**VACCINATION SITE ENROLMENT**

The South African National COVID-19 Vaccine Implementation Plan describes multiple scenarios where vaccines will be administered. Vaccination sites will be located in both public and private sector settings, and will include fixed, mobile and temporary locations.

All COVID-19 vaccination sites are required to be enrolled with the National Department of Health (NDoH). Enrolment will assist with planning, distribution, communication, monitoring and reporting on the progress of the vaccination roll-out plan.

**Acronyms**

AEFI Adverse Event Following Immunisation

EVDS Electronic Vaccination Data System

NDoH National Department of Health

**Definitions**

Immunisation station means the area in a vaccination site where vaccines are administered to clients.

COVID-19 vaccination services mean administering COVID-19 vaccines to eligible recipients.

A vaccination site means a health establishment or other site which is authorised to provide COVID-19 vaccination services to clients.

Vaccinator means the person who administers a COVId-19 vaccine to a client

**Vaccination site details**

Facility name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physical address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Postal address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Province: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

District: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sub-District: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Type of facility:**

District Hospital  Private Hospital

Regional Hospital  Private Day Hospital

Tertiary Hospital  Private Clinic

Central Hospital  Private Pharmacy

Specialised Hospital Private Practitioner

Community Day Centre

Community Health Centre

Primary Health Care Clinic

Other

Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Facility ownership:**

Government

Private for-profit

Non-government organisation

Faith-based organisation

Military

Other

Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Responsible pharmacist: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

SAPC Registration number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Responsible person: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Registration or Practice Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Registration in terms of:

Pharmacy Act 53 of 1974 (Pharmacy Act);

Medicines and Related Substances Act 101 of 1965 (Medicines Act);

Nursing Act 33 of 2005;

Health Professions Act 56 of 1974

**Cold storage capacity**

Total number of 2-8oCfridges available for vaccine storage: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Available storage capacity (2-8oC) in cm3 or litres: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Are WHO-approved continuous temperature monitoring devices present in the cold storage area:

Yes  No

*If the answer above is “No”, temporary approval to enrol as a Vaccination site will be provided, and the Vaccination site must provide an update on the status within 30 days.*

Proposed number of vaccinators: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Types of Vaccination services provided**

Static service only

Outreach services only

Static and outreach services

**Operating Hours for vaccination services**

Monday: \_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_

Tuesday: \_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_

Wednesday: \_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_

Thursday: \_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_

Friday: \_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_

Saturday: \_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_

Sunday: \_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_

Public Holidays: \_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_

**COVID-19 VACCINATION SITE REQUIREMENTS**

All COVID‑19 vaccination sites must be able to adhere to the following requirements:

1. **Compliance**
   1. Vaccination sites must comply with all applicable legislation including but not limited to:
      1. Pharmacy Act 53 of 1974 (Pharmacy Act);
      2. Medicines and Related Substances Act 101 of 1965 (Medicines Act);
      3. Nursing Act 33 of 2005;
      4. Health Professions Act 56 of 1974; and
      5. National Health Act 61 of 2003.
   2. Vaccination sites must also comply with the rules relating to good pharmacy practice made in terms of section 35A of the Pharmacy Act, 1974*.*
   3. Other applicable policies and guidelines provided by the National or Provincial Departments of Health.
2. **General**
   1. Vaccination sites must comply with the following general requirements.
   2. Vaccination sites must
      1. be easily accessible to clients;
      2. be arranged in such a way that social distancing can be maintained in both waiting areas and at immunisation stations;
      3. establish and implement a mechanism of setting up appointments to prevent crowding and plan immunisation sessions to minimise vaccine wastage.
   3. Vaccination sites will determine and make available the days and times that services will be provided at the site. This information must be readily available to the public or the community to the served at a vaccination site (as applicable).
   4. A list of vaccinators providing services at each site must be provided to the National Department of Health
   5. On enrolment as a vaccination site, the volume of cold storage available at the site will be provided. The cold chain storage will be determined and submitted (H x W x D) to determine the available volume (cm3))
   6. COVID-19 vaccines may not be sold, and vaccination sites may not seek reimbursement for any vaccines, syringes, needles, or other ancillary supplies that the government provides without cost to the site.
3. **Vaccine Management**
   1. In Phase I, Vaccines will be supplied based on the number of estimated recipients expected to visit the vaccination site. In Phases II and III, the Vaccination site will need to monitor uptake and demand and place appropriate orders as per instruction provided.
   2. Documentation relating to proof of delivery at the vaccination site must be signed by a person duly authorised to do so. The person receiving the stock must indicate receipt thereof and note any discrepancies found. Risk in and to the vaccines will pass to the vaccination site upon signature acknowledging receipt.
   3. Fine checking procedures must be completed upon receipt of the vaccines and any discrepancies reported to the relevant District Manager within two (2) days of receipt, failing which the vaccination site shall be deemed to have received the vaccines in the quantity, condition and description reflected in the signed receipt.
   4. Vaccines must always be managed in accordance with the applicable rules relating to good pharmacy practice and the provisions of the *National Cold Chain and Immunisation Manual 2015*. These requirements include, but are not limited to the following:
      1. Vaccination sites must store and handle COVID‑19 vaccines under proper conditions, in accordance with the requirements provided in the professional information supplied by the manufacturer, as well as any other policies and guidelines provided by the NDoH, including where applicable always maintaining cold chain conditions and chain of custody;
      2. Vaccination sites must monitor vaccine-storage-unit temperatures at all times using equipment and practices that comply with rules relating to good pharmacy practice and the *National Cold Chain and Immunisation Manual 2015*;
      3. Vaccination sites must comply with guidelines and reporting requirements for dealing with temperature excursions; as outlined in the *National Cold Chain and Immunisation Manual;*
      4. Vaccination sites must monitor expiry dates of COVID‑19 and apply the FEFO principle (First expiry/First out);
      5. All records related to COVID‑19 vaccine management must be maintained for a minimum period of five (5) years.
      6. Vaccination sites will monitor the vaccine wastage to identify any avoidable wastage and mitigate accordingly.
   5. Vaccination sites must comply with all requirements defined by the NDoH for disposing of COVID‑19 vaccine and diluent, including damaged, expired and/or unused doses.
4. **Vaccine administration**
   1. COVID-19 vaccines must be administered in accordance with the NDoH vaccine rollout framework relating to allocation and priority groups.
   2. COVID‑19 vaccines must also be administered in accordance with all requirements and guidelines of the NDoH.
   3. Each vaccination session should be planned, to ensure that enough vaccinators, vaccines, ancillary items, and waste disposal containers are available.
   4. Before administering a COVID‑19 vaccine, vaccination sites must ensure that consent is given for the COVID-19 vaccine to be administered to the recipient.
   5. Where access to COVID-19 vaccines is provided via section 21 of the Medicines Act informed consent should be ensured. (Note: provision for the recording of informed consent could be included in the Electronic Vaccination Data System (EVDS)
   6. Where necessary, provision must be made to facilitate clients receiving the appropriate second dose of the COVID-19 vaccine administered.
   7. A mechanism must be in place to trace any recipients who default from receiving the 2nd dose.
   8. Vaccination sites must report all adverse events following immunisation (AEFI) using the process defined by the NDoH.
5. **Reporting**
   1. After administering a COVID‑19 vaccine, the vaccinator must record the details of the vaccine administered on the recipient's vaccine record, plus any other information required using the appropriate reporting tools.
   2. Vaccination sites must provide stock-on-hand information to the NDoH at least once a week or as per the schedule defined by NDoH, using agreed reporting systems and in the correct format.
   3. Vaccination sites must report the number of doses of the COVID‑19 vaccine and diluents (if required) that were unused, spoiled, expired, or wasted.
   4. If EVDS cannot be used on-site, for any reason (remote areas with no internet access), a paper-based system may be used, and data captured on the EVDS system at the district level.
6. **Training**
   1. Vaccination sites must ensure that all persons delegated to administer COVID-19 vaccines are appropriately trained and competent to provide the service and are functioning within his/her scope of practice.
   2. Vaccination sites must ensure that all staff involved in the provision of COVID-19 vaccination services are appropriately trained to use the relevant reporting tools.
7. **Ancillary supplies**
   1. Vaccination sites must maintain an adequate supply of ancillary items required to provide vaccination services.
   2. Vaccination sites must procure ancillary supplies as per standard procedures or specific procedures put in place by the NDoH or the applicable province.
8. **Waste disposal and management**
   1. Injection equipment should be discarded immediately after use.
   2. Any unused vaccine or waste material should be disposed of in accordance with requirements.
   3. Injection equipment should be discarded immediately after use Vaccination sites must ensure safe disposal of used needles, syringes, and empty vials.
   4. Equipment used for vaccination, including used vials, ampoules or syringes, should be disposed of by placing them in a proper, puncture-resistant ‘sharps box’
   5. All Vials are to be defaced with an indelible black marker before being disposed of
   6. AstraZeneca/SII COVID‑19 Vaccine contains genetically modified organisms (GMOs). Sharps waste and empty vials should be placed into yellow lidded waste bins and sent for incineration; there is no need for specific designation as GMO waste.
   7. Each vaccination site will develop a waste disposal plan, which includes the name of the contracted waste disposal company, number of waste disposal containers available, number of red/yellow disposal bags available/ proof of regular waste disposal e.g., last destruction certificate
   8. How the waste disposal will be adapted to incorporate an increase in vaccination waste, which will include, empty/ opened vials, diluent, needles/syringes, and PPE

**MINIMUM REQUIREMENTS**

This guidance checklist will prepare the vaccination site to implement the required steps to providing the vaccine safely and efficiently.

**General**

* Vaccination sites are clean, and the area is not directly exposed to sunlight, rain, or dust.
* The vaccination site is well ventilated, and all fixed sites should be temperature controlled.
* Vaccination sites have space where clients can sit before being vaccinated.
* Vaccination sites have spaces for registration, screening, vaccinating, and recording.
* Vaccination sites require all necessary equipment and furniture to provide the vaccination services including desks, tables, and chairs.
* Vaccination sites must have appropriate waste disposal systems.

**Reporting Systems**

* Vaccination sites must have a computer or other device to report vaccination data using the EVDS.
* The computer or other device used for EVDS reporting must have appropriate connectivity to submit data.
* The vaccination site must provide stock-on-hand information to the National Department of Health as per the defined schedule and agreed reporting systems.
* It is recommended that the vaccination site make use of 1D and 2D Barcode scanners as far as possible for scanning barcodes and QR codes located on (Medical Vials, Green Barcoded ID Book, Drivers Licence, Smart-ID and Passports etc) this will assist in accurate data collection into the EVDS System.

**Vaccine storage**

* Vaccination sites must have appropriate and sufficient cold chain storage capacity to comply with the manufacturers' vaccine storage requirements and to accommodate the volume of vaccine required to be stored at the Vaccination site.
* Vaccination sites must have WHO PQS continuous temperature monitoring and logging devices to monitor the vaccines' storage temperature, which displays alarms, min/max temperatures, and a log of temperature readings.
* Vaccination sites must have alternative power sources to maintain the cold storage conditions in a power failure event.
* Vaccination sites will have a contingency plan which includes alternative storage locations if the cold storage unit fails, transport to such a facility, suitable passive containers to transport the vaccine to the specified site.

**Vaccine redistribution**

* Vaccination sites required to redistribute vaccines to another site must have a documented process, that complies with *National Cold Chain Manual*, to perform this activity.
* For redistribution purposes, the Vaccination site must have appropriate validated packaging that will maintain the temperature of vaccines during redistribution at the temperature indicated by the manufacturer.
* For redistribution purposes, the vaccination site will ensure each active/passive container will have a WHO PQS continuous temperature monitoring device during distribution/ storage of the vaccine

**Inventory management**

* Vaccination sites must have an inventory management system, including bin cards or electronic stock management systems to manage vaccines and ancillary supplies.

*Number of doses required = session size (target population) x wastage factor (15% = 1.11)*

*Number of vials required = number of doses required / number of doses per vial (e.g.,10 doses)*

**Ancillary supplies**

Ancillary supplies may vary depending on the type of COVID-19 vaccine. Vaccination sites must maintain an adequate supply of the following ancillary supplies:

* Syringes for vaccination: 1ml or 2ml (1 syringe per dose)
* Needles suitable for intramuscular vaccination: 22-25G and 25mm-38mm (1 needle per dose)
* Syringes for reconstitution - 5ml ***(if required)*** (1 per vial)
* Needles for reconstitution- 21G ***(if required)*** (1 per vial supplied)
* Diluent for reconstitution ***(if required and if not provided by the manufacturer)*** (1 per vial supplied)
* Cotton wool balls (1 per number of vaccine recipients)
* A safety box for disposal of used syringes and needles (1 per 100 doses supplied)
* Hydrogen Peroxide disinfectant\*
* PPE as outlined in infection control guidelines

*\*Vaccine spills should be disinfected with an appropriate antiviral disinfectant (e.g. Hydrogen peroxide based disinfectants).*

**Other supplies**

* Case reporting form (CRF) for reporting AEFI
* Case investigation form (CIF) for investigating serious AEFI
* Case investigation forms for adverse events of special interest (AESI)
* Stock cards/bins cards (if not using an electronic stock management system)
* Vaccination cards
* Tally sheets or relevant recording form/tool
* Fact sheets
* Posters
* Job aids

**Emergency supplies**

* Adrenalin Injection (1:1000) solution – 2 ampoules
* Hydrocortisone injection (100 mg) -1 vial
* Syringes
* Needles
* IV fluids, (Ringer- Lactate solution or normal saline) with drip set
* AEFI reporting form

**Security**

* Vaccine holding sites, rooms must be kept secure at all times
* Storage sites, rooms must be kept locked when not occupied
* All paperwork relating to the administration of the vaccine must be kept in a lockable area whilst not in use
* Only authorised personnel may have the keys to the vaccine storage location
* Access control to Storage areas must be monitored and registers of people accessing the area must be kept.
* Security protocols are in place to manage clinic attendees, ensure the safety of Vaccinator staff

**DECLARATION**

I hereby declare that the vaccination site complies with the requirements stated in this document, including all relevant legislation and the rules relating to Good Pharmacy Practice.

I acknowledge that representatives of the District or Provincial Departments of Health may inspect the vaccination site from time to time to confirm compliance.