



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Standard Operating Procedure for the identification, application for, and approval of COVID-19 vaccination sites

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List of Abbreviations

COVID-19	Coronavirus Disease 2019
EML	Essential Medicines List
EVDS	Electronic Vaccination Data System
MFL	Master Facility List
NDoH	National Department of Health (NDOH)
SAPC	South African Pharmacy Council
SOP	Standard Operating Procedure
SVS	Stock Visibility System
WHO	World Health Organisation

Definitions

Term	Definition
COVID-19 vaccination services	The administration of COVID-19 vaccines to eligible populations.
Delivery site	A place to which COVID-19 vaccines are delivered by the distributor contracted by the National Department of Health. A delivery site could be a primary distribution site, a primary vaccination site or a fixed outreach service.
Distribution services	The storage and/or distribution of COVID-19 vaccines, diluents, and ancillary items related to the administration of COVID-19 vaccines.
Electronic Vaccination Data System (EVDS)	An electronic system used to capture each vaccination event and provide data to its data analytics platform to monitor and report on vaccinations administered. The EVDS records the journey of the vaccinee who will receive the vaccine from a vaccinator registered on the EVDS at an approved vaccination site registered on the Master Facility List (MFL).
Fixed outreach service	A place, where vaccination services are provided on a semi-permanent basis that is not a health establishment - but which is linked to a health establishment. Fixed outreach services may store COVID-19 vaccines and other medicines required to support the administration of COVID-19 vaccines on-site, in accordance with applicable legislation.
Health care provider (professional)	A person providing health services in terms of any law, including in terms of the Allied Health Professions Act 63 of 1982, the Health Professions Act 56 of 1974, the Nursing Act 50 of 1978, the Pharmacy Act 53 of 1974, and the Dental Technicians Act 19 of 1979 ¹
Health establishment	The whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative, or other health services ² .
Master Facility List	A complete list of all health establishments in the country, both public and private, that comprises a set of administrative identifying information for each facility (signature domain) and basic information on the service capacity of each facility (service domain).
Mobile outreach service	A vaccination service linked to a health establishment that may provide vaccination services, known as a primary vaccination site, where vaccines are administered to clients by a team of vaccinators moving from place to place. Passive cold-chain containers are used and vaccines are not stored overnight.

¹ South African National Department of Health. National Health Act 61 of 2003

² South African National Department of Health. National Health Act 61 of 2003

Term	Definition
Pharmacy	Any place wherein or from which any service specially pertaining to the scope of practice of a pharmacist is provided ³ .
Primary distribution site	A depot, sub-depot, wholesale pharmacy, or distributor that stores and distributes vaccines to vaccination sites and does not provide vaccination services to clients.
Primary vaccination site	A place at a health establishment where COVID-19 vaccination services may be provided.
Outreach services	A vaccination service linked a health establishment. Outreach services may be provided as a <u>fixed outreach</u> service with cold chain storage (CCS), a <u>temporary outreach</u> service with passive cold chain (PCC), or by a <u>mobile</u> outreach service at multiple points.
Responsible pharmacist	A natural person who is a pharmacist and who shall be responsible to the council for complying with all the provisions of this Act (Pharmacy Act) and other legislation applicable to services which specially pertain to the scope of practice of a pharmacist, and the legislation applicable to the pharmacy which is under his or her personal supervision ⁴ .
Temporary outreach service	A place where vaccination services are provided on a temporary basis and linked to a primary vaccination site. Passive cold-chain containers are used and vaccines are not stored on-site.
Vaccination site	A place where COVID-19 vaccination services may be provided to eligible populations and may include a primary vaccination site or a place where outreach services (fixed, temporary or mobile) are provided.
Vaccinator	A designated health care provider trained, competent, and acting within their scope of practice who administers a COVID-19 vaccine to a client.
Vaccinee	A person who is vaccinated with a COVID-19 vaccine.
Vaccines	Biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer's recommendations.

³ South African National Department of Health. Pharmacy Act 53 of 1974

⁴ South African National Department of Health. Pharmacy Act 53 of 1974

Contents

List of Abbreviations	i
Definitions.....	ii
Contents.....	iv
1. Introduction	1
1.1. Purpose	1
1.2. Scope.....	1
2. Background	2
3. Legislative provisions	2
4. Vaccination site types	4
5. Application Process for Section 22A(15) permit.....	13
6. Conditions of the Section 22A(15) permit	17
7. Validity and withdrawal of the permit.....	17
8. Roles and responsibilities relating to the issuing of Section 22A(15) permits.....	18

1. Introduction

1.1. Purpose

The National Department of Health (NDoH) identified the need to put in place a mechanism for the identification, application for, and approval of vaccination sites for the national rollout of COVID-19 vaccines, to facilitate compliance with legislation dealing with the control of medicines and provide a mechanism to formalise the approval of vaccination sites, the compliance of such sites with the applicable policies and guidelines and enable oversight thereof. The provisions of section 22A(15) of the Medicines and Related Substances Act 101 of 1965 (the Medicines Act) are used to authorise vaccination sites. Section 22A(15) enables the Director General (DG) of the NDoH to issue a permit to any organisation performing a health service to acquire, possess, use or supply any specified schedule 1 to 5 substance subject to conditions determined by the DG. The permits are issued with conditions relating to compliance with the requirements for a vaccination site as determined by the NDoH, and the utilisation of trained and competent vaccinators.

The NDoH worked with the South African Pharmacy Council (SAPC) to utilise existing platforms to allow facilities that wish to apply for consideration and approval of organisations that wish to take part in the national vaccination rollout. The application process is online, using the online platforms of the NDoH's Master Facility List (MFL) web-application and the permit application system hosted by the SAPC. Health establishments (also called health facilities) register on the MFL and are listed on the Electronic Vaccination Data System (EVDS), for monitoring vaccine uptake and coverage, prioritization, planning, safety monitoring, and vaccine effectiveness studies. The EVDS supports the collection and provision of the following information:

- Patient information (including demographics, number of doses, etc.);
- Vaccination site where the vaccination service is accessible (name and type, e.g. primary vaccination site, outreach services (fixed, temporary or mobile));
- Vaccine administered (manufacturer, batch number, etc.);
- A record of vaccinations administered, including the details of the vaccinator who administered a vaccine to a client.

The purpose of this document is to outline the principles, processes and procedures for registration on MFL; and evaluation, approval, and issuing of permits to health establishments that will be COVID-19 vaccination sites, using the provisions of section 22A(15) of the Medicines Act.

1.2. Scope

This document covers the application, evaluation, and approval process (including systems to be used) to be followed by health establishments that wish to provide COVID-19 vaccination services. The document also covers aspects relating to the responsibilities of the NDoH and the SAPC in the approval of COVID-19 vaccination site permits.

2. Background

In December 2019, an outbreak of a respiratory disease associated with a novel coronavirus was reported in the city of Wuhan in the Hubei province of the People's Republic of China. The virus has spread worldwide and on 11 March 2020, the World Health Organisation (WHO) declared COVID-19 a pandemic.

On 5 March 2020, Honourable Minister of Health Dr. Zwelini Mkhize confirmed South Africa's first positive case of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, with the first COVID-19 related death being reported on 27 March 2020. On 15 March 2020, the South African President, Mr. Cyril Ramaphosa, declared a National State of Disaster and implemented measures to prepare the health care system to rapidly scale up capacity to test and treat for an influx of cases and curb the transmission of COVID-19. These measures included a risk-adjusted strategy, travel restrictions, and the closure of schools. The introduction of the COVID-19 vaccination programme is a significant public health milestone for South Africa and is expected to contribute to reducing the spread of COVID-19 and restoring South Africa's social and economic activities.

There is a need to vaccinate a large number of people as quickly as possible at multiple sites, and using a variety of health care providers who can perform vaccinations competently and deal with adverse reactions (including anaphylaxis using appropriate medicines). To vaccinate a large number of people, a mechanism was needed so that a prescription was not needed for each client receiving a COVID-19 vaccination, and broaden the categories of health care providers who can administer these vaccines. Furthermore, vaccination sites must be responsible and accountable for what happens at the site with adequate oversight and monitoring by the NDoH, provincial departments of health, and other competent bodies. Such sites must operate in accordance with applicable legislative provisions, comply with minimum requirements for vaccination sites as provided by NDoH and COVID-19 related protocols, as well as with the necessary oversight of health care providers. There must thus be a mechanism for authorising vaccination sites, as well as a way of withdrawing such authorisation (where necessary).

3. Legislative provisions

Health establishments that wish to provide vaccination services must operate in accordance with applicable legislative provisions, comply with minimum requirements for vaccination sites as provided by NDoH, as well as COVID-19 related protocols. Below are the legislative provisions for medicines to be supplied, prescribed, dispensed, and administered by organisations and/or persons and the mechanism that will be used to enable organisations to provide COVID-19 vaccination services.

- 3.1 Section 22A(5)(f) of the Medicines Act provides that any schedule 2-6 medicines shall not be sold by any person other than
- i. a pharmacist and pharmacy personnel (there must be a prescription for medicines that fall into schedule 3 or higher);
 - ii. a manufacturer or wholesale dealer in pharmaceutical products;
 - iii. a medical practitioner who may prescribe; or
 - iv. a nurse or person registered under the Health Professions Act who may only prescribe scheduled substances identified in the schedule for that purpose. (This mechanism has been used to enable certain professional groups such as optometrists and emergency personnel to supply certain medicines listed in the applicable schedule without a prescription).

- 3.2 Section 22A(14)(b) of the Medicines Act provides that:

“No nurse or person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist may prescribe a medicine or Scheduled substance unless he or she has been authorised to do so by his or her professional council concerned”.

- 3.3 The only concession that currently allows nurses to prescribe, supply, and administer medicines without a prescription is provided in section 56(6) of the Nursing Act which provides that:

“Despite the provisions of this Act, the said Medicines and Related Substances Act, 1965, the Pharmacy Act, 1974 (Act 53 of 1974), and the Health Professions Act, 1974 (Act 56 of 1974), a nurse who is in the service of -

(a) the national department;

(b) a provincial department of health;

(c) a municipality; or

(d) an organisation performing any health service designated by the Director-General after consultation with the South African Pharmacy Council referred to in section 2 of the Pharmacy Act, 1974, and who has been authorised by the Director-General, the head of such provincial department of health, the medical officer of health of such municipality or the medical practitioner in charge of such organisation, as the case may be, may in the course of such service perform with reference to—

(i) the physical examination of any person;

(ii) the diagnosing of any physical defect, illness, or deficiency in any person; or

(iii) the keeping of prescribed medicines and their supply, administering or prescribing on the prescribed conditions,

*any act which the said Director-General, head of provincial department of health, medical officer of health or medical practitioner, as the case may be, may, **after consultation with the Council, determine in general or in a particular case or cases of a particular nature, if the services of a medical practitioner or pharmacist, as the circumstances may require, are not available.”***

This mechanism has been used to authorise nurses practising in the public sector (mainly at primary health care level) and some nurses providing services in occupational health and travel clinics to diagnose, prescribe and supply medicines.

3.4 Section 22A(15) of the Medicines Act provides that:

“Notwithstanding anything to the contrary contained in this section, the Director-General may, after consultation with the South African Pharmacy Council as referred to in section 2 of the Pharmacy Act, 1974 (Act 53 of 1974), issue a permit to any person or organisation performing a health service, authorising such person or organisation to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance, and such permit shall be subject to such conditions as the Director-General may determine”.

This legislative provision is currently used to enable the provision of services by nurses, for example - Routine Immunisation as per the Essential Medicine List (EML) (Well Baby Clinic), Home Based Care (minor ailments), and Haemodialysis as well as Primary Care Drug Therapy (for pharmacists holding a supplementary qualification).

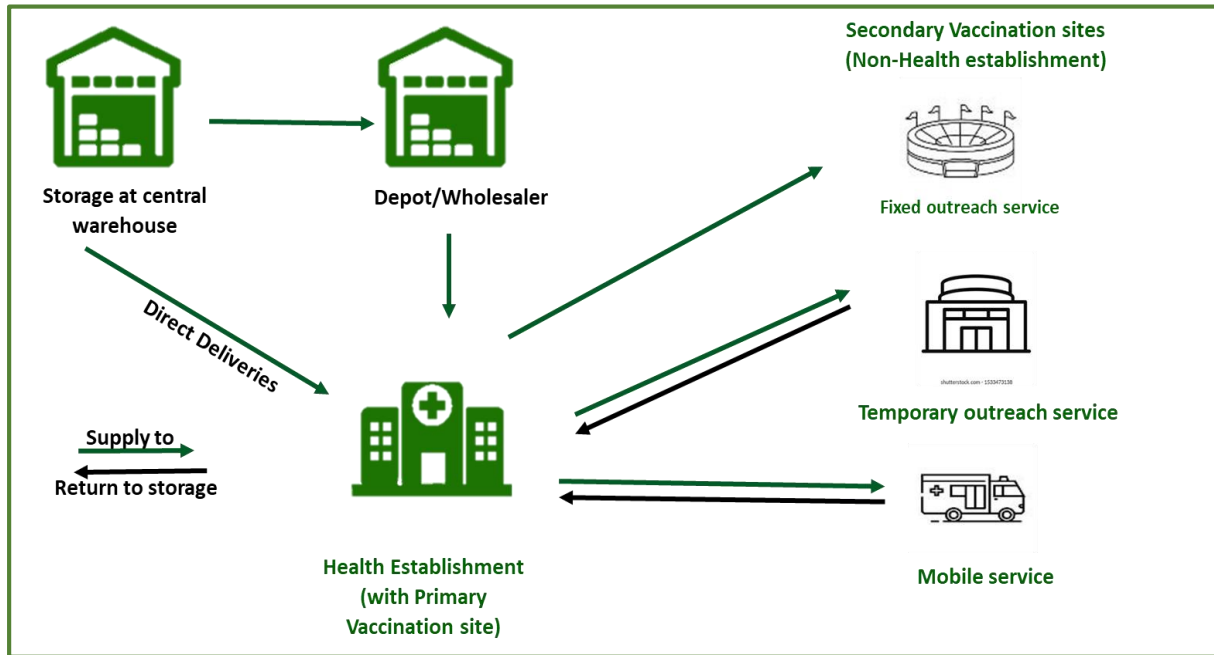
3.5 Section 22A(15) of the Medicines Act is being used to authorise organisations providing vaccination services to acquire, possess, use and supply the medicines needed and will cover all related activities including the receipt, storage, maintenance of the cold chain, administration of vaccines, record keeping, etc. (not just the pharmacy-related activities). The permit authorises the provision of services both at the primary vaccination site and/or from the primary site (where applicable).

3.6 This approach obviates the need for vaccinators to be authorised prescribers in terms of the Medicines Act, as well as being a mechanism of formalising the approval of vaccination sites. The entity holding the permit is responsible for the provision of vaccination services, including the appointment and management of vaccinators and other key health care personnel.

4. Vaccination site types

Vaccination site selection is based on population needs, geospatial planning and cold chain capacity across the private and public sectors as determined by COVID-19 vaccine programme coordinators. The different types of vaccination sites – primary vaccination sites, fixed outreach services, temporary outreach services and mobile services - are provided in Figure 1 below.

Figure 1: Vaccination site typology



The following general principles apply:

- 4.1 The provisions of section 22A(15) of the Medicines Act are used to approve health establishments, that wish to provide vaccination services for the administration of COVID-19 vaccines.
- 4.2 All health establishments that wish to provide COVID-19 vaccination services either at, or from a primary vaccination site or as a fixed outreach service must submit an application (Annexure 1) to the Director-General: Health for a permit issued in terms of section 22A(15) of the Medicines Act following the process described in this document. If a fixed outreach service will be provided from a health establishment, a separate application for a permit for the fixed outreach service must be submitted.
- 4.3 Health establishments that require a section 22A(15) permit include but are not limited to hospitals (public, private, military and mine hospitals), community health centres, primary health care clinics, community pharmacies, medical or nursing practices, medical centres (group practices), occupational health clinics, travel and other clinics authorised in terms of section 56(6) of the Nursing Act, and health establishments operated by other government departments and non-governmental organisations. (Note: In the case of health establishments with an institutional pharmacy, the permit is issued to the health establishment not to the institutional pharmacy).
- 4.4 It is the responsibility of the permit holder to ensure that the vaccinators providing vaccination services are trained, competent, and acting within their scope of practice, to provide vaccination services.
- 4.5 Permits are issued with specific conditions. (see Annexure 2 for an example of a permit) It is the responsibility of the permit holder to comply with the conditions of the permit.
- 4.6 Permit holders may only acquire, possess, use and supply the vaccines and related medicines recommended by the NDoH as part of COVID-19 vaccination services.

- 4.7 All vaccination sites at which COVID-19 vaccines are stored overnight are required to report on the NDoH Stock Visibility System (SVS). This principle also applies in cases where vaccines are only stored at a site from time to time.

Primary vaccination sites

- 4.8 A permit may be issued to a health establishment to provide vaccination services. The following principles apply:
- 4.8.1 Primary vaccination sites may provide outreach services as a fixed outreach service, temporary outreach or mobile outreach service.
- 4.8.2 Vaccination services may also be provided from a primary vaccination site at another health establishment as a temporary or mobile service. This situation would apply for example, where a temporary outreach service is provided at a small health establishment e.g a clinic or general practitioner's practice, which does not have suitable cold chain capacity to store vaccines on-site or where the target population is small.
- 4.8.3 In some cases, a primary vaccination site that holds a permit may not provide vaccination services on-site [*vaccination services are activated on the MFL*] but will support temporary or mobile services operating from the primary vaccination site. In these primary vaccination sites the scheduling function on EVDS should be disabled, to prevent a virtual queue or scheduling of clients to the primary vaccination site
- 4.8.4 A primary vaccination site may operate as a delivery site.
- 4.8.5 Distribution services may be provided from a primary vaccination site [*distribution services must be activated on the MFL*] to another primary vaccination site and/or to an outreach service.

Fixed outreach services

- 4.9 A permit may be issued to a health establishment to provide vaccination services at a site which is not a health establishment (a non-medical site). The following principles apply:
- 4.9.1 The permit is issued to the health establishment to provide vaccination services at a non-medical site e.g Hospital X/Stadium Y. The health establishment must hold a separate permit for each non-medical site at which fixed outreach services will be provided.
- 4.9.2 The permit holder is responsible to ensure that the necessary professional support and oversight, including access to emergency services is available.
- 4.9.3 If the site where a fixed outreach service will be provided is not a health establishment, the facility must be registered on the MFL as a non-medical site. In cases where the fixed outreach service is coordinated by a provincial Department of Health (DOH), e.g. a public sector mass vaccination site e.g. at a Civic Centre, the site should be registered as a non-medical site and the semi-permanent data thereof managed by the provincial DOH.
- 4.9.4 In the case of large venues fixed outreach services may be provided at different locations within the same venue (e.g Hall A, Hall C etc.) by different health establishments/service providers, with a separate permit is required for each one.

- 4.9.5 Where vaccines and other medicines are stored at a site which is a non-medical site (fixed outreach service), oversight must be provided by a pharmacy registered with the SAPC with a responsible pharmacist registered as such.
- 4.9.6 Only COVID-19 vaccines and the medicines needed to manage any adverse events which may occur at the site, may be stored at a fixed outreach service. Such storage must be done in accordance with the provisions of Rule 1.8 of the Rules relating to good pharmacy practice published in terms of section 35A of the Pharmacy Act 53 of 1974 (Minimum Standards specifically relating to a storage area for pharmaceuticals outside the physical premises of a pharmacy).
- 4.9.7 In terms of Rule 1.8.1 'Any storage area, which is not physically an integral part of the premises of a pharmacy, must constitute part of a pharmacy licensed by the Department of Health and recorded with Council (SAPC). Such a storage area must fall under the authority of the responsible pharmacist of the pharmacy of which it forms a part, and be operated in compliance with Good Pharmacy Practice. Thus, such a storage area cannot exist/operate independently of a pharmacy'.
- 4.9.8 The responsible pharmacist of a pharmacy that provides oversight of an off-site (external) storage area at a fixed outreach service, must submit an application for an internal change to the licence of that pharmacy for each external storage area (*Application for the approval of pharmacy premises – internal changes in terms of the Pharmacy Act 53 of 1974*). (Annexure 3).
- 4.9.9 The number of external storage areas that may be supervised by a pharmacy and the supervision thereof is determined by the SAPC. The SAPC has resolved that:
- a pharmacy may supervise up to five external storage areas at fixed outreach services;
 - each external storage area must be under the control of a pharmacist;
 - each storage area must be located within a reasonable geographic location of the pharmacy providing oversight and be within the same province;
 - approval will be granted for external storage areas at fixed outreach sites for a period not exceeding nine months.
- 4.9.10 A fixed outreach service may **not** provide temporary or mobile outreach services.
- 4.9.11 A fixed outreach service may operate as a delivery site.
- 4.9.12 Distribution services may not be provided from a fixed outreach site, but since vaccines are stored overnight, the distribution services on the MFL must be activated and the site should report as required on SVS.

Temporary and mobile outreach services

- 4.10 Temporary outreach services and mobile outreach service which are managed from a primary vaccination site are not required to hold their own permit, but operate under the permit issued to the primary site from which they operate. [*Temporary and mobile outreach sites (child) are linked to the primary vaccination site (parent) as an outreach service on the MFL*].
- 4.11 Distribution services may not be provided from a temporary outreach service or by a mobile team.
- 4.12 Although some mobile units are listed on the MFL as health establishments, these units will not store COVID-19 vaccines overnight and are linked to a primary vaccination site as a mobile

outreach service. *[These mobile units must be linked to the primary vaccination site (parent) as a mobile outreach service (child) on the MFL]*

Distribution services

- 4.13 Primary vaccination sites where vaccines are stored, or from which they may be distributed must be indicated on the MFL as a distribution site.
- 4.14 Community and institutional (public and private) pharmacies may provide distribution services. If such pharmacies do not provide vaccination services or support any outreach services, they do not require a section 22A(15) permit.
- 4.15 Pharmacies that hold a licence issued in terms of section 22C(1)(b) of the Medicines Act (manufacturing and wholesale pharmacies) may provide distribution services, but do not require a section 22A(15) permit. These pharmacies may not provide vaccination services or support any outreach services.
- 4.16 Employees of an organisation providing distribution services who do not hold a section 22A(15) permit may, however, be vaccinated on site as part of a workplace based vaccination programme, by a provider, who holds a section 22A(15) permit.

Refer Table 1-4 below for a summary of the different types of vaccination sites.

Table 1: Primary vaccination site

1	Primary Vaccination site		
Definition	Primary vaccination site means a place at a health establishment where vaccination services may be provided (Requires a section 22A(15) permit) (Refer also Section 4.8 above)		
Registration and permit requirements	<ul style="list-style-type: none"> • Registered on MFL as a facility (vaccination services and distribution services [if applicable] are activated under services at facility) • Listed on EVDS and SVS • Holder of a section 22A(15) permit issued by the Director General (DG) of Health in terms of the Medicines Act 		
Ownership	Public or private	Management	Management of that health establishment
Services	<ul style="list-style-type: none"> • Vaccination services (activate on the MFL) • Vaccines stored overnight at the health establishment • If provide distribution services or store vaccines overnight (activate on the MFL) • Act as a hub ('parent') to support outreach services (fixed, outreach and mobile) + health establishments that do not have capacity to store vaccines overnight 		
Example	<p>Public Sector - Hospitals, community health centres, primary health care clinics, health establishments linked to the Departments of Correctional Services, National Defence and Education</p> <p>Private sector - Private hospitals, community pharmacies, medical/nursing practices, medical centres, permanent occupational health clinics and travel clinics (operating in terms of section 56(6) of the Nursing Act), immunisation clinics, mine hospitals</p>		
Human Resources for vaccine management	<p>Vaccine champion means a person who is designated to manage the vaccine supply chain at a place where vaccines are administered. Such person may be a pharmacist, pharmacist's assistant or nurse and may also function as the vaccination site manager, or as a vaccinator.</p> <p>Vaccine controller means a pharmacist, pharmacist's assistant or other health professional designated to manage the storage and supply of vaccines, the distribution of vaccines to primary vaccination sites, fixed outreach services and/or the supply of vaccines to temporary and mobile outreach services (where applicable) and the updating of data on SVS.</p>		

Table 2: Fixed Outreach Services

2	Fixed Outreach service		
Definition	A place, where vaccination services are provided on a semi-permanent basis that is not a health establishment - but which is linked to a health establishment or organisation providing health services. Fixed outreach services may store COVID-19 vaccines and other medicines required to support the administration of COVID-19 vaccines on-site, in accordance with applicable legislation. (Refer also 4.9 above)		
Registration and permit requirements	<ul style="list-style-type: none"> • Registered as a facility on the MFL (Type: non-medical site and vaccination service activated under facility services) • Vaccination services (activate on the MFL) • Store vaccines overnight (activate distribution services on MFL) • Linked as a fixed outreach service to a health establishment on MFL • As stores vaccines, oversight must be provided by a registered pharmacy (pharmacy which has applied for and received approval for an internal change to enable external (off-site) storage at the fixed outreach service) • Listed on EVDS and SVS • Holder of a section 22A(15) permit for each site issued by the DG: Health in terms of the Medicines Act 		
Ownership	Public or private or NGO	Management	Health establishment which operates the site and holds the section 22A(15) permit Pharmacy oversees external storage Site management team
Services	<ul style="list-style-type: none"> • Provides vaccination services (with EVDS scheduling of appointments) • Has cold chain storage capacity • Does not distribute vaccines 		
Example	Any non- health site where vaccines are stored overnight (e.g. mass vaccination site at a private sector venue)		
Human Resources for vaccine management	<p>Vaccine champion means a person who is designated to manage the vaccine supply chain at a place where vaccines are administered. Such person may be a pharmacist, pharmacist’s assistant or nurse and may also function as the vaccination site manager, or as a vaccinator.</p> <p>Vaccine controller means a pharmacist, pharmacist’s assistant or other health professional designated to manage the storage and supply of vaccines, the distribution of vaccines to primary vaccination sites, fixed outreach sites and/or the supply of vaccines to temporary and mobile outreach services (where applicable) and the updating of data on SVS.</p>		

Table 3: Temporary outreach service

3	Temporary Outreach Service		
Definition	Temporary outreach service means a place which is not a health establishment where vaccination services are provided on a temporary basis and this service is linked to a primary vaccination site. Passive cold chain containers are used, and vaccines are not stored on-site. (Does not require a section 22A(15) permit). This service can be rendered by roving teams from the health establishment with a vaccination service at the specific outreach point e.g. at an old age home or community hall. (Refer also 4.10 - 4.12 above)		
Registration and permit requirements	<ul style="list-style-type: none"> • Registered as a facility on the MFL • Linked as a temporary outreach service by a health establishment (primary vaccination site) on MFL • Vaccination services NOT active on MFL • Distribution services NOT active on MFL • Listed on EVDS • Not listed on SVS • No individual permit required; operates in terms of 22A(15) permit issued to health establishment 		
Ownership	Public or private or NGO	Management	Management of the primary vaccination site
Services	<ul style="list-style-type: none"> • Vaccination services provided – EVDS scheduling appointments • Cannot store vaccines overnight • Uses passive cold chain containers (cooler boxes) • Does not distribute vaccines 		
Example	Churches, schools, halls, civic buildings, non-permanent OHS at places of work, congregate settings such as care homes, facilities for older persons		
Human Resources for vaccine management	Vaccine champion means a person who is designated to manage the vaccine supply chain at a place where vaccines are administered. Such person may be a pharmacist, pharmacist’s assistant or nurse and may also function as the vaccination site manager, or as a vaccinator.		

Table 4: Mobile outreach Service

4	Mobile Outreach service		
Definition	Mobile outreach service means a vaccination service linked to a primary vaccination site where vaccines are administered to clients by a team of vaccinators moving from place to place and from within a mobile clinic. Passive cold chain containers are used, and vaccines are not stored overnight. (Does not require a section 22A(15) permit) (Refer also 4.10 -4.12 above)		
Registration and permit requirements	<ul style="list-style-type: none"> • Registered as a facility on the MFL • Linked as a mobile outreach service by a health establishment (primary vaccination site) on MFL • Vaccination services NOT active on MFL • Distribution services NOT active on MFL • Listed on EVDS (no scheduling) • Not listed on SVS • No individual permit required; operates in terms of 22A(15) permit issued to ‘mother’ health establishment 		
Ownership	Public or private	Management	Management of the primary vaccination site
Services	<ul style="list-style-type: none"> • Vaccination services provided – No appointments • Moves from place to place • Cannot store vaccines overnight • Uses passive cold chain containers • Does not distribute vaccines 		
Example	Mobile teams of vaccinators moving from place to place		
Human Resources for vaccine management	Vaccine champion means a person who is designated to manage the vaccine supply chain at a place where vaccines are administered. Such person may be a pharmacist, pharmacist’s assistant or nurse and may also function as the vaccination site manager, or as a vaccinator.		

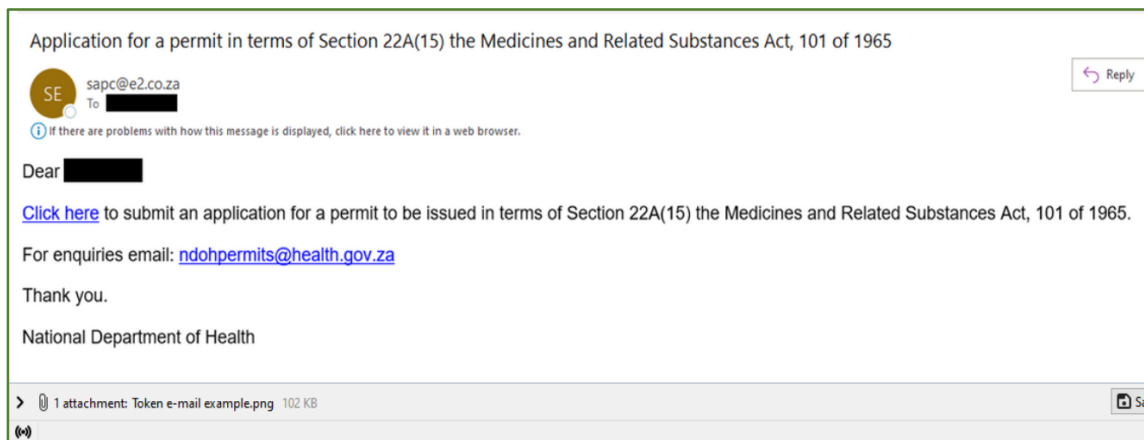
5. Application Process for Section 22A(15) permit

- 5.1 All health establishments that wish to provide COVID-19 vaccination services either at, or from a **primary vaccination site, or as a fixed outreach service** must apply to the Director-General: Health for a permit issued in terms of section 22A(15) of the Medicines Act following the process described in this document. **Note: Temporary and mobile outreach services do not require a section 22A(15) permit and must be linked to a primary vaccination site with a valid permit.**
- 5.2 A **health establishment** wishing to provide vaccination services must register on the MFL.
- 5.3 To add a new or edit an existing facility on the MFL web-application see below
- 5.3.1 **New facilities**
- 5.3.1.1 Identify a facility representative that will be responsible to add or edit semi-permanent data on the MFL web-application
- 5.3.1.2 The facility representative should register on the MFL (<https://mfl.csir.co.za/>)
- 5.3.1.3 It is important that the facility representative searches the MFL web application to ensure that the facility does not already exist before adding a new facility following the required steps so there are not duplicates (Refer Facility Representative user manual for detail).
- 5.3.1.4 For all pharmacies (as registered/recorded by SAPC) please note:
- *There is no need for pharmacies to register on the MFL since the SAPC has provided a list of curated pharmacies with active responsible pharmacists and their contact details based on the records maintained by the SAPC in terms of the Pharmacy Act 53 of 1974;*
 - *Details relating to pharmacies and responsible pharmacists e.g. pharmacy name, pharmacy address etc must not be changed on the MFL, without first updating these details with the SAPC as this information will be pulled through from the SAPC records;*
 - *If any details (pharmacy name/address) as captured on the MFL is incorrect, the applicant must submit an application to SAPC to approve the changes required.*
 - *After approval from SAPC the details (pharmacy name/address) must be updated on the MFL, by the facility representative*
- 5.3.2 **Existing Facilities**
- 5.3.2.1 For **existing facilities** verify the semi-permanent data for the facility. The contact details including contact number and email address of the facility manager must be complete and accurate. This detail is very important for communication with the facility by the various role-players.
- 5.3.2.2 In the case of a fixed outreach service, the site where vaccination services will be provided must register on the MFL as a non-health site.
- 5.4 Health establishments that are willing to offer vaccination services should ensure that the COVID-19 primary vaccination site is activated on the MFL as a service.
- 5.5 Primary vaccination sites (hub) must link the temporary outreach services - e.g. churches, civic buildings, old age facilities - and mobile outreach services – e.g. mobile teams (spokes) that will be provided from the primary vaccination site. Note temporary and mobile services do not

require a section 22A(15) permit. Any fixed outreach service must also be linked to the primary vaccination site. A separate permit is required for a fixed outreach site. Please use the attached template to plan your service delivery model and obtain approval from the Head of Department of Health or designated person. **(Annexure 1 WC template -)**.

- 5.6 Each facility grouping will have a defined semi-permanent data curation process. Curation refers to the review and confirmation that the provided semi-permanent data is correct, as well as confirmation that the identified facility is compliant with the guidelines to render a vaccination service. Examples of facility groupings are: public health establishments are curated by provincial Department of Health designated curators, Correctional Services facilities are curated by Department of Correctional Services designated curators, while community pharmacies are curated by SAPC designated curators. It must be noted that curators may change from time to time. (Refer also Table 6 below).
- 5.7 Once curated and approved the application for a section 22A(15) permit on the SAPC system will be triggered. Thus facilities that activated a primary vaccination site or fixed outreach service on the MFL will receive a token (link) via email from the permit system hosted by the SAPC addressed to the email address provided on the MFL for the facility manager or person to whom this function has been delegated by the facility manager to apply for a section 22A(15) permit.

Example of the email, the facility manager will receive. NOTE: The topic of the email is **Application for a permit in terms of section 22A(15) Medicines and Related Substances Act 101 of 1965**



- 5.8 The facility manager or a person delegated by him or her must complete the online application form (token) accessed via the link provided by the permit system hosted on the SAPC website.
- 5.9 The SAPC will make a recommendation to the NDoH official authorised by the Director-General in terms of section 34A of the Medicines Act to issue permits in terms of section 22A(15).
- 5.10 A certificate confirming approval of the COVID-19 Vaccination Site will be available for the applicant to download and print from the online system. A copy of the certificate template with the conditions applicable to the permit is attached as **Annexure 2 (example of the permit)**. If rejected the applicant will be informed accordingly. The applicant will receive a response from the NDoH, on the email address provided, why the application has been rejected, and if recourse is required.

- 5.11 Sites planned to be used in the provision of COVID-19 vaccination services should ensure that the MFL registration and vaccine site activation process, stipulated above, has been completed and the site is in possession of a section 22A(15) permit. Vaccination site selection will, however, be based on population needs and geospatial planning across the private and public sectors as determined by COVID-19 programme coordinators.

The outcome of the permit application process will be included in the semi-permanent data for the registered facility on the MFL.

NOTE

- Support for the section 22A(15) permit process is available at ndohpermits@health.gov.za
- Support on MFL related matters available is from hissupport@health.gov.za

It must be noted that the following statuses relating to permits may reflect on the MFL: Specific business rules determine the permit status on the MFL as described in [Annexure 3 \(Permit status business rules\)](#)

DEFINITIONS AND SYSTEM STATUS

Application token lapsed means that the token sent to enable the facility representative to apply for a permit issued in terms of section 22A(15) of the Medicines and Related Substances Act 101 of 1965 has not been completed within 90 days and is no longer valid. Note: The token may be resent if requested. *(System status: Application token lapsed on MFL)*

Application token withdrawn means that the token sent to enable the facility representative to apply for a permit issued in terms of section 22A(15) of the Medicines Act is withdrawn as the person/organisation is not eligible in terms of the site typology (e.g. a mobile clinic) to apply for, and/or hold such permit. *(System status: Application token withdrawn on MFL)*

Awaiting application means an application for a permit issued in terms of section 22A(15) of the Medicines and Related Substances Act 101 of 1965 has not yet been submitted by the facility representative *(System status: COVID-19 vaccine site activated as service on MFL and token sent to facility by SAPC)*

NDOH Awaiting Recommendation means that an application for a permit is awaiting evaluation by the relevant official/s of the NDoH to whom this function has been delegated. *(System status: Pending Permit on MFL)*

NDOH - Application on hold means an application for a permit requires further information or input prior to finalisation of the evaluation of the application by the relevant official/s of the NDoH to whom this function has been delegated. *(System status: NDOH Application on hold on MFL)*

NDOH Awaiting issuing/declining of Permit by DG - Health means that a recommendation has been made to the Director General of the NDoH, or to the officer of the NDoH to whom this function has been delegated by the Director General in terms of section 34A(2) of the Medicines

and Related Substances Act 101 of 1965, that a permit be issued or declined. *(System status: Pending Permit on MFL)*

Permit Declined means that the application for a permit in terms of section 22A(15) of the Medicines and Related Substances Act 101 of 1965 has been declined by the Director General of the NDoH, or the officer of the NDoH to whom this function has been delegated by the Director General in terms of section 34A(2) of the Medicines Act. *(System status: Permit declined on MFL)*

Permit Dormant means that a permit issued is still valid but that COVID-19 vaccination services are not currently being provided at a primary vaccination site and/or outreach services linked to that primary vaccination site, and/or that distribution services are not being provided by a primary vaccination site or that vaccination services are not being provided at a fixed outreach service. *(System status: Deactivated the COVID-19 vaccine site as service and/or distribution service (as applicable) on MFL (inactive) - status will show as Permit Dormant on MFL)*

Permit Expired means that a permit is no longer valid as the period for which the permit was issued (two years) has ended. *(System status: Permit expired on MFL)*

Permit Issued means that a permit has been issued by the Director General of the NDoH in terms of section 22A(15) of the Medicines and Related Substances Act 101 of 1965. *(System status: Permit issued on MFL)*

Permit not required means that a permit issued by the Director General of the NDoH in terms of section 22A(15) of the Medicines and Related Substances Act 101 of 1965 is not required – applies in the case of manufacturing, wholesale, community and institutional pharmacies where vaccines are stored, but no vaccination services are provided (either at the pharmacy or as an outreach service). These pharmacies store and distribute vaccines in terms of existing licences issued in terms of the Pharmacy Act 53 of 1974 and section 22C(1)(b) of the Medicines and Related Substances Act 101 of 1965 (as applicable) *(System status: COVID-19 distribution service activated on the MFL, vaccine site not activated as service on MFL).*

Permit Pending means an application has been submitted via the SAPC permit system, but a permit has not yet been issued or declined *(System status: Initial default status after activation of a COVID-19 vaccine site as service on the MFL).*

Permit Suspended means that a permit issued by the Director General of the NDoH has been suspended by the Director General of the NDoH in terms of Regulation 26(7)(c) of the General Regulations published in terms of the Medicines and Related Substances Act 101 of 1965 pending an investigation into suspected or alleged non-compliance with the conditions and/or requirements of the permit issued. *(System status: Permit suspended on MFL - COVID-19 vaccine site and distribution services inactivated on the MFL (following an instruction by the NDoH) – Note: It is not possible to reapply for a permit for the same premises during the period of suspension. On the permit system, the permit is suspended by the Director General of the NDoH, or the officer of the NDoH to whom this function has been delegated by the Director General in terms of section 34A(2) of the Medicines Act.*

Permit Withdrawn means that a permit has been withdrawn by the Director General of the NDoH in terms of Regulation 26(7)(c) of the General Regulations published in terms of the Medicines and Related Substances Act 101 of 1965 as a consequence of non-compliance with the conditions and/or requirements of the permit issued. *(System status: Permit withdrawn on MFL - COVID-19 vaccine site and distribution services inactivated on the MFL (following an instruction by the NDoH). Note: Can reapply for a permit for the same premises once rehabilitated. On the permit system, the permit is withdrawn by the Director General of the NDoH, or the officer of the NDoH to whom this function has been delegated by the Director General in terms of section 34A(2) of the Medicines Act.*

SAPC Manager recommendation means that a recommendation for either the issuing or declining of a permit has been made to the NDoH by a manager employed by the SAPC. *(System status: Pending Permit on MFL)*

SAPC Practitioner Evaluation means that an application for a permit has been evaluated by a practitioner employed by the SAPC. *(System status: Pending Permit on MFL)*

6. Conditions of the section 22A(15) permit

6.1 Permits are issued subject to compliance with conditions set out by the DG.

6.2 Permits are issued subject to the following conditions:

- *the health establishment must comply with the requirements for the provision of COVID-19 vaccination services as determined by the National Department of Health;*
- *vaccines must only be administered by a health care provider registered and in good standing with the relevant professional council, who has been trained in the administration of COVID-19 vaccines and the management of any related adverse events, is competent to provide such services, and in accordance with his/her scope of practice;*
- *COVID-19 vaccination services must only be provided in accordance with all relevant laws, regulations, rules and guidelines, and utilising medicines on the applicable list provided by the National Department of Health;*
- *in the case of a fixed outreach service, COVID-19 vaccination services are only provided at the site specified on the permit and with the necessary oversight provided by a pharmacy.*

7. Validity, suspension and withdrawal of the permit

7.1 A permit is valid for two (2) years unless it is withdrawn by the Director-General.

7.2 Regulation 26(7)(c) of the General Regulations published in terms of the Medicines and Related Substances Act 101 of 1965 enables the Director General to suspend, revoke or withdraw a permit. (Annexure : SOP on suspension and withdraw) or link

7.3 A valid permit may be suspended by the Director General, or the officer of the NDoH to whom this function has been delegated by the Director General, in terms of section 34A(2) of the Medicines Act, pending an investigation into suspected or alleged non-compliance with the conditions and/or requirements of the permit. Vaccination and/or distribution services may not be provided by, or from the vaccination site if the permit has been suspended. It is not possible to reapply for a permit for the same premises during the period of suspension.

- 7.4 A permit may also be withdrawn by the Director General, or the officer of the NDoH to whom this function has been delegated by the Director General, in terms of section 34A(2) of the Medicines Act, if the holder fails to comply with any condition and/or requirements of the permit. Vaccination and/or distribution services may not be provided by, or from the vaccination site if the permit has been withdrawn. A new application for a permit can be submitted once the shortcomings have been corrected.
- 7.5 In cases where a permit has been suspended or withdrawn, the permit holder may appeal against the decision of the Director General in terms of section 24 of the Medicines Act.

8. Roles and responsibilities relating to the application and issuing of section 22A(15) permits

The table below describes the roles and responsibilities of the different role-players in the process

Table 5: Roles and Responsibilities

Entity	Responsibilities
NDoH	<ul style="list-style-type: none"> • Issue section 22A(15) vaccination site permits (after consultation with SAPC) • Suspend or withdraw a permit, if needed • Develop and update minimum standards, guidelines and tools related to vaccination services and ensure availability thereof • Develop and maintain the MFL web application and linkage with other systems such as the EVDS and SVS
South African Pharmacy Council (SAPC)	<ul style="list-style-type: none"> • Review applications for a section 22A(15) permit for the provision of COVID-19 vaccination services • Evaluate permit applications for compliance with GPP and the conditions set out by the DG • Make a recommendation to the NDoH whether a permit should be issued or declined
Organisation that owns the facility	<ul style="list-style-type: none"> • Ensure registration of all health facilities on MFL • Use the MINIMUM STANDARDS FOR COVID-19 VACCINATION SITES AND THE PROVISION OF VACCINATION SERVICES (Annexure 4) as a self-assessment tool to determine if a facility is ready to function as a primary vaccination site or fixed outreach service • Nominate facility for inclusion in the national service delivery plan for the COVID-19 vaccination roll out • Once confirmed, ensure that the necessary processes are followed to record and maintain accurate and up to date data on MFL • Make sure that application forms for section 22A(15) permits are completed by the relevant facility manager or a person delegated by him/her
MFL Facility representative	<ul style="list-style-type: none"> • Register on the MFL and ensure correct details of the facility are provided in the appropriate fields • Activate vaccine services and/or distribution services as applicable

Entity	Responsibilities
	<ul style="list-style-type: none"> • Add details of outreach services (fixed, temporary or mobile) and link outreach services to a primary vaccination site • Maintain and update details on the MFL as needed from time to time • Deactivate vaccine services and/or distribution services as applicable on the MFL if vaccination services are no longer offered at the site (permit becomes dormant)
MFL Curator	<ul style="list-style-type: none"> • Review the data captured by the facility • Confirm that the data captured for vaccination sites is correct • Confirm that the vaccination site meets the <i>Minimum standards for COVID-19 vaccination sites and the provision of vaccination services</i>
Facility manager/ Responsible Pharmacist (in case of a community pharmacy)	<ul style="list-style-type: none"> • Complete application for section 22A(15) permit using the token emailed to the applicant • Ensure compliance with the conditions of the permit

Note: The entities responsible for curatorship of the entries on the MFL are provided above. Curators may be amended by the NDoH from time to time. The detail included in the MFL is described in the Master Facility List Data reference guide which could be accessed on the [following link](#): table 6: Curators (reviewers) of semi-permanent data provided on MFL about a specific facility

Public/private sector	Vaccination site	Curator	Minimum requirements for curation
Public sector	Hospitals, community health centres, primary health care clinics, and other public health establishments such as institutional pharmacies	Provincial and District Department of health	Semi-permanent data included in the MFL is correct and validated against an existing repository of such data available to the curator.
	Residential facilities for older persons	Department of Social Development or the organisation	Facility has been identified to be a vaccination site in the service delivery plan
	Correctional Services health establishments	Department of Correctional Services	There are sufficient resources to provide vaccination services as an additional

Public/private sector	Vaccination site	Curator	Minimum requirements for curation
	Clinics at educational institutions	Department of Higher Education	services to existing services
	South African Medical Service (SAMS) health establishments	Department of National Defence	
Private sector	All	All	Semi-permanent data included in the MFL is correct and validated against an existing repository of such data available to the curator
	Pharmacies - community, institutional, manufacturing, wholesale	South African Pharmacy Council	Pharmacy is active on the SAPC register
	Medical practices Medical centres	As identified by the site and communicated to NDOH	Medical practitioner is registered with HPCSA
	Hospitals (private)	Hospital groups curators with coordination through Hospital Association of South Africa (HASA)	Hospital is licenced
	Occupational Health Clinics	Coordinated through OHS work-stream	Clinic/facility is currently designated by the DG to provide occupational health services, in terms of

Public/private sector	Vaccination site	Curator	Minimum requirements for curation
			section 56(6)(d) of the Nursing Act
	Travel Clinics	As identified by the site and communicated to NDOH	Clinic/facility is currently designated by the DG to provide occupational health services, in terms of section 56(6)(d) of the Nursing Act
	Nurse practices (nurses providing services ito section 22A(15) of the Medicine Act)	National Department of Health	Nurses are holders of a section 22A(15) permit issued to an individual and the permit is still valid