider shall disclose all the known risks.

(2) If the treatment is experimental, the treatment services' provider shall disclose all the information regarding the objectives of the experiment, nature of the treatment, advantages and risks, as well as its options, even when they are just a simple possibility.

(3) Any clause that derogates from the provisions of the present article in the detriment of the patient shall be null and void.

Article 1406. Exceptions from the duty to inform

(1) The information which should be normally provided based on the treatment services' provider duty to inform may be not disclosed to the patient:

a) if there are objective reasons to consider that patient's health condition or life will be seriously and negatively influenced; or

b) if he shows expressly the wish not to be informed, under the condition that the nondisclosure of the information does not damage the health and security of third parties.

(2) The duty to inform may be not executed when the treatment is provided in emergency situation. In this case, the treatment services' provider shall provide the information later, as far as possible.

Article 1407. Duty not to treat without consent

(1) The treatment services' provider shall not treat if the patient did not provide his informed consent for this.

(2) The patient may revoke his consent at any moment.

(3) As long as the patient is unable to express his consent, the treatment services' provider may perform the treatment if only:

a) the informed consent was obtained from a person or institution empowered by law to take decision on behalf of the patient regarding the treatment;

b) all the legal provisions or procedures which allow for treatment to be offered without this consent were observed; or

c) treatment has to be provided in emergency situation.

(4) In situations envisaged in para. (3), the treatment services' provider does not start the treatment until it considers, to the extent possible, the opinion of the patent who is not able to express his consent regarding the treatment, as well as any other possible opinion expressed by the patient before he became unable to express his consent, made known to the treatment services' provider.

(5) In situations envisaged in para. (3), the treatment services' provider shall be entitled to provide only treatment meant to improve the patient's health condition.

(6) In situations envisaged in art. 1405 para. (2), consent shall be expressed directly and in relation to the specific treatment.

(7) Any clause that derogates from the provisions of the present article in the detriment of the patient shall be null and void.

Article 1408. Data

(1) The treatment services' provider shall register adequate data about the treatment. These data should refer especially to the information collected in preliminary interviews, examinations or consultations, information on patient's consent and information of fulfilled treatment.

(2) Upon reasonable request, the treatment services' provider shall:

a) ensure access to patient's data or, if the patient is unable to express his consent, to the data of the person or institution empowered by law to take decisions on behalf of the patient; and

b) answer, to a reasonable extent, the questions on data interpretation.

(3) If the patient suffered an injury and claims that this is the result of the treatment services' provided not fulfilling his duty of competence and prudence, and the treatment services' provider does not comply with the provisions of para. (2), it is presumed that the duty of competence and prudence was not fulfilled and that there causal link between the nonfulfillment and injury.

(4) The treatment services' provider shall keep the data and shall supply information on data interpretation within a reasonable period of time of at least 10 years after the end of the treatment, depending on the usefulness of these data for the patient or his successors or representatives, and for the subsequent treatments.

The data which may, reasonably, be of important nature after the reasonable period of time shall be kept by the treatment services' provider after the expiry of this period as well. In cases when, regardless of the reason, the treatment services' provider stops its activity, the data shall be archived or sent to the patient for future consultations.

(5) Any clause which derogates from the provisions of para. (1)-(4) in the detriment of the patient shall be null and void.

(6) The treatment services' provider shall be prohibited to disclose to third parties any information about the patient or other persons involved in the patient's treatment, except for the case when the disclosure is necessary for the purpose of protecting third parties or the public interest. The treatment services' provider may use the anonymized data for statistical, educational or scientific purposes.

Article 1409. Legal means for defense in case of non-execution

In case of any type of non-execution of duties resulting from treatment services' contract, the legal provisions regarding the legal means for defending the creditor in case of non-execution shall be applied with the following adjustments:

a) treatment services' provider cannot exercise the right to suspend the execution or to terminate the contract, if he will expose the patient's health to a serious danger; and

b) in so far as it has the right to suspend the execution or has the right to terminate the contract and plans to exercise this right, the treatment services' provider shall recommend the patient another treatment services' provider.

Article 1410. Duties of medical-sanitary institutions

(1) If during the process of executing the duties resulting from the treatment services' contract, the activities are carried out in a hospital or in the premises of another medical-sanitary institution, and the hospital or the medical-sanitary institution is not part of the treatment services' contract, the respective hospital or institution should clearly inform the patient about the fact that it is not a contracting part.

(2) If the treatment services' provider cannot be identified, the hospital or the medical-sanitary institution in which the treatment has been provided holds the rights and duties of treatment services' provider, except for the case when the hospital or the medical-sanitary institution informs the patient, within reasonable time, about the identity of the treatment services' provider.

(3) Any clause that derogates from the provisions of the present article in the detriment of the patient shall be null and void.

Law on Pharmaceutical Activity No. 1456/1993:

Article 14. Liability for producing and preparing

medicines and para-pharmaceutical products

The pharmaceutical enterprises and institutions shall be liable in the established manner for compliance of the manufactured medicines and para-pharmaceutical products with the requirements of the analytical-normative documentation in force, approved by the Ministry of Health , Labor and Social Protection.

Article 18[1]. Rights of citizens to assistance with medicines

Citizens of the Republic of Moldova, foreign citizens and stateless persons are entitled to:

- assistance with good quality, efficient and harmless medicines in compliance with the minimum guaranteed health insurance;

- be provided, in emergency regime, with medicines by any type of pharmaceutical or curative-preventive unit, regardless of the type of ownership and subordination;

- be provided, upon need, with orphan drugs meant for medication to treat patients with rare diseases;

- be aware of and to obtain from pharmaceutical enterprises and institutions, curative-preventive and sanitary-epidemiological institutions the information certifying the quality and harmlessness of medicines;

- request from bodies, institutions and organizations with expertise functions and to be provided the conclusion regarding the quality, efficiency and harmlessness of medicines and the level of assurance with medicines.

Article 18[2]. Citizens' rights to refuse assistance with medicines and to be compensated the damages caused to their health

The citizens of the Republic of Moldova, foreign citizens and stateless persons are entitled to:

- refuse using medicines if they are not sure about their quality, efficiency and harmlessness;

- obtain, as established by the legislation in force, a compensation for the damages caused to their health as a result of prescription, provision and administration of medicines by the respective specialists.

Article 18[3]. Citizens' duties regarding assistance with medicines

The citizens of the Republic of Moldova, foreign citizens and stateless persons are obliged to:

- observe the legislation on pharmaceutical activity;

- use the medicines prescribed in case of identifying a disease which presents a danger for other persons.

Law on Health Protection No. 411/1995:

Article 19. Right to compensation for damages caused to health

(1) Any person is entitled to compensation for damages caused to health by harmful factors generated through violation of anti-epidemics regime, sanitary-hygienic rules and norms, labor protection rules, road traffic rules, as well as ill-intended actions of certain persons.

(2) The person may challenge the illegal actions and decision of the state bodies and decision-making factors who have damaged his/her health.

(3) Patients, health insurance bodies are entitled to compensation of damages caused to patients **by medical-sanitary institutions** through non-observance of medical treatment norms, prescription of contraindicated

medicines or administration of incompliant treatments which aggravate the health condition, provoke permanent disability, threaten patient's life or end up with patient's death.

(4) If the sicknesses and trauma are generated by violation of labor protection rules, road traffic rules, law enforcement, abuse of alcoholic beverages, use of stupefying and toxic substances, as well as by flagrant violation of treatment regime, the health insurance bodies may claim, according to the law, the cost of the medical assistance from the guilty person.

Article 36. Right of the patient to challenge the actions of the medical-sanitary personnel for health damages

In case of unsatisfactory health condition as a result of inadequate medical assistance, the patient is entitled to request for a professional expertise to be carried out in the established way, as well as compensation for incurred moral and material damages.

Law on State Supervision of Public Health No. 10/2009:

Article 52. Prophylactic vaccination of population

(1) The prophylactic vaccination of population against infectious diseases includes systematic prophylactic vaccination, vaccination according to epidemiological indications and recommended vaccination.

(2) The systematic prophylactic vaccination is guaranteed and ensured by the state at the ages and for groups of population established in the National Program for Immunization.

(3) The list of infectious diseases against which the systematic prophylactic vaccination is applied and the list of risk groups are approved by the Ministry of Health , Labor and Social Protection.

(4) The conditions, indications and organization of vaccinations according to the epidemiological indications are established by the Ministry of Health , Labor and Social Protection.

(5) The organization of recommended vaccinations is established by the Ministry of Health , Labor and Social Protection.

(6) Admission of children in collectives, educational and recreational institutions is conditioned by their systematic prophylactic vaccination.

Law on Consumers' Protection No. 105/2003:

Article 2. Scope of the law

(1) The present law sets forth the general requirements for protection of consumers, assurance of the necessary framework for unhindered access to products and services, complete information about their main characteristics, defense and assurance of consumers' legitimate rights and interests in case of incorrect commercial practices, participation of consumers in founding and taking decisions they are interested in as consumers.

(2) The present law shall apply to incorrect commercial practices of traders towards consumers, specified in art. 13(10^1), before, during and after a commercial transaction related to a products or a service.

(2^1) The present law regulates aspects regarding the sale of products and the guarantees associated to them, as well as of the products to be manufactured or processed, and which are procured based on a sale-

purchase contact.

(2^2) The present law sets forth aspects regarding the conditions in which the authorities responsible for enforcing the normative acts which protect consumers' interests cooperate at the transborder level in order to guarantee the observance of these acts and the good functioning of internal market and for improving the protection of consumers' economic interests.

[Art.2 al.(2^2) introduced by LP168 of 26.07.18, MO333-335/24.08.18 art.549; in force since 24.02.19]

(3) The present law does not prejudice:

a) **the legal provisions regarding consumers' health aspects and products' safety**;

b) the legal provisions which establish courts' competence;

c) the legal provisions regulating the probing and marking of items from precious metals;

d) the specific provisions in certain areas regarding incorrect commercial practices. If such provisions exist in special laws, they apply as additional requirements to those set forth in the present law, and if special laws cover more restrictive requirements regarding the incorrect commercial practices, the requirements of special laws shall apply.

e) the special provisions regarding food products.

Annex 10. Moldova Coldchain Analysis

1. Number of healthcare institutions.

Number of healthcare institutions in Rep. Moldova Vaccination rooms	1422 1387

In 2020 were procured – 300 refrigerators PQS (50% GAVI; 50% state budget)

2. Number of refrigerators by type of healthcare unit and refrigerator

	Absent	**Home use In good operation yes/no**		**Home use Total**	**PQS In good operation yes/no**		**PQS Total**	**Total**
IMSP	Absent	yes	Nu		yes	Nu		
CIMF	5	3		3	8	1	9	**17**
CMF		24		24	28		28	**52**
CS		30		30	261	12	273	**303**
C. antirabice		1		1				**1**
CSP			2	2	166	9	175	**177**
IMS Private	1	10		10	1		1	**12**
OMF	42	154	4	158	555	29	584	**784**
OS	69	82	4	86	44	2	46	**201**
PM	10		3	3	5		5	**18**
SP		17		17	37	1	38	**55**
Total	**127**	**321**	**13**	**334**	**1105**	**54**	**1159**	**1620**

CIMF – individual office of family doctor
SP – raional hospital (maternity hospital) and institutions for children and the elderly.
Antirabic room.

3. Classification of refrigerators PQS by trademark .

Refrigerators PQS /In good operation	yes	**No**	**Total**
Frigorific room	1		1
Haer HBC 150	5		5
Haier HBC 70	3		3
MF 114	3		3
MK 074	29		29
MK 114	3		3
MK 142	76	9	85
MK 144	694	35	729
MK 204	4		4
MK 302	23	6	29
MK 304	48		48
MK 4010	68	3	71
MK 404	12		12
Polair CM1058	2	1	3

Rapsodia R700M	21	3	24
SB300	36		36
SB302	1		1
VLS 204A	59		59
VLS 400	14		14
Grand Total	**1102**	**57**	**1159**

4. Refrigerators by manufactured year

Year when manufactured	Home use	PQS	Grand Total
1970-1989	26		26
1990-1999	18	475	493
2000-2009	106	459	565
2010-2020	184	225	409
Grand Total	**334**	**1159**	**1493**

5. Number of refrigerators PQS distributed by territorial-administrative unit

Territories	1990-1999	2000-2009	2010-2020	Total
Anenii Noi	12	17	7	36
Bălți	8	8	5	21
Basarabeasca	7		4	11
Briceni	6	24	5	35
Cahul	17	16	6	39
Călărași	18	23	14	55
Cantemir	7	25	7	39
Căușeni	19	16	11	46
Ceadîr-Lunga	2	1	11	14
Chișinău	22	12	18	52
Cimișlia	6	11	3	20
Comrat	8	4	2	14
Criuleni	17	8	5	30
Dondușeni	13	4	6	23
Drochia	12	12	6	30
Dubăsari			5	5
Edineț	24	13	10	47
Fălești	23	17	3	43
Florești	17	26	3	46
Glodeni	9	11	6	26
Hîncești	14	18	4	36
Ialoveni	12	2	12	26
Leova	1	14	3	18
Nisporeni	10	13	3	26
Ocnița	10	17	3	30
Orhei	16	28	14	58
Rezina	12	9	3	24
Rîșcani	14	16	3	33
Sîngerei	13	5	10	28

Șoldănești	20		7	27
Soroca	21	22	3	46
Ștefan-Vodă	13	8	4	25
Strășeni	25	7	5	37
Taraclia	7	4	4	15
Telenești	13	22	2	37
Ungheni	23	23	7	53
Vulcănești	4	3	1	8
Grand Total	**475**	**459**	**225**	**1159**

6. Number of refrigerators of home use type distributed by territorial administrative unit

Territories	**19690-1989**	**1990-1999**	**2000-2009**	**2010-2020**	**Total**
Anenii Noi	1		1	5	7
Bălți	1		1	2	4
Basarabeasca		1		2	3
Cahul	1			12	13
Călărași			1	2	3
Cantemir				5	5
Căușeni	1		1		2
Ceadîr-Lunga				1	1
Chișinău			9	28	37
Cimișlia		1	6	4	11
Comrat			3	2	5
Criuleni			5	3	8
Dondușeni		1		4	5
Drochia			3	9	12
Dubăsari			3	2	5
Edineț	2				2
Fălești	1		13	15	29
Florești	3	1	2	8	14
Glodeni	2			4	6
Hîncești	1		1	8	10
Ialoveni	1		2		3
Leova			3	9	12
Nisporeni	1	2	1	5	9
Ocnița	1		1		2
Orhei			8	10	18
Rezina	1	4	3	8	16
Rîșcani	3	4		1	8
Sîngerei	2		4	7	13
Șoldănești				5	5
Soroca		1	13	6	20
Ștefan-Vodă				6	6
Strășeni	4		1	1	6
Telenești		3	5	1	9

Ungheni			16	6	22
Vulcănești				3	3
Grand Total	**21**	**18**	**106**	**184**	**334**

Annex 11. Regulation on the Performance of Pharmacovigilance Activities

O R D E R

mun. Chişinău

„12„ May 2017 no. 358

On Approving the Regulation on the Performance of Pharmacovigilance Activities

With a view to transposing Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on establishing a Community code relating to medicinal products for human use, (EU) Regulation no. 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards the pharmacovigilance of medicinal products for human use, Implementing (EU) Regulation No. 520/2012 of the Commission of 19 June 2012 on the performance of pharmacovigilance activities provided for in (EC) Regulation No 726/2004 of the European Parliament and of the Council, as well as under Law no. 1409-XIII of 17 December 1997 on Medicines, Law no. 1456-XII of 25 May 1993 on Pharmaceutical Activity, Order of the Ministry of Health No. 739 of 23.07.2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments, with the subsequent amendments and completions and point 9 of the Regulation on the Organization and Functioning of the Ministry of Health , approved by Government Decision no. 397 of 31 May 2011, with the subsequent amendments and completions, in order to ensure the effectiveness, quality and safety of medicines allowed on the pharmaceutical market.

I ORDER:

1. To approve:
   1) The Regulation on the Performance of Pharmacovigilance Activities, as set out in Annex no.1
   2) Communication Sheet on Adverse Reactions and/or Lack of Effectiveness of Medicines and Other Medicinal Products as provided by Annex no. 2.
   3) Communication Sheet on Adverse Reactions to Medicines and Other Medicinal Products "Patient Communicates" as provided by Annex no. 3.
2. The holder of the medicine registration certificate, or his official representative, must at all times have at his disposal an appropriately qualified person responsible for pharmacovigilance activities to establish and maintain a system to ensure that all information collected on the safety of medicinal products are accessible to the Medicines and Medical Devices Agency;
3. Chiefs of health facilities, regardless of the legal form of organization and type of ownership:
   1) to appoint persons responsible for pharmacovigilance in their health facilities within 1 month from the date of issue of this order;
   2) to ensure the recording and reporting of adverse reactions or the ineffectiveness of

medicines and other medicinal products to the Medicines and Medical Devices Agency, in accordance with this order;

4. the Medicines and Medical Devices Agency (Director General Mr. Vladislav Zara) to ensure:
   1) methodological support for the implementation of this order;
   2) creation of a system to facilitate the exchange of information on pharmacovigilance issues concerning the medicines used in the Republic of Moldova.
   3) informing the healthcare specialists about the adverse drug reactions, current issues related to the safety, effectiveness and quality of medicines and other medicinal products, current rational pharmacotherapy topics in various ways and means.
   4) Cooperation with the WHO International Pharmacovigilance Centre (Uppsala, Sweden) and National Pharmacovigilance Centres in other countries, in order to monitor adverse reactions to medicines and other medicinal products and to exchange information in the field of pharmacovigilance.
5. Order of the Ministry of Health no. 20 of 12 January 2006 "On Monitoring the Adverse Drug Reactions and Other Medicinal Products in the Republic of Moldova" to be repealed.
6. To place this order on the website of the Ministry of Health and the Medicines and Medical Devices Agency.
7. To publish this Order in the Official Gazette of the Republic of Moldova.
8. The control of the execution of the provisions of this Order is assigned to Mrs. Liliana Iașan, Vice Minister.

Minister Ruxanda GLAVAN

Annex no. 1 by the Order of the Ministry of Health no. of 2017

Regulation on the Performance of Pharmacovigilance Activities

Chapter I

General provisions

1 The Regulation on Pharmacovigilance Activities (hereinafter - the Regulation) is developed under Law no. 1409-XIII of 17 December 1997 on Medicines, Law no. 1456-XII of 25 May 1993 on Pharmaceutical Activity, Order of the Ministry of Health Nr. 739 of 23.07.2012 on Regulating the Authorization of Medicinal Products for Human Use and the introduction of post-authorization amendments, with a view to transposing Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 on amending, as regards the pharmacovigilance of medicinal products for human use, the Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the Performance of the Pharmacovigilance Activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council, and to ensure the effectiveness, quality and safety of medicinal products allowed on the pharmaceutical market.

2 This Regulation establishes the basic requirements for pharmacovigilance activities that cover the entire safety cycle of medicinal products for human use.

3 Within the Medicines and Medical Devices Agency (hereinafter - the Agency), a pharmacovigilance system is organized and operated to perform pharmacovigilance tasks and to participate in pharmacovigilance activities. This system is used to collect information on the risks of medicines to patients or public health. Such information should relate in particular to the adverse reactions in humans as a result of the use of a medicine.

4 The coordination and performance of the activities of the pharmacovigilance system is carried out through the specialized structure within the Agency - Pharmacovigilance and Rational Use of Medicines Section (hereinafter - PVRUMS).

5 PVRUMS, through the pharmacovigilance system, shall evaluate all information, consider the possibilities for minimizing and preventing the risk, and adopt regulatory measures on the registration certificate for the medicinal product, as appropriate.

6 The information on side effects, ineffectiveness and any other problems associated with the use of medicines is provided to PVRUMS by:

1) doctors and pharmacists of all health facilities, regardless of their legal form of organization and type of ownership;
2) holders of a registration certificate/producers or their official representatives;
3) representatives of international organizations (WHO - World Health Organization, WTO, CoE - Council of Europe, EMA, FDA), etc .;
4) medical information sources and scientific publications;
5) civic organizations, which represent the interests of medicine users and citizens in general;
6) patients.

Chapter II
Definitions

7. For the purposes of this Regulation, the following definitions and terms shall apply:

Pharmacovigilance system - *t*he system used by the state and the holders of registration certificates to fulfil their tasks and responsibilities in the field of pharmacovigilance and meant to monitor the safety of authorized medicines, and to detect any changes in their specific risk-benefit ratio.

Spontaneous communication - communications on all types of adverse reactions to

the practical use of medicinal remedies.

Adverse reaction - a harmful and undesirable response associated with the use of a medicine. The adverse reaction may also occur under conditions of use of the medicinal product outside the terms of the medicinal product registration certificate, such as *off-label use (With additional directions other than direct authorized ones*), overdose, misuse, abuse and medication errors.

Severe adverse reaction - *a*dverse reaction (RA) that causes death, endangers life, requires hospitalization or prolongation of hospitalization, causes a permanent or significant disability or incapacity, causes congenital anomalies/malformations or of medical importance.

Non-severe adverse reaction - *a*ny adverse reaction that does not meet the criteria defined for a severe adverse reaction.

Causality criteria - the cause-effect relationship to medicines, according to the terminology of the French School of Pharmacovigilance, recommended by the WHO, is classified into 6 types: safe, probable, possible, unlikely, conditioned/unclassified, non-evaluable/unclassifiable adverse reaction.

Certain adverse reaction - a clinical event (including related paraclinical changes) that occurs after administration of the medication or other pharmaceutical product and cannot be explained by associated diseases or concomitant therapies. When the administration is stopped, the clinical picture regresses. The event must be well defined pharmacologically or phenomenologically, using, if necessary, re-administration (on re-administration, the adverse reaction occurs again).

Likely adverse reaction - a clinical event (including related paraclinical changes) that occurs after administration of the medicine or other pharmaceutical product and is unlikely to be caused by other conditions or factors (concomitant therapies), regresses after discontinuation. Re-administration is not required.

Possible adverse reaction - clinical event (including related paraclinical changes), possibly related to the administration of the medicine or other pharmaceutical product but which can also be explained by associated diseases or other factors (other concomitant treatments, chemical factors, etc.). The information on the clinical response to discontinuation of administration may be missing or unclear.

Unlikely adverse reaction - a clinical event (including related paraclinical changes), which occurs in an unclear temporal relationship with the administration of the medicine or other pharmaceutical product and which may be explained by associated diseases or other factors (other concomitant treatments, chemical factors, etc.)

Conditioned/unclassified adverse reaction - a clinical event, including paraclinical changes, reported as a side effect but for which more data are essential for a correct evaluation or the information is still being examined.

Unevaluable/unclassifiable adverse reaction - A report suggesting an adverse reaction but which cannot be judged because the information is insufficient or contradictory and cannot be supplemented or verified.

Expected adverse reaction - an adverse reaction whose character and degree of expression matches the information in the Summary of Product Characteristics (for authorized preparations).

Unexpected adverse reaction - an adverse reaction whose nature, severity or evolution does not match the information in the Summary of Product Characteristics.

Medicinal interaction reactions - reactions that occur as a result of the administration of a number of medicinal preparations and are caused by their pharmacodynamic and/or pharmacokinetic interactions.

Harmlessness (safety) of medicinal remedies - lack of severe and unforeseen adverse reactions in clinical trials or in the therapeutic use of medicinal remedies, which meet the benefit/risk criterion.

Additional clinical trials - trials launched in view of detecting or confirming any dangerous actions of the pharmaceutical product when used in he medical practice, which could present a risk to the health of patients.

Medicine registration certificate - a document that allows the use, import

and sale of the medicine in the territory of the Republic of Moldova

Medicine abuse - permanent or sporadic, intentionally excessive use of medicines, accompanied by harmful effects on the physical or mental level.

Risk minimization activity - public health intervention to prevent or reduce the likelihood of an adverse reaction associated with exposure to a medicine or to reduce its severity if it occurs.

Direct communication to healthcare workers (DCHCW) - communication-level intervention whereby the holder of the registration certificate for a medicinal product or the competent authority conveys directly to each healthcare worker important information on the need to take certain actions or to adapt their professional practice in relation to a particular medicine. DCHCW is not answers to questions from health workers.

Holder of the medicine registration certificate (hereinafter - Holder of the registration certificate) - the inventor, manufacturer or other legal entity empowered by them, responsible for the effectiveness, quality and safety of the medicinal product.

User - a person who is not a health worker, such as a patient, lawyer, friend or relative/parent/child of a patient, for the purpose of reporting suspected adverse reactions.

Minimum reporting criteria - in view of reporting suspected adverse reactions, the minimum elements for a case are: the existence of an identifiable reporter, an identifiable patient, an adverse reaction and a suspected medicine.

European reference date - for the medicinal products containing the same active substance or combination of active substances, the date of the first marketing authorization in the European Union of a medicinal product containing that active substance or that combination of active substances; If that date cannot be determined, the oldest of the known marketing authorization dates for a medicinal product containing that active substance or combination of active substances.

Development International Birth Date (DIBD) - the date of the first authorization (or approval) to conduct an interventional clinical trial in a country, whatever it may be.

International Birth Date –

(IBD) - the date of the first marketing authorization for a medicinal product in any country in the world.

Name of the medicinal product - a name assigned to a medicinal product which may be an invented name that does not lead to confusion with the common name or a common or scientific name, accompanied by the mark or the name of the holder of the registration certificate.

International Nonproprietary Name (INN) is the name recommended by the World Health Organization (WHO) or, failing that, the usual common name.

Pharmacovigilance system master file – PSMF - a detailed description of the pharmacovigilance system used by the holder of the registration certificate in respect of one or more authorized medicinal products.

Adverse event in clinical trial (AE) - any harmful manifestation in a patient or participant in a clinical trial who has been given a medicine and that is not necessarily causally related to this treatment. Consequently, an adverse event may consist of any unfavorable and undesirable sign (for example, an abnormal laboratory finding), symptom or disease, temporarily associated with the use of a medicinal product, whether or not it is considered to be related to the medicinal product.

Occupational exposure to a drug - is an exposure to a medicine at the work

place.

Pharmacovigilance - the science and activities related to the detection, evaluation,

understanding and prevention of side effects or any other problems with
medicines.

Pharmacovigilance in the field of vaccines - the science and activities related to the detection, evaluation, understanding and communication of post-immunization adverse events.

Safety reference information - in the periodic risk-benefit assessment reports for medicinal products, all relevant safety information contained in the medicinal product reference information (e.g. Company Essential Information Document) prepared by the holder of the registration certificate and listed therein requires it in all countries where the medicine is marketed, unless the local competent authority requests a specific change.

Risk management plan (RMP) - a detailed description of the risk managementsystem.

Risk management system - a set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks related to a medicinal product, including the evaluation of the effectiveness of such activities and interventions

Safety issue - a significant risk identified, potentially significant risk or missing information.

Health worker - in view of reporting suspected adverse reactions, health workers define themselves as qualified in the medical field, such as doctors, pharmacists, nurses and forensic doctors.

Individual case safety report - ICSR; synonym: Adverse reactions report (to the medicine) - the format and content of reporting of one or more suspected adverse reactions to a medicine, occurring in a single patient and at a certain time.

Periodic Safety Update Report (PSUR) - the format and content of the benefit-risk analysis of a medicinal product, for submission by the holder of the registration certificate at certain well-defined times during the post-authorization stage.

*Risk-benefit ratio - e*valuation of the positive therapeutic effects of the medicine, compared to the risks, defined as any risk to the patient's health or to public health, related to the quality,

safety or effectiveness of a medicine.

Chapter III

Minimum requirements for quality control systems for the performance of pharmacovigilance activities

Section 1. Quality control system

8 Holders of a registration certificate and the Agency shall establish and use a quality control system that is appropriate and effective for the performance of their pharmacovigilance activities.

9 The quality control system comprises the organizational structure, responsibilities, procedures, processes and resources, proper management of resources, compliance management and records management.

10 The quality control system is based on all the following activities:

1) quality planning: establishing structures and planning integrated and coherent processes;
2) adherence to quality: fulfilment of tasks and responsibilities in accordance with the quality requirements;
3) quality control and assurance: monitoring and evaluating the efficiency of the way structures and processes have been set up and the effectiveness of the processes that are being carried out;
4) quality improvements: correction and improvement of structures and processes, when necessary.

11 All elements, requirements and provisions adopted for the quality control system shall be based on systematic and orderly documentation in the form of written policies and procedures, such as quality plans, quality manuals and quality records.

12 All persons involved in the procedures and processes of the quality control systems set up by the Agency for the performance of pharmacovigilance activities shall be responsible for the proper functioning of such quality control systems and shall implement a systematic approach to quality and implementation and maintenance of the quality control system.

Section 2. Performance indicators

13 Holders of a registration certificate and the Agency shall use performance indicators to continuously monitor the proper conduct of pharmacovigilance activities.

14 The Agency shall ensure the publication of a list of performance indicators.

Chapter IV

Minimum requirements for quality control systems for the performance of pharmacovigilance activities by holders of a registration certificate

Section 1. Human resources management

15 Holders of a registration certificate shall have competent, qualified and properly trained personnel to perform pharmacovigilance activities. Holders of a registration certificate shall ensure that the local contact person responsible for pharmacovigilance, who must reside and operate in the territory of the Republic of Moldova, has acquired adequate theoretical and practical knowledge to carry out pharmacovigilance activities.

16 The tasks of the management and supervisory staff, including the local contact persons responsible for pharmacovigilance, are detailed in the job description.

17 All staff involved in pharmacovigilance activities benefit from initial and ongoing training on their role and responsibilities. Holders of a registration certificate shall keep records and training

plans for the documentation, maintenance and development of staff skills and shall make them available for audit or inspection.

18 Holders of a registration certificate shall provide appropriate instructions on the processes to be used in an emergency, including on business continuity.

Section 2. Compliance management

19 Procedures and processes specific to the quality control system shall be put in place to ensure the following:

1) the holders of a certificate of registration carry out continuous monitoring of pharmacovigilance data, examination of risk minimization and prevention options and adoption of appropriate measures;

2) scientific evaluation by the Holders of a registration certificate of all information on the risks presented by medicines.

3) transmission of accurate and verifiable data on severe adverse reactions and non-severe adverse reactions to the VigiBase database*;*

4) the quality, integrity and completeness of the information submitted on the risks posed by medicinal products, including procedures to avoid duplication of transmission and validation of signals

5) effective communication between the Holders of a registration certificate and the Agency, including communication of the new or changing risks, pharmacovigilance system master file, risk management systems, risk minimization measures, periodic safety update reports, corrective actions and preventive and post-authorization studies;

6) proper communication by the Holders of a registration certificate of relevant safety information to health workers and patients.

20 Where a holder of a registration certificate subcontracts some of his pharmacovigilance tasks, he shall retain the responsibility for ensuring that an effective quality control system is applied in respect of those tasks.

Section 3. Records management and data retention

21 Holders of a registration certificate shall record all pharmacovigilance information and ensure that it is managed and stored in such a way as to enable accurate reporting, interpretation and verification of the information. Holders of a registration certificate shall set up a system of record-keeping of all documents used for pharmacovigilance activities to ensure the possibility of retrieving such documents as well as the traceability of measures taken to investigate safety concerns, deadlines for such investigations and decisions on safety issues, including the date on which they occurred and the decision-making process. Holders of a registration certificate shall establish mechanisms to allow for the traceability and subsequent monitoring of adverse reaction reports.

22 Holders of a registration certificate shall take the necessary steps to ensure that the elements of the pharmacovigilance system master file are kept for at least five years after the system described in the pharmacovigilance system master file has been officially disposed of by the holders of a registration certificate. Pharmacovigilance data and documents relating to the authorized individual medicinal products shall be kept for as long as the medicinal product is authorized and for at least 10 years after the registration certificate ceases to exist.

Section 4. Audit

23 Audits of the quality assurance system based on the identification of risks shall be carried out at regular intervals to ensure that the quality assurance system meets the requirements of such systems and to determine their effectiveness. Such audits are performed by individuals who do not have a

direct involvement or responsibility for the issues or processes that are audited.

24. When (a) non-compliance(s) is (are) identified, corrective action(s), including a follow-up audit of deficiencies, shall be taken in accordance with the standard procedures within the Quality Management System. A report on the results of the audit shall be prepared for each audit and each monitoring audit. The audit report is submitted to the manager responsible for the audited issues. The data and results of audits and monitoring audits are documented.

Chapter V
Minimum requirements for quality control systems for the performance of pharmacovigilance activities by the Agency

Section 1. Human resources management

25. The Agency shall have competent, qualified and properly trained staff to carry out pharmacovigilance activities.

26. The organizational structures and the distribution of tasks and responsibilities are clear and, to the extent necessary, accessible.

27. All staff involved in the performance of pharmacovigilance activities receive initial and ongoing training. The Agency shall keep training records and plans for the documentation, maintenance and development of staff competencies, and shall make them available for audit.

28. The Agency shall provide its staff with adequate instructions on the procedures to be used in an emergency, including on business continuity, in accordance with approved internal procedures.

Section 2. Compliance management

29. The Agency shall establish specific procedures and processes with a view to achieving all of the following objectives:

1) ensure assessment of quality, including of completeness of pharmacovigilance data submitted;
2) ensure assessment of pharmacovigilance data and their processing;
3) ensure independence in the performance of pharmacovigilance activities;
4) ensure effective communication between the various competent international authorities and the Agency, as well as with patients, health workers, registration certificate holders and the general public;

30. In addition to the procedures referred to in point 29, the Agency shall have procedures in place to collect and record all suspected adverse reactions in the territory of the Republic of Moldova, regulated according to standards of the Quality Management System.

31. The Agency shall establish procedures for monitoring the specialized literature.

Section 3. Records management and data retention

32. The Agency shall record all pharmacovigilance information and ensure that it is managed and stored in such a way as to enable accurate reporting, interpretation and verification of the information. It establishes a system of records of all documents used for pharmacovigilance activities, ensuring the possibility of retrieving such documents, as well as the traceability of measures taken to investigate safety concerns, decisions on safety issues, including the date on which they occurred and the decision-making process.

33. The Agency shall take the necessary steps to ensure that the essential documents describing its pharmacovigilance system are kept for at least five years after the system has been officially abolished. Pharmacovigilance data and documents concerning authorized individual medicinal products shall be kept for as long as the medicinal product is authorized and for at least 10 years after the expiry date of the medicinal product registration certificate.

Section 4. Audit

34 Audits of the quality control system based on risk identification shall be performed at regular intervals, in accordance with a documented methodology, to ensure that the quality control system meets the requirements and to ensure its effectiveness.

35 When (a) non-compliance(s) is (are) found, corrective actions are taken, including a follow-up monitoring audit of the deficiencies, according to the standard procedures of the Quality Management System. The audit report is submitted to the manager responsible for the audited issues. The data and results of audits and monitoring audits are documented.

Chapter VI

Minimum requirements for monitoring the data present in databases

Section 1. General requirements

36 The Agency shall cooperate with other national authorities with a view to monitoring the data in the VigiFlow database.

37 The Agency shall ensure the continuous monitoring and updating of the VigiFlow database (national adverse reaction database and computer network) with a frequency that must be proportionate to the risks identified, to the potential risks, and to the need for additional information.

38 The Agency is responsible for monitoring the data in the territory of the Republic of Moldova.

Chapter VII

Use of terminology, formats and standards

Section 1. Use of internationally agreed terminology

39 To classify, access, present, evaluate and assess risks and benefits, exchange and communicate information on pharmacovigilance and medicinal products in electronic format, the holders of a registration certificate and the Agency shall use the terminology contained in Annex 1 to this Regulation.

40 Holders of a registration certificate and the Agency shall monitor the use of the terminology referred to in Annex 1 to this Regulation.

Section 2. Use of internationally agreed formats and standards

41 To describe, access, present, evaluate and assess risks and benefits, exchange and communicate information on pharmacovigilance and medicinal products in electronic format, the holders of a registration certificate and the Agency shall use the formats and standards set out in Annex 2 to this Regulation.

Chapter VIII

Submission of reports on suspected adverse reactions

Section 1. Individual safety reports

42 Individual safety reports are used to record in Vigiflow (the database and the national computer network for adverse reactions) suspected adverse reactions to a medicinal product, which occur in a single patient at a given time.

Section 2. Content of individual safety reports

Holders of a registration certificate shall ensure that safety reports are as complete as possible and shall communicate them to the Agency by e-mail, e-reporting in an accurate and reliable manner to the VigiFlow database.

43 For accelerated reporting, individual safety reports shall include at least one identifiable

reporter, an identifiable patient, a suspected adverse reaction and the medicinal product(s) concerned.

44 Holders of a registration certificate shall record the details necessary to obtain information on the follow-up monitoring of individual safety reports. The information on the monitoring of the reports is documented in the manner established in the procedure.

45 When reporting suspected adverse reactions, the holders of a registration certificate shall provide all available information on each individual case.

Section 3. Format of electronic submission of suspected adverse reactions

46 The holders of a registration certificate, for the electronic submission of suspected adverse reactions, shall use the formats approved in Annex 2 to this Regulation, as well as the terminology provided in accordance with Annex 1 to this Regulation.

Chapter IX

Agency duties in the pharmacovigilance system

47. The Agency shall take all necessary measures to encourage patients, doctors, pharmacists and other health workers to report suspected adverse reactions to the Agency or to the holders of a registration certificate; in this context, consumer organizations, patients' organizations and health worker organizations may be involved, as appropriate;

48 The Agency facilitates patient reporting by providing alternative reporting formats in addition to electronic formats, such as hard copies;

49 The Agency shall take all necessary steps to obtain accurate and verifiable data for the assessment of reports on suspected adverse reactions;

50 The Agency shall make sure that the public receives timely information of interest on pharmacovigilance issues regarding the use of a medicinal product, through publication on web portals and other public information means, as appropriate;

51 The Agency shall ensure, through methods of collecting information and, where appropriate, by monitoring reports on suspected adverse reactions, that all necessary measures are taken to clearly identify all medicinal products, distributed or marketed in the territory of Moldova and which are the subject-matter of a report on suspected adverse reactions, paying due attention to the trade name of the medicinal product and the batch/serial number;

52 The Agency shall take the necessary measures to ensure that a holder of a registration certificate who does not fulfil the obligations laid down in this Regulation is subject to effective and proportionate penalties.

53 The Agency, in view of establishing the veracity of the data, has the right to request and receive copies of medical records, regardless of their form of ownership.

54 In case of unforeseen adverse reactions, PVRUMS informs the Medicines Commission and the Ministry of Health within up to 30 days, in view of suspending or removing the authorization of the preparation until receipt of the results of the additional clinical study and specialized evaluation to assess the safety of the pharmaceutical product.

55 Following a specialized evaluation of information on adverse reactions to medicinal products and other medicinal products, PVRUMS may submit proposals to the Medicines Commission for imposing restrictions on the use of the preparation, namely, changes to the indications and contraindications included in the Package Leaflet and Summary of Medicinal Product Characteristics, or changes to other sections.

PVRUMS notifies the drug manufacturers/holders of registration certificates (or their official representatives) about the changes proposed.

Chapter X

Implementation of the pharmacovigilance system by health facilities, regardless of their form of ownership

56 Doctors, pharmacists and other health facilities, regardless of their form of ownership, are required to report adverse reactions or medicine ineffectiveness and to be informed of pharmacovigilance reports.

57 Doctors and health workers of health facilities, regardless of their form of ownership, pharmacy specialists regardless of subordination and forms of ownership are required to report any adverse reactions to medicines or other medicinal products or lack of efficacy of the medicine, or any other problems associated with the medicines used in the country, to the Agency.

58 Heads of health facilities, regardless of their form of ownership, authorize the deputy medical directors to organize, monitor and implement the pharmacovigilance activity, who in turn will be persons responsible for pharmacovigilance or will appoint a clinical pharmacologist or clinical pharmacist in this position.

59 The persons responsible for pharmacovigilance in health facilities are empowered by the heads of health facilities to organize and monitor the implementation of pharmacovigilance activities regardless of subordination and form of ownership, by collecting information on AR cases or medicine ineffectiveness or any other problems associated with medicines, with regular reporting to the Agency.

60 Doctors and health workers of health facilities, regardless of their form of ownership, are obliged to communicate adverse reactions to medicines and other medicinal products, by completing the Form on AR communication or medicine ineffectiveness (Annex No. 2 to the Order approving the Regulation on the Performance of Pharmacovigilance Activities), in electronic or paper format, through agreed communication channels, by the established deadline:

1) Severe and/or unexpected spontaneous, death-causing or life-threatening adverse reactions shall be referred to the Agency within 24 hours from the onset;

2) Non-severe spontaneous adverse reactions or lack of efficacy, shall be referred to the Agency within 15 days from the receipt of the adverse reaction information.

61 Pharmacy specialists, regardless of their form of ownership, are obliged to report adverse reactions to medicines and other medicinal products, completing the Form for communicating adverse reactions to medicines and other medicinal products (Annex no. 3 to the order on approving the Regulation on Pharmacovigilance Activities), in electronic or paper format.

Chapter XI
Implementation of the pharmacovigilance system by the holder of the registration certificate

Section 1. Responsibilities of the holder of a registration **certificate**

62 Manufacturers of medicines/holders of a registration certificate or their official representatives are obliged to supervise new medicines during the first 5 years after registration of the medicine, and to submit to the Agency information on adverse reactions to their own medicines, authorized in the Republic of Moldova.

63 The holder of a registration certificate shall use a pharmacovigilance system approved by the Agency to carry out his pharmacovigilance tasks.

64 With the help of the pharmacovigilance system, the holder of a registration certificate shall carry out an assessment of all information, consider existing options for minimizing and preventing risks and take the necessary measures, as appropriate. The holder of a registration certificate shall perform a periodic audit of his pharmacovigilance system. It shall record the main audit findings in the pharmacovigilance system master file and, based on the audit findings, shall ensure that an appropriate corrective action plan is developed and implemented. Once the corrective actions have been fully implemented, the entry can be removed.

Chapter XII

Pharmacovigilance system master file

Section 1. Structure of the pharmacovigilance system master file

65 The information in the pharmacovigilance system master file is accurate and reflects the pharmacovigilance system in force.

66 The holder of a registration certificate shall use, as appropriate, separate pharmacovigilance systems for different categories of medicinal products. Each such system is described in a separate pharmacovigilance system master file. All medicinal products for which the holder of a registration certificate has obtained a registration certificate in accordance with the regulations in force shall be subject to a pharmacovigilance system master file.

Section 2. Content of the pharmacovigilance system master file

67. The pharmacovigilance system master file shall contain at least the following elements:

1) Information on the local contact person responsible for pharmacovigilance: responsibilities of the local contact person for pharmacovigilance issues, including his/her contact details;
2) A description of the organizational structure of the holder of a registration certificate, including the location(s) of the following pharmacovigilance activities: collection of individual safety reports, assessment, registration of cases in the safety database, production of periodic safety update reports, detection and signal analysis, preparation of the risk management plan, management of pre- and post-authorization studies and management of safety variations of the terms for granting a registration certificate;
3) A description of the location, functionality and operational responsibility of the computer systems and databases used to receive, record and report safety information, and to assess how they meet the purpose;
4) A description of the management and recording of data and the process used for each of the following pharmacovigilance activities:
a) continuous monitoring of the risk-benefit ratio for the medicinal product(s) concerned, the outcome of such monitoring and the decision-making process for taking appropriate action;
b) operation of the risk management system(s) and monitoring of results of risk minimization measures;
c) collection, evaluation and submission of individual safety reports;
d) drafting and submitting periodic updated safety reports;
e) procedures for communicating safety issues and safety variations of the summary of medicinal product characteristics and package leaflet to health workers and the general public;
5) A description of the quality control system for the performance of pharmacovigilance activities, including the following:
a) a description of the human resources management, which contains the following elements: the organizational structure for carrying out the pharmacovigilance activities, with reference to the location of the information on the qualification of the staff; a brief description of the training concept, including a reference to the location of the training files; instructions for critical processes;
b) a description of the record system, including the location of the documents used for pharmacovigilance activities;
c) a description of the pharmacovigilance system monitoring system;
6) Where applicable, a description of the services and/or activities subcontracted by the holder of a registration certificate.

Section 3. Content of the Annex to the pharmacovigilance system master file

68 The pharmacovigilance system master file contains the following documents in the annex:

1) A list of medicinal products contained in the pharmacovigilance system master file, including the name of the medicinal product, the international non-proprietary name (INN) of the active substance(s);
2) A list of written rules and procedures*;*
3) List of subcontractors*;*
4) A list of tasks that have been delegated by the local contact person responsible for pharmacovigilance;
5) A list of all scheduled and completed audits;
6) If applicable, a list of performance indicators;
7) Where applicable, a list of other pharmacovigilance system master files held by the same holder of a registration certificate;
8) A journal containing information on any changes to the content of the pharmacovigilance system master file made in the last 5 years.

Section 4. Maintenance

69 The holder of a registration certificate shall update the pharmacovigilance system master file and revise it to take into account the experience gained and the technical and scientific progress, as well as the changes to the legislation.

70 The pharmacovigilance system master file and the annex shall be subject to checks and shall indicate the version number and the date on which they were last reviewed by the holder of a registration certificate.

71 Any deviation from the pharmacovigilance procedures, the impact, and its management shall be recorded in the pharmacovigilance system master file until the deviation is resolved.

72 The holder of a registration certificate shall immediately notify the Agency of any change in the location of the pharmacovigilance system master file or any change in the contact information and the name of the local contact person responsible for pharmacovigilance.

Section 5. The format of the documents contained in the pharmacovigilance system

Master file

73 The documents contained in the pharmacovigilance system master file are complete and readable. Where appropriate, the information may be provided in the form of flow charts or diagrams. All documents are indexed and archived in such a way as to ensure their accurate and rapid retrieval throughout the retention period.

74 The information and documents in the pharmacovigilance system master file may be submitted in modules, in accordance with the system defined in detail in the guidelines on good pharmacovigilance practice.

75 The pharmacovigilance system master file may be kept in electronic form, provided that the media used for storage remain readable over time and that a easy-to-consult hard copy is made available to the Agency for audit and inspections.

76 The holder of the registration certificate shall record in the logbook any changes in the content of the pharmacovigilance system master file made in the last five years, except for the information referred to in point 68 (1) (b) to (e) and point 69. The holder of a registration certificate shall enter in the logbook the date, the person responsible for the change and, where applicable, the reason for the change.

Section 6. Subcontracting

77 The holder of a registration certificate may subcontract to third parties certain activities

of the pharmacovigilance system. However, the holder of a registration certificate shall be fully responsible for the completeness and accuracy of the pharmacovigilance system master file.

78 The holder of a marketing certificate shall draw up a list of all existing subcontracts between him and the third parties referred to in point 78, specifying the product(s) concerned.

Section 7. Availability and location of the pharmacovigilance system

Master file

79 The pharmacovigilance system master file is kept at the location where the main pharmacovigilance activities are carried out by the holder of a registration certificate, or at the location where the local contact person responsible for pharmacovigilance operates.

80 The pharmacovigilance system master file shall be available at all times and immediately for inspection at the place where it is stored. If the pharmacovigilance system master file is kept in electronic format, it is sufficient that the data stored in electronic format are directly available in the location where the pharmacovigilance system master file is kept.

81 The Agency may limit its request to certain modules or parts of the pharmacovigilance system master file, and the holder of a registration certificate shall bear the costs of submitting a copy of the pharmacovigilance system master file.

82 The Agency is entitled to request the holder of a registration certificate to send a copy of the logbook at regular intervals.

Chapter XIII

The method of reporting by the holders of certificates of registration of adverse reactions to medicines or other medicinal products used in the medical practice.

83 Holders of registration certificates are required to report AR cases to the Agency.

1) Holders of registration certificates shall report to the Agency, through agreed communication channels, adverse reactions to medicinal products:
a) Immediately or within 15 days, in case of severe adverse reactions;
b) Within 90 days, for other (non-severe) adverse reactions;
c) Within 24 hours, for adverse reactions requiring urgent safety measures to protect public health;
2) Holders of registration certificates shall report to the Agency all AR cases in CIOMS or XML formats;
3) Holders of registration certificates shall report the ineffectiveness of medicines in the territory of the Republic of Moldova within 15 days.

84 Holders of registration certificates shall submit the information about unforeseen severe, death-causing or life-threatening RAs within 90 calendar days from the receipt of information, and non-severe RAs outside the country shall be reported in the Periodic Safety Update Report (PSUR)

CHAPTER XIV

Risk management plan

Section 1. Content of the risk management plan

85 The risk management plan established by the holder of a registration certificate shall contain the following elements:

1) an identification or characterization of the safety profile of the medicinal product(s) concerned;
2) an indication of how to further characterize the safety profile of the medicinal product(s) concerned;

3) a documentation of the measures to prevent or minimize the risks associated with the medicinal product, including an evaluation of the effectiveness of such interventions;

4) a documentation of the post-authorization obligations, which were imposed as a condition of obtaining the certificate of registration of the medicinal product.

86 Products containing the same active substance and belonging to the same holder of the registration certificate may be included, where applicable, in a single risk management plan.

87 If a risk management plan refers to post-authorization studies, it shall be indicated whether the holder of a registration certificate initiates, manages or finances such studies, voluntarily or as a result of the obligations imposed by the Agency. All post-authorization obligations are mentioned in the summary of the risk management plan, together with their timetable.

Section 2. Summary of the risk management plan

88 The summary of the risk management plan shall be made available to the public and shall include the key elements of the risk management plan, with a special focus on risk minimization activities and, as regards the safety specification of the medicinal product concerned, important information on potential and identified risks, as well as the missing information.

89 Where a risk management plan covers more than one medicinal product, a separate summary of the risk management plan shall be provided for each medicinal product.

Section 3. Updates to the risk management plan

When the holder of a registration certificate updates a risk management plan, he shall submit the updated risk management plan to the Agency. Once an agreement has been reached with the Agency, the holder of a registration certificate shall only submit the modules that have been updated. Where appropriate, the holder of a registration certificate shall send the Agency an updated summary of the risk management plan.

Each presentation of the risk management plan shall bear a separate version number and date.

Section 4. Risk management plan format

The risk management plan shall be drawn up in the format specified in Annex 3 to this Regulation.

CHAPTER XV

Periodic safety update reports

Section 1. Provisions set out in periodic safety update reports

90 A regular safety report provides up-to-date data on the safety of a product in the post-authorization period. The holder of a registration certificate is obliged to submit such reports to the Agency at the set time intervals, so as to provide brief information on the medicinal product, as well as a risk-benefit assessment; the report shall determine whether further investigations or changes are required in the certificate of registration of the medicinal product or product information.

91 The frequency of submission of periodic safety update reports shall be specified in accordance with the authorization procedures. Submission data according to the specified frequency shall be calculated from the date of authorization. Periodic safety update reports shall be submitted to the Agency immediately, at its request, or in accordance with the following provisions:

1) once every six months during the first two years after the primary marketing of the medicinal product;
2) once a year for the following three years;
3) The reports are then submitted at five-year intervals: at the repeated authorization stage.

92 The Agency accepts the submission of periodic safety update reports, according to the harmonized submission frequency, from the EU reference date.

Section 2. Content of periodic safety update reports

93 The periodic safety update report is based on all available data and focuses on new information that has emerged since the data were completed in the previous periodic safety update report.

94 Periodic safety update reports provide an accurate estimate of the population exposed to the medicine, including all sales volume and medical prescription volume. This exposure estimate shall be accompanied by a qualitative and quantitative analysis of the actual use, indicating, where appropriate, how the actual use differs from the indicated use, based on all data available to the holder of a registration certificate, including the results of observational studies or studies on the use of medicines.

95 The periodic safety update report shall contain the results of the evaluations of the effectiveness of the risk minimization activities relevant for the assessment of the risk-benefit ratio.

96 Holders of a registration certificate are not required to include systematically detailed lists of individual cases or case descriptions in the periodic updated safety report. However, holders of registration certificates shall include case descriptions in the relevant section of the periodic safety update report when they are an integral part of the scientific analysis of a safety signal or concern.

97 Based on the assessment of the cumulative safety data and the risk-benefit analysis, the holder of a registration certificate, at the end of the periodic safety update report, shall enter conclusions on the need for changes and/or actions, including the implications for the approved summary of product characteristics for which the periodic safety update report is submitted.

Section 3. Format of periodic safety update reports

The periodic safety update reports shall be submitted in the format set out in Annex 4 to this Regulation.

CHAPTER XVI

Post-authorization safety studies Section 1. Scope

98 This Chapter applies to non-interventional post-authorization safety studies, which are launched, managed or funded by the holder of a registration certificate under the obligations imposed by the Agency.

99 The holder of a registration certificate shall submit the study protocol and the final study report, an English translation of the title and summary of the study protocol, as well as an English translation of the final study report summary.

100 The holder of the registration certificate shall ensure that all information in the study is managed and stored in such a way as to enable accurate reporting, interpretation and verification of that information and that the confidentiality of the records of the study subjects is protected. The holder of the registration certificate shall ensure that the statistical data set and analytical programs used to generate the data included in the final study report are kept in electronic format and are available for audit and inspection.

Section 2. Format of post-authorization safety studies

For post-authorization non-interventional safety studies, the protocols, summaries and final reports on the studies are submitted in the format provided in Annex no. 5 to this Regulation.

CHAPTER XVII

Final provisions

Section 1. Data protection

101 This Regulation shall apply without prejudice to the obligations of the holders of the registration certificate with regard to the processing of private data or to the obligations of the Agency with regard to the processing of private data.

Annex no.
1 to the
Regulation

Internationally agreed terminology for the classification, access, presentation,
evaluation and assessment of risks and benefits, exchange and communication in electronic format of information on pharmacovigilance and medicinal products

1. Accepted references:

1) Medical Dictionary for Regulatory Activities
- MedDRA) produced by the International Conference on the Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH), the multidisciplinary theme M1;

2) lists of standard conditions published by the European Pharmacopoeia Commission;
3) terminology established in the standard EN ISO 11615: 2012, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO/FDIS 11615: 2012);
4) terminology established in the standard EN ISO 11616: 2012, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (ISO/FDIS 11616: 2012);
5) terminology set out in EN ISO 11238: 2012, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances (ISO/FDIS 11238:2012);
6) terminology set out in standard EN ISO 11239: 2012, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging (ISO/FDIS 11239:2012);
7) terminology established in the standard EN ISO 11240: 2012, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement (ISO/FDIS 11240:2012).

Annex no.2 to the Regulation

Internationally agreed formats and standards for the description, access, presentation, evaluation and assessment of risks and benefits, exchange and electronic communication of information on pharmacovigilance and medicinal products

1. Accepted references:

1) ICH E2B (R2) standard "Maintenance of the ICH guideline on clinical safety data management: data elements for transmission of individual case safety reports";
2) ICH M2 standard 'Specification for the electronic transmission of individual safety reports

3) Standard EN ISO 27953-2: 2011 Health informatics. Individual case safety reports (ICSRs) in pharmacovigilance — Part 2: Human pharmaceutical reporting requirements for ICSR (ISO 27953-2: 2011);
4) standard EN ISO 11615: 2012, Health informatics — Identification of medicinal products (IDMP),
Data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO/FDIS 11615:2012);

5) standard EN ISO 11616:2012, Health informatics — Identification of medicinal products (IDMP),
Data elements and structures for the unique identification and exchange of regulated

pharmaceutical product information (ISO/FDIS 11616: 2012);

6) standard EN ISO 11238:2012, Health informatics — Identification of medicinal products (IDMP),
Data elements and structures for the unique identification and regulated exchange of information

on substances (ISO/FDIS 11238:2012);

7) standard EN ISO 11239:2012, Health informatics — Identification of medicinal products (IDMP),
Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging (ISO/FDIS 11239:2012);

8) standard EN ISO 11240:2012, Health informatics — Identification of medicinal products (IDMP),
Data elements and structures for the unique identification and exchange of units of measurement

(ISO/FDIS 11240:2012).

Annex no.
3 to the
Regulation

Risk management plan format

1. The risk management plan consists of the following modules:
Part I: Overview of the medicinal product(s) Part II: Safety specification
Module SI: Epidemiology of the indication(s) and target population(s) Module SII: Nonclinical part of the safety specification
Module SIII: Exposure in a clinical trial
SIV Module: Non-Clinical Populations SV Module: Post-Authorization Experiences
SVI Module: Additional European Union Requirements for the Safety Specification SVII Module: Identified Risks and Potential Risks
Module SVIII: Summary of safety concerns
Part III: Pharmacovigilance plan (including post-authorization safety studies)
Part IV: Plans for post-authorization efficacy studies
Part V: Risk minimization measures (including assessment of the effectiveness of risk minimization activities)
Part VI: Summary of the risk management plan Part VII: Annexes RO

Annex 4 to the Regulation **Format of periodic electronic safety update reports**

Periodic safety update reports consist of the following modules:

Part I Title and signature page

Part II Summary Part III Contents

1. Introduction
2. Global marketing authorization stage
3. Actions taken for safety reasons within the reporting period
4. Changes to safety reference information
5. Estimated exposure and use patterns

5.1. Cumulative exposure of participants in clinical trials

5.2. Cumulative and interval exposure of patients, according to experience gained when placing on the market

6. Data from summary tables

6.1. Reference information

6.2. Cumulative summary tables for severe adverse events resulting from clinical trials conducted

6.3. Cumulative summary tables for severe adverse events in clinical trials conducted

7. Summaries of significant findings from clinical trials conducted during the reporting interval

7.1. Completed clinical trials

7.2. Ongoing clinical trials

7.3. Long-term monitoring

7.4. Other therapeutic uses of the medicine

7.5. New safety data for fixed combination therapies

8. Findings of non-interventional studies
9. Information from other clinical trials and other sources
10. Nonclinical data
11. Specialty literature
12. Other periodic reports
13. Lack of efficacy in clinical trials checked
14. Breaking news
15. Overview of signals: new, ongoing or completed
16. Signal and risk assessment

16.1. Summary of safety concerns

16.2. Signal evaluation

16.3. Risk assessment and new information

16.4. Risk characterization

16.5. Risk minimization efficiency (if applicable)

17. Evaluation of benefits

17.1. Important baseline information on efficacy and efficiency

17.2. Recent information on efficacy and efficiency

17.3. Characterization of benefits

18. Integrated risk-benefit analysis for authorized directions

18.1. The context of the risk-benefit ratio - medical needs and important alternatives

18.2. Evaluation of the risk-benefit analysis

19. Conclusions and actions
20. Annexes to periodic safety update reports

Annex no.5 to the Regulation

Protocols, summaries and final reports of post-authorization safety studies

1. Study protocol format

1. Title: Informative title including a usual term indicating the design of the study and the medicinal product, substance or class of medicinal products concerned, and a subtitle indicating the identification number of the version and the date of the latest version

2. Holder of a registration certificate

3. Responsible parties, including a list of all institutions that collaborated in the study, as well as other relevant places of study

4. Summary: independent synthesis of the study protocol, with the following subsections:

(a) the title and subtitles stating the version and date of the protocol and the name and affiliation of the lead author

(b) justification and context

(c) subject and objectives of the research

(d) design of the study

(e) population

(f) explained

(g) data sources

(h) study size

(i) data analysis

(j) stages

5. Changes and updates: any substantial change and update of the study protocol after the start of data collection, including a justification for the change or update, the date of the change and a reference to the section of the protocol if the change has been made.

6. Stages: the table with the planned data for the following stages:

(a) start of data collection

(b) end of data collection

(c) the interim progress report(s) referred to in Article 107m

paragraph 5 of Directive 2001/83/EC

(d) interim report(s) on the results of the study, if any

(e) final report on the results of the study

7. Justification and context: description of the safety risk(s), safety profile or risk management measures that have led to the mandatory study for the registration certificate

8. Subject and objectives of the research in accordance with the decision of the competent national authority which made the study mandatory

9. Research methods: description of research methods, including:

(a) design of the study

(b) framework: the population to be studied, in particular the persons, place, time period and selection criteria, including the justification for any inclusion and exclusion criteria. If a sample from a source population is used, a description of the source population and details on the methods for selecting the sample shall be provided. If the study design is a systematic review or a meta-analysis, the criteria for the selection and eligibility of variable studies are explained

(c) data sources: strategies and data sources to determine exposures, effects and all other variables relevant to the study objectives. If the study will use an existing data source, such as electronic medical records, any information on the validity of the data recording and coding shall be reported. If a systematic review or meta-analysis is performed, the search strategy and processes shall be described, as well as any methods for confirming the data by the researchers;

(d) study dimensions: any expected study sizes, the desired level of accuracy of the study estimates and any calculation of the study size estimate that would allow at least one predetermined risk with

a predetermined statistical interpretive power to be detected;
(e) data management;
(f) data analysis;
(g) quality control;
(h) limitations of research methods;
10. Protection of human subjects: safeguard measures to comply with national and European Union requirements to ensure the well-being and rights of participants in non-interventional post-authorization safety studies;
11. Management and reporting of adverse events / reactions and other medically important incidents that occurred during the study
12. Plans for dissemination and communication of study results;
13. References;
2. Format of the summary of the final report on the study;
1. Title and subheadings stating the date of the summary as well as the name and affiliation of the lead author;
2. Keywords (maximum of five keywords indicating the main characteristics of the study);
3. Justification and context;
4. Research topic and objectives;
5. Design of the study;
6. Framework;
7. Subjects and size of the study, including those who dropped out of the study
8. Variables and data sources;
9. Results;
10. Discussion (including, where appropriate, an assessment of the impact of the results of the study on the risk-benefit ratio of the medicinal product concerned);
11. Holder of the registration certificate;
12. Name and affiliation of principal researchers;
3. Format of the final report on the study;
1. Title: title and usual term indicating the design of the study; subheadings stating the date of the final report and the name and affiliation of the lead author;
2. Summary: an independent summary as referred to in section 2 of this Annex
3. Holder of registration certificate: name and address of the holder of the registration certificate;
4. Researchers: the names, titles, degrees, addresses and affiliations of the principal researcher and all cooperating researchers, as well as the list of all primary institutions that collaborated in the study and other relevant places of study;
5. Stages: data for the following stages:
(a) start of data collection (planned and actual data);
(b) end of data collection (planned and actual data);
(c) study activity reports;
(d) interim reports on the results of the study, as appropriate;
(e) final report on the results of the study (planned and actual date);
(f) any other important stage applicable to the study, including the date of registration of the study in the electronic
study register;
6. Justification and context: description of safety concerns that have led to the initiation of the study and analysis of relevant published and unpublished data, assessing relevant information and knowledge gaps that the study is intended to compensate for.
7. Study topic and objectives
8. Protocol changes and updates: list of possible substantial changes and updates to the initial study protocol after the start of data collection, including a justification for each change or update

9. Research methods
9.1. Study design: the essential elements of the study design and the reason for choosing this design
9.2. Framework: framework, locations and data relevant to the study, including recruitment, monitoring and data collection periods. For a systematic review or meta-analysis, the characteristics of the studies used as eligibility criteria, including the justification, must be specified
9.3. Subjects: all source populations and eligibility criteria for the study subjects. Sources and methods of selecting participants shall be provided, including, where appropriate, methods of case assessment, as well as the number of people who dropped out of the study and the reasons for dropping out of the study
9.4. Variables: all results, exposures, predictors, potential confounding factors and effect modifiers, including operational definitions. Diagnostic criteria are provided, if applicable
9.5. Data sources and measurement: for each variable of interest, data sources and details of measurement and evaluation methods. If the study used an existing data source, such as electronic medical records, any information on the validity of the data recording and coding is reported. In case of systematic review or meta-analysis, description of all sources of information, search strategy, study selection methods, data extraction methods and any procedure used by researchers to obtain or confirm the data
9.6. Systematic errors
9.7. Study size: study size, considerations underlying a possible calculation of the study size and any method used to achieve the expected study size
9.8. Data transformation: transformations, calculations or operations with the data, including how the quantitative data were treated in the analyses and which were the chosen groups, as well as the reasons for that choice
9.9. Statistical methods: description of the following elements:
(a) main synthesis measures
(b) all statistical methods applied to the study
(c) any methods used to examine subgroups and interactions
(d) of how missing data were treated
(e) in any sensitivity analyses
(f) any modification of the data analysis plan included in the study protocol, with the justification of the respective modification
9.10. Quality control: mechanisms to ensure data quality and integrity
10. Results: with the following subsections:
10.1. Participants: the number of study subjects in each stage of the study. For a systematic review or meta-analysis, the number of studies analyzed, evaluated in terms of eligibility and included in the review, as well as the reasons for exclusion at each stage
10.2. Descriptive data: characteristics of study participants, information on potential exposures and confounding factors and number of participants for which data are missing. For a systematic review or meta-analysis, the characteristics of each study from which data were extracted
10.3. Effect data: number of study subjects, by main effect categories
10.4. Main results: unadjusted estimates and, where appropriate, estimates adjusted for confounding factors and their accuracy. If relevant, the relative risk estimates are converted into absolute risks for a significant period of time
10.5. Other analyses
10.6. Incidents and adverse reactions
11. Discussion
11.1. Main results: main results in relation to the objectives of the study, previous research supporting or contradicting the conclusions of the completed post-authorization study and, where

appropriate, the impact of the results on the risk-benefit ratio for the medicinal product concerned.
11.2. Limitations: limitations of the study taking into account the circumstances that may have affected the quality or integrity of the data, limitations of the study approach and methods used to overcome them, sources of systematic errors or potential inaccuracies and validation of events. Both the direction and extent of potential systematic errors need to be commented on
11.3. Interpretation: interpretation of results, taking into account the objectives, limitations, multitude of analyses, results of similar studies and other relevant evidence
11.4. Potential for generalization
12. References

Annex no. 2 to the Order of the Ministry of Health no. of 2017

Form for Communicating Adverse Reactions /or Lack of Effectiveness of Medicines and Other Medicinal Products, (underline/check version of accepted answer)

The confidentiality of the identity data mentioned in this form will be protected !!!

PATIENT INFORMATION *Full name or initials: *Date/month/year of birth/Age *Sex: ☐ M ☐ F *Body weight (kg): Height *Allergy (please indicate to what): ☐ Yes ☐ No	*__The adverse reaction caused:__ ☐ patient death, please indicate (time/date/month/year) ☐ a danger for the patient's life ☐ hospitalization or extension of hospitalization ☐ significant or lasting disability/incapacity ☐ developmental abnormality/congenital malformation ☐ healing without sequelae *(consequences)* ☐ state without dynamics ☐ not known ☐ others, please indicate
Diagnosis: Treatment: ☐ outpatient ☐ inpatient ☐ self-medication № of outpatient card or observation sheet _____	☐ **Lack of efficacy of the given drug (LE)**

* **DESCRIPTION OF ADVERSE REACTION(S) (AR)):**	*Date/time of initiation of AR ___/___/____ ___ :
	Date/time of healing of AR ___/___/____ ___ :
	*Duration:

*__MEDICINAL PRODUCT (MP) suspected of producing an adverse reaction (RA)/ Lack of efficacy of the given drug (LE)__							
Trade name (TN)			International Nonproprietary Name (INN)				
Manufacturer			Country		№ of series/ date of manufacture		
For what the MP (disease or pathological process) was	Route of administratio	Single dose	Dose/day (nictemeral)	Beginning of administration of MP	End of administration of MP	Date of detection of AR	Dose that caused the

indicated	n			date/month /year	date/month /year		AR
				/ /	/ /	/ /	
* **OTHER MEDICINES administered concomitantly, including self-medication** ☐ yes ☐ no ☐ self-medication							

Trade name (TN)	International nonproprietary name (INN)	Route of administration	Single dose	Dose/day (nictemeral)	Beginning of administration date/month/ year	Discontinuation of administration date/month / year	For what the MP was indicated (disease or pathological process)
					/ /	/ /	
					/ /	/ /	
					/ /	/ /	
					/ /	/ /	
					/ /	/ /	

* **Measures taken:**	Was stopping of the suspicious medicinal product followed by a regression of the adverse effect? ☐ yes ☐ no ☐ MP was not stopped
☐ Suspension of suspicious MP ☐ Dose reduction of suspected MP ☐ Stopping concomitant medications ☐ Medicinal therapy to relieve RA ☐ Medicinal therapy (including surgery) ☐ No treatment ☐ Others, please indicate	Has the adverse reaction repeated or worsened by repeated administration of the medicinal product? ☐ yes ☐ no ☐ MP was not administered repeatedly
	Medicinal therapy to relieve RA (if necessary)

RELEVANT ADDITIONAL INFORMATION

- Relevant history of the case (other concomitant diseases, allergic conditions, medicinal allergy in the past, suspected medicinal interactions, kidney or liver disease, pregnancy, lactation, special diets, harmful habits, exposure to ionizing radiation, etc.);
- For developmental abnormalities/congenital malformations occurring following the administration of the suspicious
  medicinal product, please indicate all medicines administered during pregnancy, also the date of the last menstruation, other relevant data;
- Additional adverse event data (clinical, paraclinical, radiological examinations, relevant laboratory tests (if possible) concentration of the medicine in the blood and tissues, in case
  of death of the patient (cause of death, if the death is related to the administration of the medicinal product
  suspected of AR, autopsy data). Describe the pathological changes, indicating in parentheses the values of the norm;
- Relevant data to argue the lack of efficacy of the suspected medicinal product (where applicable).

*__DOCTOR or other person who has registered AR__ * Full name: *Specialty: *Work place: *Address of the institution: **Telephone: **Fax: *e-mail: *Date of filling in the form:
Please send the communication form to: Medicines and Medical Devices Agency, Pharmacovigilance and Rational Use of Medicines Section, MD-2028, mun. Chişinău, str. Korolenko 2/1, tel. 88-43-38, Fax: 88-43-38, e-mail: farmacovigilenta@amed.md

Fields marked with * are mandatory. If you are available, please also fill in the other fields as they are also important.

** Fill in at least one of the contact information

Please fill in the fields requesting information on the specialty, place of work, e-mail address, telephone, fax. This information is required so that you can be contacted if additional information

about the adverse reaction or the patient's condition is needed.

An acknowledgment of receipt followed by an evaluation of the adverse reaction will be sent to you by e-mail or fax.

Annex no. 3 to the Order of the Ministry of Health no. of 2017

The patient

COMMUNICATION FORM ON ADVERSE REACTIONS TO MEDICINES

/OR LACK OF EFFECTIVENESS OF MEDICINES AND OTHER PRODUCTS

The confidentiality of the identity data mentioned in this form will be protected !!!

INFORMATION ABOUT THE PERSON WHO HAS EXPERIENCED THE ADVERSE REACTION (AR)

* Full name or initials:
* Date/month/year of birth/Age *Sex: ☐ M ☐ F * Body weight (kg): * Height
City (District) Village _ Tel
Habits: ☐ Smokes ☐ Drinks alcohol Other:
Presence of pregnancy ☐
*Allergy (please indicate to what): ☐ Yes
☐ No
Diseases the person concerned suffers from:

* **DESCRIPTION OF ADVERSE REACTION (AR)** (AR symptoms, how they appeared):	* Date/time of AR occurrence: ___/___/____: Date/time of RA healing: ___/___/____: * Duration:	*Select the severity of the adverse reaction: ☐ Mild ☐ Unpleasant, but did not affect physical activity ☐ Severe enough to affect physical activity ☐ Severe as to consult a doctor ☐ Required hospitalization ☐ Caused death

MEDICATION (M) suspected of producing an adverse reaction (AR)

* Name of the suspected drug	
Manufacturer/Country/№ series/date of manufacture (if available)	
* Dosage/Administration (eg 1 tablet of 100 mg twice a day)	
What you used the medicine for (disease or pathological condition)	

Beginning of M administration (date/month/year) / /	End of M administration (date/month/year) / /	Duration of M administration (days)
*The medicine has been used before ☐ no ☐ yes (specify if there were AR)		
***OTHER MEDICINES administered concomitantly** (at the same time) ☐ no ☐ yes		
If Yes, please specify what these medicines are		

*__Measures taken to improve AR:__ ☐ The administration of the suspicious medicine has been discontinued ☐ The dose of the suspected medicine has been reduced ☐ Concomitant administration of medicines has been discontinued ☐ Has received treatment for A symptoms (what (s)he has been treated with (if you have the information)) ☐ No treatment ☐ Others, please indicate	* How the person feels at the time of filling the form: ☐ No longer has the symptoms described ☐ Still has the symptoms but is feeling better ☐ Still has the symptoms, condition has not improved ☐ The condition has worsened ☐ The person has died
* **Measures to improve AR were taken by:** ☐ doctor ☐ nurse ☐ pharmacist ☐ ☐ others patient	
* **Person filling in the form:** ❑ Patient or consumer of the medicinal preparation ❑ Patient's relative ❑ Doctor ❑ Pharmacist ❑ Nurse Another specification	**Adverse reaction reported by:** Full name: Address: **Telephone: **e-mail: *Date of filling in the form:
Please send the communication form to: Medicines and Medical Devices Agency, Pharmacovigilance and Rational Use of Medicines Section, MD-2028, mun. Chişinău, str. Korolenko 2/1, tel. 88-43-38, fax: 88-43-38, e-mail: farmacovigilenta@amed.md	

Fields marked with * are mandatory. If you are available, please also fill in the other fields as they are also important! ** Fill in at least one of the contact information in order to obtain additional data if necessary

Annex 12. Resource List: COVID-19 Guidance

Given the COVID-19 situation is rapidly evolving, a version of this resource list will be regularly updated and made available on the World Bank COVID-19 operations intranet page (http://covidoperations/).

WHO Guidance

Advice for the public

- WHO advice for the public, including on social distancing, respiratory hygiene, self-quarantine, and seeking medical advice, can be consulted on this WHO website: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public

Technical guidance

- Infection prevention and control during health care when novel coronavirus (nCoV) infection is suspected, issued on March 19, 2020
- Recommendations to Member States to Improve Hygiene Practices, issued on April 1, 2020
- Severe Acute Respiratory Infections Treatment Center, issued on March 28, 2020
- Infection prevention and control at health care facilities (with a focus on settings with limited resources), issued in 2018
- Laboratory biosafety guidance related to coronavirus disease 2019 (COVID-19), issued on March 18, 2020
- Laboratory Biosafety Manual, 3rd edition, issued in 2014
- Laboratory testing for COVID-19, including specimen collection and shipment, issued on March 19, 2020
- Prioritized Laboratory Testing Strategy According to 4Cs Transmission Scenarios, issued on March 21, 2020
- Infection Prevention and Control for the safe management of a dead body in the context of COVID-19, issued on March 24, 2020
- Key considerations for repatriation and quarantine of travelers in relation to the outbreak COVID-19, issued on February 11, 2020
- Preparedness, prevention and control of COVID-19 for refugees and migrants in non-camp settings, issued on April 17, 2020
- Coronavirus disease (COVID-19) outbreak: rights, roles and responsibilities of health workers, including key considerations for occupational safety and health, issued on March 18, 2020
- Oxygen sources and distribution for COVID-19 treatment centers, issued on April 4, 2020
- Risk Communication and Community Engagement (RCCE) Action Plan Guidance COVID-19 Preparedness and Response, issued on March 16, 2020
- Considerations for quarantine of individuals in the context of containment for coronavirus disease (COVID-19), issued on March 19, 2020
- Operational considerations for case management of COVID-19 in health facility and community, issued on March 19, 2020

- Rational use of personal protective equipment for coronavirus disease 2019 (COVID-19), issued on February 27, 2020
- Getting your workplace ready for COVID-19, issued on March 19, 2020
- Water, sanitation, hygiene and waste management for COVID-19, issued on March 19, 2020
- Safe management of wastes from health-care activities, issued in 2014
- Advice on the use of masks in the community, during home care and in healthcare settings in the context of the novel coronavirus (COVID-19) outbreak, issued on March 19, 2020
- Disability Considerations during the COVID-19 outbreak, issued on March 26, 2020

WORLD BANK GROUP GUIDANCE

- Technical Note: Public Consultations and Stakeholder Engagement in WB-supported operations when there are constraints on conducting public meetings, issued on March 20, 2020
- Technical Note: Use of Military Forces to Assist in COVID-19 Operations, issued on March 25, 2020
- ESF/Safeguards Interim Note: COVID-19 Considerations in Construction/Civil Works Projects, issued on April 7, 2020
- Technical Note on SEA/H for HNP COVID Response Operations, issued in March 2020
- Interim Advice for IFC Clients on Preventing and Managing Health Risks of COVID-19 in the Workplace, issued on April 6, 2020
- Interim Advice for IFC Clients on Supporting Workers in the Context of COVID-19, issued on April 6, 2020
- IFC Tip Sheet for Company Leadership on Crisis Response: Facing the COVID-19 Pandemic, issued on April 6, 2020
- WBG EHS Guidelines for Healthcare Facilities, issued on April 30, 2007

ILO GUIDANCE

- ILO Standards and COVID-19 FAQ, issued on March 23, 2020 (provides a compilation of answers to most frequently asked questions related to international labor standards and COVID-19)

MFI GUIDANCE

- ADB Managing Infectious Medical Waste during the COVID-19 Pandemic
- IDB Invest Guidance for Infrastructure Projects on COVID-19: A Rapid Risk Profile and Decision Framework
- KfW DEG COVID-19 Guidance for employers, issued on March 31, 2020
- CDC Group COVID-19 Guidance for Employers, issued on March 23, 2020