



Republic of Zambia
Ministry of Health

**Guidelines on Involvement of the Private Sector and
Non-State Actors in the COVID-19 Vaccination
Programme in Zambia**

April 2021

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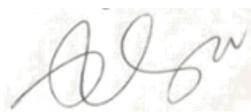
i. Foreword

The Government of the Republic of Zambia, through the Ministry of Health (MoH) together with its Co-operating Partners, has been deploying the COVID-19 Vaccine as an integral part of the overall National COVID-19 Response. This response is being executed in line with the National COVID-19 Vaccine Deployment Strategy (NVDS) and global guidance as part of the National COVID-19 Multi-sectoral Contingency and Response Plan (MCRP) to ensure seamless coordination with all relevant stakeholders. In the spirit of accelerating the involvement of the Private Sector and Non-State Actors (NSA) in the national COVID-19 response, the Government of the Republic of Zambia through Ministry of Health constituted a Task Team consisting of representatives from the Private Sector, Non-State Actors, Ministry of Health, and other Government line Ministries. The main purpose of the Task Team was to develop Guidelines on the involvement of the Private Sector and Non-State Actors in the COVID-19 Vaccination Programme in Zambia.

Between 7th-9th April 2021, a consultative meeting was convened at which the Task Team deliberated on several key aspects related to the involvement of the Private Sector and Non-State Actors in the COVID-19 programme such as vaccine procurement platforms and modalities, funding mechanisms, regulatory requirements and procedures, distribution and transportation of vaccines, storage, standard operating procedures, pricing, and coordination of the partnership. These deliberations culminated in the development of these Guidelines.

The Guidelines shall provide direction on the modalities of engagement between the Ministry of Health, the Private Sector and Non-State Actors. As such, it is expected that the Guidelines shall enable a systematic and harmonised approach in the implementation of the COVID-19 Vaccination Programme by the Public, Private Sector and Non-State Actors (NSA).

The Ministry of Health wishes to express its appreciation to those involved in the development and finalisation of these Guidelines whose implementation shall not be possible without the good work and dedication of all relevant Private Sector and Non-State Actors at various levels. We therefore wish to urge all responsible relevant partners at various levels and capacities to work diligently and contribute to the successful deployment of this life saving vaccine. The Ministry of Health assures all Private Sector and Non-State Actors support to facilitate processes required to ensure success in this undertaking.



Hon. Dr. Jonas Kamima Chanda, MP

Minister of Health

ii. Acknowledgements

The Ministry of Health has been working with Cooperating Partners to ensure that efforts towards the COVID-19 Vaccination Programme are well coordinated, and adequately resourced. To enhance this aspiration, the Ministry of Health saw it appropriate to develop Guidelines on the involvement of the Private Sector and Non-State Actors in the COVID-19 Vaccination Programme. These Guidelines have therefore been developed with the desire to strengthen and legitimise collaboration between the Ministry of Health, Public Sector and Non-State Actors in the COVID-19 Vaccination Programme. Partnerships play a critical role in enabling the Ministry of Health to fulfil its obligations and these Guidelines will help facilitate participation of the Private Sector and Non-State Actors in the COVID-19 Vaccination programme with the goal of improving health and well-being of all Zambians. The Guidelines shall play a key role in contributing to the National COVID-19 Multi-sectoral Contingency and Response Plan (MCRP) as a mechanism to enhance participation for all relevant Private Sector and Non-State Actors.

The development of these Guidelines was consultative and made possible by the hard work and dedicated efforts of representatives of the Private Sector and Non-State Actors working together with the Ministry of Health.

On behalf of the Ministry of Health, I wish to acknowledge the financial and technical support rendered to us by our Cooperating Partners, especially the Churches Health Association of Zambia, Zambia Private Sector Alliance, World Health Organization (WHO), United Nations Children's Fund (UNICEF), Zambia Association of Private Hospitals (ZAPH), Centre for Infectious Disease Research in Zambia (CIDRZ), First Quantum Minerals (FQM), Mary Begg Health Services and the Aspen Management Partnership for Health (AMP Health) who contributed immensely to the development of the Guidelines.

I wish to thank Zambia National Public Health Institute (ZNPHI), Zambia Medicines Regulatory Authority (ZAMRA) and my staff at the Ministry of Health (MoH), especially the Department of Public Health and Research who were instrumental in coordinating the Task Teams effort that led to the finalisation of these Guidelines.



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1. Background

The first two cases of COVID-19 in Zambia were reported on 18th March 2020. By 21st April 2021, a total of 91,119 cases and 693 COVID-19 deaths and 545 COVID-19 associated deaths had been recorded. The most affected age group ranged from 20-49 years with females slightly more affected than males. The positivity rates had ranged between 0.6% and 25.4%. Zambia has already experienced two distinct waves as of February 2021¹, while a third wave of the COVID-19 transmission is anticipated in June-July 2021. There had been notable decline in the country's Gross Domestic Product with estimates of (GDP) for the fourth quarter of 2020 showing contraction of the economy by 2.7 % from a 0.2 % growth in fourth quarter of 2019. However, this was an improvement compared to second and third quarter growth rates of minus 5.9 % and minus 3.1 % based on the year on-year comparison of GDP at constant 2010 prices.²

This contraction in GDP was attributed to the underperformance of five industries where negative postings on contributions to overall growth were recorded (Wholesale and retail trade (-2.4%), Education (-1.7%), Public administration (-1.1%), Accommodation and food (-0.6%) and Arts, entertainment & recreation (-0.2%).

The Government of the Republic of Zambia through the Ministry of Health has implemented a multi-pronged approach under nine (9) pillars to mitigate the pandemic: Surveillance, case investigation and contact tracing, case management, Infection Prevention and Control, Laboratory diagnosis, Logistics and supply chain management, appropriate competent and adequate workforce, Risk Communication and Community Engagement, Continuation of Essential services and now Vaccination as an addition. On 24th March 2021, Cabinet at its 4th Meeting approved the COVID-19 Vaccination Programme, which provides for vaccine acquisition, deployment, and financing through four pillars, namely: (i) the COVAX Facility (ii) Donations from donors and Co-operating Partners; (iii) Private Sector involvement; and (iv) Government resource mobilisation. It is anticipated that COVID-19 Vaccination Programme will play a key role in mitigating the negative impact of the pandemic to ensure that essential services, key societal functions, and business continuity are sustained.

The Government continues to enforce public health measures and interventions to control the spread of COVID-19 countrywide as outlined in the Statutory Instruments

¹ Zambia COVID-19 Situation Report No. 207 (ZNPHI/MoH/WHO), 21st April 2021

² ZamStats Monthly Bulletin March 2021 | Volume 216

(SI) 21 and 22 of 2020 on COVID-19 and the Presidential directives. In addition, the National COVID-19 Multi-sectoral Contingency and Response Plan (MCRP) outlines the country's COVID-19 preparedness and response activities. Partnerships are a critical part of the Zambia COVID-19 response and will help reinforce the true spirit of having a multi-sectoral response by Government working with both the Private Sector and the Non-State Actors. These Guidelines developed by the Task Team as abovementioned provides direction on the engagement between the Government of the Republic of Zambia through the Ministry of Health with the Private Sector and Non-State Actors (NSA).

2. Objectives

The objectives of these Guidelines are to:

- (i) Develop coordination mechanisms of Private Sector and Non-State Actors partnerships regarding COVID-19 vaccines.
- (ii) Clarify regulatory requirements and processes.
- (iii) Facilitate acquisition of COVID-19 vaccines by NSAs for their employees and immediate communities.
- (iv) Provide mechanisms for the Private Sector and Non-State Actors to contribute towards financing for COVID-19 vaccines.
- (v) Outline COVID-19 vaccine procurement platforms and modalities in Zambia.
- (vi) Outline key processes for the importation of COVID-19 vaccines.
- (vii) Provide direction on pricing mechanisms for COVID-19 vaccines in private facilities.
- (viii) Stipulate mechanisms for the storage and reporting of COVID-19 vaccines.
- (ix) Define how different players will be involved in the distribution and/or transportation of COVID-19 vaccines in-Country.
- (x) Outline standard operating procedures (SOPs) for the administration of COVID-19 vaccines in Private Sector health facilities and outreach posts, including data management, waste management, reporting and pharmacovigilance.

3. Guidelines

These Guidelines assume that the Private Sector and Non-State Actors are implementing the policies and measures to combat COVID-19 as stipulated by the Government of the Republic of Zambia (GRZ) and in keeping with guidance from the World Health Organization (WHO) and the Africa Centres for Disease Control and Prevention (Africa CDC).

3.1. Acquisition, Financing, Procurement, and Pricing

- (i) Government shall lead the vaccine procurement and delivery through three main procurement platforms namely:
 - (a) COVAX Facility through UNICEF³;
 - (b) Africa Medical Supplies Platform (AMSP), an initiative under the African Union (AU); and
 - (c) Direct procurement from manufacturers with approval from Government.
- (ii) The Zambia Private Sector Alliance shall put in place a mechanism to coordinate mobilisation and pooling of resources required for acquisition, financing, and procurement of vaccines as well as supporting deployment by the Private Sector.
- (iii) The Churches Health Association of Zambia (CHAZ) shall put in place a mechanism to coordinate mobilisation and pooling of resources required for acquisition, financing, and procurement of vaccines as well as supporting deployment by the Non-State Actors.
- (iv) For Private Sector and Non-State Actors (NSA) that contribute to procure for its employees and immediate communities, their contributions shall be the total, inclusive of the cost of the vaccine per dose plus 10% to go towards Government's first three (3) tiers of the most vulnerable population as per tiered approach based on the National COVID-19 Vaccine Deployment Strategy (NVDS).
- (v) Government shall bear the responsibility for indemnity and liability based on the Indemnity and Liability Agreements (ILA) signed with the COVID-19 vaccine manufacturers.

³ United Nations Children's Fund

3.2 Importation of Vaccines, Regulatory Issues and Coordination

Mechanisms

- (i) **Importation:** Government shall ensure that only vaccines which are of good quality, safe, efficacious, and approved by the Ministry of Health through ZAMRA are imported.

- (ii) **Pharmaceutical supply and retailing:** Pharmaceutical suppliers and retailers that hold appropriate pharmaceutical license shall follow the existing regulatory and approval procedures. Such Private Sector and NSAs shall be allowed to sell to health facilities, with a margin not exceeding 25% of the total cost through their direct purchasing platforms approved by the Government of the Republic of Zambia.

- (iii) **Donations:** All donations shall adhere to Ministry of Health and ZAMRA Guidelines:
 - (a) Vaccines shall be registered in the country of origin and manufactured under Good Manufacturing Practices (GMP).
 - (b) Vaccines shall be those approved by Ministry of Health through ZAMRA. ZAMRA will recognise WHO EUL / Approval for the purposes of approving vaccine importation.
 - (c) Waivers on the requirement for a minimum shelf life of 12 months may be granted to the importer, on a case-by-case basis.

- (iv) **Demand generation:** The Private Sector and NSAs will collaborate with the Government in demand generation and Risk Communication & Community Engagement in accordance with the COVID-19 vaccination communication strategy.

- (v) **Collaboration:** The Private Sector and NSAs shall be integrated into the existing health system at District, Provincial and National level where necessary, to ensure data management and reporting requirements are met or as determined through the NVDS.

3.3 Distribution, Transportation, Storage, Reporting & Vaccine Administration

3.3.1 Distribution and transportation

- (i) COVID-19 vaccines received at National Vaccines Stores through MOH systems shall be distributed through routine Government immunisation supply chain system to identified and approved Private Sector and NSA facilities for service delivery.
- (ii) Private Sector and NSAs shall report vaccine stocks and management of vaccines throughout the immunisation supply chain to MOH in line with requirements (i.e., status of stocks, temperature management in fast and slow chain).
- (iii) Where Private Sector and NSAs procure vaccines directly, they shall make provision for appropriate transportation, storage, and distribution.
- (iv) Ministry of Health shall identify gaps, develop, or use existing improvement plans for storage and distribution systems.
- (v) Private Sector and NSAs shall address the identified gaps in storage and distribution systems (Logistics, Cold Chain) based on system strengthening approach.
- (vi) Participating NSAs and entities in the Private Sector shall be required to provide inventories of status of available equipment (appropriate Cold Chain).

3.3.2 Administration of vaccines

- (i) Ministry of Health shall conduct orientations, for both NSAs and Private Sector participating entities.
- (ii) Private Sector and NSA shall provide COVID-19 Vaccine service delivery in line with the National Vaccine Deployment Strategy (NVDS).
- (iii) The Private Sector and NSAs shall facilitate access to their facilities for supervision and mentorship for COVID19 Vaccination services by the Ministry of Health vaccination teams
- (iv) Ministry of Health shall provide Guidelines and SOPs on COVID-19 vaccination.
- (v) Only health personnel shall be allowed to administer vaccines.

3.3.3 Storage

- (i) Ministry of Health shall provide Guidelines and SOPs for vaccine storage, cold chain, and vaccine management.
- (ii) Ministry of Health or designated entities shall carry out capacity building activities in vaccine and cold chain management.
- (iii) Ministry of Health shall conduct assessment of COVID-19 vaccination readiness of participating entities in the Private Sector and NSAs.

3.3.4 Reporting

- (i) Ministry of Health shall work with the Private Sector and NSAs to strengthen systems for Monitoring and Evaluation based on existing MoH systems with all COVID-19 vaccine-related data flowing through established MOH systems at district level.
- (ii) Private Sector and NSAs shall utilise the appropriate Ministry of Health tools and Guidelines for reporting COVID-19 vaccination, pharmacovigilance, and surveillance data.

3.3.5 Waste management

- (i) Ministry of Health shall ensure existing Guidelines on health care waste management are disseminated to all participating facilities within the Private Sector and NSAs.
- (ii) Private Sector and NSAs shall dispose of COVID-19 vaccination waste in line with national medical waste Guidelines.

4. Monitoring and Evaluation

To monitor and evaluate the implementation of these Guidelines, the following outcome and progress indicators will be utilised against the respective objectives and included in periodic meetings and reports set for the Task Team.

- (i) Develop coordination mechanisms of Private Sector and Non-State Actors partnerships regarding COVID-19 vaccines.
 - a. *A coordination mechanism is set-up for the Private Sector and Non-State Actors for COVID-19 vaccines through agreements.*
- (ii) Clarify regulatory requirements and processes.
 - a. *Number of Private Sector and Non-State Actors adhering to regulatory requirements and processes.*
- (iii) Facilitate acquisition of COVID-19 vaccines by NSAs for their employees and immediate communities.

- a. *Number of Private Sector and Non-State Actors who have acquired vaccines.*
 - b. *Number of employees and immediate communities of Private Sector and NSAs vaccinated.*
- (iv) Provide mechanisms for the Private Sector and Non-State Actors to contribute towards financing for COVID-19 vaccines.
 - a. *Number of Private Sector and Non-State Actors financing mechanisms created and operational.*
- (v) Provide direction on pricing mechanisms for COVID-19 vaccines in private facilities.
 - a. *Proportion of Private Sector and Non-State Actors adhering to pricing requirements by relevant Private Sector and Non-State Actors.*
- (vi) Outline COVID-19 vaccine procurement platforms and modalities in Zambia.
 - a. *Number of Private Sector and Non-State Actors utilising Government COVID-19 Vaccine procurement platforms and modalities.*
- (vii) Stipulate mechanisms for the storage and reporting of COVID-19 vaccines.
 - a. *Number of Private Sector and Non-State Actors contributing to storage and reporting of COVID-19 vaccination.*
 - b. *Percentage contribution of the Private Sector and Non-State Actors towards storage of the COVID-19 vaccine.*
- (viii) Define how different players will be involved in the distribution and/or transportation of COVID-19 vaccines in-Country.
 - a. *Proportion of COVID-19 vaccines transported and distributed by the Private Sector and NSAs.*

5. Memorandum of Understanding

- (i) The Private Sector through the Zambia Private Sector Alliance and Non-State Actors through Churches Health Association of Zambia (CHAZ) shall sign and operationalise an agreement with the Government of the Republic of Zambia on involvement in the COVID-19 vaccine programme in Zambia. The MOUs shall guide resource mobilisation strategies and other aspects necessary for the Private Sector and NSAs to secure and deploy COVID-19 vaccines.

(ii) It is the expectation of the Government of the Republic of Zambia through the Ministry of Health that all concerned parties will comply with these Guidelines in facilitating the effective collaboration with the Private Sector and Non-State Actors. The Government would reserve the right to disengage with Private Sector and NSA players who do not comply with these Guidelines.

6. Revision of Guidelines

These Guidelines are subject to revision by the Task Team depending on emerging issues and gaps as the COVID-19 Vaccination Programme evolves.