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Report No: PAD4816

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT

PROJECT APPRAISAL DOCUMENT ON A PROPOSED LOAN

IN THE AMOUNT OF EUR 454.4 MILLION (US\$480.0 MILLION EQUIVALENT)

TO THE

REPUBLIC OF SOUTH AFRICA

FOR A SOUTH AFRICA COVID-19 EMERGENCY RESPONSE PROJECT

May 20, 2022

UNDER THE
COVID-19 STRATEGIC PREPAREDNESS AND RESPONSE PROGRAM (SPRP)

USING THE MULTIPHASE PROGRAMMATIC APPROACH (MPA)

WITH A FINANCING ENVELOPE OF

UP TO US\$6 BILLION APPROVED BY THE BOARD ON APRIL 2, 2020 AND

UP TO US\$12 BILLION ADDITIONAL FINANCING APPROVED BY THE BOARD

ON OCTOBER 13, 2020

Health, Nutrition & Population Global Practice Eastern and Southern Africa Region

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CURRENCY EQUIVALENTS

(Exchange Rate Effective April 30, 2022)

Currency Unit = South Africa Rand (ZAR)

US\$1 = ZAR 15.9

US\$1 = EUR 0.95

GOVERNMENT FISCAL YEAR April 1 – March 31

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ABBREVIATIONS AND ACRONYMS

ACG	Anti-Corruption Guidelines
AEFI	Adverse Event Following Immunization
AF	Additional Financing
BIOVAC	Biological and Vaccines Institute of Southern Africa
CDC	Centers for Disease Control and Prevention
COVAX Facility	COVID-19 Vaccines Global Access Facility
COVID-19	Coronavirus Disease 2019
CPF	Country Partnership Framework
DP	Drug Product
DS	Drug Substance
E&S	Environmental and Social
EPI	Expanded Program on Immunization
ESCP	Environmental and Social Commitments Plan
ESF	Environmental and Social Framework
ESS	Environmental and Social Standard
EUL	Emergency Use Listing
EVDS	Electronic Vaccination Data System
FM	Financial Management
FTCF	Fast Track COVID-19 Facility
Gavi	Global Alliance for Vaccines and Immunizations
GBV	Gender based Violence
GDP	Gross Domestic Product
GoSA	Government of South Africa
GRM	Grievance Redress Mechanism
GRS	Grievance Redress Service
HCI	Human Capital Index
HCW	Health Care Worker
HNP	Health, Nutrition, and Population
IBRD	International Bank for Reconstruction and Development
IDA	International Development Association
IFC	International Finance Corporation
IMF	International Monetary Fund
IPC	Infection Prevention and Control
IPF	Investment Project Financing
M&E	Monitoring and Evaluation
MAC	Ministerial Advisory Committee
MPA	Multiphase Programmatic Approach
NCD	Non-Communicable Disease
NDoH	National Department of Health
NICD	Notice of Lordin to Communicate Disease
	National Institute for Communicable Diseases
NT	National Treasury

OPRC	Operational Procurement Review Committee
PAD	Project Appraisal Document
PDO	Project Development Objective
PDoH	Provincial Department of Health
PHC	Primary Health Care
POPI	Protection of Personal Information
PPSD	Project Procurement Strategy for Development
PQ	Prequalification
PRAMS	Procurement Risk Assessment and Management System
PrDO	Program Development Objective of SPRP (Global COVID-19 Response MPA)
QLFS	Quarterly Labour Force Survey
RCCE	Risk Communication and Citizen Engagement
SAGE	Strategic Advisory Group of Experts on Immunization
SAHPRA	South African Health Products Regulatory Authority
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	2019 Novel Coronavirus
SEA	Sexual Exploitation and Abuse
SEP	Stakeholder Engagement Plan
SH	Sexual Harassment
SOP	Standard Operating Procedures
SPRP	Strategic Preparedness and Response Program, also known as Global COVID-19 MPA
SRA	Stringent Regulatory Authority
SSA	Sub-Saharan Africa
StatsSA	Statistics South Africa
STEP	Systematic Tracking of Exchanges in Procurement
SVS	Stock Visibility System
UMIC	Upper Middle-Income Country
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VAC	Vaccine Approval Criteria (of the World Bank)
WBG	World Bank Group
WDI	World Development Indicator
WEO	World Economic Outlook
WHO	World Health Organization

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DATASHEET

BASIC INFORMATION		
DASIC IN ORWATION		
Country(ies)	Project Name	
South Africa	South Africa COVID-19 Emer	gency Response Project
Project ID	Financing Instrument	Environmental and Social Risk Classification
P174259	Investment Project Financing	Substantial
Financing & Implementar	ion Modalities	
[√] Multiphase Programn	natic Approach (MPA)	[] Contingent Emergency Response Component (CERC)
[] Series of Projects (SOP)	[] Fragile State(s)
[] Performance-Based Co	onditions (PBCs)	[] Small State(s)
[] Financial Intermediario	es (FI)	[] Fragile within a non-fragile Country
[] Project-Based Guarant	ee	[] Conflict
[] Deferred Drawdown		[√] Responding to Natural or Man-made Disaster
[] Alternate Procuremen	t Arrangements (APA)	[] Hands-on Enhanced Implementation Support (HEIS)
Expected Project Approva	Expected Project Closing Date	Expected Program Closing Date
13-Jun-2022	31-Mar-2024	31-Mar-2025
Bank/IFC Collaboration		
No		
MPA Program Developme	•	ect and respond to the threat posed by COVID-19 and
-	ms for public health prepared	
MPA Financing Data (US	, Millions)	
MPA Program Financing E	nvelope	18,000.00

Proposed Project Development Objective(s)

The project development objective is to increase COVID-19 vaccination coverage among the population of South Africa.

Components

Component Name Cost (US\$, millions)

Component 1. Emergency COVID-19 Response

480.00

Organizations

Borrower: Republic of South Africa

Implementing Agency: National Department of Health

MPA FINANCING DETAILS (US\$, Millions)

Board Approved MPA Financing Envelope:	18,000.00
MPA Program Financing Envelope:	18,000.00
of which Bank Financing (IBRD):	9,900.00
of which Bank Financing (IDA):	8,100.00
of which other financing sources:	0.00

PROJECT FINANCING DATA (US\$, Millions)

SUMMARY

Total Project Cost	480.00
Total Financing	480.00
of which IBRD/IDA	480.00
Financing Gap	0.00

DETAILS

World Bank Group Financing

Expected Disbursements (in US\$, Millions) WB Fiscal	
WB FISCAL	
Year 2022 2023 2	024
Annual 0.00 445.00 35	.00
Cumulative 0.00 445.00 480	.00

INSTITUTIONAL DATA

Practice Area (Lead)

Contributing Practice Areas

Health, Nutrition & Population

Climate Change and Disaster Screening

This operation has been screened for short and long-term climate change and disaster risks

SYSTEMATIC OPERATIONS RISK-RATING TOOL (SORT)

Risk Category	Rating
1. Political and Governance	Moderate
2. Macroeconomic	Substantial
3. Sector Strategies and Policies	Moderate
4. Technical Design of Project or Program	Substantial
5. Institutional Capacity for Implementation and Sustainability	Substantial
6. Fiduciary	Moderate
Fiduciary 7. Environment and Social	ModerateSubstantial
·	
7. Environment and Social	Substantial
7. Environment and Social 8. Stakeholders	Substantial

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Does the project depart from the CPF in content or in other significant respects?

[] Yes [√] No

Does the project require any waivers of Bank policies?

[] Yes [√] No

Environmental and Social Standards Relevance Given its Context at the Time of Appraisal

E & S Standards	Relevance
Assessment and Management of Environmental and Social Risks and Impacts	Relevant
Stakeholder Engagement and Information Disclosure	Relevant
Labor and Working Conditions	Relevant
Resource Efficiency and Pollution Prevention and Management	Relevant
Community Health and Safety	Relevant
Land Acquisition, Restrictions on Land Use and Involuntary Resettlement	Not Currently Relevant
Biodiversity Conservation and Sustainable Management of Living Natural Resources	Not Currently Relevant
Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities	Relevant
Cultural Heritage	Not Currently Relevant
Financial Intermediaries	Not Currently Relevant

NOTE: For further information regarding the World Bank's due diligence assessment of the Project's potential environmental and social risks and impacts, please refer to the Project's Appraisal Environmental and Social Review Summary (ESRS).

Legal Covenants

Conditions

Disbursement IBRD/IDA No withdrawal shall be made for payments made prior to the Signature Date, except that withdrawals up to a aggregate amount not to exceed EUR 454,400,000 made be made for payments made prior to this date but on after March 1, 2021 for Eligible Expenditures.

I. PROGRAM CONTEXT

This Project Appraisal Document (PAD) describes the emergency response to South Africa under the coronavirus disease (COVID-19) Strategic Preparedness and Response Program (SPRP) using the Multiphase Programmatic Approach (MPA), approved by the World Bank's Board of Executive Directors on April 2, 2020 (PCBASIC0219761) with an overall Program financing envelope of up to US\$6 billion¹ and the Additional Financing (AF) of US\$12 billion to the SPRP, approved on October 13, 2020. On November 9, 2021, the Government of South Africa (GoSA) formally requested World Bank financing of up to US\$800 million to assist in retroactively financing vaccine procurement contracts as part of South Africa's COVID-19 vaccination strategy. The purpose of the proposed project is to support the GoSA to purchase 47 million COVID-19 vaccines that meet the World Bank's vaccine approval criteria (VAC) to vaccinate the target population.³ The GoSA with the support from other partners will finance vaccine deployment and health system strengthening, which will enable affordable and equitable access to COVID-19 vaccines. The project financing for COVID-19 vaccines will follow the World Bank's updated VAC: (a) the vaccine has received regular or emergency licensure or authorization from at least one of the stringent regulatory authorities (SRAs) identified by the World Health Organization (WHO) for vaccines procured and/or supplied under the COVID-19 Vaccines Global Access Facility (COVAX Facility), as may be amended from time to time by WHO; or (b) the vaccine has received WHO Prequalification (PQ) or WHO Emergency Use Listing (EUL). South Africa is providing vaccination free of cost to the population.

A. MPA Program Context

- 2. An outbreak of the COVID-19 caused by the 2019 novel coronavirus (SARS-CoV-2) has been spreading rapidly across the world since December 2019, following the diagnosis of the initial cases in Wuhan, Hubei Province, China. Since the beginning of March 2020, the number of cases outside China increased rapidly worldwide and on March 11, 2020, the WHO declared a global pandemic. As of May 16, 2022, there have been approximately 519.1 million confirmed COVID-19 cases, and 6.3 million deaths globally, according to the WHO dashboard.⁴
- 3. **COVID-19** is one of several emerging infectious diseases outbreaks in recent decades that have emerged from animals in contact with humans, resulting in major outbreaks with significant public health and economic impacts. The last moderately severe influenza pandemics were in 1957 and 1968; each killed more than a million people around the world. Although countries are now far more prepared than in the past, the world is also far more interconnected, and many more people today have behavior risk factors such as tobacco use and pre-existing chronic health problems that make viral respiratory infections particularly dangerous. With COVID-19, scientists are still trying to understand the full picture of the disease symptoms and severity. The pandemic poses unparalleled challenges with respect to global containment and mitigation. These issues reinforce the need to strengthen the

¹ Global MPA PAD P173789. Report No. PCBASIC0219761

² The World Bank approved a US\$12 billion WBG Fast Track COVID-19 Facility (FTCF or "the Facility") to assist IBRD and IDA countries in addressing the global pandemic and its impacts. Of this amount, US\$6 billion came from IBRD/IDA and US\$6 billion from the International Finance Corporation (IFC). The IFC subsequently increased its contribution to US\$8 billion, bringing the FTCF total to US\$14 billion. The AF of US\$12 billion (IBRD/IDA) was approved on October 13, 2020 to support the purchase and deployment of vaccines as well as strengthening the related immunization and health care delivery system.

³ The National Vaccination Strategy prioritizes 77.0 percent of the total population for vaccination (i.e., target population, see table 3). The government aims to fully vaccinate up to 70.0 percent of the target population with project vaccines and other vaccines.

⁴ WHO. 2022. WHO Coronavirus (COVID-19) Dashboard. https://covid19.who.int/

⁵ Marquez, PV. 2020. "Does Tobacco Smoking Increases the Risk of Coronavirus Disease (Covid-19) Severity? The Case of China." http://www.pvmarquez.com/Covid-19

response to COVID-19 across all International Development Association (IDA)/International Bank for Reconstruction and Development (IBRD) countries to minimize the global risk and impact posed by this disease.

4. As of May 16, 2022, the World Bank has approved 96 operations (including MPA-Vaccine operations) to support vaccine procurement and rollout in 73 countries amounting to US\$8.1 billion. The 96 operations approved, include six operations that involved restructuring of parent projects or another health project. Of the 96 approved operations: (a) 54 are in Africa – 24 in Africa East and 30 in Africa West; (b) 9 in East Asia and the Pacific; (c) 10 in Europe and Central Asia; (d) 8 in Latin America and the Caribbean; (e) 7 in Middle East and North Africa; and (f) 8 in South Asia. Fifty projects are disbursing. Twenty-two new operations are under various stages of processing. Total disbursements as of May 16, 2022 under these projects amount to US\$3.3 billion or 40 percent of overall commitments. As with the MPA operations, streamlined procedures, delegated approval, coupled with flexible project design, and intensified efforts across the World Bank have contributed to the rapid design and processing of the operations. Eighty-five loan/financing agreements have been signed. Also, 80 loan/financing agreements have become effective; several others are expected to become effective in the coming weeks. Implementation of the AFvaccine operations, as with MPA operations is facing challenges as several countries are still under different levels of lockdown or mobility restrictions and counterparts and World Bank teams are operating from home. Countries are dealing with new waves of infections, as the Omicron variant is spreading rapidly among populations.

B. Updated MPA Program Framework

5. The MPA Program Framework for the proposed project is as follows.

Estimated Estimated Estimated Phase's **Estimated Phase IBRD IDA** Other **Estimated Environmental** Project Sequential or **Proposed** IPF, DPF Numb **Amount Amount Amount Approval** Number Simultaneous Development or PforR and Social Risk (US\$ (US\$ (US\$ **Date** er **Objective** Rating million) million) million) Please see June 13, IPF 1 P174259 Simultaneous 480.0 Substantial relevant PAD 2022 **Board Approved Financing Envelope** 18,000 Total 9,900 8,100

Box 1. MPA Program Framework

Note: IPF: Investment Project Financing; DPF: Development Policy Financing; PforR: Program for Results Financing

C. Learning Agenda

6. The proposed project under the MPA program will finance procurement of vaccines to complement GoSA's deployment efforts and support adaptive learning as applicable. The proposed project will also incorporate lessons learned from the ongoing global vaccine rollout and COVID-19-related service delivery. Key areas include:

• Forecasting: The South Africa Genomic Surveillance Project⁶ will support South Africa's capacity to model, monitor, and regionally collaborate to track and anticipate the progression of the pandemic, both in terms of new cases and deaths, as well as the economic impact of disease outbreaks under different scenarios.

⁶ The Accelerating Genomics-based Surveillance for COVID-19 Response in South Africa Project (P177439) was approved on April 11, 2022 and will be financed by US\$5 million from the Health Emergency Preparedness and Response Fund, administered by the World Bank.

- The Genomic Surveillance Project will also contribute to strengthening genomic surveillance capacities of SARS-CoV-2 in South Africa and the Africa region.
- Technical: Data generated and lessons learned from the South Africa COVID-19 vaccination program to deploy vaccines partially financed by the proposed project can contribute to knowledge around the strengths and limitations of vaccine logistics and monitoring systems, as well as effectiveness of vaccines delivered in different contexts and against new variants. This will also contribute to enhanced preparedness for future emergencies, including those driven by climate change, building on the lessons from COVID-19 vaccine procurement and distribution.
- Social behaviors: The South Africa COVID-19 vaccination program, which the proposed project is supporting, can contribute to a better understanding of beneficiary perceptions and constraints for vaccine access and acceptability, particularly in the context of gender and other inequalities.
- 7. Preparation of the proposed project has been informed by the lessons learned from implementation of COVID-19 emergency response projects in other countries. Such lessons include the need to: (a) build on the existing country systems; (b) invest in coordination with development partners supporting various aspects of COVID-19 response; (c) regularly engage with the relevant stakeholder groups to support the country efficiently; (d) remain flexible to respond to evolving situations quickly and effectively; and (e) invest in risk communication and citizen engagement (RCCE) to reduce vaccine (brand) hesitancy and improve service utilization.

II. CONTEXT AND RELEVANCE

A. Country Context

- 8. **South Africa is an upper-middle income country that is still emerging from economic and racial inequality.** With a population of approximately 60 million people, the country's gross domestic product (GDP) per capita (current US\$) in 2021 is US\$6,964.⁷ South Africa is multi-racial with Black South Africans comprising the majority, followed by Colored, Whites, and Indians. After the apartheid government ended in 1994, it was replaced by a constitutional democracy and had 15 years of significant development progress. However, the country still suffers from its legacy of apartheid with inequality. With a Gini coefficient of 63, South Africa is ranked as the most unequal country in the world by the World Bank.⁸ The richest 20.0 percent of the people in South Africa still control almost 70.0 percent of the resources.⁹
- 9. **COVID-19** hit the South African economy at a time when GDP growth was already on a downward trend. From 2010 to 2019, South Africa recorded its weakest decade for growth with high unemployment and poverty levels which worsened with the onset of the pandemic. Real GDP growth in the decade leading up to 2019 averaged less than two percent. GDP growth had fallen to 0.1 percent in 2019 before the pandemic-induced recession of -6.4 percent in 2020. ^{10,11} Boosted by a favorable global environment and demand recovery domestically, GDP growth rebounded to 4.9 percent in 2021. Output in the year remained below the pre-pandemic level while the growth rebound was jobless. GDP growth is projected to slow to 2.1 percent in 2022. The unemployment rate reached 29.1

World Bank. 2022. Macro Poverty Outlook. http://macropovertyoutlook.worldbank.org/mpo_files/mpo/mpo-sm22-zaf-scope.pdf

⁸ World Bank. 2021. Overview (Last updated March 18, 2021). https://www.worldbank.org/en/country/southafrica/overview

 $^{^9}$ World Bank. 2018. South Africa Economic Update. https://thedocs.worldbank.org/en/doc/798731523331698204-0010022018/original/SouthAfricaEconomicUpdateApril2018.pdf

¹⁰ Statistics, South Africa (StatsSA). 2021. National Accounts: Sources and Methods. Report No. 04-04-04 (2021)

¹¹ International Monetary Fund (IMF). 2022. World Economic Update. https://www.imf.org/en/Countries/ZAF

percent in the fourth quarter of 2019 and soared to a record of 35.3 percent in the fourth quarter in 2021, with 7.9 million unemployed work seekers. ^{12,13} The upper-middle-income-country (UMIC) poverty rate worsened to an estimated 58.8 percent in 2021. ¹⁴ The COVID-19 shock is estimated to have put an additional 2 million people into poverty. ¹⁵ The ongoing Russia-Ukraine war is having a negative impact on the South African economy through higher costs of inputs, especially fuel, and its effect on global growth. However, as South Africa is a major mineral exporter, higher metal prices are more than compensating for the impact of elevated global oil prices in the trade account. High commodity prices should further support fiscal revenues. ¹⁶

- 10. The COVID-19 pandemic is expected to reverse some progress in human capital formation which may have long-lasting consequences for human capital accumulation and productivity growth. Based on the World Bank Group (WBG) Human Capital Index (HCI) 2020 Update, ^{17, 18} South Africa's HCI is at 0.43, which has been stagnant since 2010. South Africa's HCI is slightly above the Sub-Saharan Africa (SSA) average (0.40) and significantly below the average of UMICs (0.56). ¹⁹ South Africa's years of schooling (10.2) performs better than the average of Sub-Saharan Africa (SSA) (8.3); however, the harmonized test score (343) is lower than the average of SSA (374), which may suggest lower quality of education in South Africa. HCI's health indicators (adult survival rate [0.69] and not stunted rate [0.73]) are generally comparable to the average of SSA (0.74 and 0.69, respectively). Girls' HCI (0.45) is slightly better than boys' (0.41) largely due to better harmonized test scores and adult survival rates for females. ²⁰ The sub-optimal performance of South Africa's human capital development is largely due to persistent underinvestment in social sectors and human capital. ²¹ Fiscal constraints aggravated by COVID-19 may further limit increases in social spending over the coming years. In addition, disproportionately high rates of pandemic-induced job loss and livelihood damage among women may further degrade human capital development in South Africa. ²²
- 11. **South Africa is the epicenter of the COVID-19 pandemic in Africa.** As of May 16, 2022, South Africa registered the highest number of infections (cumulative cases: 3.89 million) on the continent and the highest cumulative deaths per million with 100,771 deaths (figure 1). ^{23, 24} South Africa, to date, has gone through four waves of COVID-19 with subsequent peaks reaching higher than that of the previous wave. The first wave commenced around June of 2020 shortly after the mobility restrictions had been eased. A significant proportion of people who were affected were the elderly. More than a third of the confirmed cases were from long-term care

¹² StatsSA. 2020. South Africa Quarterly Labour Force Survey (QLFS). 2nd quarter, 2021.

 $^{^{13}}$ StatsSA. 2022. South Africa QLFS. 4^{th} quarter, 2021

¹⁴ World Bank. 2022. Macro Poverty Outlook. http://macropovertyoutlook.worldbank.org/mpo_files/mpo/mpo-sm22-zaf-scope.pdf

¹⁵ World Bank. 2021. Overview (Last updated March 18, 2021). https://www.worldbank.org/en/country/southafrica/overview; Living below the poverty line for upper-middle income countries, US\$5.5 per day in 2011 purchasing power parity exchange rates

¹⁶ World Bank. 2022. Macro Poverty Outlook. http://macropovertyoutlook.worldbank.org/mpo_files/mpo/mpo-sm22-zaf-scope.pdf

¹⁷ World Bank. 2020. The Human Capital Index 2020 Update: Human Capital in the Time of COVID-19. World Bank, Washington, DC. © World Bank. https://openknowledge.worldbank.org/handle/10986/34432

¹⁸ The Human Capital Index (HCI) measures the human capital that a child born today can expect to attain by her 18th birthday, given the risks of poor health and poor education prevailing in her country. The index incorporates measures of different dimensions of human capital: health (child survival, stunting, and adult survival rates) and the quantity and quality of schooling (expected years of school and international test scores).

¹⁹ World Bank. 2021. WDI. https://databank.worldbank.org/source/world-development-indicators

²⁰ World Bank. 2020. The Human Capital Index 2020 Update: Human Capital in the Time of COVID-19. World Bank, Washington, DC. © World Bank. https://openknowledge.worldbank.org/handle/10986/34432

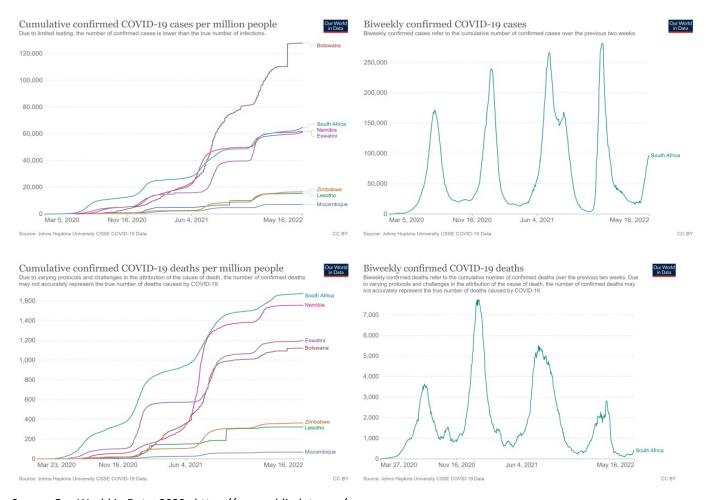
²¹ Brookings Institute, Foresight Africa 2021 Report. 2021. Washington, DC. https://www.brookings.edu/research/foresight-africa-2021/ ²² Ibid.

²³ South Africa Government Portal. 2022. Covid-19 Daily Updates & Cases. https://sacoronavirus.co.za/covid-19-daily-cases/

²⁴ Our World in Data. 2021. https://ourworldindata.org/covid-deaths

facilities in the initial phase of the pandemic.²⁵ The second wave was driven by the Beta variant in January 2021, whereas the third and fourth waves were driven by the Delta variant and the Omicron variant respectively. South Africa's higher proportions of COVID-related deaths ²⁶ could be associated with the higher median age of the population ²⁷ (27.6 years in 2020 compared with the regional average of 18.7 years ²⁸), higher number of the elderly living in long-term care facilities, and higher prevalence of both communicable (human immunodeficiency virus [HIV] and tuberculosis) and non-communicable diseases (NCDs). ²⁹

Figure 1: Cumulative and biweekly COVID-19 cases and deaths per million people in South Africa and its neighboring countries (as of May 16, 2022)



Source: Our World in Data. 2022. https://ourworldindata.org/

²⁵ Ashwell, A., Jacobs, R., Docrat, S. and Schneider, M., 2020. How Long-term Dementia Care Facilities in South Africa Have Coped with the Covid-19 Lockdown: Synthesis Report From 2 Rounds of a Survey. LTCcovid. org, International Long-Term Care Policy Network, CPEC-LSE, 21. ²⁶ COVID-19 Excess Mortality Collaborators. 2022. Estimating excess mortality due to the COVID-19 pandemic: a systematic analysis of COVID-19-related mortality, 2020–21. *The Lancet. https://doi.org/10.1016/S0140-6736(21)02796-3*

²⁷ Ausubel J. 2020. Populations skew older in some of the countries hit hard by COVID-19. Pew Research Center. https://www.pewresearch.org/ fact-tank/2020/04/22/populations-skew-older-in-some-of-the-countries-hit-hard-by-covid-19/

²⁸ United Nations, Department of Economic and Social Affairs, Population Division. 2019. World Population Prospects 2019, custom data acquired via https://population.un.org/wpp/DataQuery/

²⁹ Schlüter J., Sörensen L., Bossert A. et al. 2021. Anticipating the impact of COVID19 and comorbidities on the South African healthcare system by agent-based simulations. Scientific Reports. 11, 7901. https://doi.org/10.1038/s41598-021-86580-w

12. The Government introduced unprecedented measures in its fight against COVID-19. ³⁰ In less than two weeks from registering its first case (March 5, 2020), South Africa declared a national state of disaster on March 16, 2020 with a partial travel ban, closing of schools and prohibiting gatherings of more than 100 people, among other measures. The GoSA implemented almost a month-long lockdown at the end of March 2020. However, the lockdown was eased from May 1, 2020 due to its impact on the economy. The government also enacted a number of relief measures to counter the adverse impacts of the lockdown on economic activity, especially for low-wage workers and poorer households. In April 2020, the government had announced a ZAR 500 billion (US\$31.5 billion) ³¹ about a tenth of South Africa's GDP) support package to fight COVID-19 and its economic and social effects with a focus on protecting the poor and livelihoods. This included a social relief of distress grant of ZAR 350 (US\$22) per month for ten million people. In addition, the Parliament passed the Disaster Management Tax Relief Bill 2020 and Disaster Management Tax Relief Administration Bill 2020. These bills offered tax relief measures such as tax subsidies and payments of employment tax incentive reimbursements which alleviated cash flow burdens on small to medium sized businesses.

B. Sectoral and Institutional Context

Overall health outcomes and system

- 13. **Prior to the COVID-19 pandemic, health outcomes in South Africa improved, but challenges persist.** There have been significant improvements in maternal and child health. ³² Maternal mortality per 100,000 live births decreased from 160 in 2000 to 119 in 2017. ³³ Under-five mortality per 1,000 live births decreased from 71.1 in 2000 to 34.5 in 2019 and infant mortality rate decreased from 46.3 deaths per 1,000 live births to 27.5 during the same period. The country, however, suffers from a high burden of preventable illness and premature death and a rising burden of NCDs. Although life expectancy increased from 56 years in 2000 to 64 years in 2019, it is lower than the average of UMICs (76 years). HIV incidence per 1,000 at-risk population among ages 15-49 declined from 22.0 in 2000 to 7.8 in 2020, but one in five people aged 15-49 are infected with HIV. According to the recent NCD Countdown 2030 Report, South Africans have a 51.9 percent probability of dying from NCDs. ³⁴ Mortality from cardiovascular diseases, cancer and diabetes between ages 30-70 is still high at 24.1 percent in 2019 compared with 16.6 percent for UMICs. The COVID-19 pandemic and disruptions in routine essential healthcare services due to the pandemic, including services in malaria prevention and treatment, vaccinations, and maternal and child health services, resulted in a significant rise in crude death rates in 2021 (8.7 deaths per 1,000 people in 2020 to 11.6 deaths per 1,000 people in 2021) and a drop in life expectancy (62.4 in 2020 to 59.3 in 2021). ^{35, 36, 37}
- 14. Although health service coverage in South Africa has improved over the last couple of decades, the COVID-19 pandemic has had an adverse impact on access to and utilization of health services. While immunization coverage against measles (second dose) slightly increased from 75.0 percent in 2008 to 79.0 percent in 2019, the

³¹ US\$ 1 equivalent to ZAR 15.9. This rate will be used throughout the document.

³⁰ GoSA. 2021. https://www.gov.za/Coronavirus

³² World Bank. 2021. WDI. https://databank.worldbank.org/source/world-development-indicators

³³ This is the modelled estimate from the WHO, UNICEF, UNFPA, World Bank Group, and the United Nations Population Division. Trends in Maternal Mortality: 2000 to 2017. Geneva, World Health Organization, 2019. https://data.worldbank.org/indicator/SH.STA.MMRT

³⁴ Bennett J., Stevens G., Mathers C. et al. 2018. NCD Countdown 2030: worldwide trends in non-communicable disease mortality and progress towards Sustainable Development Goal target 3.4. The Lancet, 392(10152), pp.1072-1088.f

³⁵ World Bank.2021. WDI. https://databank.worldbank.org/source/world-development-indicators

³⁶ StatsSA. 2021. COVID-19 Epidemic Reduces Life Expectancy in 2021. http://www.statssa.gov.za/?p=14519

³⁷ Dyer O. 2020. COVID-19: Excess deaths point to hidden toll in South Africa as cases surge. BMJ 2020;370:m3038

National Department of Health (NDoH) reported that there has been a significant decline in child immunization services: both full immunization and second dose of measles coverage declined to less than 60.0 percent in 2020/21. 38, 39 An analysis of health utilization data in 2019 and 2020 also showed a decline in access to routine health services. For example, primary health care (PHC) attendance declined from 99.6 million visits in 2019 to 81.2 million visits in 2020 and full immunization coverage which decreased by 4.3 percent in the same period. 40 These declines could be attributed to demand-side challenges (e.g., fear of contracting COVID-19 while seeking care at a health facility, limited access to transportation) and supply-side constraints (e.g., overstretched supply chain, diversion of resources to the pandemic response, shortage of health care workers [HCWs]).

- 15. While the health outcomes are slightly better among females in general, there is still work that needs to be done in South Africa to achieve gender equality. Life expectancy is higher for females (68 years) than males (61 years) in 2019. 41,42 Similar trends are observed for stunting where 25.0 percent of boys under the age of five are stunted in 2017 compared with 17.8 percent among girls. HIV prevalence, however, is higher for women aged 15-24 years (10.4 percent) by almost threefold compared with male peers (3.5 percent) in 2020. 43 Although these indicators show better results among females in general, coverage of essential services shows mixed results: according to the 2016 Demographic and Health Survey, boys aged 12-23 months were more likely to get all basic vaccinations than girls (63.5 percent vs. 58.7 percent), while boys under the age of five with diarrhea were less likely to be taken for advice or treatment than girls (59.9 percent vs. 67.1 percent). 44 Also, women in South Africa are still suffering from sexual violence and gender inequality. In 2018, 13.1 percent of women aged 15-49 years reported that they had been subject to physical and/or sexual violence by a current or former intimate partner in the previous 12 months. 45
- 16. **South Africa has a two-tiered and unequal healthcare system.** The South African healthcare system can be traced back to the apartheid period (1948–1994) when it was highly fragmented and inequitable between racial groups. When the household members were ill or had accident, the majority of the population (71.5 percent) first consulted the public sector health facilities, managed by the Provincial Departments of Health (PDoHs), while less than a third of the population (27.1 percent) consulted the private sector health facilities. In terms of financing, 85.2 percent of the population is covered by the State, whereas the remaining 14.8 percent are financed through medical schemes. The GoSA is trying to address the fragmented health financing, with poor and rich utilizing

³⁸ WHO. WHO and UNICEF. 2020. Estimates of National Immunization Coverage. https://www.who.int/immunization/monitoring_surveillance/data/zaf.pdf

³⁹ NDoH. 2021. Annual Performance Plan 2021/22. Coverage of full immunization and measles 2nd dose are 58.4 percent and 55.8 percent. in FY20/21, significantly lower than 83.6 percent and 79.6 percent respectively during the FY19/20.

⁴⁰ Pillay, Y, Pienaar, S, Zondi, T. 2021. Impact of COVID-19 on routine primary healthcare services in South Africa. *South Africa Medical Journal*. 111(8);714-719.

⁴¹World Bank. 2021. WDI. https://databank.worldbank.org/source/world-development-indicators

⁴² According to StatsSA, life expectancy at birth for males declined from 62.4 in 2020 to 59.3 in 2021 and from 68.4 in 2020 to 64.6 for females. http://www.statssa.gov.za/?p=14519

⁴³ World Bank. 2021. WDI. https://databank.worldbank.org/source/world-development-indicators

⁴⁴ NDoH, Statistics South Africa, South African Medical Research Council, and ICF. 2019. South Africa Demographic and Health Survey 2016

⁴⁵ UN Women. South Africa. 2020. https://data.unwomen.org/country/south-africa

⁴⁶ Maphumulo W. and Bhengu B. 2019. Challenges of quality improvement in the healthcare of South Africa post-apartheid: A critical review. Curationis. 42(1):e1-e9. Published 2019 May 29. https://doi:10.4102/curationis.v42i1.1901

⁴⁷ StatsSA. 2018. General Household Survey 2018. http://www.statssa.gov.za/publications/P0318/P03182018.pdf#page=36

⁴⁸ Council for Medical Schemes. 2021.Industry Report 2020: Regulating through a pandemic. https://www.medicalschemes.co.za/download/3611/industry-report-2020-21/24593/cms_industry-report-2020_web.pdf

separate revenue collection and pooling mechanisms, by introducing a national health insurance (NHI)⁴⁹ and moving toward universal health coverage.

Quality of health care in South Africa has been a challenge, especially in the public sector, contributing to 17. slow improvements of health outcomes. Delivering quality health care in the country is a constitutional obligation, and there have been major changes in health policy and legislation to ensure compliance in delivery of quality care. 50 Despite these commendable achievements, services in public health facilities are not always meeting basic standards of care and patient expectation: poor quality of care is reportedly associated with shortage of human resources for health, adverse events, poor hygiene and infection control measures, increased litigation because of avoidable errors, shortage of resources in medicine and equipment and poor record-keeping. 51 Although human resources for health in South Africa during the apartheid years were strongly developed through establishments of training centers, significant workforce shortages have been a challenge: there are only 0.9 physicians and 1.3 nurses/midwives per 1,000 people, compared with 2.2 physicians and 3.7 nurses/midwives in UMICs. 52 The difference in quality of services becomes starker between public and private health facilities mainly due to its unequal distribution of HCWs between the well-resourced private sector and the poorly resourced public sector and between urban and rural areas. 53 For example, an estimated 70.0 percent of doctors and 80.0 percent of specialists work in the private sector, primarily serving middle- and upper-class families, as well as expats. 54,55,56 Like other countries, the rural areas are historically underserved. 57

South Africa's health response to COVID-19, vaccine rollout strategy, and World Bank support

18. The GoSA proactively responded to the pandemic and prepared a National Plan for COVID-19 Health Response. On January 30, 2020, the NDoH established an Incident Management Team modeled after the WHO's Framework for a Public Health Emergency Operations Center to create a structured approach for managing a public health emergency. ⁵⁸ A National COVID-19 Command and Control Council, comprising ministers from various departments, was established on March 15, 2020 to lead intergovernmental coordination and influence government-wide decision concerning the response to COVID-19. The NDoH developed the National Plan for COVID-19 Health Response ⁵⁹ which identified nine strategic priorities: (a) provide effective governance and leadership; (b)

⁵⁵ Maphumulo WT and Bhengu BR. 2019. Challenges of quality improvement in the healthcare of South Africa post-apartheid: A critical review. *Curationis*. 42(1):e1-e9. Published 2019 May 29. doi:10.4102/curationis.v42i1.1901

⁵⁹ NDoH. 2020. National Plan for COVID-19 Health Response. Final Draft (May 7, 2020)

⁴⁹ The NHI implementation had three phases. The first phase (2012-2017) focused on piloting various health-systems strengthening (HSS) interventions in preparation for the full implementation of NHI. The current phase (2018 - 2022) focused on the development of NHI legislation and amendments to existing legislation, as well as a fully functional NHI Fund and its structures. It also involves purchasing personal healthcare services for vulnerable groups. The last phase (2023 - 2026) will focus on HSS activities to be implemented to full scale, and mobilization of additional resources. Following the public comments process in 2018, and a number of iterations, the bill was further revised and submitted to the Parliamentary Portfolio Committee on Health in August 2019.

⁵⁰ South Africa International Insurance. 2020. https://www.internationalinsurance.com/health/systems/south-africa.php.

⁵¹ Maphumulo W. and Bhengu B. 2019. Challenges of quality improvement in the healthcare of South Africa post-apartheid: A critical review. *Curationis*. 42(1):e1-e9. Published 2019 May 29. https://doi:10.4102/curationis.v42i1.1901

⁵² World Bank.2021. WDI. https://databank.worldbank.org/source/world-development-indicators

⁵³ South Africa International insurance. 2020. https://www.internationalinsurance.com/health/systems/south-africa.php.

⁵⁴ Ibid.

⁵⁶ George A, Blaauw D, Thompson J, and Green-Thompson L. 2019. Doctor retention and distribution in postapartheid South Africa: tracking medical graduates (2007–2011) from one university. Human Resources for Health. 17:100 https://doi.org/10.1186/s12960-019-0439-4

⁵⁷ van der Hoeven M., Kruger A. and Greeff M. 2012. Differences in health care seeking behaviour between rural and urban communities in South Africa. *International Journal of Equity in Health*. 11. https://doi.org/10.1186/1475-9276-11-31

⁵⁸ Blecher M. 2020. South Africa: Decision Making for Social and Movement Measures in the Context of COVID-19 https://cdn.who.int/media/docs/default-source/health-governance-and-financing/south-africa.pdf?sfvrsn=450a601a_11

strengthen surveillance and strategic information; (c) augment health systems readiness; (d) enhance community engagement; (e) improve laboratory capacity and testing; (f) clarify care pathways; (g) scale up infection prevention and control (IPC) measures; (h) boost capacity at ports of entry; and (i) expedite research and introduction of therapeutics, diagnostics and vaccines. To contain the spread of COVID-19 and manage the gradual ease of lockdown, a five-level alert risk-adjusted strategy was developed which is informed by, among others, epidemiological trends of infections, health system capacity to respond to the disease burden, the extent of the implementation of public health interventions, and the economic and social impact of continued restrictions. ⁶⁰

- 19. Since the start of the pandemic, the GoSA has implemented public health and social measures to reduce transmission and minimize pressure on the health system. The GoSA's health response comprises eight overlapping stages: (a) preparation which included building diagnostic testing capacity; (b) prevention which included interventions such as banning international travel, closing schools, restricting social gatherings, promoting social distancing; (c) lockdowns which restricted movement and activity; (d) active case finding which included contact tracing and scaling up community testing; (e) identification of hot spots to contain localized outbreaks; (f) medical care which included strengthening case management capacity through construction of field hospitals; (g) preparation for deaths burials and mental health challenges of bereavement; and (h) vigilance which focuses on continuous monitoring of population immunity levels and preparing for subsequent waves through surveillance and serosurveys. ^{61, 62} Over time, the GoSA has tried to balance the public health and social measures and their social and economic impact on vulnerable households and communities. For example, the GoSA implemented a strict national lockdown at the end of March 2020, but gradually eased restrictions between May and August 2020 in part due to the burden on livelihoods. ⁶³
- 20. **The GoSA has committed to a robust whole-of-government response where decision-making is driven by evidence.** The GoSA has focused on an open line of communication with the public and all stakeholders for clear, accessible, and scientifically accurate information about COVID-19 and the government's response. South Africa has been successful in building local vaccine development and manufacturing capacity through strategic partnerships and technology transfer. ^{64, 65} South Africa is the regional hub for SARS-CoV-2 genomic sequencing for the entire Africa region ⁶⁶ and as of May 7, 2022, sequenced 39,463 South African genomes (6,657 in 2020, 25,811 in 2021, and 6,995 in 2022). ⁶⁷ A critically important change in the state of science since the early stages of the pandemic has been the emergence of new therapies and also the successful development and expanding production of COVID-19 vaccines (see annex 1 for vaccine development and approval status).

60 South African Government. 2021. About Alert System. https://www.gov.za/covid-19/about/about-alert-system

⁶¹ Abdul Karim, S.S.. 2020. The South African Response to the Pandemic. The New England Journal of Medicine 382;24;

⁶² Baxer C., Abdul Karim Q.A., and Abdul Karim S.S. 2021. Identifying SARS-CoV-2 Infection in South Africa: Balancing public health imperatives with saving lives. *Biochemical and Biophysical Research Communications*. 538;221-225.

⁶³ Partnership for Evidence Based Response to COVID-19. Updated August 19, 2020. Finding the Balance: Public Health and Social Measures in South Africa.

⁶⁴ The Conversation. 2021. Want to develop vaccines in Africa? Then invest in expertise and infrastructure. September 26, 2021. https://theconversation.com/want-to-develop-vaccines-in-africa-then-invest-in-expertise-and-infrastructure-167660

⁶⁵ International Finance Corporation. 2022. Biovac and Development Partners Collaborate to Support South Africa's Vaccine Manufacturing Expansion and Advance Long-Term Health Security Across Africa. https://pressroom.ifc.org/all/pages/PressDetail.aspx?ID=26842

⁶⁶ The WHO selected the South African National Bioinformatics Institute (SANBI) and KwaZulu-Natal Research Innovation and Sequencing Platform (KRISP) as their reference laboratories for genomic sequencing. Further, the Centre for Epidemic Response and Innovation (CERI) has been established at Stellenbosch University to expand the efforts of KRISP.

⁶⁷ Network for Genomic Surveillance in South Africa. 2022. SARS-CoV-2 Sequencing Update. https://www.nicd.ac.za/diseases-a-z-index/disease-index-covid-19/sars-cov-2-genomic-surveillance-update/

21. The proposed project, along with the Genomic Surveillance Project (P177439) and the South Africa COVID-19 Response Development Policy Operation (P174246), 68 will form part of World Bank's expanded response to the pandemic, building on support of other development partners in the context of the overall Government's COVID-19 vaccination program: WHO, United Nations Children's Fund (UNICEF), Governments of United States, Germany, and United Kingdom, and others have played a key role in supporting the GoSA technically and/or financially, in response to COVID-19 including vaccination rollout (box 2). The increased financial and technical support from the World Bank on the national COVID-19 vaccination program at country level will help accelerate efforts by the GoSA and other development partners. The proposed project will also complement the WBG's support through the South Africa COVID-19 Response Development Policy Operation (P174246) for electronic registration of vaccine sites and vaccinees through the use of the Electronic Vaccination Data System (EVDS).

Box 2: Supportive Roles for Key Partner Agencies in Implementation

WHO	Financing amount
Facilitating health partner coordination for COVID-19 response and vaccine roll out	In-kind
 Providing policy and strategic support to COVID-19 response including development and 	contribution
implementation of Resurgence Plan	
 Supporting development of the National Vaccine Rollout Strategy 	
 Strengthening continuity of essential health care services in the context of COVID-19 response 	
 Providing technical support to NDoH to manage NCD and Mental Health services and 	
interruptions due to COVID-19 and develop recovery plans through and after the pandemic.	
 Building capacity of key national and provincial staff in vaccine planning and rollout, and adverse 	
events following immunization (AEFIs) monitoring	
 Setting up data systems for monitoring and evaluation (M&E) 	
 Deploying national and international experts and interns for vaccine rollout, including 	
deployment of 58 officers in 8 provinces to support vaccine rollout	
Supporting development of RCCE strategies and plans for vaccine demand creation	
UNICEF	
 Supporting the subnational cold chain system management for COVID-19 vaccines and routine 	US\$1.10 million
immunization in 5 Provinces (Gauteng, Northwest, KwaZulu-Natal, Western Cape, Eastern Cape)	
 Supporting RCCE on COVID-19 vaccine deployment including social listening, social behavior 	
change, community engagement, and video production	
 Supporting vaccine rollout and continuity of services including child health and nutrition services 	
Providing oxygen equipment and training for healthcare facilities	
Gavi/COVAX	
 Providing access to vaccines to cover the first prioritized 10 percent of the population 	Not applicable
Government of United States	
 Providing about 7.88 million doses of Pfizer vaccines 	In-kind
Providing support for vaccine logistics and supply planning, through the United States Agency for	contribution of
International Development (USAID) Global Health Supply Chain Program	7.88 million doses
 Supporting the national COVID-19 Vaccine Rollout Strategy and EVDS 	of Pfizer vaccine
 Supporting vaccination site activation process 	
Supporting RCCE to reduce vaccine hesitancy and generate demand	US\$33.39 million
 Providing epidemiological surveillance and analyses to inform resource allocation 	
 Providing sequencing equipment to strengthen the capacity to track current and new variants 	
 Capacitating health facilities and healthcare workers to mitigate transmission by supporting IPC 	

⁶⁸ The project was approved on January 20, 2022. The PDO is to protect the poor and vulnerable from the adverse socio-economic impacts of the COVID-19 pandemic, and to pave the way for a resilient sustainable recovery (PGD208).

	1
 Providing case management technical assistance and oxygen-related commodities for patient 	
hospital care	
Government of Germany	
 Financial Cooperation (KfW): Providing cold chain equipment including vaccine fridges, passive 	EUR 18.0 million
containers, continuous temperature monitoring devices	
 Financial Cooperation (KfW): Providing support to Department of Science and Innovation for 	EUR 20.0 million
vaccine development	
 Technical Cooperation (GIZ): Providing support to NDoH on vaccine roll-out (mobile teams, 	EUR 18.7 million
communication, digitalization and integration into routine care) and to Department of Science	
and Innovation on vaccine production	
Government of United Kingdom Better Health Programme	
 Supporting reimbursement management through collection from medical aid schemes and 	ZAR 1.50 million
payment for private sector services	(US\$ 94,340)
Douglas George Murray Trust (funded by Bill and Melinda Gates Foundation, ELMA Foundation,	
and other foundations)	
 Supporting national coordination 	Not available
 Supporting provincial cold chain and supply coordination 	
Supporting the EVDS	
 Supporting demand generation and RCCE 	
 Providing coordination support for the procurement and donation of the cold chain equipment 	
provided by the Government of Germany	
Vodacom	
 Providing cold chain equipment including -20°C freezers for districts, vaccine fridges and 	US\$1.50 million
continuous temperature monitoring devices, and passive containers	
Solidarity Fund	
Supporting the national contact center	Not available
 Supporting logistics for donated vaccines and imported needles 	
 Supporting mass vaccination sites and other delivery support 	
 Supporting communication programs 	

National Capacity and COVID-19 Vaccination Strategy

22. Under the leadership of the Ministerial Advisory Committee (MAC) on COVID-19 Vaccines, the NDoH developed the COVID-19 Vaccine Rollout Strategy in January 2021. 69, 70 Based on the vaccination readiness assessment (table 1), the strategy specifically aims to: (a) ensure sufficient supply and adequate access to a safe and effective vaccine to achieve population immunity; (b) protect vulnerable population groups from acquiring COVID-19; (c) contribute to South Africa's social and economic recovery following the negative impact of COVID-19; (d) enhance South Africa's preparedness for response to future disease outbreaks; and (e) develop, with civil society, a comprehensive communication program to address vaccine hesitancy and increase vaccine confidence. An updated strategy, along with the South African COVID-19 Vaccine Strategic Plan 71 and the COVID-19 Vaccine Implementation Guide and Toolkit, 72 guides the vaccine delivery mechanisms and defines the roles and responsibilities of various stakeholders for vaccine introduction, purchasing mechanisms, funding implication, and priority groups for vaccination. Considering the uncertainties related to the COVID-19 vaccine market, including

⁶⁹ MAC Advisories. 2021. COVID-19: Vaccine Strategy. https://sacoronavirus.co.za/2021/01/03/covid-19-vaccine-strategy/

⁷⁰ NDoH. 2021. COVID-19 Vaccine Rollout Strategy (January 3, 2021). The strategy and implementation guide will be updated as new financial, technical, and epidemiological information becomes available and, therefore, should be considered as a living document.

⁷¹ NDoH. 2021. South African COVID-19 Vaccine Strategic Plan (May 14, 2021)

⁷² NDoH. 2021. COVID-19 Vaccine Implementation Guide and Toolkit (May 20, 2021)

testing, approval, availability, and pricing, as well as the evolving technical and epidemiological information, the GoSA continuously assesses the evolving situation and updates the strategy and implementation guidelines.

Table 1. Summary of Vaccination Readiness

Readiness		
domain	Readiness of government	Key gaps to address
Planning and	A South Africa COVID-19 Vaccine Rollout Strategy has been developed.	None
coordination	The statutory National Health Council makes the policy decisions.	
	■ The GoSA has set up a non-statutory MAC on COVID-19 vaccines.	
	The vaccine rollout is led nationally in close coordination with the PDoHs and	
	the private health care sector. Committees are established at various levels	
	with the relevant stakeholders and expertise to coordinate the rollout of the	
	various phases of the vaccine delivery. For example, planning and coordination	
	with private sector takes place at the Joint Strategic Operations Committee.	
	 A National Vaccine Coordinating Committee is responsible for overall 	
	coordination of vaccine roll out. The committee is led by the Director General	
	with representatives from the Expanded Program on Immunization (EPI),	
	communicable disease cluster, medicines supply chain management,	
	information systems, human resources, PHC and M&E. Other representatives	
	include the chair of the provincial coordinating committee, the chair of the	
	national private sector coordinating committee and WHO.	
Budgeting	 An estimated ZAR 14.1 billion (US\$886.8 million) has been budgeted to the 	There is no major gap.
	national COVID-19 vaccination program.	However, the budget
	The GoSA has signed contracts with 3 entities (Pfizer, Janssen Pharmaceutica	may be limited when
	NV, and COVAX) to procure vaccines.	more vaccination sites
	 The GoSA has allocated budget for deployment including RCCE and capacity 	are needed to improve
	building among others. It is complemented by the health sector budget.	access and scale up
		RCCE.
Regulatory	 COVID-19 vaccines require authorization by the national regulator, the South 	None
	African Health Products Regulatory Authority (SAHPRA). To date, SAHPRA has	
	approved vaccines from Pfizer (March 16, 2021), Johnson & Johnson (J&J) (April	
	1, 2021), Sinovac (July 3, 2021), and MC Pharma/Sinopharm (January 31, 2022).	
	SAHPRA is currently evaluating a number of applications for emergency use	
	and/or registration of COVID-19 vaccines.	
Prioritization,	Prioritization and targeting are based on the framework of prioritization and	None
targeting,	need, emphasizing an evidence-based approach and an ethical and moral	
surveillance	perspective in particular from an African indigenous values context in line with	
	the WHO Strategic Advisory Group of Experts on Immunization (SAGE)	
	Roadmap for Prioritizing Uses of COVID-19 Vaccines.	
	A booster was introduced for all adults 18 years or older in December 2021.	
	 Target populations register through the EVDS and every vaccination is recorded 	
Camila dalla m	on the EVDS.	Code a mation of a continuity of
Service delivery	Vaccinations are provided through a network of public and private sector vaccination sites including both fixed sites (both facility and non-boalth facility)	Suboptimal availability of HCWs in some
	vaccination sites including both fixed sites (heath facility and non-health facility	
	sites) and outreach/mobile sites.	locations. Partners (e.g.,
	All vaccination sites are registered on the Master Facility List. Advance registration through EVDS is strongly encouraged, and walk income.	WHO, etc) are providing
	Advance registration through EVDS is strongly encouraged, and walk-ins are	technical assistance.
	allowed.	
	Informed consent is required.	

		I
	Mechanisms are in place to allow for insured and uninsured persons to	
	vaccinate in either the public or the private sector.	
	People do not need to pay for the COVID-19 vaccine. The cost of vaccine and its	
	administration for the uninsured is covered by GoSA, while that of the insured	
	is covered by the medical aid schemes.	
	 Integration of COVID-19 vaccination into health services at all PHC facilities, 	
	vertical programs (HIV/Tuberculosis and Maternal, Newborn, Child Health) and	
	hospitals is planned for FY22/23.	
Training and	■ The NDoH has teamed up with the South African Vaccination and Immunisation	None
supervision	Centre at the Sefako Makgatho Health Sciences University and other support	
•	partners to package a short course, with tools, to prepare vaccinators to	
	implement the COVID-19 vaccination.	
	 Partners (e.g., WHO) have also provided training for specific topics such as 	
	safety surveillance and causality assessment, and AEFI management.	
	 All vaccinators are registered after receiving training. 	
	 Training is continuously updated to align with program changes over time. 	
M&E	 Vaccine registration is done in the EVDS across the public and private sector. 	M&E at local level to
IVICE	The NDoH performs advanced analytics using data from EVDS, laboratory	identify areas for
	· · · · · · · · · · · · · · · · · · ·	
	results, hospitalization, and other clinical outcomes.	targeted efforts
	■ The NDoH has a National Indicator COVID-19 Vaccination Set which measures	
	key indicators across eight categories: (a) vaccination sites; (b) vaccinators; (c)	
	supply chain; (d) vaccination coverage; (e) dose uptake; (f) drop out; (g) AEFI;	
	and (h) post vaccination infection.	
	South Africa has robust genomic sequencing capacity and serves as the regional	
	l hub.	
	A national cold chain inventory assessment was conducted in all provinces in	Currently, there are no
chain, logistics,	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity 	major gaps. However,
	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity and assess the requirements for additional cold chain equipment to ensure 	-
chain, logistics,	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity 	major gaps. However,
chain, logistics, infrastructure	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity and assess the requirements for additional cold chain equipment to ensure 	major gaps. However, this will be continually
chain, logistics, infrastructure	A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity and assess the requirements for additional cold chain equipment to ensure access to a safe and potent vaccine to the target population.	major gaps. However, this will be continually
chain, logistics, infrastructure	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity and assess the requirements for additional cold chain equipment to ensure access to a safe and potent vaccine to the target population. Cold chain audit tools are being developed to ensure yearly facility level cold 	major gaps. However, this will be continually
chain, logistics, infrastructure	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity and assess the requirements for additional cold chain equipment to ensure access to a safe and potent vaccine to the target population. Cold chain audit tools are being developed to ensure yearly facility level cold chain audits and contribute to future pandemic preparedness. 	major gaps. However, this will be continually
chain, logistics, infrastructure	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity and assess the requirements for additional cold chain equipment to ensure access to a safe and potent vaccine to the target population. Cold chain audit tools are being developed to ensure yearly facility level cold chain audits and contribute to future pandemic preparedness. The NDoH has developed standard operating procedures (SOPs) for vaccine 	major gaps. However, this will be continually
chain, logistics, infrastructure	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity and assess the requirements for additional cold chain equipment to ensure access to a safe and potent vaccine to the target population. Cold chain audit tools are being developed to ensure yearly facility level cold chain audits and contribute to future pandemic preparedness. The NDoH has developed standard operating procedures (SOPs) for vaccine logistics from entry into the country, distribution, and storage. The SOPs 	major gaps. However, this will be continually
chain, logistics, infrastructure	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity and assess the requirements for additional cold chain equipment to ensure access to a safe and potent vaccine to the target population. Cold chain audit tools are being developed to ensure yearly facility level cold chain audits and contribute to future pandemic preparedness. The NDoH has developed standard operating procedures (SOPs) for vaccine logistics from entry into the country, distribution, and storage. The SOPs consider the cold chain requirements of the different vaccines. The NDoH uses a digital Stock Visibility System (SVS) to monitor the availability 	major gaps. However, this will be continually
chain, logistics, infrastructure	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity and assess the requirements for additional cold chain equipment to ensure access to a safe and potent vaccine to the target population. Cold chain audit tools are being developed to ensure yearly facility level cold chain audits and contribute to future pandemic preparedness. The NDoH has developed standard operating procedures (SOPs) for vaccine logistics from entry into the country, distribution, and storage. The SOPs consider the cold chain requirements of the different vaccines. The NDoH uses a digital Stock Visibility System (SVS) to monitor the availability of vaccines and to proactively identify stock outs. All public and private 	major gaps. However, this will be continually
chain, logistics, infrastructure	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity and assess the requirements for additional cold chain equipment to ensure access to a safe and potent vaccine to the target population. Cold chain audit tools are being developed to ensure yearly facility level cold chain audits and contribute to future pandemic preparedness. The NDoH has developed standard operating procedures (SOPs) for vaccine logistics from entry into the country, distribution, and storage. The SOPs consider the cold chain requirements of the different vaccines. The NDoH uses a digital Stock Visibility System (SVS) to monitor the availability of vaccines and to proactively identify stock outs. All public and private vaccination sites and stores are required to report stock levels daily. 	major gaps. However, this will be continually
chain, logistics, infrastructure	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity and assess the requirements for additional cold chain equipment to ensure access to a safe and potent vaccine to the target population. Cold chain audit tools are being developed to ensure yearly facility level cold chain audits and contribute to future pandemic preparedness. The NDOH has developed standard operating procedures (SOPs) for vaccine logistics from entry into the country, distribution, and storage. The SOPs consider the cold chain requirements of the different vaccines. The NDOH uses a digital Stock Visibility System (SVS) to monitor the availability of vaccines and to proactively identify stock outs. All public and private vaccination sites and stores are required to report stock levels daily. The NDOH's EPI is responsible for the COVID-19 vaccination program and 	major gaps. However, this will be continually assessed.
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chain, logistics, infrastructure	 A national cold chain inventory assessment was conducted in all provinces in both the public and private sectors to determine national cold chain capacity and assess the requirements for additional cold chain equipment to ensure access to a safe and potent vaccine to the target population. Cold chain audit tools are being developed to ensure yearly facility level cold chain audits and contribute to future pandemic preparedness. The NDoH has developed standard operating procedures (SOPs) for vaccine logistics from entry into the country, distribution, and storage. The SOPs consider the cold chain requirements of the different vaccines. The NDoH uses a digital Stock Visibility System (SVS) to monitor the availability of vaccines and to proactively identify stock outs. All public and private vaccination sites and stores are required to report stock levels daily. The NDoH's EPI is responsible for the COVID-19 vaccination program and therefore collaborates with SAHPRA on pharmacovigilance. The SAHPRA has multiple reporting tools for pharmacovigilance including the Med Safety App, Ereporting on the SAHPRA website, and paper-based reporting captured through the Vigilance Hub which feeds into the Vigiflow system. The National Immunization Safety Expert Committee (NISEC) is responsible for reviewing all AEFIs and providing feedback to SAHPRA, NDoH and EPI. The AEFI reporting system is designed to report all AEFIs to the national level within 24 hours. 	major gaps. However, this will be continually assessed.
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	■ South Africa, with Nigeria, Ghana and Ethiopia, is participating in the African	
	Union Smart Safety Surveillance, which aims to establish an African Union	
	pharmacovigilance surveillance network in Africa.	
Demand	■ The NDoH has developed COVID-19 Vaccine Rollout Communication Strategy:	Currently, there are no
generation and	Mapping the road ahead (2021) and a COVID-19 online resource and news	major gaps, but
communication	portal which provides daily updates on vaccine deployment and a link to the	additional RCCE may be
	EVDS among other useful monitoring data.	needed to improve
	Partners including the WHO and UNICEF are working closely with the NDoH to	vaccination rates
	understand and address the drivers of vaccine (brand) hesitancy.	especially among young
	 The NDoH has introduced a new communication strategy specifically targeting 	people and the
	young people in February 2022.	underserved.

- 23. While the GoSA is the sole purchaser of vaccines, the government is working closely with the private sector for effective deployment of vaccines. The importation and distribution of vaccines are contracted by the government to private sector operators. The Biological and Vaccines Institute of Southern Africa (Biovac) and Imperial Logistics South Africa Group are responsible for importing COVID-19 vaccines into the country. DSV HealthCare, the Biovac, and Kawari Wholesalers are responsible for transporting, warehousing and distributing COVID-19 vaccines to vaccination sites across the country. The NDoH, with support from the USAID funded Global Health Supply Chain program, coordinates orders between the vaccination sites and three distributors. Orders are received, vetted, and collated for allocation to the distributors weekly for delivery in the following week. Currently, there are over 3,000 fixed and satellites/mobile vaccination sites in the public and private sectors, 73 including private hospitals (e.g., Clinix, Netcare, Life Mediclinic, etc), corporate pharmacies (e.g., Dischem, Clicks, Multicare, etc), independent pharmacies, occupational health sites (e.g., mines and manufacturing sites, schools, universities, etc), non-health sites (e.g., medical aid schemes like Momentum, Discovery, etc) and general practitioners. The private sector is administering approximately one-third of vaccines – the majority of which are in Gauteng and Western Cape. The cost of vaccines and administration costs for the uninsured are covered by GoSA, while the cost for the insured population is covered by the medical aid schemes. However, some private vaccination sites reported challenges with maintaining vaccination sites due to lack of demand from people for vaccination.
- The COVID-19 vaccination program is managed through the EVDS. Launched in February 2021, the EVDS is designed to: (a) capture the relevant metrics of all South African residents who will be vaccinated (e.g., information regarding vaccinees, vaccination sites, vaccines, safety as part of pharmacovigilance); (b) ensure vaccinees are contactable and alerted to optimize adherence to the vaccination regime; and (c) complete the certification process such that vaccine certificates are easy to obtain for those vaccinated and authorities that may require the certification. The EVDS collects and provides the following: (a) patient information ⁷⁴; (b) establishment where vaccinated; (c) vaccine administered including manufacturer and batch number; (d) safety information as part of pharmacovigilance; and (e) record of vaccination issued to individuals vaccinated. The system can also provide a response mechanism for any future health emergencies. As every vaccination is recorded on the EVDS, detailed coverage data are available to national and provincial program managers on a daily basis for monitoring and planning, while the public can access a simpler dashboard. Also, all patient related data such as hospitalization are linked to EVDS. Relevant information from EVDS is used to facilitate reimbursement of vaccination costs for the insured. South Africa has an adequate legal framework to protect personal information (i.e., Protection of Personal Information [POPI] Act) and EVDS is POPI Act compliant and allows for capturing of user and client consent in the

73 NDoH. 2022. COVID-19 Online Resource & News Portal. Active Vaccination Sites. https://sacoronavirus.co.za/active-vaccination-sites/

⁷⁴ NDoH is in working on a system that will allow people without identify documents to get vaccinated (e.g., undocumented South Africans, migrants, etc). Some provinces have used a paper-based system to provide vaccination to the undocumented.

case of capturing personal information.⁷⁵ The GoSA uses the SVS to monitor the availability of COVID-19 vaccines and related ancillary supplies and all vaccination sites and stores are required to report stock level daily to inform decision-making and help ensure that stock is replenished in the right quantities and on time. COVID-19 Online Resources and News Portal⁷⁶ and the National Institute for Communicable Diseases (NICD) website provide daily updates of the latest COVID-19 statistics including the daily cases, hospitalization vaccination coverage, and other essential information to the public.⁷⁷

- 25. The GoSA has put in place an accountability mechanism to ensure that COVID-19 vaccines and therapeutics meet all the regulatory requirements of safety, efficacy, and quality. All vaccines that are made available in South Africa require authorization by the national regulator, SAHPRA, which is mandated to ensure the safety, quality, and efficacy of health products available in the country. SAHPRA has fast tracked all COVID-19 vaccine registration application with a dedicated team and introduced a rolling review mechanism to facilitate the submission and review of application and data. In addition, as a member of the WHO Collaborative Registration Procedures, SAHPRA works closely with other regulators to use their assessment reports to reduce evaluation processing timeline and relies on the WHO PQ and EUL. As of January 14, 2022, SAHPRA has provided an emergency use authorization for the Janssen's COVID-19 vaccine, Pfizer/BioTech's "Comirnaty", and Sinovac's "CoronaVac" vaccines with product specific requirements for ongoing monitoring.⁷⁸ SAHPRA registered, with conditions, the Comirnaty vaccine by Pfizer on January 25, 2022, and the COVID-19 vaccine MC Pharma, by MC Pharma (globally known as Sinopham) on January 31, 2022. SAHPRA is also currently evaluating a number of applications for emergency use and/or registration of COVID-19 vaccines. SAHPRA is responsible for its own assessment of project COVID-19 vaccines' safety and efficacy and is solely responsible for the authorization and deployment of the vaccines in the country.
- 26. **The NDoH and SAHPRA** are responsible for pharmacovigilance. SAHPRA monitors the overall safety of vaccines using the Med Safety App, e-reporting portal on SAHPRA website, and paper-based system. Data directly feed into Vigiflow system that is primarily used for reporting suspected adverse drug reactions in South Africa. The National Immunization Safety Committee reviews and assesses all reported serious and severe AEFIs, performs and provides feedback on the causality assessment, and submits recommendations to the NDoH who engages with the AFEI reporters. The total number of AEFIs reported between May 17, 2021 and April 15, 2022 is 5,815 (0.0173 percent of all doses administered).⁷⁹
- 27. RCCE including timely dissemination of information is central to the GoSA's vaccination program. The NDoH has developed a COVID-19 Vaccine Rollout Communication Strategy: Mapping the road ahead (2021). The strategy supports the roll out of COVID-19 vaccines through (a) dissemination of timely, accurate, and transparent

⁷⁷ The NICD has implemented Daily Hospital Surveillance (DATCOV) system to record laboratory results from public and private labs and to report admissions and bed availability in all COVID designated wards of all hospitals in the public and private sectors. South Africa Medical Research Council (SAMRC) collects data on officially reported deaths to the Department of Home Affairs and publishes data on excess deaths compared to those formally reported in the DATCOV system. The EVDS data analytics team integrates the vaccine, vaccination, laboratory test results, hospital admissions (general wards, high care and ICU) into information used for planning.

⁷⁵ NDoH. 2021. EVDS Data Protection and Privacy Policy. *https://sacoronavirus.co.za/evds/tscs/*. The policy specifies (a) the extent to which the EVDS collects information when people use it, (b) how personal information is used, (c) who personal information is shared with, (d) how personal data is kept securely, and (e) the extent to which any personal information is transferred and stored.

⁷⁶ NDOH. 2022. COVID-19 Online Resources and News Portal. https://sacoronavirus.co.za/

⁷⁸ SAHPRA. 2022. Vaccines-News and Updates. https://www.sahpra.org.za/news-and-updates/vaccines-news-and-updates/

⁷⁹ SAHPRA. 2022. Total number of AEFIs reports received. *http://aefi-reporting.sahpra.org.za/aefis.html*; AEFIs reported on this site have not been assessed for causality, and therefore, the events may not necessarily have a causal relationship with the administration of the vaccines.

information about the vaccines and (b) training of HCWs to communicate effectively with the clients. A COVID-19 online resource and news portal and the NICD website provide COVID-19 resources including technical and communication resources, guidelines, tips and advice for the public, and reports such as daily updates on COVID-19 and vaccine deployment. Several analyses have explored the drivers of vaccine (brand) hesitancy and suboptimal uptake. ^{80, 81, 82, 83} In collaboration with WHO, the NDoH has prepared an Accelerating Demand for COVID-19 Vaccination Project Plan (2021, updated in 2022) which focuses on (a) increasing the perceived value of vaccination and (b) increasing access but reducing the barriers to vaccination. In early October 2021, the President launched the Vooma campaign with the goal of improving accessibility and availability of vaccination program and vaccinating 70 percent of the adult population. Between November 2021 and February 2022, the GoSA provided Vooma vouchers ⁸⁴ to specific target groups (e.g., 50+) to incentivize vaccination. In order to address the low vaccination rates among younger people, especially males, the NDoH has also introduced a new communication strategy specifically targeting this group in February 2022. The new demand creation campaign, called #KeReady ("I am ready"), puts young people at the center of communication, employs open, two-way, and non-didactic communication, engages young people to co-design interventions in sync with their norms, interacts through a panel of youthful health workers, and proposes to go to young people's space.

- 28. **South Africa has access to over 81 million doses of vaccines to cover the priority groups.** Sourrently, the GoSA has commitments to purchase 73 million doses from COVAX, Janssen, and Pfizer, and as of May 16, 2022, received over 60.6 million doses including about 7.9 million doses of Pfizer vaccine donated by the United States Government and about 1.0 million doses of J&J vaccine donated by J&J for the Sisonke Early Access Program (table 2). They are enough to vaccinate the target groups (46.04 million people, 77.0 percent of the total population), with two doses of Pfizer vaccine or one dose of J&J vaccine.
- 29. **The GoSA has entered into indemnification arrangements with manufacturers**. The GoSA has established the necessary indemnification frameworks per manufacturer agreements prior to the acquisition. Box 3 below highlights measures the GoSA is providing as part of the COVID-19 vaccination program.

⁸⁰ NDoH. 2022. South Africa COVID-19 and Vaccine Social Listening Reports. https://sacoronavirus.co.za/category/academic-articles/

⁸¹ Cooper, S., van Rooyen, H and Wiysonge, C. S. 2021. COVID-19 vaccine hesitancy in South Africa: how can we maximize uptake of COVID-19 vaccines? Expert Review of Vaccines. 20:8, 921-933, DOI: 10.1080/14760584.2021.1949291.

⁸² Southern Africa Labour and Development Research Unit, University of Cape Town. 2021 & 2022. COVID-19 Vaccine Survey: Survey 1 and Survey 2 Key Findings: Policy Briefs. https://www.opensaldru.uct.ac.za/

⁸³ Kollamparambil, U., Oyenubi, A. and Nwosu, C. 2021. COVID19 vaccine intentions in South Africa: health communication strategy to address vaccine hesitancy. *BMC Public Health* 21, 2113 https://doi.org/10.1186/s12889-021-12196-4

⁸⁴ The voucher for Shoprite, Checkers or Usaves stores (ZAR 200) is for people 50 year or older who come for their first time.

⁸⁵ Based on the current guidelines of two doses of Pfizer vaccine and one dose of J&J vaccine, except for the immune-compromised. On December 10, 2021, the NDoH announced their plan to offer a third dose of Pfizer vaccine to people who have had two Pfizer vaccinations from early 2022. https://businesstech.co.za/news/government/545754/when-you-can-get-your-third-covid-19-booster-shot-in-south-africa/

Box 3: Liability and Indemnification Issues in Vaccine Acquisition

- The rapid development of vaccines increases manufacturers' potential liability for AEFIs.
- Manufacturers want to protect themselves from this risk by including immunity from suit and liability clauses, indemnification provisions, and other limitation of liability clauses in their supply contracts.
- Contractual provisions and domestic legal frameworks can all operate to allocate that risk among market participants, but no mechanism will eliminate this risk entirely.

For vaccines purchased/donated through COVAX:

- In providing vaccines through COVAX, COVAX requested South Africa to have in place an indemnity agreement directly with manufacturers, and the necessary indemnity and liability frameworks for that purpose prior to bilateral arrangements with manufacturers.
- South Africa considered what it will take to implement these indemnification provisions (including statutory implementation).

For vaccines purchased outside of COVAX:

- South Africa entered direct indemnification arrangements with manufacturers.
- South Africa does not have legislation in place to provide statutory immunity for manufacturers.
- South Africa has a national no fault compensation scheme.
- Adoption of any such indemnification provisions or compensation scheme would have to be in accordance with South Africa's own national strategy and framework.

Possible World Bank support to South Africa, depending on needs, may include:

- Information sharing on: (a) statutory frameworks in Organization for Economic Cooperation and Development (OECD) countries and other developing countries; and (b) overall experience in other countries.
- Providing training and workshops for government officials to familiarize them with the issues. For World Bank-financed contracts, World Bank can provide Hands on Expanded Implementation Support.

Table 2: National Vaccine Coverage and Acquisition Plan

[Based on the available estimates as of May 16, 2022]

Source of financing	Population targeted ^a		Vaccines		Number of dose	Estimated	World		Vaccines arrived in the country	
	%	Number (million)	Source	Name	purchased/ donated (million)	Estimated total US\$ (million)	Bank's VAC Status	Current Status	Name	Doses (millions)
Phases 1-4: Frontline H	ICWs, esser	tial worker	s, persons in o	ongregate se	ttings, persons	>60 years, pe	rsons >18 yea	rs with co-mo	rbidities, Othe	r persons >18
years, and adolescent	12-17 years									
Donation from J&J for Sisonke program		77.0 46.04	1&1	1&1	0.95	0	Approved	Delivered	1&1	0.50 (Sisonke) 0.45 (Sisonke2)
Donation from United States Government	77.0		COVAX	Pfizer	7.88	0	Approved	Delivered	Pfizer	7.88
			Pfizer	Pfizer	56.00	571.53	Approved	Delivered	Pfizer	
Government (IBRD if approved) and medical			181	1&1			Approved	Delivered	1&1	51.39
aid schemes b			COVAX	Pfizer			Approved	Delivered	Pfizer	
alu scrienies			COVAX	TBD ^c			Approved	Pending	TBD	
Government/TBD			1%1	1%1	17.00	148.88	Approved	Signed, being delivered	1%1	0.38
			COVAX	TBD			Approved	Pending	TBD	
NATIONAL TOTAL	77.0	46.04			81.83	720.41				60.61

Note: ^a Percentage of population based on mid-year 2020 population estimates (59,797,539) from StatsSA used in EVDS. ^b The Government (with support from the IBRD) will cover the uninsured (84 percent of the population) and medical aid schemes will cover the insured (16 percent of the population). ^cTBD: To be determined.

30. The COVID-19 Vaccination Strategy prioritizes 77.0 percent of the total population in a phased manner, based on the WHO SAGE Values Framework (table 3). The vaccination roll-out started with vaccination of public and private sector health workers under the Sisonke Program on February 17, 2021, followed by people aged 60 years and above and essential sector workers (e.g., education, police, social development, correctional facilities, customs, media and others) on May 17, 2021. Vaccination was sequentially opened up to age cohorts as follows: people aged 50-59 years on July 1, 2021, those aged 35-49 years on August 1, 2021, and those aged 18-34 years on August 20, 2021. The updated strategy expanded the priority group to cover adolescents aged 12-17 years on October 20, 2021. The GoSA updated the vaccine roll-out strategy criteria recently: (a) two doses of Pfizer vaccine were recommended for adolescents, instead of one dose; (b) a booster was introduced for adults 18 years or older: (i) J&J booster vaccinations to anyone who received their primary dose at least 60 days prior or their first booster dose at least 90 days prior, and (ii) Pfizer booster vaccinations to anyone who receive their last doses at least 90 days since the second dose; and (c) administration of heterologous booster doses is introduced. ^{86, 87, 88} The GoSA may further expand the eligible population to children younger than 12 years like other countries. Currently, the GoSA targets to reach 70 percent of adults aged 18 years and older and 50 percent of adolescents aged 12-17 years.

Number of people **Phase Population group** % of population (million) **First** Frontline HCWs 1.25 2.1 % Second Essential workers, person in congregate settings, persons>60 16.60 27.8 % years, persons>18 years with co-morbidities Third Other persons >18 years 21.95 36.7 % **Fourth** Persons 12-17 years 10.4 % 6.24 **Total** 46.04 77.0 %

Table 3: Priority Groups for Vaccination in South Africa

Source: NDoH. 2021. COVID-19 Vaccination Rollout Strategy (January 3, 2021); Circular on changes to vaccine roll-out eligibility criteria and vaccination schedules (October 15, 2021)

Update on COVID-19 Vaccination Status

31. South Africa started its national COVID-19 vaccination program in February 2021 under the Sisonke ("Together") program which provided early access to vaccines to HCWs, while licensing for the J&J vaccine was underway in the United States, Europe and South Africa. The Sisonke program is a collaboration between the NDoH, Janssen, J&J, the South African Medical Research Council, the Desmond Tutu Health Foundation and Centre for the AIDS Programme of Research in South Africa. It is linked to the EVDS and provides data on real-world effectiveness of the vaccine among HCWs. The study monitors, tracks and assesses the occurrence of hospitalizations, the incidence of severe infections, the diversity of breakthrough infections and evaluates vaccine uptake among HCWs. On February 17, 2021, the first doses of vaccines were administered to HCWs⁸⁹ and on November 9, 2021, the NDoH rolled out Sisonke 2 which offers a booster dose of J&J vaccine to the HCWs who received the first dose of J&J

⁸⁶ South African Government. 2021. Health on implementation of COVID-19 vaccine booster doses. https://www.gov.za/speeches/health-implementation-covid-19-vaccine-booster-doses-23-dec-2021-0000

NDoH. 2022. Changes to dosing intervals and introduction of heterologous booster doses. https://sacoronavirus.co.za/2022/02/21/national-vaccination-programme-circular-2-of-2022-changes-to-dosing-intervals-and-introduction-of-heterologous-booster-doses/
 NDoH. 2022. Introduction of second booster dose after vaccination with COVID-19 Vaccine Janssen®. https://sacoronavirus.co.za/2022/

^{03/11/}national-vaccination-programme-circular-4-of-2022/

vaccine as part of the Sisonke program. 90 As of May 16, 2022, 500,523 HCWs have been vaccinated with at least one dose of J&J vaccine under the Sisonke program and 240,925 HCWs have received a booster under Sisonke 2.91

As of May 16, 2022, about 35.5 million vaccine doses have been administered in South Africa. ⁹² This represents about 58.6 percent of the vaccine doses received in country. Despite a relatively slow start, vaccination steadily increased from June 2021 and reached more than 200,0000 doses per day (7 day rolling average) at the end of August 2021, with the highest number of vaccinations reaching to 290,000 per day. However, COVID-19 vaccine demand has gradually slowed down to less than 100,000 per day since mid-December 2021 (figure 2). As of May 16, 2022, about 19.8 million adults aged 18 years or older (49.7 percent of the adult population) have been vaccinated including about 18.0 million adults fully vaccinated (45.2 percent of the adult population). ⁹³ The total number of adolescents vaccinated with at least one dose of vaccine is about 1.7 million (27.8 percent of adolescents aged 12-17 years) and about 581,000 adolescents (9.3 percent of adolescents aged 12-17 years) have been fully vaccinated. In total, about 36.0 percent of total population has been vaccinated (31.0 percent fully vaccinated).

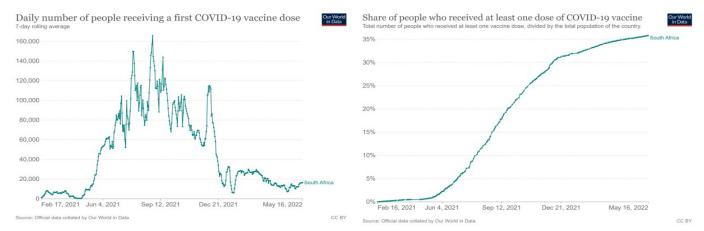


Figure 2. Vaccination Status (as of May 16, 2022)

Source: Our World in Data.2022. https://ourworldindata.org/

33. Vaccination status varies by multiple factors (figure 3). ⁹⁴ There is a substantial gender gap in the vaccination rate among individuals younger than 50 years old: females younger than 50 years old consistently have a higher rate of COVID-19 vaccination compared with their male counterparts. For example, as of May 16, 2022, about 31.9 percent of males aged 18-34 years have been vaccinated, compared with 41.6 percent of females in the same age. The vaccination coverage is as high as 95.0 percent among males aged 60 years or older in Limpopo and as low as 23.8 percent among males aged 18-34 years in KwaZulu-Natal (annex 2). While a little over a third of adults are 'fully' vaccinated in KwaZulu-Natal, more than half of adults are vaccinated in Free State, Western Cape, and Limpopo. The coverage of vaccination among adolescent varies widely from 19.4 percent in KwaZulu-Natal to 50.6

⁹⁰ NDoH. 2021. Sisonke booster study for health workers. https://sacoronavirus.co.za/2021/11/08/press-release-sisonke-booster-study-for-health-workers-starting-at-selected-vaccination-sites-from-tomorrow-9-november-2021/

⁹¹ NDoH. 2022. Latest Vaccine Statistics. https://sacoronavirus.co.za/latest-vaccine-statistics/

⁹² NDoH. 2022. Latest Vaccine Statistics. https://sacoronavirus.co.za/latest-vaccine-statistics/

⁹³ Full vaccination here refers 2 doses of Pfizer vaccine and 1 dose of J&J vaccine.

⁹⁴ NDoH. 2022. Latest Vaccine Statistics. https://sacoronavirus.co.za/latest-vaccine-statistics/

percent in Free State. The vaccination rate is also lower among people without medical aid (i.e., uninsured) compared with the those with medical aid.⁹⁵

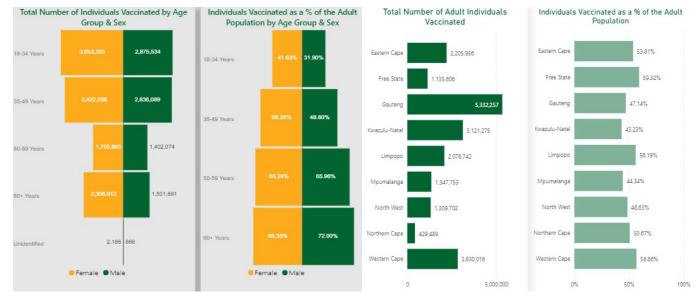


Figure 3: Vaccination Status among Adults by Age, Sex, and Province (as of May 16, 2022)

Source: NDoH. Latest Vaccine Statistics (https://sacoronavirus.co.za/latest-vaccine-statistics/)

34. While the GoSA has been implementing unprecedented level of political and social mobilization activities in every district to increase the uptake, demand is still elastic and mitigation measures such as Vooma weekend are not fully optimized due to human resource constraints with only half of the sites opening over the weekend. 96 In order to accelerate demand among the lagging groups and areas, the GoSA has been analyzing data to identify enablers and barriers to vaccination, engaging sub-national leaderships, intensifying public communication, and implementing location specific strategies. However, vaccination uptake has been slow, due possibly to sub-optimal accessibility (e.g., problems getting to the sites, cost of getting to vaccination sites, no time, low awareness of vaccination schedule), in addition to vaccine hesitancy (e.g., due to concerns over vaccines' effectiveness, safety, and side effects, low perceived susceptibility and severity to COVID-19, and an aggressive anti-vax movement). 97, 98, 99

C. Relevance to Higher Level Objectives

35. The proposed project is aligned with WBG's strategic priorities, particularly its mission to end extreme poverty and boost shared prosperity. By supporting the country's vaccination program against COVID-19, the proposed project will help the country better cope with the pandemic and reduce unemployment, poverty and

⁹⁵ NDoH. 2021. Evaluation Report Vooma Weekend (1-3 Oct). https://sacoronavirus.b-cdn.net/wp-content/uploads/2021/10/Vooma-Weekend-Evaluation-8-Oct-2021.pdf

⁹⁶ NDoH. 2021. Vaccine Roll-out Update: Health Partners Forum. (October 27, 2021)

⁹⁷ Southern Africa Labour and Development Research Unit, University of Cape Town. 2021 & 2022. COVID-19 Vaccine Survey: Survey 1 and Survey 2 Key Findings: Policy Briefs. https://www.opensaldru.uct.ac.za/

 ⁹⁸ AskAfrika. 2021. COVID-19 Tracker. A Gender Report on South Africa. South Africa Adjusted Level 3 Lockdown Week 1, 2021 Results
 February 3-11, 2021). https://www.askafrika.co.za/wp-content/uploads/2021/05/Ask-Afrika-COVID-19-Omnibus-Week-1-2021-GENDER.pdf
 99 Gibbs A. 2021. Men are slower to get COVID-19 vaccines in South Africa: lessons from HIV research. September 2, 2021. https://theconversation.com/men-are-slower-to-get-covid-19-vaccines-in-south-africa-lessons-from-hiv-research-166800

inequity. Also, it will help to improve health and education outcomes and thus have a positive impact on human capital for sustained economic growth. The economic rationale for investing in the COVID-19 vaccination program is strong, given that success can reduce the economic burden suffered both by individuals and countries. The proposed project complements both the GoSA and development partner investments in health systems strengthening, disease control and surveillance, attention to changing individual and institutional behavior, and/or citizen engagement.

- 36. The WBG remains committed to providing a fast and flexible response to the COVID-19 epidemic, utilizing all WBG operational and policy instruments and working in close partnership with government and other agencies. Grounded in One-Health, which provides for an integrated approach across sectors and disciplines, the proposed WBG response to COVID-19 will include emergency financing, policy advice, and technical assistance, building on existing instruments to support IDA/IBRD-eligible countries in addressing the health sector and broader development impacts of COVID-19. The WBG COVID-19 response will be anchored in the WHO's COVID-19 global SPRP outlining the public health measures for all countries to prepare for and respond to COVID-19 and sustain their efforts to prevent future outbreaks of emerging infectious diseases.
- 37. The proposed project contributes directly to the development objective of the WBG SPRP to prevent, detect and respond to the threat posed by the COVID-19 and strengthen national systems for public health preparedness. It will focus on acquisition of COVID-19 vaccines to support South Africa's objective to access vaccines under the right conditions of value-for-money, regulatory approvals, and delivery time among other key features. This is occurring in a rapidly evolving context where COVID-19 variants have emerged, new vaccines are coming on the market, and there is growing vaccine and vaccine brand hesitancy among the general population and HCWs.
- 38. The proposed project aligns with the World Bank's emergency support to COVID-19 in South Africa, and South Africa's Country Partnership Framework (CPF) of the WBG for FY22-26 (Report No. 154318-ZA discussed by the Board of Executive Directors on July 22, 2021). 100 Drawing on the 2018 Systematic Country Diagnostic, An Incomplete Transition: Overcoming the Legacy of Exclusion in South Africa, 101 and aligning with the South African Economic Reconstruction and Recover Plan 102 and the WBG COVID-19 Crisis Response Approach paper, 103 the FY22-FY26 CPF is designed to help South Africa move towards a new socio-economic transformation model for more sustainable growth and shared prosperity, while responding to the impact of COVID-19 in the short run. Specifically, the proposed project will contribute to the CPF's Focus Area 2: Strengthen micro-, small-, and medium-enterprises performance and skills development to support job creation by enabling the country to strengthen employment services and expanding access to skills training programs, both of which cannot be achieved without controlling the ongoing pandemic. Also, the proposed project will contribute to Cross-Cutting Theme 2. Gender - empowering women and girls for shared prosperity by protecting the frontline HCWs, the majority of whom are female. Overall, the COVID-19 vaccination program will be critical in putting the country back on a growth path and reducing unemployment, poverty, and inequity.

¹⁰⁰ WBG. 2021. Country Partnership Framework for the Republic of South Africa for the Period of FY22-FY26 (Report No. 154318-ZA)

¹⁰¹ WBG. 2018. An Incomplete Transition: Overcoming the Legacy of Exclusion in South Africa. (Report No. 125838-ZA)

 $^{^{\}rm 102}$ GoSA. 2020. The South African Economic Reconstruction and Recover Plan.

¹⁰³ WBG. 2020. Saving Lives, Scaling-up Impact and Getting Back on Track World Bank Group COVID-19 Crisis Response Approach Paper

III. PROJECT DESCRIPTION

A. Development Objectives

39. The project objective is aligned with the results chain of the COVID-19 SPRP.

Project Development Objective (PDO) statement:

The project development objective is to increase COVID-19 vaccination coverage among the population of South Africa.

PDO indicators are 104:

- Percentage of population aged 18 years or older fully vaccinated ¹⁰⁵ by sex
- Percentage of population aged 12 to 17 years fully vaccinated, by sex
- Ratio of fully vaccinated female to male population aged 18 to 34 years
- Percentage of population aged 60 years and older vaccinated with at least one booster
- Number of provinces with at least 70 percent of population aged 60 years and older fully vaccinated

B. Project Components

- Component 1. Emergency COVID-19 Response (US\$480.0 million equivalent) aims to support the GoSA to 40. procure 47 million COVID-19 vaccine doses to reach the target population and thus reduce the spread of COVID-19 and deaths. Specifically, the proposed project will finance vaccine procurement, while the GoSA, with support from other partners, will finance deployment of the vaccines including RCCE. Since the GoSA has signed contracts with COVAX, Janssen and Pfizer between December 2020 and June 2021 (table 2) to procure vaccines and some are already deployed, retroactive financing will be made available under the proposed project covering up to 100 percent of the IBRD loan allocation for expenditure incurred before the signing of the legal agreement. Raising the retroactive financing ceiling up to 100 percent will give the GoSA flexibility to pay for the procurement of eligible vaccines before the loanbecomes effective and will allow the government to continue financing priority COVID-19 response activities and the deployment of the COVID-19 vaccines procured by the project. The vaccines procured and to be funded through retroactive financing meet the World Bank's VAC. The World Bank's Operational Procurement Review Committee (OPRC) has reviewed and cleared all three purchase agreements with Janssen, Pfizer, and COVAX, subject to manufacturers/suppliers' submission of the Letter of Acceptance of the Anti-Corruption Guidelines (ACGs) and Sanctions Framework and the GoSA's publication of the contract award notice. The suppliers have accepted the ACG provisions, and the contracts are modified to that effect. The GoSA is in the process of publishing the contract award notice. An exception to increase the retroactive financing limit indicated under Section III paragraph 16 of the World Bank Directive: Investment Project Financing on Retroactive Financing up to 100 percent was approved by the World Bank Management on February 22, 2022. An exception to extend the maximum retroactive financing period up from 12 months to 18 months from the expected date of the signing of the legal agreements for World Bank financing was also approved by the World Bank Management on March 7, 2022.
- 41. Given the recent emergence of COVID-19 and its variants, there is limited data available on the duration of immunity that vaccines will provide. While some evidence suggests that an enduring response will occur, this

¹⁰⁴ Given that the proposed project is retroactively financing vaccines, data are collected using the following dates: baseline from May 16, 2021 and end target from March 29, 2024.

¹⁰⁵ Two doses of Pfizer vaccine or one dose of J&J vaccine

will not be known with certainty until clinical trials follow participants for several years. As such, the proposed project will allow for re-vaccination efforts (e.g., additional dose or booster) as warranted by peer-reviewed scientific knowledge as it becomes available, taking into consideration constraints on vaccine production capacity and equity (i.e., tradeoffs between broader population coverage and re-vaccination). As of November 9, 2021, the GoSA has begun administering a booster dose of J&J vaccine among the Sisonke program participants. On December 23, 2021, the GoSA also announced that individuals older than 18 years of age who have received one dose of the J&J vaccine are eligible to receive a booster dose after an interval of 60 days and individuals older than 18 years of age who have received two doses of the Pfizer vaccine are eligible to receive a booster dose after an interval of 90 days. As of March 11, 2022, individuals who have received one booster dose following primary vaccination with the J&J vaccine are allowed to receive a second booster dose 90 days after the first booster dose. Booster doses may be homologous or heterologous.

- 42. The GoSA, with support from other partners, has already established institutional and implementation arrangements for the safe and effective deployment of vaccines and have administered approximately 35.5 million doses of vaccines as of May 16, 2022, accounting for about 58.6 percent of available vaccines in country. The GoSA has also made efforts to strengthen the immunization and service delivery capacity to successfully deliver COVID-19 vaccines at scale. To this end, the GoSA has worked to overcome bottlenecks building on existing vaccine logistics capacity and prioritizing RCCE to address vaccine hesitancy (table 1). For example, as the vaccination coverage is lower than expected especially among people aged 18 to 34 years, the GoSA has recently prepared a targeted risk communication strategy and launched interventions to engage them more strategically and improve the vaccination rate among them. The GoSA will continuously review and adjust the vaccine rollout strategy and program to improve its effectiveness, efficiency, and equity.
- 43. The GoSA will finance activities that will strengthen public structures for the coordination and management of the proposed project as part of the national COVID-19 vaccination program, including national and provincial arrangements for coordination of activities, financial management (FM), procurement, and environmental and social (E&S) risk management. The GoSA will also finance activities that will improve the country E&S system and practices agreed with the World Bank and set out in the project Environmental and Social Commitment Plan (ESCP). Existing coordination structures operating within the NDoH for the national vaccination program will be responsible for coordination of project activities, as well as fiduciary tasks of procurement and FM. The relevant structures will be strengthened by the appointment and/or recruitment of additional staff/consultants responsible for overall administration, procurement, and FM under the project if/when needed. The NDoH will also support M&E of overall vaccination and related surveillance (e.g., AEFI) program, as well as project reporting as part of the national program.

C. Project Beneficiaries

44. **The expected project beneficiaries are the population at large** given the nature of the disease, particularly at-risk populations such as the elderly and people with chronic conditions, medical and emergency personnel, medical and testing facilities, and public health agencies engaged in the response. The direct beneficiaries are eligible population of the national COVID-19 vaccination program (i.e., people 12 years or older). About 77.0 percent of the total population are eligible to receive vaccines (table 3) and currently, the NDoH aims to vaccinate 70 percent of adults and 50 percent of adolescents with the project and other vaccines (see Section VIII. Results Framework).

D. Project Cost and Financing

45. **The overall project cost will be US\$480.0 million.** The Project will finance vaccine purchase, while the GoSA will finance deployment as well as project management and M&E (table 4). Table 5 provide a summary of vaccine sourcing and World Bank financing.

Table 4: Project Cost and Financing

Project Components	Project Cost (US\$ million)	IBRD (US\$ million)		
Component 1: Emergency COVID-19 Response	480.0	480.0		
Total Costs	480.0	480.0		

Table 5: Summary of COVID-19 Vaccine Sourcing and World Bank Financing

National plan	Source of vaccine financing and population coverage ^a					Specific vaccines	No. of doses		
target (% population)	COVAX Grant	Through COVAX	d Bank-fina Through AVAT	Through direct purchase	Other ^b	and sourcing plans	purchased with World Bankfinance	with World World Bank financin	Estimated allocation of World Bank financing ^c
Phases 1-4: 77.0%		4.2%		49.2%	23.6%	J&J, Pfizer	47 million	Purchase: U\$\$480.0 million Deployment and other (e.g., M&E): U\$\$0	

Note: ^a Population coverage for primary doses (i.e., 2 Pfizer and 1 J&J). ^b Other includes coverage financed by the government, medical aid schemes and donations. Vaccines procured under the proposed project will also be used for booster. ^c Deployment and others including M&E as well as fiduciary and E&S risk management will be financed by the GoSA.

IV. IMPLEMENTATION ARRANGEMENTS

A. Institutional and Implementation Arrangements

46. The proposed project will be implemented by the NDoH in line with government mandates. The NDoH will be responsible for procuring vaccines and setting the strategies, plans, and guidelines, while PDoHs will implement the vaccination program in close coordination with NDoH as well as private sector. The proposed project will be implemented by an already existing team for the national COVID-19 vaccination program within the NDoH, headed by Deputy Director General, National Health Insurance. The team includes officials responsible for: vaccine contracting and stock; allocation and logistics management; private sector engagement; provincial planning; vaccination sites; AEFI; no fault compensation scheme; RCCE; reimbursement; data management and analytics, and coordination/oversight teams/committees (e.g., MAC on COVID-19 vaccines, MAC on COVID, MAC on social impact, Joint Strategic Operations Committee, Incident Management Team, etc). The team, supported by the extended NDoH teams, will: (a) plan and coordinate the implementation; (b) monitor and periodically report on progress, including fiduciary and E&S requirements; and (c) liaise with the World Bank and other partners supporting the GoSA. The existing government structure of the national vaccination program, including MAC on COVID-19, COVID-

19 vaccines, and social impact as well as other coordination committees, ¹⁰⁶ will be used to provide strategic guidance and oversight. Once the management of the COVID-19 vaccination program is integrated into the communicable diseases program within the NDoH (expected in FY22/23), the communicable diseases program structure will provide oversight of E&S issues.

- 47. The NDoH will be responsible for the FM and procurement functions. The proposed project will use the GoSA FM system, called Basic Accounting System, for the recording and reporting on the use of funds. The FM systems for the NDoH are established and adequate to account for the funds. The allocated envelope will fully finance three vaccine contracts, including any additional vaccine supply agreement within the scope and budget availability of the project. This lowers fiduciary risk as the contracts undergo the World Bank due diligence review before final approval of the proposed project. This also gives a full assurance that funds will be used for the intended purposes as the funds cannot be diverted for other purposes. Procurement implementation will also be carried out by the NDoH. Procurement and contracts management capacity assessment shows that the NDoH does not have prior experience with World Bank Procurement Regulations for Investment Project Financing (IPF) Borrowers, including processing of retroactive financing. However, given that contracts for these vaccines supply have already been signed and about 70.9 percent of the vaccines already delivered, there is less likelihood of the project being exposed to procurement and market approach risks associated with a new vaccine purchase activity. NDoH's procurement capacity and risk assessment has been carried out virtually using the Procurement Risk Assessment and Management System (PRAMS) Questionnaire to review the NDoH procurement unit's organizational structure and capacity for implementing the project. The assessment reveals that the risk management of the ongoing contracts including logistical distribution arrangements is minimal as the NDoH contracts out the logistics management to private firms. Therefore, the available arrangement for successful delivery of the remaining vaccine contacts is adequate.
- The proposed project will build on the existing government E&S risk management systems. The NDoH has 48. developed guidelines, toolkits and SOPs to mitigate potential E&S risks and impacts. As part of the retroactive financing, the World Bank undertook an E&S review to determine whether the existing COVID-19 vaccination response policies and guidelines meet the requirements of the relevant WHO guidelines, World Bank Environmental and Social Standards (ESSs), WBG General Environmental, Health, and Safety Guidelines (EHSG), and WBG EHSG for Health Care Facilities. The E&S Review focused on accessible and equitable supply of safe and effective vaccines, the method of storage, transportation and handling of vaccines, the management of health care waste generated at vaccination sites including agreements in place with private sector health care waste service providers, the adequacy and efficiency of occupational health and safety (OHS) and IPC measures at vaccination sites, and the communications and outreach activities, including the access to grievance redress mechanism (GRM). The observations and findings from the E&S review are being translated into an Environmental and Social Monitoring and Reporting Framework, which will build on existing government systems, while assuring consistency with the Environmental and Social Framework (ESF) and will include specific performance indicators that will be used to monitor the environmental and social performance of the project. The Environmental and Social Monitoring and Reporting Framework will be prepared by the GoSA who will be responsible for its implementation and performance reporting to the World Bank.

¹⁰⁶ There are several coordination committees (CC) to better coordinate the country's vaccination program such as National/Provincial CC, Private Health Sector CC, etc. Vaccine Acquisition Task Team also coordinate the private sector vaccine financing, procurement, logistics and

administration

B. Results Monitoring and Evaluation Arrangements

- 49. The NDoH team for the national COVID-19 vaccination program in coordination with the M&E unit will be responsible for the project M&E. As the proposed project supports the implementation of the national COVID-19 vaccination program, the proposed indicators to measure the project implementation progress are aligned with the national vaccination program and can be monitored through the existing health management information systems (e.g., EVDS, SVS) and/or NDoH administrative data. The M&E unit with support from the NDoH team will: (a) monitor implementation progress of the national vaccination program including PDO and intermediate results indicators in the results framework; and (b) report results to the national COVID-19 vaccination program team for onward transmission to the National Treasury (NT) and share them with World Bank biannually.
- 50. The NDoH team for the national COVID-19 vaccination program will also prepare/compile and share reports on fiduciary and E&S management biannually. In particular, the team will report on the E&S performance indicators as per the Environmental and Social Monitoring and Reporting Framework. The E&S performance indicators will include reporting on labor management and worker conditions, needle stick injuries, health care waste audit findings and recommendations by the Health and Safety Committee including implementation status of corrective actions and sexual exploitation and abuse/sexual harassment (SEA/SH) related cases specific to the COVID-19 vaccine roll-out among other. In addition, the team will monitor and report on the implementation of the Stakeholder Engagement Plan (SEP), and Grievance Redress Service (GRS) to the national COVID-19 vaccination program through the national contact center and the existing national web-based patient safety incident reporting and complaint, compliment and suggestion management information system, ¹⁰⁷ once the COVID-19 vaccination program is integrated into the routine service delivery. These reports will be submitted to the World Bank on a biannual basis within 45 days of the end of the semester.

C. Sustainability

51. There is strong political commitment in South Africa to mobilize financial resources for COVID-19 response, including for vaccine procurement and deployment. Having the funds through the proposed project for vaccine purchase will establish an enabling environment for other donors, multilateral development banks and United Nations agencies to further support vaccination efforts in the country. Investments under the project are expected to help the GoSA provide fiscal space to strengthen the health system in the country, ensuring institutional sustainability to deal with infectious diseases. Also, according to the Medium-Term Budget Policy Statement 2021, economic recovery and reconstruction through both short-term spending measures and structural reforms along with rebuilding the public finances will lead to a primary fiscal surplus in FY24/25, bringing an end to fiscal consolidation. 108

V. PROJECT APPRAISAL SUMMARY

A. Technical, Economic and Financial Analysis

52. The successful development, production, and delivery of a vaccine has the best potential to reverse the massive health, social, and economic impact of the COVID-19 pandemic and generate benefits that will far exceed vaccine-related costs. A rapid and well-targeted deployment of COVID-19 vaccines can help reduce poverty and

¹⁰⁷ NDoH. 2022. National Guideline to Manage Complaints, Compliments and Suggestions in the Health Sector of South Africa (Version 2)

¹⁰⁸ NT. 2021. Medium Term Budget Policy Statement. http://www.treasury.gov.za/documents/mtbps/2021/mtbps/FullMTBPS.pdf

accelerate economic recovery. Even at levels of imperfect effectiveness, a COVID-19 vaccine that is introduced and deployed effectively to priority populations can assist in significantly reducing severe morbidity and mortality as well as the spread of the coronavirus and accelerating a safe reopening of key sectors that are impacted. It can also reverse human capital losses by ensuring schools are reopened. The effective administration of COVID-19 vaccines will also help avoid the associated health care costs for potentially millions of additional cases of infection and associated health-related impoverishment. Global experience with immunization against diseases shows that by avoiding these and other health costs, vaccines are one of the best buys in public health. For the most vulnerable population groups, especially in countries without effective universal health coverage, the potential health-related costs of millions of additional cases of COVID-19 infection in the absence of a vaccine represent a significant or even catastrophic financial impact and risk of impoverishment. The pandemic is also having direct effects on other non-COVID-19 health outcomes. COVID-19 and its containment measures hinder access to essential care for other health needs of the population, including maternal and child health care services and routine immunization services, potentially leading to new outbreaks of preventable diseases, with their own related deaths, illnesses, and longterm costs. Simultaneous epidemics are overwhelming public health systems in different countries, and services needed to address the needs of people with chronic health conditions, and mental and substance use disorders have also been disrupted.

- COVID-19 vaccines have been considered as a global public good, ¹⁰⁹ and global public goods must be non-rivalrous and non-excludable. Public goods are those goods and services that allow humans to live with dignity and which the entire population should enjoy in equal quantity and quality. ¹¹⁰ The fact that everyone benefits from COVID-19 vaccination whether or not they contributed to the vaccination effort provides a justification to make vaccines available through the public sector. In addition, COVID-19 vaccine deployment is the largest mass vaccination effort in the history of humankind and as such, it requires a level of coordination and involvement of the healthcare delivery system that calls for a publicly provided approach to deployment of COVID-19 vaccines. It is critical that the government sets the guiding policy, and directives and provide financing for rapid implementation of the vaccination program. Public provision of the vaccine can ensure equitable and based on public health criteria distribution and access to COVID-19 vaccines for all who are recommended for vaccination. Nonetheless, as COVID-19 vaccination is an investment with extremely high health and economic returns due to averted lives and productivity and the reopening of economic activity, this itself is a justifiable public investment. Consequently, financing COVID-19 vaccination is a government-wide responsibility, and governments and their development partners need to explore how best it should be financed.
- Although there are still gaps in knowledge of the scope and features of the COVID-19 pandemic, it is apparent that one main set of economic effects will derive from increased sickness and death among humans and the impact this will have on the potential output of the global economy. In the Spanish Influenza pandemic (1918-19), 50 million people died about 2.5 percent of the then global population of 1.8 billion. The most direct impact would be through that of increased illness and mortality on the size and productivity of the world labor force. The loss of productivity as a result of illness which, even in normal influenza episodes, is estimated to be ten times as large as all other costs combined will be quite significant.
- 55. Another significant set of economic impact will result from the uncoordinated efforts of private individuals to avoid becoming infected or to survive the results of infection. The severe acute respiratory syndrome (SARS) outbreak of 2003 provides a good example. The number of deaths due to SARS was estimated at "only" 800

¹⁰⁹ Gavi. Are Vaccines a Global Public Good? 2020. https://www.gavi.org/vaccineswork/are-vaccines-global-public-good. ¹¹⁰ Ibid.

deaths and it resulted in economic losses of about 0.5 percent of annual GDP for the entire East Asia region, concentrated in the second quarter. The measures that people took resulted in a severe demand shock for services sectors such as tourism, mass transportation, retail sales, and increased business costs due to workplace absenteeism, disruption of production processes and shifts to more costly procedures. Prompt and transparent public information policy can reduce economic losses.

56. The economic rationale for investment in a COVID-19 vaccine is strong, considering the massive and continuing health and economic losses due to the pandemic. As vaccine effectiveness varies by many factors (e.g., type of vaccine, number of doses, time between doses, time since the last does, vaccinees' characteristics such as age, sex, pre-existing health conditions, etc), it is difficult to calculate the economic benefits and cost-effectiveness of vaccination accurately. However, it is clear that an effective COVID-19 vaccination program will have direct benefits in terms of averted costs of treatment and disability, as well as strengthened health systems, especially in the longer-term. According to a 2021 South African study, the economic savings of vaccination are tremendous: vaccinating 40 percent of the population was estimated to decrease approximately 85 percent of deaths and result in approximately 45 percent lower total health care costs. 111 Even when the vaccination cost per person was estimated to be high at US\$75 and the vaccine effectiveness against infection was estimated to be low at 20 percent, the incremental cost-effectiveness ratio was estimated to be less than US\$2,000 per years-of-life saved compared with no vaccination. In South Africa, the estimated costs of vaccinating 70 percent of the population with two doses of COVID-19 vaccine are at approximately US\$1.1 billion. 112 This covers four areas—vaccine package (US\$912 million), supply chain (US\$52 million), climate-friendly cold chain (US\$35 million), and service delivery (US\$121 million). 113, 114 This cost of vaccination will provide substantial returns on investments, which includes broad health, economic, and social benefits beyond avoided morbidity and mortality. Investments in vaccine delivery systems generate health and economic benefits beyond just delivering the COVID-19 vaccines. 115 First, investments in lastmile delivery systems to administer the COVID-19 vaccine to remote communities will require strengthening community health systems, which can have spillover effects to effective delivery of other services, helping close the significant urban-rural gap. Second, as COVID-19 vaccines are introduced and lockdowns and movement restrictions are eased, patients can continue to access care for other conditions. Third, the economic benefits of slowing down the economic downturn are likely to significantly exceed the funds needed to vaccinate 70 percent of the population, leaving aside the immediate health benefits. Given both the economic and health system benefits, effectively deployed COVID-19 vaccines present significant benefits.

¹¹¹ Reddy, K.P., Fitzmaurice, K.P., Scott, J.A. et al. 2021. Clinical outcomes and cost-effectiveness of COVID-19 vaccination in South Africa. Nature Communications. 12, 6238. https://doi.org/10.1038/s41467-021-26557-5

¹¹² Yoo K.J., De Francisco Serpa, N., Gordillo-Tobar A. 2021. Calculating Sub-Saharan Africa's COVID vaccination financing gap. World Bank. Washington DC. https://blogs.worldbank.org/health/calculating-sub-saharan-africas-covid-vaccination-financing-gap.

¹¹³ Vaccine package includes the costs from safety boxes and syringes (devices), UNICEF Supply Division procurement fees, all costs until arrival in country at the airport (freight and transport fees), and wastage costs. The estimated costs do not include buffer stocks. Labor, capital costs.

¹¹⁴ Costing assumptions: Vaccination: two doses of vaccine at \$10.55/dose; supply chain: \$0.71/dose.; service delivery: \$1.65/dose; CC: Additional 20 percent on the unit costs, \$2.36/dose (70 percent of the total population: 41,735,645).

¹¹⁵ Bloom DE, Cadarette D, Ferranna M. 2021. The Societal Value of Vaccination in the Age of COVID-19. American Journal of Public Health. 111(6):1049-1054. doi:10.2105/AJPH.2020.306114

B. Fiduciary

Procurement

- 57. Procurement Arrangement: The proposed project is an IPF emergency response project, and the World Bank's Procurement Regulation, Fourth Edition, November 2020 will apply. The full project financing is to be spent on already procured contracts. There may be no new procurement activity envisaged and therefore no need for comprehensive procurement strategy preparation. Since vaccine supply contracts are direct contracting, comprehensive market research and procurement strategy may not add value even if additional vaccines will be procured and a new contract will be awarded. A simple and short Project Procurement Strategy for Development (PPSD) has been developed with objectives of helping the GoSA plan for successful delivery, deployment, and management of the ongoing vaccines supply contracts. All the vaccine contracts to be financed under the proposed project have already been awarded and are under delivery prior to signing the legal agreement. Contracts were signed over a year ago and would be over 12 months old at the time of signing the legal agreement. However, the World Bank management, considering the emergent nature of the proposed project, has approved the exception to include those contracts signed within 18 months prior to the signing of the legal agreement. The proposed project will also be subject to the Guidelines on Preventing and Combating Fraud and Corruption in Projects Financed by IBRD Loans and IDA Credits and Grants dated October 15, 2006, and revised in January 2011 and July 1, 2016, and World Bank's right to audit. To this effect, the suppliers are required to sign a letter of acceptance of ACGs and Sanctions Framework, including World Bank's audit and sanction regime. For additional vaccine supply contracts, a procurement plan will be submitted in the Systematic Tracking of Exchanges in Procurement (STEP) in advance and implemented once the procurement plan is agreed.
- Expected procurement risk would be related to delivery and proper deployment of already awarded vaccine contracts. These risks may include: (a) target population's low willingness to receive vaccination against COVID-19; (b) short shelf-life of vaccines and compatibility of vaccines supply with deployment rate; and (c) capacity limitations in managing contract changes and payments to suppliers.
- 59. **Retroactive Financing.** Retroactive financing will apply to the contracts procured and either fully or partly delivered. Those contracts that are already awarded, but payment is to be made after the signing of the loan agreement will be treated as advance procurement. Both retroactive financing and advance procurement contracts are required to be processed consistent with Sections I, II and III of the World Bank's Procurement Regulations and meet the provisions of the project loan agreement. The GoSA has already shared the copies of vaccine purchase agreements with the World Bank and the World Bank has conducted a review (OPRC level) and cleared the contracts with the conditions that the suppliers sign a letter of acceptance of World Bank's ACG and Sanctions Framework and World Bank's right to audit. The suppliers have accepted the ACG provisions and the contracts are modified to that effect. The signed vaccine purchase agreements include a non-disclosure agreement clause. Therefore, the GoSA has communicated with the relevant vaccine suppliers, so that the suppliers agree to the disclosure of contract award information as this is a requirement by the World Bank's policy.
- 60. **Publication of Contract Award Notice.** The World Bank's Procurement Regulations require that certain information for World Bank-financed contracts be made public both by the borrower and by the World Bank. This includes the name of the successful bidder/proposer/consultant, the final total contract price, the contract duration, and a summary of the contract scope, among other details. The details of information for publication will also depend on the bilateral agreement between the parties to the contract. The project will use the STEP to record the activities and publish the contract award notices.

- 61. **Procurement Risk**. The proposed project is financing already procured vaccine supply contracts. In case additional supply contract is to be awarded and signed, it would be direct contract and follow the same procedures that the NDoH had followed during procuring the ongoing contracts. The risk of management capacity of the ongoing contracts including logistics and distribution arrangements and successful delivery of the remaining vaccines is assessed and rated to be **Moderate**. The NDoH procurement and contract management capacity has been assessed virtually, using PRAMS Questionnaire. The following risks or concerns are identified:
 - The NDoH has no prior experience of working on World Bank financed projects. Therefore, meeting World Bank's standard reporting and ability to effectively use World Bank's STEP may be a challenge.
 - Obtaining suppliers' agreement to disclose contract information may delay the process.
 - Gap of adequate and quality contract delivery monitoring, change or variation management, timely payments and reporting could also be a risk.
- 62. The risk mitigation measures include the followings:
 - The World Bank will provide STEP platform orientation/training to the NDoH team in charge of the vaccine procurement.
 - The GoSA will conduct regular and closer monitoring of delivery of vaccines and share with the World Bank, the contracts delivery status and performance review report.
 - The World Bank team will carry out regular implementation support; and
 - With the objectives of enhancing ongoing contracts implementation management, the NDoH is required to take the following proactive measures: (a) Any contract modifications need to be made in writing and the contract agreement needs to be modified/amended to that effect. This is a good practice in public contracts administration and helps to avoid any audit query down the line; and (b) The NDoH has reported that delivery of remaining vaccines is delayed for balancing of vaccine supply and demand. This could be a good strategy due to shelf-life sensitivity of vaccines. The revised delivery dates should be reflected through modifications to the contract agreement.
- 63. **Project Procurement Plan.** All contracts that were procured and to be financed retroactively will be recorded in the procurement plan and captured in STEP. In case of additional or new supply contract needs, the Borrower will prepare a procurement plan and submit it to the World Bank, in STEP, and implement once the procurement plan is agreed.

Financial Management

- 64. The Chief Financial Officer at the NDoH will take the ultimate responsibility for FM of the project. The project is using the GoSA FM system, called Basic Accounting System, for the recording and reporting on the use of funds. The FM systems for the NDoH are established and adequate to account for the funds. The allocated envelope will finance three vaccine contracts. This lowers fiduciary risk as the contracts will undergo the World Bank due diligence review before final approval of the proposed project. This also gives a full assurance that funds will be used for the intended purposes as the funds cannot be diverted for other purposes.
- 65. **Disbursements**: The proposed project will finance three contracts retroactively and the *reimbursement* method will be used for disbursements. The disbursement request will be prepared partly based on a simplified financial (vaccines) report prepared monthly by NDoH for the NT, which was a condition to the Minister of Finance's

approval of additional vaccine allocations in terms of section 6(4)b of Appropriation Act. The report is prepared in accordance with the approval letter, which stipulates that the allocation will be monitored on a monthly basis by NDoH providing the NT with monthly updates on: (a) available supply; (b) expenditure to date, broken down by supplier/contract; and (c) projected delivery schedule for remaining orders including costs thereof. Before any additional vaccines are procured by NDoH, the NT must be consulted. The monthly reports will be consolidated to cover the period of the requested reimbursement. The expenditure will be verified against other financial reports, such as the in-year monitoring report.

- 66. **Financial Reporting**: The NDoH is currently preparing a detailed vaccines report for the NT and the same report will be used for monitoring of the project. The report contains: (a) the requirements of the Minister of Finance's approval letter mentioned above; (b) available supply on hand for NDoH and participating partners in the value chain at the end of the reporting period; (c) stock on hand per supplier and number of days for such stock; (d) total vaccines received to date per supplier; (e) vaccines administered; (f) expenditure to date; and (g) cost recovery/revenue generation. When the report is shared with the NT, it will also be shared with the World Bank for monitoring of the project. The NDoH also submits monthly in-year monitoring reports on expenditure, including detailed expenditure by line item on the COVD-19 response.
- Auditing arrangements: The NDoH prepares detailed annual financial statements per program each year as per the requirements of the Public Finance Management Act and is audited by the Office of the Auditor General. Detailed COVID-19 response expenditures are reported under Vote 18 with a detailed annex. The audited financial statements are detailed and adequate to be relied on for the operation. The audited financial statements will be submitted to the World Bank six months after the financial year end, namely, September 30. The current vaccination report will serve as an added assurance of the proper use of funds.
- 68. **The FM Risk:** The FM is rated Moderate based on: (a) the current detailed reporting and monitoring mechanism in place as per the Appropriation Act; (b) financing of retroactive contracts that will be subjected to the World Bank due diligence review before the project is approved; and (c) financing of committed contracts with minimum risk of funds used for the unintended purposes.

C. Legal Operational Policies

	Triggered?
Projects on International Waterways OP 7.50	No
Projects in Disputed Areas OP 7.60	No

D. Environmental and Social Standards

69. The E&S risk rating for this project has been classified as Substantial. The proposed project is envisaged to have long term positive social impacts as it will enable equitable access to COVID-19 vaccines by retroactively financing COVID-19 vaccines. However, there are also potential E&S risks and impacts if the vaccines and related wastes were not administered and managed correctly. Based on global evidence, the E&S risks for the proposed project are associated with the generation, management, transport, and disposal of infectious and health care waste; transportation, cold chain supply and logistical arrangements for safe vaccine deployment in relation to community health and safety; OHS risks for HCWs; uneven access to vaccine related information and the administering of

vaccines, especially of marginalized/vulnerable groups; vaccine hesitancy; inadequate or conflictual public engagement and consultations; reprisals and retaliation against HCWs and researchers; lack of access to effective GRM; and risks of SEA/SH to project workers and beneficiaries.

- 70. The GoSA is considered a high-capacity client and has developed SOPs and guidelines for managing cold chain logistics, health care waste, accessibility to vaccine facilities, communication and social expectations regarding vaccines among others in line with the requirements of the WHO guidelines at the national level. Further, the South African COVID-19 Vaccine Strategic Plan 2021, the South Africa COVID-19 Vaccine Rollout Communication Strategy 2021, COVID-19 Vaccination Guideline 2021, and the Accelerating Demand for COVID-19 Vaccination Project Plan 2021 (updated in 2022), have been introduced to ensure inclusiveness and equity in access to vaccine related information and the administering of vaccines. Together these plans, strategies and guidelines provide a robust framework for community consultations, communications campaign, social mobilization and information dissemination on COVID-19 vaccine, with a focus on: (a) ensuring that the public receives timely, consistent, and factually correct information on COVID-19 vaccines (availability, safety, timelines) in order to build and maintain trust, and avoid people being influenced by false or inaccurate information, myths, and misconceptions; (b) generating awareness of the phased approach of the vaccine rollout and understanding of the prioritization of target groups; (c) reducing vaccine hesitancy and public resistance towards COVID-19 vaccines; (d) mitigating misconceptions about any AEFIs that may occur; and (e) providing effective channels for the public to receive up-to-date information on active vaccination centers, registration process, latest vaccine statistics, and other related information. The South African COVID-19 Vaccine Implementation Guide and Toolkit 2021, the National Infection Prevention and Control Framework and its Practical Manual for Implementation of the National Infection Prevention and Control Strategic Framework 2020, the Vaccinators Manual 2012, SOPs for vaccine waste, vaccination site readiness and the various procedures developed at provincial and district level, among others, were prepared in line with the WHO guidelines and national legislative requirements and contains robust requirements for managing health care waste, OHS including IPC at health care facilities and vaccination sites. The plans, strategies and SOPs address methods for the correct storage of health care waste generated during vaccination and how it is incorporated in the health care waste streams of the associated health care facilities for treatment and final disposal. Furthermore, the documents address personal protective equipment requirements for HCWs, procedures to address and report needle stick injuries, minimum requirements for vaccination site readiness such as provision of passive cold chain equipment and vaccine temperature monitoring and controls, emergency response requirements such as medial emergency kit in the event of adverse events following immunization and spill kits for accidental vaccine spillage, vaccination site accessibility and structural safety including guidelines for vaccination site layout to ensure social distancing.
- 71. The World Bank completed the E&S review at a national, provincial, and district levels to determine the effectiveness of the systems. The existing systems were assessed against the relevant requirements set out in the ESF, mainly: ESS1. Assessment and Management of Environmental and Social Risks and Impacts; ESS2. Labor and Working Conditions; ESS3. Resource Efficiency and Pollution Prevention and Management; ESS4. Community Health and Safety; ESS7. Indigenous People/Sub-Saharan African Historically Underserved Traditional Local Communities; and ESS10. Stakeholder Engagement and Information Disclosure and the relevant WBG Environmental Health and Safety Guidelines.

72. The E&S review highlighted the following findings:

a. **Equal access and inclusiveness**: Prioritization and phased approach adopted for vaccination is consistent with World Bank's ESF requirements and international practices. The extensive networks of vaccine delivery mechanisms provide for equitable allocation of vaccine. South Africa does not practice forced vaccination, and

vaccines are being administered for free and with consent. Governance structures, including area-based approach allows for access and delivery based on local context, and incentives such as Vooma vouchers and Vooma weekends supportive of addressing time and financial constraints that individuals may experience while traveling to the vaccination centers. Vulnerable groups and other traditional local communities have been sufficiently identified and consulted, and efforts to vaccinate the old aged, people in remote areas, poor, people with disabilities, undocumented persons, and so on are consistent with World Bank's ESS7 requirements and the Directive on Addressing Risks and Impacts on Disadvantaged or Vulnerable Individuals or Groups. However, resource constraints are affecting vaccine delivery in remote areas and the low vaccination coverage among youth needs to be addressed. The recent practice of upfront planning and mapping of vaccination rates across demographic groups and localities needs to be scaled up and continued.

- b. **Health care waste management**: South Africa has a robust legal framework and system in place at all levels for managing risk associated with the anticipated health care waste generated during the deployment of the COVID-19 vaccination program, consistent with ESSs 1, 2, 3 and 4. Some gaps identified in the E&S review include: (i) weak management of health care waste contracts at provincial level, which had led to short term service disruptions; (ii) substandard health care waste storage areas due to facilities not being upgraded to ensure compliance with national and international standards; (iii) lack of training of health care staff on health care waste management practices; (iv) insufficient resources at district and provincial level to monitor compliance; (v) budget constraints for health care waste management; and (vi) inconsistencies across provinces with transportation of vaccine health care waste from outreach sites to health care facilities.
- c. **Labour and working conditions**: The South African labour laws are well developed, and the health sector is well regulated in terms of labor management, working conditions, OHS, and also supportive of the principles of freedom of association and collective bargaining. There are also stringent OHS legislative requirements which apply to the health care facilities and service providers such as the cold chain, distribution and waste service providers. So far, the use of security forces has been primarily in the form of armed escort from the airport to the central warehouse and while distributing vaccines from the warehouse to the vaccination centers, especially in areas where the crime rates are high. Thus, the World Bank's Policy on Use of Security Forces will not apply to this project. However, moving forward, it will be important to ensure that the national regulations in relation to labor management and working conditions continue to be adhered to, while also ensuring that the existing process for reporting worker grievances is strengthened in the context of additional burden and stress to HCWs and that the government's programs on GBV/SEA/SH related matters are widely disseminated.
- d. **Communication and outreach strategy**: Framework for consultations and communications strategy for vaccine roll-out is robust and also aligned with the WHO guidelines and ESS 10 requirements. A few gaps identified in the E&S review include: (i) strategies for communication, consultation, identification and analysis of stakeholder needs and interest are spread across different strategies and guidelines which makes consolidation of information problematic; (ii) capacity in low-performing districts is sub-optimal to improve capacity to carry out communication strategies effectively; and (iii) budget for communication strategies is limited.
- 73. Based on the findings of the E&S Review, the NDoH will prepare an Environmental and Social Monitoring and Reporting Framework within 90 days of the loan's effectiveness date. The Environmental and Social Monitoring and Reporting Framework will build on the existing NDoH systems in place and will include measurable performance indicators against which the E&S performance of the project will be measured. Performance indicators will include, among others, reporting on labor management and worker conditions, needle stick injuries, health care waste audit findings and recommendations by the Occupational Health and Safety Committee and status of implementation of

corrective actions, and SEA/SH related cases specific to the COVID-19 vaccine roll-out etc. The GoSA will be required to report on the performance indicators as part of the E&S monitoring report submitted on a biannual basis. A SEP and ESCP have been prepared for the project and were disclosed in-country and by the World Bank, prior to appraisal, on May 3, 2022.

Gender

74. The project aims to address a critical gender gap in the vaccination rate especially among men aged 18-34 years. As of May 16, 2022, the vaccination rate among the males in this age group is 31.9 percent compared with 41.6 percent for female in the same age group. ¹¹⁶ The low vaccination rate is reportedly due to lower trust in the safety of the vaccines, lower awareness levels about the vaccination schedules, lower perceived susceptibility and severity, in addition to sub-optimal accessibility of vaccination sites (e.g., no time, problems getting to the sites, cost of getting to vaccination sites, etc). 117, 118, 119 Possible reasons for men's limited access to health services including COVID-19 vaccination may stem from ideas about masculinity (e.g., expectation of not showing vulnerability), ideas about the health system as a place for women (e.g., women aged 18-49 years visit health facilities more often for reproductive, maternal and child health services), and perceived ability to avoid the risk of infection (e.g., the number of COVID-19 confirmed cases is lower among men). 120 In order to address the lower vaccination rates among individuals younger than 50 years, especially among those aged between 18 and 34 years, the NDoH recently launched a new communication strategy to substantially increase demand for vaccination among young people by putting young people at the center of communication, employing open, two-way, and non-didactic communication, engaging young people to co-design interventions in sync with their norms, interacting through a panel of youthful health workers, and proposing to offer services near them. As part of the youth communication strategy, the GoSA plans to scale up outreach services to youth venues such as university residences and recreational venues and provide rewards (e.g., free data) for vaccination and vaccination advocates who get others to be vaccinated. In addition, the GoSA plans to provide targeted interventions to improve the vaccination rate of young males. For example, Eastern Cape PDoH plans to organize district boys seminars and traditional tribal council imbizos (meeting) encouraging them to get vaccination. Likewise, NDoH in collaboration with Isibaya Samadoda (the circle of men) intends to add a topic on vaccination. Cumulatively, these actions will help males aged 18-34 utilize vaccination services better throughout the country. To track progress toward closing the gender gap in the vaccination rate among males and females aged 18 to 34 years, the project has a PDO indicator on "ratio of fully vaccinated female to male population aged 18 to 34 years" with the baseline of 2.62 and the end target of 1.15.

Climate

75. The proposed project has been screened for long- and short-term climate and disaster risks and risks to the project activities were found to be high while risks to project outcomes were moderate based on the climate policy context. South Africa is at high risk for climate shocks, primarily drought, wildfires, high winds, coastal storm surges, and both coastal and river floods. The country is highly vulnerable to climate change, which are anticipated to increase both the frequency and intensity of these climate shocks. Further, mean annual temperatures have

¹¹⁶ NDoH. 2022. Latest Vaccine Statistics. https://sacoronavirus.co.za/latest-vaccine-statistics/

¹¹⁷ Southern Africa Labour and Development Research Unit, University of Cape Town. 2021 & 2022. COVID-19 Vaccine Survey: Survey 1 and Survey 2 Key Findings: Policy Briefs. https://www.opensaldru.uct.ac.za/

¹¹⁸ AskAfrika. 2021. COVID-19 Tracker. A Gender Report on South Africa. South Africa Adjusted Level 3 Lockdown Week 1, 2021 Results February 3-11, 2021). https://www.askafrika.co.za/wp-content/uploads/2021/05/Ask-Afrika-COVID-19-Omnibus-Week-1-2021-GENDER.pdf ¹¹⁹ Gibbs A. 2021. Men are slower to get COVID-19 vaccines in South Africa: lessons from HIV research. September 2, 2021. https://theconversation.com/men-are-slower-to-get-covid-19-vaccines-in-south-africa-lessons-from-hiv-research-166800 lbid.

increased by 1.5 degrees since the 1960s and since the 1990s South Africa's temperature has increased at more than twice the global rate. The country has put into place proactive climate change policies, including a National Climate Change Adaptation Strategy (2018), a National Climate Change Response Policy (2004), and a National Climate Change Response White Paper (2017), which include climate adaptation measures for the health sector. This policy framework is anticipated to support adaptation to climate shocks that may impact distribution of vaccines financed by the proposed project.

Citizen Engagement

76. Mechanisms to engage citizens, and target beneficiaries more specifically, in providing ideas and feedback on program delivery are helpful in identifying gaps at the point of service delivery (information availability, access to testing and vaccination, access to relevant care, equal treatment etc.), build community knowledge and confidence, establish trust, ensure governments respond to community needs (including vulnerable groups), and thus optimize the impact of the COVID-19 emergency response. The GoSA and partners have been implementing various RCCE activities to generate demand and increase the vaccination rate. For additional information on the RCCE activities please refer to paragraph 27. Furthermore, in order to ensure timely response to all vaccination related questions, the project is leveraging the contact center linked to the national vaccination program. The contact center is an integral component of communication between the people in the country and all stakeholders responsible for the national vaccination program. The contact center operating in multiple languages through various platforms (phone, emails, instant messaging, webchat, etc) has been enhancing the stakeholder experience by providing a wide range of information in support of the national vaccination program, from vaccination registration to health queries about COVID-19 and vaccination, and post vaccination services. The contact center operates four tiers of services to address various queries in a stipulated timeframe as per the service level agreement: Tier 1 responds to general vaccination and COVID related queries (e.g., registration, appointment, certificate, COVID preventive measures) and Tier 2 responds to queries that require further investigation or need to contact external stakeholders to verify or capture information (e.g., change of personal details in EVDS, service delivery challenges, etc). Health related queries (e.g., provision of COVID-19 test results, COVID-19 queries related to an individual's specific health conditions, potential side effects, concerns about pre-existing medical conditions) and post vaccination services (e.g., post-vaccination events reporting, management of clinical emergency) are addressed by health professionals from the National Health Laboratory Service in Tier 3 and Tier 4, respectively. Accordingly, the contact center generates a vast amount of data including call reasons. This information is then used for ongoing planning and continuous improvement of its operation and user experience. Also, ad hoc analysis of data has been carried out to improve the quality of national vaccination programs as well. The project will continuously use the contact center to monitor citizens' feedback and improve accountability. Progress in improving citizen engagement will be measured through the indicator "Percentage of contacts responded to within the stipulated timeline as per the service level agreements."

VI. GRIEVANCE REDRESS SERVICES

77. Communities and individuals who believe that they are adversely affected by a World Bank supported project may submit complaints to existing project-level GRM or the World Bank's GRS. The GRS ensures that complaints received are promptly reviewed in order to address project-related concerns. Project affected communities and individuals may submit their complaint to the World Bank's independent Inspection Panel which determines whether harm occurred, or could occur, as a result of World Bank non-compliance with its policies and procedures. Complaints may be submitted at any time after concerns have been brought directly to the World Bank's attention, and World Bank Management has been given an opportunity to respond. For information on how to submit complaints to the

World Bank's corporate GRS, please visit: http://www.worldbank.org/en/ projects-operations/products-and-services/grievance-redress-service. For information on how to submit complaints to the World Bank Inspection Panel, please visit www.inspectionpanel.org.

VII. KEY RISKS

- 78. The overall risk to achieving the PDO is Substantial. The large-scale acquisition and deployment of COVID-19 vaccines entails risks. Also, a mass vaccination effort stretches capacity, in particular in low-capacity environments, entailing risks. The GoSA has access to over 81 million doses of vaccines to cover the 77.0 percent of the population and about 35.5 million doses have been administered as of May 16, 2022. The GoSA has implemented various interventions to increase the vaccination rate including organizing Vooma Vaccination Weekends and distributing Vooma Vouchers. In addition, the government, under the leadership of the President, is committed to implementing additional mitigation measures to address identified gaps as the country deploys vaccines until the target population is covered. However, the residual risk is rated Substantial given vaccine hesitancy, inequitable utilization of essential health services including COVID-19 vaccination and the evolving situation that may affect the effectiveness of the overall vaccination program. This section describes the risks that are rated Substantial, and the risks that are rated Moderate are described in Annex 3.
- 79. The macroeconomic risk is rated Substantial. After years of fiscal deterioration, the pandemic shock triggered a sharp increase in the budget deficit, amplifying concerns about the sustainability of the trajectory of public debt. The government has since embarked on an ambitions fiscal consolidation program which seeks to stabilize the debt ratio in FY24. Revenues have overperformed in the last fiscal year boosted by increased mining tax receipts, due to the upswing in global commodity prices, and the rebound from the 2020 recession. The durability of the mining revenue windfall is uncertain but is likely to be temporary. Fiscal deficits are expected to remain wide relative to history over the medium term while the fiscal consolidation plan mostly relies on controlling the public sector wage bill. Fiscal risks persist, mainly relating to the growth performance, financially distressed state owned enterprises, the wage bill and the possible introduction of new spending plans which are currently unfunded (extension of Basic Income Support). In this context, South Africa may continue to face the risk of not having sufficient additional fiscal space for the purchase and deployment of vaccines at scale and other COVID-related response interventions. While the proposed project specifically aims to mitigate this risk by providing financing for vaccine purchase, and the adoption and implementation of fiscal and structural measures announced in the 2022 Budget Review in February 2022 will help mitigate the risk, residual macroeconomic risk to the PDO is substantial. This is because the risks related to the overall macroeconomic situation remain in the short term and may prevent the GoSA from providing significant financing needed for prioritized deployment of vaccines especially to vulnerable groups in a timely manner. The macroeconomic risk could increase further in the case of a resurgence of the COVID-19 cases, as a result of the ongoing Russia-Ukraine War or, more broadly, a weaker global growth slowdown than currently anticipated. South Africa has insignificant trade links with Russia and Ukraine which combined account for about 1.1 percent of total trade. However, the war-induced increase in global oil prices is translating into higher inflation. Annual headline inflation was 5.9 percent in April 2022, just below the upper end of the 3-6 percent official target in April 2022. Higher metal prices, of which South Africa is a major exporter, should help cushion the impact on the trade balance and growth and support fiscal revenue. As domestic growth drivers remain weak, South Africa is vulnerable to changes in the global environment. The ongoing economic recovery is further constrained by persistent power supply shortfalls, while devastating flooding in the major economic hub of KwaZulu-Natal in mid-April 2022 has had a negative impact on growth momentum.

- 80. Technical design risk is rated Substantial. Emergency response operations often face elevated technical design risks due to limited preparation time, ability to conduct detailed assessments, availability of sector analytics, access to counterparts, and ability to conduct stakeholder consultations. These risks may be exacerbated by pandemic restrictions on mobility and on-the-ground preparation work. There could also be unprecedented institutional capacity demands associated with COVID-19 response operations (e.g., need for adequate personal protective equipment, distancing and hygiene protocols, large scale of COVID response deployment), as well as in countries where the World Bank has had limited or no engagement in the health sector, and where the client has limited familiarity with World Bank operations like South Africa. In addition, the proposed project will provide up to 100 percent retroactive financing for vaccine purchase, while associated activities such as vaccine deployment including RCCE to address vaccine hesitancy, immunization system strengthening, and health care waste management are under the responsibility of the government. While the GoSA has been implementing the vaccination program relatively well including intensive RCCE, the residual technical risk remains Substantial, considering (a) vaccine hesitancy in the country; (b) shortage of HCWs to run vaccination, COVID-19 response and routine services concurrently for a prolonged-period of time in some districts; and (c) possibility of limited budget available for scaling up vaccine deployment including targeted RCCE where needed and maintaining other essential service delivery.
- 81. The institutional capacity for implementation and sustainability risks related to vaccine deployment and distribution are Substantial. While the GoSA has strengthened vaccine distribution and deployment capacity, they are still sub-optimal especially for the anticipated scale and population group coverage for COVID-19 vaccination. The GoSA is mitigating this risk in coordination with the private sector and development partners in their provision of systems strengthening support. As the vaccine deployment will be implemented through the existing government structures with the budget allocated by the NT and without additional (financial and human) resources under the proposed project, the proposed project is expected to have limited influence over the mitigation measures in addressing any evolving institutional capacity risks especially at the provincial and district levels where services are provided. The residual institutional capacity risk is Substantial, considering the inherent risk and the mitigation via the system strengthening only through the ongoing investments by the government and by partners.
- The environmental and social risks are Substantial. The environmental risk is rated Substantial. The 82. environmental risk of with the vaccination program is largely associated with the deployment of the vaccines which is not directly supported under this project. The main environmental risks associated with the deployment of the vaccines include: (a) environmental and community health and safety risks associated with health care waste management practices such as inadequate storage, transportation, treatment and disposal; (b) OHS risks associated with needle stick injuries during vaccination; and (c) community health and safety risks due to infectious prevention and control measures and lack of social distancing at vaccination sites. The GoSA has well-established COVID-19 vaccine management systems and a robust legislative framework in place for managing E&S aspects in line with the WHO guidelines. The E&S review highlighted some shortcomings at implementation level with regards to management of health care waste. The NDoH indicated that it is working closely with PDoHs to put measures in place to strengthen health care waste management practices at health care facilities. The project will use existing structures to provide oversight and monitoring of E&S requirements during project implementation. Some capacity challenges in terms of shortage human resources and budget were reported at provincial and district level. The World Bank will continue to provide technical and implementation support to the GoSA to strengthen existing systems and health care waste management compliance.
- 83. The social risk is rated Substantial due to vaccine hesitancy, uneven uptake and supply-side constraints affecting vaccination coverage in some parts of the country; but efforts to address these issues are already in place and being implemented by GoSA. Specifically, the GoSA has adopted a robust multi-sectoral approach to contain and

mitigate the spread of COVID-19 that is in line with WHO guidelines and the World Bank's ESSs. At a strategic level, the policy framework includes the National IPC Strategic Framework, COVID-19 Vaccine Rollout Communication Strategy, and Accelerating Demand for COVID-19 Vaccination Project Plan, among others. To identify and ensure inclusive vaccination rollout, the GoSA adopted the WHO SAGE Values Framework and implemented the vaccination program in a phased manner. To ensure easy access, vaccines are administered in a variety of centers, including district-level public and private hospitals/facilities, vaccination centers, mobile clinics, remote/facility-based vaccination centers (e.g., community pharmacies), outreach clinics (e.g., elderly home, workplaces, schools, etc). While advance registration for vaccination through the EVDS is strongly encouraged, walk-ins are allowed, and an informed consent is required prior to being vaccinated. Vaccination is open to all individuals residing in South Africa regardless of their residential status or nationality. Recently, the GoSA has also introduced an alternate pathway through the EVDS to cater for all undocumented migrants as well as people without identity documents. For the uninsured, the cost of the vaccine and its administration is covered by GoSA, while the insured are covered by medical schemes. To generate demand for vaccination while addressing barriers and constraints that individuals may experience to get vaccinated, the government has introduced various schemes such as the Vooma vaccination vouchers (R200) for individuals aged 50+, a demand acceleration strategy targeting youth, and free mobile data for youth.

84. Partnerships with local governments, civil society organizations, non-governmental organizations, private sector, educational institutions, and local, traditional and leaders, etc; extensive strategies to engage communities in combating mistrust and build public confidence in the vaccine; demand acceleration plans, are all important part of the vaccine rollout and communication strategy. Consultations have been carried out with traditional local communities as per ESS7 and there is broad-based support from these groups. The labor legislation in South Africa that would apply to the project workers is aligned with ESS2, including in matters relating to working conditions, child labor, forced labor, etc. The SEA/SH/GBV risks for the project is rated 'moderate' and services, such as GBV Command Centre, hotlines, and a Code of Good Practice on the Handling of Sexual Harassment in the workplace, provide effective mechanisms for addressing such risks. The vaccination program contact center with several channels for obtaining information and getting issues addressed together with the existing mechanisms at the health care facilities (e.g., suggestion box) provide a sound mechanism for grievance redressal. However, in the absence of a single platform, the tracking as well as effective resolution of grievances has been a challenge. Further, despite the inclusive mechanisms for communication and outreach as well as vaccine access, vaccination uptake has been slow with notable regional and demographic variation in vaccination rates; for example, less than a third of males aged 18-34 years have been vaccinated, compared with 41.6 percent of females in the same age group. To increase vaccine uptake among younger age cohort, the GoSA has recently introduced demand acceleration strategy targeting the youth, and the results are yet to be known.

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VIII. RESULTS FRAMEWORK AND MONITORING

Results Framework

COUNTRY: South Africa
South Africa COVID-19 Emergency Response Project

Project Development Objective(s)

The project development objective is to increase COVID-19 vaccination coverage among the population of South Africa.

Project Development Objective Indicators

Indicator Name	PBC	Baseline	End Target						
To increase COVID-19 vaccination coverage among the population of South Africa									
Percentage of population aged 18 years and older fully vaccinated (Percentage)		1.23	70.00						
Percentage of female population aged 18 years and older fully vaccinated (Percentage)		1.74	70.00						
Percentage of population aged 12 to 17 years fully vaccinated (Percentage)		0.00	50.00						
Percentage of female population aged 12 to 17 years fully vaccinated (Percentage)		0.00	50.00						
Ratio of fully vaccinated female to male population aged 18 to 34 years (Number)		2.62	1.15						
Percentage of population aged 60 years and older vaccinated with at least 1 booster (Percentage)		0.00	50.00						
Number of provinces with at least 70% of the population aged 60 years and older fully vaccinated (Number)		0.00	9.00						

Intermediate Results Indicators by Components

Indicator Name PBC		Baseline	End Target
COVID-19 Emergency Response			
Percentage of active public vaccination sites with vaccine availability (Percentage)		0.00	95.00
Rate of AEFI reported to NDOH/SAHPRA (per 100,000 vaccines administered) (Number)		0.00	10.00
Percentage of contacts responded to within the stipulated timeline as per the service level agreements (Percentage)		0.00	90.00

	Monitoring &	Evaluation Pla	an: PDO Indicato	rs	
Indicator Name	Definition/Description	Frequency	Datasource	Methodology for Data Collection	Responsibility for Data Collection
Percentage of population aged 18 years and older fully vaccinated	Numerator: Total number of individuals aged 18 years and older vaccinated with one dose regiment of J&J or two dose regiment of Pfizer as per the national guidelines Denominator: Total number of individuals aged 18 years and older as per	Biannual	EVDS	EVDS report	NDoH

	the SA 2020 midyear population estimates				
Percentage of female population aged 18 years and older fully vaccinated	Numerator: Total number of females aged 18 years and older vaccinated with one dose regiment of J&J or two dose regiment of Pfizer as per national guidelines Denominator: Total number of females aged 18 years and older as per the SA 2020 midyear population estimates	Biannual	EVDS	EVDS report	NDoH
Percentage of population aged 12 to 17 years fully vaccinated	Numerator: Total number of individuals aged 12 to 17 years vaccinated with two dose regiment of Pfizer as per national guidelines Denominator: Total number of individuals aged 12 to 17 years as per the SA 2020 midyear population estimates	Biannual	EVDS	EVDS report	NDoH
Percentage of female population aged 12 to 17 years fully vaccinated	Numerator: Total number of females aged 12-17 years vaccinated with one	Biannual	EVDS	EVDS report	NDoH

	dose regiment of J&J or two dose regiment of Pfizer as per national guidelines Denominator: Total number of females aged 12 – 17 years as per the SA 2020 midyear population estimates				
Ratio of fully vaccinated female to male population aged 18 to 34 years	Numerator: Percentage of females aged 18 – 34 vaccinated with one dose regiment of J&J or two dose regiment of Pfizer as per national guidelines Denominator: Percentage of males aged 18 – 34 vaccinated with one dose regiment of J&J or two dose regiment of Pfizer as per national guidelines	Biannual	EVDS	EVDS report	NDoH
Percentage of population aged 60 years and older vaccinated with at least 1 booster	Numerator: Total number of individuals aged 60 years and older vaccinated with at least 1 booster Denominator: Total number of individuals aged 60 years and older as per	Biannual	EVDS	EVDS report	NDoH

	the SA 2020 midyear population estimates				
Number of provinces with at least 70% of the population aged 60 years and older fully vaccinated	Number of provinces with at least 70% of the population aged 60 years and older vaccinated with one dose regiment of J&J or two dose regiment of Pfizer	Biannual	EVDS	EVDS report	NDoH

Monitoring & Evaluation Plan: Intermediate Results Indicators							
Indicator Name	Definition/Description	Frequency	Datasource	Methodology for Data Collection	Responsibility for Data Collection		
Percentage of active public vaccination sites with vaccine availability	Numerator: Number of active public sector vaccination sites reporting availability of at least one COVID-19 vaccine Denominator: Number of active public sector vaccination sites reporting on COVID-19 vaccines	Biannual	SVS	SVS electronic system	NDoH		
Rate of AEFI reported to NDOH/SAHPRA (per 100,000 vaccines administered)	Numerator – Number of AEFI reported Denominator - 100,000 vaccination	Biannual	SAHPRA Vigiflow System	SAHPRA report	SAHPRA		

	0 vaccines stered.				
Percentage of contacts responded to within the stipulated timeline as per the service level agreements contact grievan within to timeline timeline as per the service level agreements	rator: number of ts (including nces) responded to the stipulated ne in the SLA ninator: total ers of contacts ed by the National nter	Biannual	Tiers 1 and 2: BPO Contact Center database (currently CCI South Africa) Tiers 3 and 4: National Health Laboratory Service database	Monthly National Call Center reports	NDoH through the following: Tiers 1 and 2: BPO Contact Centre service provider (currently CCI South Africa) Tiers 3 and 4: National Health Laboratory Service

ANNEX 1: Summary Table on Vaccine Development and Approval Status

(as of April 2, 2022)

COUNTRY: South Africa South Africa COVID-19 Emergency Response Project

December 11, 2020 European Union: December 21, 2020 Switzerland: December 19, 2020 Australia: January 25, 2021 Australia: January 25, 2021 Deliment suppliers: Pfizer Perth, Australia. June 18, 2021 Presenius Kabi, USA. September 20, 20. Pfizer Manufacturing Belgium. Novembar 30, 2021 Shelf-life extension: 09 months at -70 to 90°C. December 17, 2021 Booster dose approved for adults 18 yea age and older. December 14, 2021 Belpharm, Saint-Remy FRANCE (DP). September 17, 2021 Sanofi-Aventis Deutschland GmbH, Germany (DP) November 11, 2021 Patheon Italia S.p.A, Italy (DP). December 07, 2021 Catalent Agnani. January 21, 2022 Diluent suppliers: Pfizer Perth, Australia. June 18, 2021 Fresenius Kabi, USA. September 20, 20. Pfizer Manufacturing Belgium. Novembar 30, 2021 Kwang Myung Pharm Co., Ltd. October 2021 Booster dose approved for adults 18 yea age and older. December 14, 2021		Manufacturer /	Name of	SRA approval			WHO EUL*
1. Proper Mirward BioNTech Mirward Tozinameran (INN) BioNTech Manufacturing GmbH Canada: December 9, 2020 United States of America: December 11, 2020 European Union: December 21, 2020 Switzerland: December 19, 2020 Switzerland: December 19, 2020 Australia: January 25, 2021 Australia: January 25, 2021 BioNTech Manufacturing Belgium. Novembar 30, 2021 Figer Perth, Australia. June 18, 2021 Firesenius Kabi, USA. September 20, 202 Diluent suppliers: Figer Perth, Australia. June 18, 2021 Fresenius Kabi, USA. September 20, 20 Figer Manufacturing Belgium. Novembar 30, 2021 Kwang Myung Pharm Co., Ltd. October 2021 Shelf-life extension: 09 months at -70 to 90°C. December 17, 2021 Booster dose approved for adults 18 yea age and older. December 14, 2021 Age extension to children 5-11 years of a general page and older. December 14, 2021 Age extension to children 5-11 years of a general page and older. December 14, 2021		WHO EUL holder	Vaccine	received	Platform	NRA of	Status of assessment
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age and older. December 14, 2021 • Age extension to children 5-11 years of a	1.	BIONTECH BioNTech Manufacturing	MIRNATY Tozinameran	December 2, 2020 Canada: December 9, 2020 United States of America: December 11, 2020 European Union: December 21, 2020 Switzerland: December 19, 2020 Australia: January		EMA	 Additional sites: Baxter Oncology GmbH Germany (DP). June 30, 2021 Novartis Switzerland. July 08, 2021 Mibe (Dermapharm) Germany (DP). July 16, 2021 Delpharm, Saint-Remy FRANCE (DP). September 17, 2021 Sanofi-Aventis Deutschland GmbH, Germany June 18, 2021 Siegfried Hameln GmbH, Germany (DP). November 11, 2021 Patheon Italia S.p.A, Italy (DP). December 07, 2021 Catalent Agnani. January 21, 2022 Exela Pharma Science, LLC, NC. March 16, 2022 Diluent suppliers: Pfizer Perth, Australia. June 18, 2021 Fresenius Kabi, USA. September 20, 2021 Pfizer Manufacturing Belgium. November 30, 2021 Kwang Myung Pharm Co., Ltd. October 06, 2021 Shelf-life extension: 09 months at -70 to -90°C. December 17, 2021
February 12, 2022							 Booster dose approved for adults 18 years of age and older. December 14, 2021 Age extension to children 5-11 years of age.
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McPherson (DP). July 16, 2021						USFDA	– Pharmacia & Upjohn, Kalamazoo (DP)PGS
30, 2021							·
2. A A7D1222 ILIK: December 30 FMA Core data finalized. April 16, 2021	2.	A	AZD1222	■ UK: December 30,		EMA	
		AstraZeneca 22	Vaxzevria		Recombinant		Additional sites:

	AstraZeneca, AB		EU: January 29, 2021Australia: February 16, 2021 (overseas		KOREA Japan MHLW/P MDA Australia TGA COFEPRIS (Mexico) ANMAT	 SK-Catalent Wuxi (DS). April 16, 2021 Chemo Spain. April 30, 2021 Amylin Ohio US (DP). July 23, 2021 WuXi Biologics, Germany (DP). March 8, 2022 Finalized. February 15, 2021 Finalized. July 09, 2021 Additional site: Nipro Pharma Corporation Ise, Japan. October 11, 2021 Finalized. July 09, 2021 Additional site: Siam Bioscience Co., Ltd Thailand. October 11, 2021 Finalized. December 23, 2021
	SERUM INSTITUTE OF Cyrus Poonawall Serum Institute of India Pvt.Ltd	Covishield (ChAdOx1_nCo V-19)			(Argentin a) DCGI	 Finalized. February 15, 2021 DS and DP Manjari Bk Pune. November 12, 2021
4.		COVOVAX™ COVID-19 vaccine (SARS- CoV-2 rS Protein Nanoparticle [Recombinant]		nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant		■ Finalized. December 17, 2021
5.	moderna		 USA: December 18, 2020 Canada: December 23, 2020 EU: January 6, 2021 Switzerland: January 12, 2021 UK: January 8, 2021 	vaccine encapsulatedin lipid nanoparticle (LNP)	USFDA	 Finalized. April 30, 2021 Shelf-life extension to 09 months - 20±5°C. February 14, 2022 Additional Sites. August 06, 2021 ModernaTx. Norwood (DS) Catalent Indiana, LLC (DP) Lonza Biologics, Inc. Portsmouth, USA (DS) Baxter, Bloomington, USA (DP) Finalized. December 23, 2021

7.	Sinopharm /Beijing Institute of Biological Products Co., Ltd. (BIBP) Sinovac Life Sciences Co., Ltd. Sinovac Life	SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) COVID-19 Vaccine (Vero Cell), Inactivated/ Coronavac TM		Inactivated, produced in Vero cells Inactivated, produced in Vero cells	NMPA	 Finalized. May 07, 2021 2 and 5 dose presentation (new manufacturing site) TBC after ongoing inspection Finalized. June 01, 2021 2 dose presentation. September 30, 2021
	Janssen Infection & Vaccine PRINCEUTE AL COMPANIES OF MARKET Janssen—Cilag International NV		 Canada: March 05, 2021 EU: March 11, 2021 Switzerland: March 22, 2021 	replication- incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2)	EMA	 Core data finalized (US +NL sites). March 12, 2021 Additional sites: Aspen RSA (DP). June 25, 2021 Catalent Agnani Italy (DP). July 02, 2021 Grand River Aseptic Manufacturing Inc., USA. November 05, 2021 MSD (Merck), West Point/PA, USA (DP). November 05, 2021 Sanofi Pasteur France (DP). January 27, 2022 Storage conditions extension at 2-8°C from 4.5 months to 11 months within the 24 months of shelf-life at -25°C to -15°C. March 16, 2022
	BHARAT BIOTECH Land Grandow Bharat Biotech, India	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)/ COVAXIN		Whole-Virion Inactivated Vero Cell	DCGI	 Finalized. November 03, 2021 Suspension of production for export. April 2, 2022
10.	NOVAX Creating Tomorrow's Vaccines Today	NVX- CoV2373/Nuva xovid		Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant	EMA	■ Finalized. December 20, 2021

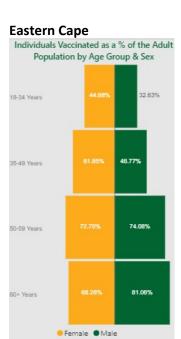
Source: * WHO. 2022. Status of COVID-19 Vaccines within WHO EUL/PQ Evaluation Process. https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_02April2022.pdf

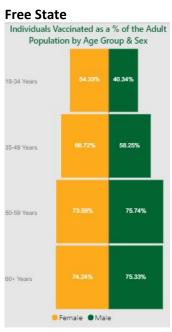
Note: ANMAT-Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (National Administration of Drugs, Food and Medical Technology); DCGI-Drugs Controller General of India; COFEPRIS-Comisión Federal para la Protección contra Riesgos Sanitarios (Federal Committee for Protection from Sanitary Risks); DP-Drug Product; DS-Drug Substance; EMA-European Medicines Agency; EU-European Union; FDA-Food and Drug Administration; EUL-Emergency Use Listing; MFDS-Ministry of Food and Drug Safety; MHLW-Ministry of Health, Labour, and Welfare; NMPA-National Medical Products Administration; PDMA-Pharmaceuticals and Medical Devices Agency; SRA-Stringent Regulatory Authority; and TGA-Therapeutic Goods Administration

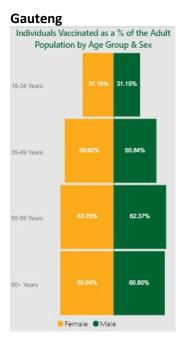
ANNEX 2: Vaccination Status among Adults by Age and Sex

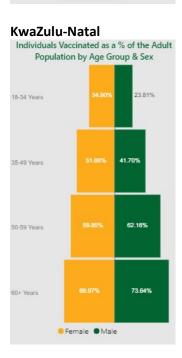
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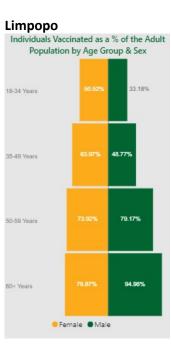
COUNTRY: South Africa South Africa COVID-19 Emergency Response Project

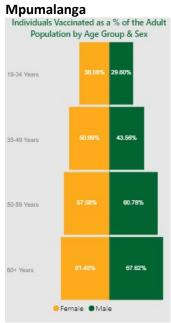




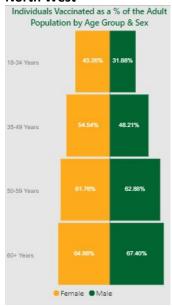




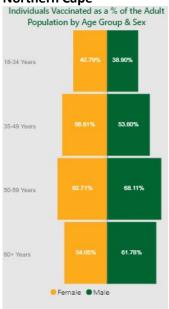




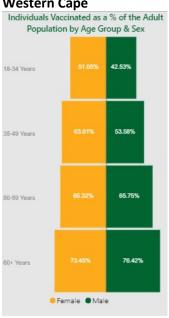
North West







Western Cape



ANNEX 3: Implementation Arrangements and Support Plan

COUNTRY: South Africa
South Africa COVID-19 Emergency Response Project

Strategy and Approach for Implementation Support

- 1. The implementation support plan for the project is based on the following considerations. The implementation agency, the National Department of Health (NDoH), will: (a) implement the vaccination program with minimum support from the World Bank and other development partners; and (b) require technical and operational assistance in implementing procurement and environmental and social (E&S) risk management in line with the World Bank policy at least for the first year.
- 2. **Biannual review and implementation completion and results review.** Biannual missions will be organized to review the progress and mitigate any risks in advance in addition to the routine implementation support. Biannual missions will be complemented by technical assistance missions as needed. At the end of the project implementation, a formal implementation completion and results review will be organized to assess project implementation progress and results.
- 3. Fiduciary and E&S risk management. Project fiduciary risks are rated Moderate (described below) and E&S risks are rated Substantial (paragraphs 82 and 83). The procurement and FM risks assessed for the project cover risks associated with the procurement and distribution of vaccines. Since the proposed project is financing already procured vaccine supply contracts, there will be no procurement risk. The NDoH's procurement and contract management capacity has been assessed virtually, using PRAMS Questionnaire. The risk of managing the ongoing contracts including logistics and distribution arrangements and successful delivery of the remaining vaccines is rated Moderate. Given the vaccine contracts to be financed have already been signed and over 70 percent of the vaccines delivered, there is low likelihood of the project being exposed to the key procurement and market approach risks associated with a new vaccines purchase activity. The FM risk is rated Moderate based on: (a) the robust existing routine financial reporting systems as well as the current detailed reporting and monitoring mechanism in place as per the Minister of Finance's funding approval in terms of the Appropriation Act; (b) financing of retroactive contracts that will be subjected to the World Bank due diligent review before the project is approved; and (c) financing of committed contracts with minimum risk of funds used for the unintended purposes. As the NDoH has not prepared and/or implemented a World Bank financed project, fiduciary and E&S team will provide training and/or hands-on support as needed to support the implementation. The fiduciary and E&S team will also join implementation progress review meetings regularly to address any implementation bottlenecks and challenges.
- 4. **Monitoring and evaluation (M&E)**. The existing team for the national COVID-19 vaccination program in coordination with support from the M&E unit will be responsible for project M&E. The proposed indicators are aligned to the indicators measuring progress for the national vaccination program and can be monitored through the health management information system (e.g., Electronic Vaccination Data System, Stock Visibility System) and/or NDoH administrative data. The Deputy Director General, National Health Insurance, who leads the national COVID-19 vaccination program, will consolidate biannual financial and technical reports for project implementation and share with the NT, copying the World Bank. Task team will work closely with the NDoH to plan and implement the required project M&E activities especially those related to fiduciary and E&S risk management.