

# Environmental Safeguards Due Diligence Report (Draft)

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## AFG: COVID-19 Vaccine Support Project under the Asia Pacific Vaccine Access Facility (APVAX)

Prepared by Ministry of Public Health, Islamic Republic of Afghanistan, for the Asian Development Bank (ADB) and the Ministry of Finance, Government of Afghanistan.

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## **CURRENCY EQUIVALENTS**

(as of 9 March 2021)

Currency Unit	=	Afghan Afghani (AF)
AF 1.00	=	\$ 0.013
\$ 1.00	=	AF 78.62

## **ABBREVIATIONS**

ADB	—	Asian Development Bank
AFRM	—	Afghanistan Resident Mission
EIA	—	Environmental Impact Assessment
EMP	—	Environmental Management Plan
IEE	—	Initial Environmental Examination
DDR	—	Due-Diligence Report
MOF	—	Ministry of Finance
MOPH	—	Ministry of Public Health
NGO	—	Non-governmental Organization
GCMU	—	Grant and Services Contract Management Unit
SCO	—	Sehatmandi Coordination Office
PPP	—	Projects, Plans, Policies
WHO	—	World Health Organization
SPS	—	Safeguard Policy Statement
EA	—	Executing Agency

## **WEIGHTS AND MEASURES**

km (kilometer) — 1000 meters m (meter) — 0.001 kilometer

## **NOTE**

In this report, "\$" refers to US dollars.

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## I. INTRODUCTION

1. Afghanistan is classified as a fragile and conflict-affected situations (FCAS) country. The coronavirus disease (COVID-19) pandemic has adversely impacted Afghanistan's economy and its population. To mitigate these impacts, the government has adopted a National Plan for COVID-19 Vaccination in Afghanistan (NPCVA). The proposed project will protect the population from morbidity and mortality due to COVID-19 disease while targeting poor and vulnerable groups and ensuring gender mainstreaming.

2. The project will provide the Government of Afghanistan with urgently needed and flexible financing for COVID-19 vaccine procurement and logistics, and capacity strengthening activities through the Asia Pacific Vaccine Access Facility (APVAX).<sup>1</sup> The project investment component under the APVAX will be utilized. The project will support the NPCVA in line with the FCAS approach and Strategy 2030 of the Asian Development Bank (ADB).<sup>2</sup> It supports the National Emergency Response Plan for Coronavirus 2020 and will contribute to limiting the impact of COVID-19, which has resulted in additional 1.9 million–6.0 million people falling into poverty in 2020.<sup>3</sup> It is an integral part of the development partner package and will help the government's efforts to mitigate the health, social, and economic impacts of the pandemic and strengthen the country's immunization systems. It will also complement efforts to contain the COVID-19 pandemic and foster economic growth in the Central Asia Regional Economic Cooperation (CAREC) region.

Asia Pacific

3. The proposed support for the COVID-19 vaccine responds to the government's formal request to Asian Development Bank (ADB) made on 7 January 2021 for support for the COVID-19 vaccine in Afghanistan. The grant will have the following two outputs:

- (i) Output 1 – COVID-19 vaccine procured and delivered to designated points.
- (ii) Output 2 – Capacity of MOPH to procure and deliver the vaccines strengthened.

4. The executing agency (EA) of this project is the Ministry of Public Health (MOPH). The objective of the project is to support MOPH in COVID-19 vaccine procured and delivered to designated points and strengthening capacity of the MOHP and to respond to deliver the vaccines to targeted areas.

5. Minimal quantities of medical waste (used syringes, vials, PPE's) will also be generated from this activity. The same will need to be disposed as per the national healthcare waste management plan. Hence, an environmental due diligence study has been carried out to determine adequacy of the healthcare waste management plan and to provide recommendation to overcome any identified gaps.

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<sup>1</sup> The proposed project was prepared under the "One ADB" approach following the streamlined business processes outlined in the APVAX policy paper. ADB. 2020. [ADB's Support to Enhance COVID-19 Vaccine Access](#). Manila.

<sup>2</sup> Islamic Republic of Afghanistan, Ministry of Public Health (MOPH). 2020. *National Plan for COVID-19 Vaccination In Afghanistan*. February; ADB. 2017. Strategy 2030 recognizes the special needs of FCAS and calls for following a differentiated approach to this group of countries. ADB. 2018. [Strategy 2030: Achieving a Prosperous, Inclusive, Resilient, and Sustainable Asia and the Pacific](#). Manila; Contribution to Strategy 2030 Operational Priorities (accessible from the list of linked documents in Appendix 2). The project is aligned with operational priority 1 through increasing access to COVID-19 vaccines, operational priority 2 by generating skilled jobs for women, and operational priority 7 by breaking the chain of COVID-19 transmission in Asia and the Pacific.

<sup>3</sup> World Bank. 2020. [Afghanistan Development Update: Surviving the Storm](#). Washington, DC.

## II. ASSESSMENT OF LEGAL FRAMEWORK AND INSTITUTIONAL CAPACITY

6. The proposed project (support for the COVID-19 vaccine) has been screened, classified, and assessed based on ADB's Safeguard Policy Statement (2009), and environmental legislation of the Islamic Republic of Afghanistan, and reviewed and approved by ADB and if necessary be reviewed and approved by the National Environmental Protection Agency (NEPA). This also includes complying with international agreements which Afghanistan is party to.

### A. Afghanistan's Legislative and Policy Framework

7. The following national environmental acts, laws, regulations, guidelines and policies are relevant to the project:

- (i) **Environmental Act, 2007.** This act has been promulgated to give effect to Article 15 of the Constitution of Afghanistan and provide for the management of issues relating to rehabilitation of the environment and the conservation and sustainable use of natural resources, living organisms and non-living organisms.
- (ii) **Law on Managing Land Affairs, 2008.** The 2008 Law on Managing Land Affairs sets out definitions for various land types and classifications, requirements for land deeds, and principles governing allocations of state land, land leasing, land expropriation, settlement of land rights, and restoration of lands.
- (iii) **Draft Forest Law, 2009.** The Draft Forest Law reflects the principles of community based natural resource management enshrined in the Cabinet-endorsed National Strategy for Forests and Rangeland. The draft is currently with the Ministry of Justice for processing.
- (iv) **Interim Environmental Impact Assessment Regulations, Draft 2.3.** These regulations govern the process of environmental impact assessment in Afghanistan on an interim basis pending the establishment of the Environmental Impact Assessment (EIA) Board of Expert in terms of Article 20 of the Environmental Law and issuing of final regulations. These regulations provide the detailed process of EIA and list the projects into category A and B based on potential impacts.

### B. Institutional Framework in Afghanistan

8. The primary executing agency (EA) will be MOPH. This and other central government institutions potentially linked to the project and the implementation of the environmental management plan (EMP) are described below.

- (i) **Ministry of Public Health (MOPH):** MOPH is responsible for planning, constructing, operating and maintaining regional, national and provincial hospitals, health care in Afghanistan. The MOPH will be responsible for implementation of the project. The procurement activities will be undertaken by the Implementing Unit - Grant and Services Contract Management Unit (GCMU) which was set up for the World Bank Sehatmandi Project, within the Ministry of Public Health. The GCMU's capacity will be augmented with additional staff (consultants) to implement the ADB project. The additional staff will be selected as individual consultants under the proposed grant. The individual consultants for Grant and Services Contract Management Unit (GCMU) will work full time in Kabul. The expertise will include project

coordination, financial management, procurement, accountancy as well as monitoring and evaluation.

- (ii) **Infection Prevention and control Policy, 2005:** The MOPH's National Policy on Infection Prevention and Control for Hospitals and Health Centers (2005) provide the broad principles of Infection Prevention and control (IPC) for all Afghanistan healthcare facilities. The procedures manual provides the specific guidelines for implementation of effective IPC program in the hospitals and health centers. The objectives of the manual are twofold i.e. (a) to facilitate the implementation of effective implementation of the national IPC policy, and (b) to provide the technical guidance necessary for the clinical managers of health facilities to be able to implement an effective IPC program. The IPC Program covers the Nosocomial Infection Surveillance system, Environmental Sampling, occupation Health Program and Safe Injection Practices. The IPC for housekeeping, waste disposal and pest control also has been provided.
- (iii) **MOPH Strategic Plan: MOPH Strategic Plan (2011-15)** developed by the Ministry of Public Health (MOPH) has 8 strategic directions which also emphasis upon the regulation and standardization of quality health services, advocate and promote healthy environment.
- (iv) **National Environmental Protection Agency (NEPA):** NEPA's goal is "to protect the environmental integrity of Afghanistan and support sustainable development of its natural resources through the provision of effective environmental policies, regulatory frameworks and management services that are also in line with the Afghanistan Millennium Development Goals (MDGs)".
- (v) **Civil Society Organizations.** Save the Environment Afghanistan (SEA) is Afghanistan's only major grassroots and Afghan-managed conservation organization. SEA (then SAVE) was active in environmental issues during the civil war when there was no active government involvement in environmental issues. SEA's mission is protection of the environment, sustainable resource utilization, conservation of biodiversity and integrated development of natural resources. SEA is member of IUCN, IUFRO (The Global Network for Forest Science Cooperation) and APAFRI (Asia Pacific Association of Forestry Research Institutions) and works closely with the International Crane Foundation, the World Wide Fund for Nature (WWF), the International Centre for Integrated Mountain Development (ICIMOD), the International Snow Leopard Trust and other environmental organizations (source: Afghanistan's Fourth National Report to the Convention on Biological Diversity (2009).

9. Afghanistan has ratified a number of international agreements and conventions relating to the protection of the environment and biodiversity.

5. **The Stockholm Convention, The Basel Convention, and The Rotterdam Convention:** Provides the Guidelines on best available techniques and provisional guidance on best environmental practices deal specifically with Healthcare wastes. Afghanistan through NEPA is the signatory of all the three conventions and have ratified and the treaty came in force in June 2013.

- (i) The **Ramsar Convention on Wetlands**, signed in Ramsar, Iran in 1971, is an intergovernmental treaty which provides the framework for national action and international cooperation for the conservation and wise use of wetlands and their resources. Afghanistan is currently not a Contracting Party to the Ramsar Convention.
- (ii) The **World Heritage Convention (WHC)** is an international agreement that was adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1972. It is based on the

- premise that certain places on earth are of outstanding universal value and should therefore form part of the common heritage of mankind. The Convention seeks to identify and safeguard the world's most outstanding natural and cultural heritage. Afghanistan became a Party to the Convention in March 1979.
- (iii) The United Nations Framework **Convention on Climate Change** (UNFCCC) sets an overall framework for intergovernmental efforts to tackle the challenge posed by climate change. Afghanistan signed the UNFCCC in June 1992. The Transitional Authority ratified the Convention in September 2002 and the Convention entered into force in December 2002. The Kyoto Protocol is an extension to the Convention adopted in 1997 that outlines legally binding commitments to emission cuts. Afghanistan has yet to accede to the Kyoto Protocol.
  - (iv) The **Convention on International Trade in Endangered Species** (CITES) is an international agreement between governments which came into force in 1975. Its aim is to ensure that international trade in specimens of wild animals and plants does not threaten their survival. Afghanistan acceded to CITES on 30 October 1986 but has not been actively implementing the Convention.
  - (v) Afghanistan signed the **Convention on Biological Diversity** (CBD) in 1992 and ratified it in 2002. Afghanistan submitted the Fourth National Report to the CBD Secretariat in 2009.
  - (vi) Afghanistan is not a Party to the Cartagena Protocol on Biosafety, a supplementary agreement to the CBD. Afghanistan does not currently consider biosafety to be a significant issue relative to other challenges facing the country (source: Fourth National Report to the CBD Secretariat, 2009)

### C. Government's regulation on environmental impact assessment

6. The Government's regulation on environmental impact assessment is based on the Environmental Act of Islamic Republic of Afghanistan (Gazette No. 912) dated 23 Jadi, 1384 (25 January 2007). The National Environmental Protection Agency (NEPA), as an independent institutional entity, is responsible for coordinating and monitoring conservation and rehabilitation of the environment, and for implementing this Act. Article 16 and 17 of Chapter 3 of the Environmental Act describes the process of preparing a preliminary assessment, an environmental impact statement and a comprehensive mitigation plan to be conducted by the proponent of each project.

7. Article 21 mentions public consultation is required for all the projects. Article 18 describes the approval procedure of environmental impact assessment. The NEPA will appoint an EIA Board of Experts to review, assess and consider applications and documents submitted by the proponent. Acting on the advice of the EIA Board of Experts, NEPA shall either grant or refuse to a grant permit in respect of the project. A permit granted will lapse if, in case of the proponent fails to implement the project within three years of the date of which the permit was granted.

8. Article 19 describes the appeal procedure. Any person may, within thirty (30) days of the granting or refusal of a permit, appeal the decision to the Director-General of the NEPA. The Director-General shall review the appeal application and thereafter make an appropriate decision. Should the appellant wish to appeal the Director-General's final decision, the matter shall be referred to the relevant court.

9. **Administrative Guidelines for the Preparation of Environmental Impact Assessments, Draft 2, March 2007.** These guidelines are in draft form and have been prepared by NEPA in coordination with UNEP. The purpose of guidelines is to provide guidance to proponents while undertaking a development project that may have a potential

impact on the environment. The guidelines also provide guidance on how public should be consulted and defines the roles and responsibilities of various stakeholders in the process.

#### **D. Environmental Impact Assessment Policy – “An Integrated Approach to Environmental Impact Assessment in Afghanistan”, November 2007.**

10. NEPA with the assistance from UNEP has developed the EIA Policy of Afghanistan. The policy stipulates energy sector guidelines to the project proponents to integrate EIA in the process of development and the procedures to address environmental consequences and involve necessary institutions in the process of project implementation.

11. **National Environment Strategic Documents.** These includes (i) The Millennium Development Goals: Vision 2020; (ii) The Afghanistan Compact; (iii) The Afghanistan National Development Strategy (ANDS 2008-2013), and (iv) The National Environment Strategy.

#### **E. World Bank / IFC EHS Guidelines for Health Care Facilities**

12. The WB/IFC Environmental Health and Safety (EHS) Guidelines for Health Care Facilities include information relevant to the management of EHS issues associated with health care facilities (HCF) which includes a diverse range of facilities and activities involving 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, and blood banks and collection services. A description of activities in this sector are also provided in these guidelines.

13. Table presents a list of IFC guidelines applicable to all activities supported under the project and are referred to in this safeguard Due Diligence Report (DDR) where appropriate.

**Table 1: IFC Guidelines Applicable to All Activities Supported under the Project**

EHS Guideline	Description, Relevance to project
EHS General Guidelines (2007)	<p>Key sections of the General Guidelines of relevance to project include:</p> <ul style="list-style-type: none"> <li>- Environmental Guidelines (covering air emissions, wastewater and ambient water quality, hazardous materials management, waste management, noise)</li> <li>- Occupational health and safety</li> <li>- Community health and safety</li> <li>- Construction and decommissioning</li> </ul> <p>The General Guidelines are designed to be used together with the relevant Industry Sector EHS Guidelines which provide guidance to users on EHS issues in specific industry sectors (see below).</p>
EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing (2007)	<p>The EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing include information relevant to pharmaceuticals and biotechnology manufacturing facilities. They cover the production of active pharmaceutical ingredients and secondary processing, including intermediates, formulation, blending, and packaging, and related activities research, including biotechnology research and production. Most importantly, the guidelines cover the following aspects that should be considered in the design and operation of pharmaceutical manufacturing activities to be supported by the project:</p> <ul style="list-style-type: none"> <li>- Management of environmental issues such as air emissions</li> </ul>



EHS Guideline	Description, Relevance to project
	(volatile organic compounds, acid gases, and particulates), odors, industrial process wastewater, solid and hazardous wastes <ul style="list-style-type: none"> <li>- Management of threats to biodiversity from the collection of genetic resources (bioprospecting), biosafety, and bioethics</li> <li>- Occupational health and safety</li> <li>- Process safety, pathogenic and biological hazards</li> <li>- Community health and safety</li> </ul>
EHS Guidelines for Waste Management Facilities (2007)	Provide guidance for facilities or projects dedicated to the management of municipal solid waste and industrial waste, including waste collection and transport; waste receipt, unloading, processing, and storage; landfill disposal; physicochemical and biological treatment; and other waste disposal options. Most importantly, the guidelines cover the following aspects that should be considered in the design and operation of solid waste management activities to be supported by the project: <ul style="list-style-type: none"> <li>- Municipal solid waste management (collection and transport, processing and storage, treatment, disposal)</li> <li>- Industrial non-hazardous waste management (such as sludge from water supply treatment plant, wastewater treatment plant, inert construction/demolition waste)</li> <li>- Occupational health and safety</li> <li>- Community health and safety</li> </ul>

EHS = Environmental, Health, and Safety; GIIP = Good International Industry Practice.

14. The WHO established the World Health Organization Expanded Program on Immunization (WHO-EPI) more than 40 years ago to increase vaccine coverage rates around the world, reduce disease burden, and to increase smaller access inequities between low- and high-income countries. To ensure quality and safety, the WHO issues norms and standards on the production and control of biological products and technologies which are based on scientific consensus and consultations. The WHO assists member countries in ensuring the quality and safety of biological medicines and related in vitro biological tests worldwide. The WHO guidelines provide information on a range of topics for the National Regulatory Authorities (NRA) and manufacturers as well as recommendations to establish the technical specifications for manufacturing and quality control for specific products that meets international standards. The regulatory guidance documents produced by WHO aim to establish a harmonized regulatory framework for products moving in international markets.

15. WHO assesses the quality, safety and efficacy of vaccines for procurement to low- and middle-income countries. Vaccines that meet the WHO standards are prequalified and listed on the WHO website for information. The United Nations Children's Fund (UNICEF)<sup>4</sup>, PAHO Revolving Fund, and GAVI, the Vaccine Alliance<sup>5</sup> refer to the WHO list of prequalified vaccines when purchasing. The WHO prequalification process includes WHO site audit and review of clinical experience of a manufacturer with the candidate vaccine by external reviewers of WHO that also makes recommendations on available clinical evidence of efficacy, immunogenicity, and safety of the product. The recommendations from the WHO site audit and external reviewers are taken into account by WHO in the decision-making process for prequalification.

<sup>4</sup> UNICEF is the global lead in vaccine procurement. The agency works in partnership with governments, global partners, and a large number of suppliers.

<sup>5</sup> GAVI mainly ensures access to immunization in poor countries and provides support to routine vaccination programs.

16. Table 2 presents a list of key WHO guidelines applicable to all activities supported under the project and should be used and referred to in DDR. A more comprehensive list of WHO good manufacturing practice (GMP) and guidelines are presented in Appendix 1.

**Table 2: WHO Good Manufacturing Practice Guidelines Applicable to all Activities under the Project**

WHO Guideline	Description, Relevance to project
WHO GMP for pharmaceutical products: main principles <sup>6</sup>	<p>Provides good practices in production and quality control and is used as a standard to justify GMP status, which constitutes one of the elements of the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. The certification is granted through the assessment of applications for manufacturing authorizations and as a basis for the inspection of manufacturing facilities. The basic elements of quality management are:</p> <ul style="list-style-type: none"> <li>- an appropriate infrastructure or pharmaceutical quality system, encompassing the organizational structure, procedures, processes and resources.</li> <li>- systematic actions necessary to ensure adequate confidence that a product (or service) will satisfy given requirements for quality.</li> </ul>
WHO GMP for biological products <sup>7</sup>	<p>Serves as a basis for establishing national guidelines and the application of risk-based approaches to GMP. The guidance applies manufacturing procedures related to growth of strains of microorganisms and eukaryotic cells, extraction of substances from biological tissues, including human, animal and plant tissues, and fungi, recombinant DNA (rDNR) techniques, hybridoma techniques, and propagation of microorganisms in embryos or animals.</p>
WHO GMP for sterile pharmaceutical products <sup>8</sup>	<p>Provides the guidelines for the production of sterile preparations in various operations (such as those involving containers and closures, product preparation, filling and sterilization), quality control, sanitation, levels of environmental cleanliness in accordance with ISO 14644, sterilization methods, and personnel and premises requirements.</p>
WHO Technical Report Series TRS <sup>9</sup>	<p>The WHO TRS guidelines cover all the pharmaceutical topics as: Process validation; Cleaning validation; Analytical method validation; Qualification of equipment; Water system validation; HVAC validation; Computer system validation; Market complaint handling; Product recalls, and others.</p> <p>Most relevant TRS guidelines for the project include: WHO-TRS 902/2002, WHO-TRS 908/2003, WHO-TRS 929/2005, WHO-TRS 980-2014, WHO TRS 937-2006.</p>

<sup>6</sup> WHO good manufacturing practices (GMP) for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report. Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.

<sup>7</sup> WHO good manufacturing practices (GMP) for biological products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report. Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 3.

<sup>8</sup> WHO good manufacturing practices (GMP) for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report. Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.

<sup>9</sup> [https://www.who.int/biologicals/WHO\\_TRS\\_980\\_WEB.pdf](https://www.who.int/biologicals/WHO_TRS_980_WEB.pdf)

WHO Guideline	Description, Relevance to project
PIC/S Guide to Good Manufacturing Practice for Medical Products (PE 009-14, 2018)	International guidance from the Pharmaceutical Inspection Convention, Pharmaceutical Inspection Cooperation Scheme (PIC/S) to ensure harmonized GMP standards. Originally derives from the WHO GMP Guides and has been further developed in order to comply with stringent manufacturing and health requirements, to cover new areas (e.g. biologicals) and to adapt to scientific and industrial technology (e.g. biotech).
WHO GMP for water for pharmaceutical use <sup>10</sup>	Provides information on available specifications for water for pharmaceutical use (WPU), guidance about which quality of water to use for specific applications, such as the manufacture of active pharmaceutical ingredients (APIs) and dosage forms, and good manufacturing practices regarding the design, installation and operation of pharmaceutical water systems.
WHO GMP for Pharmaceutical Products Containing Hazardous Substances <sup>11</sup>	Sets out good practices applicable to facilities handling pharmaceutical products including APIs that contain hazardous substances such as certain hormones, steroids or cytotoxins. The guidelines also sets additional workers' safety criteria, standards for air-conditioning and ventilation systems of the facility, and procedures in all zones where the handling of products could lead to cross-contamination, exposure of personnel or discharge to the environment. The production of certain products containing hazardous substances should generally be conducted in separate, dedicated, self-contained facilities.
WHO guidelines on quality risk management <sup>12</sup>	Covers activities such as research and development, sourcing of materials, manufacturing, packaging, testing, storage and distribution. The guidelines define the following: <ul style="list-style-type: none"> <li>- Quality risk management (QRM) process</li> <li>- QRM application for pharmaceuticals</li> <li>- QRM considerations for medicines regulatory authorities</li> <li>- risk management tools.</li> </ul>

## E. ADB Safeguard Policy Statement (2009) Requirement

17. The SPS 2009 consists of three operational policies on environment, indigenous peoples, and involuntary resettlement. This policy provides the scope, triggers, and principles to avoid, minimize, or mitigate adverse environmental and social impacts, including protecting the rights of those likely to be affected marginalized by the development process.

18. The environmental requirements of SPS 2009 aim to ensure project environmental soundness and sustainability, integrate environmental considerations into the project decision-making process. The principal objective is to conduct an environmental assessment for each proposed project to identify potential impacts, and then mitigate the negative impacts. The

<sup>10</sup> WHO Good Manufacturing Practices (GMP): water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.

<sup>11</sup> WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.

<sup>12</sup> WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2.

proposed mitigation measures, monitoring and reporting requirements, institutional arrangements, schedules, cost estimates, and performance indicators are documented in the environmental assessment report. The ADB requires environmental assessment of all project loans, program loans, sector loans, sector development program loans, financial intermediation loans, and private sector investment operations. Environmental assessment is a process rather than a one-time report and includes necessary environmental analyses and environmental management planning that take place throughout the project cycle.

19. Each subproject is first categorized through ADB's Rapid Environmental Assessment (REA) Checklists that enable to identify potential risk/impacts of the subprojects and determine the appropriate extent and type of environmental assessment an early stage of project cycle. According to the findings of the REA checklist, the project will be categorized as A, B, or C. The definitions and reporting requirements of the environmental categories are summarized below.

**Table 3: ADB Environmental Categories**

<b>Category</b>	<b>Project Impact</b>	<b>Reporting Requirement</b>
A	A proposed project is classified as category A, if it is likely to have significant adverse environmental impacts that are irreversible, diverse, or unprecedented. These impacts may affect an area larger than the sites or facilities subject to physical works.	Environmental Impact Assessment (EIA)
B	A proposed project is classified as category B, if its potential adverse environmental impacts are less adverse than those of category A projects. These impacts are site-specific, few if any of them are irreversible, and in most cases mitigation measures can be designed more readily than for category A projects.	Initial Environmental Examination (IEE)
C	A proposed project is classified as category C, if it is likely to have minimal or no adverse environmental impacts.	No environmental assessment is required although environmental implications need to be reviewed.

20. The proposed project is categorized as 'C' for environmental safeguards considering minimal impacts related with incremental medical waste generation are anticipated. However, as per guidance provided in the policy paper on COVID-19<sup>13</sup>, a due diligence on country's national medical waste management plan will be carried out to identify any gaps and provide suitable recommendations.

<sup>13</sup> ADB. 2020. [ADB's Support to Enhance COVID-19 Vaccine](#). Manila.

### III. DESCRIPTION OF THE PROJECT

21. The project is aligned with the following outcome: priority populations vaccinated against COVID-19.

22. The government requested ADB to support its COVID-19 vaccination program. Following the guidance provided in Appendix 4 of the APVAX policy paper, the project investment component will be utilized. This approach will provide the flexibility needed to respond to the challenging operating environment in Afghanistan.

23. The project has two outputs:

24. **Output 1: COVID-19 vaccines procured and delivered to designated points.** The project will provide financing to procure vaccines through the COVAX AMC facility with UNICEF support, as well as procurement of vaccines by UNICEF outside of the COVAX AMC facility, if required. A minimum of 6 million doses of COVID-19 will be delivered to the national store in Kabul and regional and provincial centers. The expenditure items will include (i) vaccines that meet any of the eligibility criteria in Appendix 3 of the APVAX policy paper, including advance payments; (ii) safety boxes, syringes, and other items required for the administration of the vaccines; and (iii) international and national logistics and related services required for the transportation of vaccines from the place of purchase to designated delivery points. UNICEF will also provide transportation support from the national store in Kabul to regional and provincial vaccine store centers and to other designated points of delivery to support the overall COVID-19 vaccine rollout under the NPCVA, including for vaccines procured by other development partners (such as GAVI, the Vaccine Alliance through the COVAX AMC) that meet the eligibility criteria in Appendix 3. Prior to the disbursement of the grant proceeds, the MOPH shall submit to ADB purchase agreements for the vaccines that comply with the APVAX vaccine eligibility criteria.

25. **Output 2: Vaccine program implementation capacity strengthened.** This output will support strengthening the capacity of the MOPH to effectively and efficiently manage vaccine implementation. The output will provide consultant support to strengthen the MOPH's capacity related to planning, communications, coordination, and implementation at the national and provincial levels. The project will also support the strengthening of the project implementation unit (PIU) within the MOPH, which is also used for the Emergency Assistance Grant,<sup>14</sup> by providing additional consultant support. All capacity strengthening activities will ensure women staff's participation. Technical trainings will include tailored gender sensitivity sessions to ensure that vaccines are administered to women in a culturally sensitive manner. Community campaigns to promote the demand for vaccines from the targeted population groups will set targets for women to be reached. Under this output, a performance auditing firm will be engaged to ensure that ADB-financed vaccines are delivered as per the NPCVA, and a waste management firm will be engaged to provide the technical support and capacity building for waste disposal. The capacity strengthening activities will be coordinated with other regional technical assistance.

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<sup>14</sup> ADB. 2020. [Report and Recommendation of the President to the Board of Directors: Proposed Grant to the Islamic Republic of Afghanistan for the Emergency Assistance for COVID-19 Pandemic Response](#). Manila.

#### IV. ANTICIPATED ENVIRONMENTAL IMPACTS and MITIGATION MEASURES

26. It is anticipated that the project will have environmental impacts characteristic of minimal and small-scale consist of vaccine procurement and delivering to designated sites. Hence, a waste management plan (Health Care Waste Management Plan) would be sufficient to manage these impacts.

27. The potential environmental impacts include:

- (i) **Medical Waste Generation:** The main potential impacts during operation are expected from the storage and disposal of medical waste. Potential impacts are generation of solid waste/paper waste, medical waste and occupational and community health risks. This may comprise of used personal protective equipment's (PPE's), used syringes, vials, etc. Hence, the same would need to be properly handled, stored and disposed off in accordance with various national and international guidelines and best practices. Afghan government has revised health care waste management plan in 2018. Moreover, an update to this waste management plan is also under preparation to deal with the incremental medical waste generated due to COVID-19 testing and vaccination. This plan will provide guidance for segregation according to color coding for different types of bio-medical waste; collection using different types of containers; designated storage location within health care facilities; safe transportation for treatment (on-site and off-site); use of personnel safety device mandatory for all personnel handling waste; and adequate treatment and disposal (Further details are provided in Section V):
- (ii) Moreover, management of medical waste generated from COVID-19 immunization is also provided in the National Vaccination Allocation Plan prepared by the Afghan government (Further details on medical waste management are provided in Section V of this report).
- (iii) ADB has also developed a guidance note on Managing Infectious Waste during COVID-19 Pandemic. The guidance note (Appendix 2) provides suitable consideration and recommendations to enable DMC's deal with such waste types. Hence, the incremental medical waste will be handled, stored, and disposed off in accordance with the national waste management plan, ADB's guidance note as well as other international best practices (e.g., those developed by WHO).
- (iv) **Socio-Economic and Occupational Health and Safety.** It is anticipated that potential impacts to the socioeconomic environment will be mostly positive and on income and unemployment trends. However, potential impacts in term of spreading and transmitting of COVID19 in employees of MOPH and workers during vaccination and transportation operation is anticipated. Mitigation measure such as social distancing, use of PPE's (face mask, hand gloves, etc.) wash of hands with soap and hot water, and use of sanitizer after regular interval. Moreover, adherence with national and international (i.e., WHO Standard Operating Procedures [SOPs]) will need to be followed to ensure any such impacts remain minimal.

28. Summary of potential environmental impacts and mitigation measures are provided in Table 4.

**Table 4: Summary of Potential Environmental Impacts**

Phase	Potential Environmental Impact	Possible Mitigation Measure
<b>Operation and Maintenance</b>		
Community health, safety and security	<ul style="list-style-type: none"> <li>• Increased vehicle traffic around health care facilities from patients, employees and visitors leading to congestion and risk of accident</li> <li>• Increased emergency vehicle traffic and associated noise</li> </ul>	<ul style="list-style-type: none"> <li>• Traffic Management Plan will be prepared to avoid traffic congestions and accidents.</li> <li>• Provide clear and visible traffic signs within the facility</li> <li>• Provide adequate space for emergency vehicles</li> </ul>
Occupational health and safety (OHS)	<ul style="list-style-type: none"> <li>• Nosocomial (hospital acquired) infections among patients and staff</li> <li>• Needle-sticks, surgical cuts, and other injuries posing transmission risk of blood-borne diseases such as Hepatitis C, HIV-AIDS, etc.</li> <li>• Environmental services (sanitation) workers' exposure to infectious and communicable diseases</li> <li>• Occupational dermatitis and allergic reactions due to workplace exposures (e.g. disinfectants and cleaning agents or latex)</li> <li>• Negative impacts on mental health to health workers due to high levels of stress</li> <li>• High rates of fatigue, gastrointestinal, psychological and cardiovascular conditions, and increased injury rates due to long working hours and shift work</li> <li>• Injuries from repetitive manual work (e.g. improper patient movement or cleaning activities)</li> <li>• Exposure to violence, including verbal or physical assaults, from patients and their attendants</li> </ul>	<ul style="list-style-type: none"> <li>• Implement suitable safety standards for all workers and facility visitors</li> <li>• Provision of first aid facility and mandatory use of personal protective equipment and safety gears, where required</li> <li>• Arrangements for safe drinking water and sanitation facilities for health</li> <li>• Provide regular OHS training to healthcare workers</li> <li>• Provide incentives to staff and create a work-life balance in work schedule</li> <li>• Refer to IFC EHS Guidelines for Healthcare Facilities (2007), IFC EHS General Guidelines (2007), and relevant WHO Guidelines and Protocols</li> <li>• Exposure to hazardous substances such as cytotoxic drugs, anesthetic gases, and substances used for sterilization (e.g. ethylene oxide, formaldehyde, and glutaraldehyde)</li> </ul>
Medical Waste management	<ul style="list-style-type: none"> <li>• Generation and inadequate management of medical waste during immunization (used needles, syringes, PPE's etc.) that require</li> </ul>	<ul style="list-style-type: none"> <li>• Proper implementation of National Healthcare waste Management Plan to ensure safe storage, transportation and disposal of medical waste.</li> </ul>

Phase	Potential Environmental Impact	Possible Mitigation Measure
	<p>special handling and treatment;</p> <ul style="list-style-type: none"> <li>• Spreading of waste, bad odor, deterioration of aesthetics</li> <li>• Increased volume of water, sanitation and related effluent discharges in the health care facilities, medical colleges, hospitals and research centers</li> <li>• Limited capacity of current medical waste disposal system to cater for the additional medical waste generated from COVID-19 immunization process.</li> <li>• Inadequate training of health care staff on medical waste management plan</li> </ul>	<ul style="list-style-type: none"> <li>• Awareness raising on medical waste management with waste minimization, recovery and recycling</li> <li>• Training program for relevant healthcare workers, staff and maintenance and housekeeping</li> <li>• Discourage and/or ban use of plastic products in health facilities</li> <li>• Safe disposal of hazardous waste at designated disposal sites (off site incineration facility or land fill site)</li> <li>• As part of COVID-19 Emergency Assistance Grant for Afghanistan processed earlier by ADB, appropriate waste disposal options (except for onsite incineration) have been provided in the Environmental Assessment and Review Framework (EARF) in accordance with ADB's guidance note on managing infectious medical waste. Some of these newly installed equipment's can cater for the medical waste generated from this activity. Moreover, it is recommended to carry out a due diligence study during the implementation phase to identify any gaps in the updated medical waste management plan (still under preparation) and to provide suitable recommendations to fill any gaps.</li> <li>• Trainings will be provided to health care workers and NGO's dealing with the medical waste to increase capacity related with management of waste.</li> </ul>



## V. NATIONAL HEALTH CARE WASTE MANAGEMENT PLAN

29. Ministry of Public Health revised the country's Health Care Waste Management Plan (HCWMP) in 2018 for handling and disposal of medical waste in Afghanistan. The HCWMP described the existing waste management practices in Afghanistan e.g., waste generation, collection, segregation, transportation, color coding, treatment & waste, disposal, training etc. The HCWMP also provide information on waste categories that are generated during operation and guidance for segregation, storage and treatment of health-care waste.

30. The proposing treatment/disposal for the processing the medical waste e.g., autoclaving, microwaving, deep burial and disposal of sharp materials are provided in detail. The existing Policy Framework which is relevant for healthcare waste management is also included in the plan.

31. Monitoring and reporting for medical waste is provided in the detail. Third party monitoring and independent technical audits of HCWMP implementation is also part of the plan.

32. The updated waste management plan is still under preparation. However, the following details related with incremental immunization medical waste has been provided by MOPH:

- (i) According to the HMIS data, there is a total of 839 WHO approved medical waste destruction or sterilization facilities and 1,597 facilities with burn and bury methods for medical waste disposal in the country.
- (ii) Currently there is no provision of waste recycling, although the same is mentioned as a long-term goal under 2018 health care waste management plan.
- (iii) The waste generated will be managed either at health facility level (Maximum of 1 safety box per day) or at provincial hospitals with WHO approved medical waste destruction or sterilization facilities of accumulated boxes from few health facilities per week.
- (iv) Medical waste will be collected by NGO's operating in provinces and be processed at WHO approved medical waste destruction or sterilization facilities in provincial hospital.
- (v) The monitoring of waste management plan will be carried out by technical and operation committees at national level and regional and provincial sub-national level will lead the performance review process with support from relevant partners such as WHO, UNICEF, E/BPHS, IFRC based on the data reported by the service providers.
- (vi) Common treatment and disposal facilities' performance is monitored by the Environmental Health Directorate, National Environmental Protection Agency and Municipality (HCWMP-MOPH).
- (vii) Comprehensive training on waste management has been included in the training plan for COVID-19 vaccine introduction, and training sessions (ToT) are already conducted by NEPI to the regional trainers and through them to provincial trainers. Cascade training has been facilitated by provincial trainers at provincial level (NDVP).
- (viii) The MOPH also held training on health care waste management for health care workers in the national capital, regional and provinces hospitals in 2019 (ESMF).

32. The estimated quantity of medical waste generated during COVID-19 vaccination is provided in Table 5.

**Table 5: Summary of Expected Medical Waste Generated During Project Implementation**

Description	Number of empty vials	Number of Syringes	Number of safety boxes <sup>15</sup>	Disposal Volume
For every 100 doses administered <sup>16</sup>	10	105 <sup>17</sup>	1	5 liters
For every 1 million <sup>18</sup> doses administered across 1,000 health facilities	105,000	1.05 million	10,000 <sup>19</sup>	50m <sup>3</sup> or 1.5 m <sup>3</sup> per province <sup>20</sup> Or 50 liters per health facility (10 safety boxes)
Total waste generation for 20% of population (vaccinating 8 million people – 16 million doses plus vaccine wastage)	1.68 million	16.8 million	160,000	816 m <sup>3</sup> , 24 m <sup>3</sup> per province

### A. Major Gaps in Incremental Medical Waste Management

33. The health care waste management plan is well drafted with details provided on waste collection, segregation, and disposal. Moreover, details on institutional structure, capacity building and monitoring is also provided. However, the following gaps have been identified in the management of incremental medical waste:

- (i) Implementing the waste management plan may pose some challenges as facilities outlined in the plan are not in place yet and so temporary measures will be used to implement the waste strategy until such facilities are available.
- (ii) It will be good to include recycling in the updated waste management plan. Items such as used boxes, glasses etc. can be recycled to reduce burden on disposal options.
- (iii) Burning (other than WHO approved medical waste destruction or sterilization facilities) of medical waste should be phased out. Moreover, the same should be disposed through other suitable options as mentioned in ADB guidance note as well as other international best practices (e.g., those developed by WHO).
- (iv) It should be ensured that the WHO approved medical waste destruction or sterilization facilities are in good condition to ensure proper destruction or sterilization of the medical waste without excessive emissions.
- (v) Monitoring of the incremental medical waste management should be carried out after regular intervals to ensure the same is managed and disposed as per the national health care waste management plan as well as according to various international guidelines. The monitoring reports should also be submitted to ADB for compliance.

<sup>15</sup> Filled with 100 syringes each and empty vials.

<sup>16</sup> Estimated volume per day per health facility.

<sup>17</sup> Considering 5% wastage rate of syringes.

<sup>18</sup> Approximate volume expected addressing one round of supplies per health facility.

<sup>19</sup> 10 boxes per health facility by average and from 1,000 health facilities (10x1,000 = 10,000 safety boxes)

<sup>20</sup> Considering one facility per province from 34 provinces.

## VI. CONCLUSIONS AND RECOMMENDATIONS

34. The project will have positive social benefits because of improvements to public health from increased availability of vaccines and the chance for populations to be immunized. The project will help the country to meet MOPH's vaccination implementation strategy targets. Vulnerable groups such as health care workers and elderly will be prioritized for vaccination.

35. As per the ADB Safeguard Policy Statement 2009 and based on currently available information on the project activities, it can be concluded that the proposed works (related with procurement and distribution of vaccines only) will have minor environmental impacts during the implementation phase mainly related with medical waste generation. It is also confirmed that national waste management plan is quite adequate to deal with such type of waste. A firm commitment to manage the medical waste in an adequate manner has also been provided in the Governor's letter. However, implementing the plan may pose some challenges as facilities outlined in the plan are not in place yet and so temporary measures will be used to implement the waste strategy until such facilities are available.

36. Following recommendations have been made:

- (i) It is recommended to carry out a due diligence study during the implementation phase to identify any gaps in the updated medical waste management plan (still under preparation) and to provide suitable recommendations to fill any gaps. An environmental consultant will be recruited during the implementation phase to carry out this due diligence study.
- (ii) Monitoring reports providing details on monitoring of medical waste will be submitted to ADB on a regular basis.
- (iii) Trainings will also be provided by the Environmental Consultant to health care workers and NGO's dealing with the medical waste to increase capacity related with management of waste.

## WHO Good Manufacturing Practices and other Guidelines

The following are WHO GMP guidelines relevant to the project:

**WHO good manufacturing practices (GMP) for pharmaceutical products: main principles.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.

Short name: WHO TRS No. 986, Annex 2

[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/trs\\_986/en/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/)

**WHO good manufacturing practices (GMP) for biological products.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 3

Short name: WHO TRS No. 996, Annex 3

[http://www.who.int/medicines/publications/pharmprep/WHO\\_TRS\\_996\\_annex03.pdf](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex03.pdf)

**WHO good manufacturing practices (GMP) for sterile pharmaceutical products.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6

Short name: WHO TRS No. 961, Annex 6

[http://whqlibdoc.who.int/trs/WHO\\_TRS\\_961\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)

**WHO Good Manufacturing Practices (GMP): water for pharmaceutical use.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2

Short name: WHO TRS No. 970, Annex 2

[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/trs\\_970/en/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/)

**WHO guidelines for sampling of pharmaceutical products and related materials.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4

Short name: WHO TRS No. 929, Annex 4

[http://whqlibdoc.who.int/trs/WHO\\_TRS\\_929\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1)

**Supplementary guidelines on good manufacturing practices (GMP): validation.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4

Short name: WHO TRS No. 937, Annex 4

[http://whqlibdoc.who.int/trs/WHO\\_TRS\\_937\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1)

**WHO Good Practices for Pharmaceutical Quality Control Laboratories.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1

Short name: WHO TRS No. 961, 957), Annex 1

<http://www.who.int/medicines/publications/44threport/en/>

**WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2

Short name: WHO TRS No. 957, Annex 2

<http://www.who.int/medicines/publications/44threport/en/>

**WHO guidelines on transfer of technology in pharmaceutical manufacturing.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7

Short name: WHO TRS No. 961, Annex 7

[http://whqlibdoc.who.int/trs/WHO\\_TRS\\_961\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)

**WHO model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9

Short name: WHO TRS No. 961, Annex 9

[http://whqlibdoc.who.int/trs/WHO\\_TRS\\_961\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)

**WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5

Short name: WHO TRS No. 992, Annex 5

[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/WHO\\_TRS\\_992\\_web.pdf](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf)

**WHO general guidelines for the establishment, maintenance and distribution of chemical reference substances.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-first Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3

Short name: WHO TRS No. 943, Annex 3

[http://whqlibdoc.who.int/trs/WHO\\_TRS\\_943\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1)

**WHO good practices for pharmaceutical microbiology laboratories.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2

Short name: WHO TRS No. 961, Annex 2

[http://whqlibdoc.who.int/trs/WHO\\_TRS\\_961\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)

**WHO guidelines on quality risk management.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2

Short name: WHO TRS No. 981, Annex 2

[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/trs\\_981/en/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/)

**WHO guidelines on variation to a prequalified product.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3

Short name: WHO TRS No. 981, Annex 3

[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/trs\\_981/en/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/)

**WHO guidelines for drafting a site master file.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14

Short name: WHO TRS No. 961, Annex 14

[http://whqlibdoc.who.int/trs/WHO\\_TRS\\_961\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)

**WHO General guidance on hold-time studies.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4

Short name: WHO TRS No. 992, Annex 4

[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/WHO\\_TRS\\_992\\_web.pdf](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf)

**WHO Guidance on good data and record management practices.** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5

Short name: WHO TRS No. 996, Annex 5

[http://www.who.int/medicines/publications/pharmprep/WHO\\_TRS\\_996\\_annex05.pdf](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf)

**ADB Guidance Note on Managing Infectious Medical Waste**  
(see attached)

# Managing Infectious Medical Waste during the COVID-19 Pandemic

During the COVID-19 outbreak in Hubei Province, People's Republic of China (PRC), infectious medical waste increased by 600% from 40 tons per day to 240 tons per day. This quickly overwhelmed existing medical transport and disposal infrastructure around hospitals.<sup>1</sup>

Other countries will face similar challenges. It is critical that additional waste management systems are put in place to help reduce the further spread of COVID-19 and the emergence of other diseases.

To support its developing member countries, the Asian Development Bank (ADB) has compiled the following list of considerations and recommendations to enable governments to rapidly respond to these unprecedented challenges.

## KNOW YOUR COUNTRY'S INFECTIOUS MEDICAL WASTE MANAGEMENT CAPACITY

### GOVERNMENT CONSIDERATIONS

#### What is the current infectious medical waste management plan for my country?

Some governments have existing legislation and regulations in place for the disposal of infectious medical waste from hospitals and households. Continue to follow these and consider if additional capacity and resources are needed to maintain compliance. Others that need assistance in operationalizing international regulations may seek guidance from the [World Health Organization \(WHO\)](#),<sup>2</sup> the [Basel Convention](#),<sup>3</sup> and the [United Nations Environment Programme](#).<sup>4</sup>

#### What existing medical waste disposal equipment does my country have?

Sanitary landfills, medical incinerators, and medical autoclaves are used to deal with pre-pandemic waste amounts. Other resources including mobile incinerators, industrial furnaces, and cement kilns could be assessed for use if existing systems are overloaded and capacity is limited. For more information read: [Technical Guidelines on the Environmentally Sound Co-Processing of Hazardous Wastes in Cement Kilns](#).<sup>5</sup>

#### What is the existing transport capacity for infectious medical waste in my country?

Safe transport requires vehicles that can be sterilized, trained drivers and waste collectors, dedicated routes, and vehicle and waste tracking systems. Training must be conducted for crews who will be exposed to household infectious medical waste.



For more information read: [Technical Guidelines on Transport of Infectious Clinical Waste UN3291](#).<sup>6</sup>

#### How much infectious medical waste should my country expect based on the PRC's experience?

The table below shows probable volumes based on the experience of the PRC.<sup>7</sup> Few cities have the capacity to deal with the expected excessive amounts of waste. Governments should consider dealing with excess waste as soon as possible.

City	Population (World Population Review)	Additional Medical Waste	Total Possible Production Over 60 Days
Manila	14 million	280 t/d	16,800 tons
Jakarta	10.6 million	212 t/d	12,750 tons
Kuala Lumpur	7.7 million	154 t/d	9,240 tons
Bangkok	10.5 million	210 t/d	12,600 tons
Ha Noi	8 million	160 t/d	9,600 tons

Metric ton = 1000 kilograms t/d = metric tons per day  
Source: Extracted from data cited in footnote 1.

#### What measures are needed to ensure compliance?

Ensure that transport and disposal systems implement duty of care, waste tracking and labelling, disposal unit licensing, record keeping, and emissions monitoring. Consider enhanced security measures.

#### How long will these emergency measures need to be in place?

The peak management and treatment campaign lasted over 60 days in Wuhan. Other countries will experience different emergency timelines, which are dependent on specific policies and predicted infection curves.

<sup>1</sup> J. Shi and W. Zheng. 2020. Coronavirus: China struggling to deal with mountains of medical waste created by epidemic. 5 March. <https://www.scmp.com/news/china/society/article/3065049/coronavirus-china-struggling-deal-mountain-medical-waste-created>.

<sup>2</sup> World Health Organization (WHO). *Rolling updates on coronavirus disease (COVID-19)*. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen>.

<sup>3</sup> Secretariat of the Basel Convention. 2020. Waste management an essential public service in the fight to beat COVID-19. *Basel Convention*. 20 March. <http://www.basel.int/Implementation/PublicAwareness/PressReleases/WastemanagementandCOVID19/tabid/8376/Default.aspx>.

<sup>4</sup> United Nations Environment Programme (UNEP). 2020. Waste Management and essential public service in the fight to beat COVID-19. *United Nations Environment Programme*. 24 March. <https://www.unenvironment.org/news-and-stories/press-release/waste-management-essential-public-service-fight-beat-covid-19>.

<sup>5</sup> Basel Convention. 2011. *Technical Guidelines on the Environmentally Sound Co-processing of Hazardous Wastes in Cement Kilns*. Paper prepared for the tenth meeting of the Conference of the Parties to the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal. Cartagena, Colombia. 17-21 October. <http://www.basel.int/Portals/4/Basel%20Convention/docs/pub/techguid/cement/tg-cement-e.pdf>.

<sup>6</sup> Wash in Health Care Facilities. 2013. *Technical Guidelines of Transport of Infectious Clinical Waste (UN3291)*. <https://www.washinhc.org/wp-content/uploads/2019/03/Guidelines-Transport-of-infectious-waste-UN3291.pdf>.

<sup>7</sup> Extracted from data cited in footnote 1.

## ACT NOW




### WASTE MANAGEMENT RECOMMENDATIONS

#### General Municipal Solid Waste Management Services

- Reschedule municipal solid waste collection frequency according to reduced workforce availability and reallocate available assets for infectious medical waste management.
- Recycling activities should be avoided to prevent human contact with any potentially infectious domestic and medical waste. All municipal waste should be treated as non-recyclable and disposed of through incineration or sanitary landfill. Landfill sites with informal waste picking will need increased management and security.

For more information on what other cities are doing, consult the [Association of Cities and Regions for sustainable Resource Management](#).<sup>8</sup>

#### Household Infectious Medical Waste Management

- Swan neck tie**
-  Households containing a person under investigation (PUI) or person under monitoring (PUM) should be encouraged to segregate all medical waste (face masks, wipes, tissues).
  -  Where possible the monitoring agency responsible for PUI/PUM management should provide yellow medical bags and collection services for PUI/PUM related waste.
  -  All PUI/PUM related waste should be double bagged, “swan neck” tied and the outside sprayed with a 0.5% chlorine disinfectant solution (1% household bleach solution).
- If dedicated medical waste collection is available, then the double-bagged waste should be disposed of immediately.

- If no dedicated medical waste collection is available, then the double-bagged waste should be stored for 72 hours before being disposed with the general household waste.

For more information see footnote 8.

#### Infectious Medical Waste in Hospitals, Medical Centers, and Emergency Medical Facilities

Local governments can estimate the potential increase in tonnage over time:

$$\text{Estimated Infected Persons} \times 3.4 \text{ kilograms} = \text{Increase in Infectious Medical Waste per Day of Outbreak}^a$$

<sup>a</sup> Equation compiled from data cited in footnote 7.

All medical waste should continue to be handled in line with your existing national legislation. However, experience from Hubei Province, PRC, has shown that **transport** and **disposal** elements of the system will be the first to be overwhelmed (footnote 1).

### TRANSPORT



Additional vehicles should have a non-absorbent, sealed load area capable of being locked, disinfected, and separate from the driver’s cabin. Their vehicle identification numbers (VIN) or chassis numbers should be recorded to allow future control. For more information see footnote 6.

### DISPOSAL



Infectious medical waste is typically segregated by hospital staff at the time of packing. The double-bagged items are sprayed with 0.5% chlorine solution before onsite temporary storage.<sup>9</sup> The method of disposal then varies between hospitals:

- Sterilization through steam (autoclave) or irradiation prior to disposal in a licensed landfill
- Disposal through incineration on-site or at a remote specialist facility

If these resources begin to be overwhelmed, alternatives are available for temporary capacity increase:

- Mobile incineration or autoclave units may be used to support the existing infectious medical waste infrastructure

Some cement kilns and industrial furnaces may be used as temporary disposal facilities. The Government of the PRC has successfully made use of cement kilns for this purpose ( $>1s$  Residence Time  $>1100^{\circ}\text{C}$ ). For more information see footnote 5.

- As a temporary measure, secure facilities can be used as temporary storage in anticipation of additional emergency resources becoming available in the medium term.

#### Special Provisions with Countries with Large Informal Waste Management Sectors

Intermediate sorting of waste will result in higher infection rates and dispersal of infected waste. The risk of infected waste being handled multiple times needs to be avoided. This risk is particularly high with informal sector workers.

#### For more information:

Additional information is available through the links in this document, the ADB Data Room, and from the World Health Organization, the Basel Convention, and the United Nations Environment Programme.

ADB may be able to provide assistance to our developing member countries in emergency planning, emergency assistance, and remote training of operators. Please contact [ADB resident missions and offices](#) to request assistance.

Photo: Medical waste management in the People’s Republic of China. Properly managing infectious medical waste is essential for preventing further spread of COVID-19 and other diseases (photo by Lu Guang).

Note: ADB recognizes “China” as the People’s Republic of China.



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