

PHARMACY MONTH 2024

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**Senior Manager: CPD & Registrations
SAPC**

Immunisation Services Provided by Pharmacists



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



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What is the difference between offering immunisation services **“with”** and **“without”** a Section 22(A) 15 permit?

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Overview

- Legislative Provisions
- Requirements for a pharmacist to provide immunisation services
- Scope of practice for a pharmacist offering immunisation services
- Link between scope of practice and competency standard
- Benefits of a Section 22(A)15 permit
- Number of permits issued
- Documents issued

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Legislative Provision

MRSA - Section 22A(15) states that *the Director General may, after consultation with the South African Pharmacy Council as referred to in Section 2 of the Pharmacy 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.*

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Legislative Provision

Pharmacy Act – Section 33. Pharmacy education and training.—conduct, recognise and control supplementary training of a person registered in terms of this Act;

Regulations relating to supplementary training - *“supplementary training” means training approved in terms of Section 33 (1) of the Act which gives a registered person additional professional competency, powers or recognition in terms of the Act or any other law, and which, after successful completion thereof and the payment of the prescribed registration fees, is entered in a register kept in accordance with Section 14 of the Act, and “supplementary training course” has a corresponding meaning.*

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Legislative Provision

Regulations relating to the practice of pharmacy – Regulation 18(6)(b) Community or institutional pharmacy.—Except as provided for in the Medicines Act, the following services pertaining to the scope of practice of a pharmacist may be provided in a community or institutional pharmacy –

- the promotion of public health in accordance with guidelines and standards as determined by a competent authority which includes but shall not be limited to:
 - the provision of immunisation, mother and childcare

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Legislative Provision

Board Notice 241 of 2021 published on 22 April 2022 for a Pharmacist who offers Immunisation services in South Africa for implementation –

- Scope of Practice;
- Competency Standards; and
- The criteria to accredit the supplementary training course

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Requirements for a pharmacist to provide immunisation services

- A pharmacist already offering immunisation services, who completed the immunisation course with a non-accredited provider in the past –
 - may continue to offer immunisation services; however, they are not eligible to apply for a Section 22(A)15 permit.
 - may only prescribe, administer medicines/adjunct medicines up to Schedule 2.
- A pharmacist wishing to offer immunisation services must -
 - enrol and complete a supplementary training short course with an SAPC accredited provider;
 - must record the certificate of completion of the course with the SAPC; and
 - must apply to the NDoH for a Section 22(A)15 permit on the SAPC website (optional but recommended).

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Scope of practice for a pharmacist offering immunisation services

In addition to the scope of practice of the pharmacist, a pharmacist who has completed the supplementary training on immunisation and injection technique; and who has obtained a permit in terms of Section 22A(15) of the Medicines and Related Substances Act, 101 of 1965, may be allowed to acquire, possess, use and supply vaccines and medicines required for adjunct therapy, and perform consultations with patients at a pharmacy or in an approved setting, which includes:

- (a) comprehensive patient history taking;
- (b) administering of vaccines in line with the Expanded Programme on Immunisation in South Africa (EPI-SA) and any other vaccine programme as may be approved by the Director-General: Health;
- (c) monitoring, measuring and reporting of the outcomes of the immunisation;
- (d) treating of adverse events following immunisation and anaphylactic shock;
- (e) reporting of adverse events following immunisation;
- (f) referral to another health care provider where necessary; and
- (g) record keeping and maintaining confidentiality.

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Link between scope of practice and competency standard

Scope of practice item

Treating of adverse events following immunisation and anaphylactic shock.



CS behavioural statement

Provide management of adverse events following immunisation, including the performance of cardio-pulmonary resuscitation and refer to an appropriate healthcare professional where necessary.

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Benefits of having a Section 22(A)15 permit

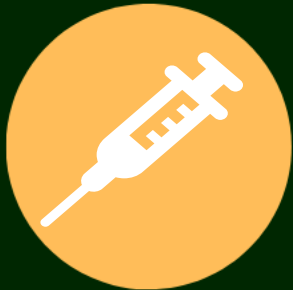
- Broader scope in the types of vaccines to administer.
 - Expanded Programme on Immunisation (EPI), essential vaccines identified in the Standard Treatment Guidelines (STG) and Essential Medicines List (EML), vaccines for COVID-19.
- Access to higher scheduled medicines for adjunct treatment and AEFI/Anaphylaxis
 - e.g. Hydrocortisone IV (S4), Epinephrine (adrenaline) (S4), Promethazine IV (S5), Oxygen (S4), Salbutamol (S3), Ipratropium (S3), Dextrose IV (S3), Albendazole (S4) and Mebendazole (S4).

Note: It is the responsibility of the permit holders to keep abreast with the changes in the STG EML and/or EPI schedule.

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Number of Permits Issued



854 PERMITS FOR
IMMUNISATION
SERVICES HAVE
BEEN ISSUED



DATE RANGE –
MARCH 2021 TO DATE



1 344 IS TOTAL
NUMBER OF PERMITS
ISSUED



% CONTRIBUTION =
64%

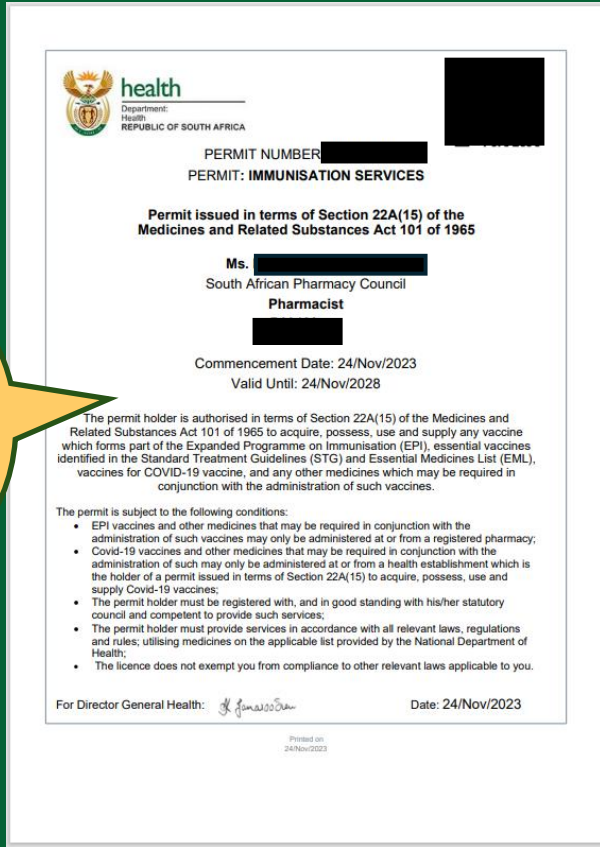
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Documents issued

Recording/
Registration
of Permit
with SAPC

A
Section
22(a)15
Permit



health
Department:
Health
REPUBLIC OF SOUTH AFRICA

PERMIT NUMBER: [REDACTED]
PERMIT: IMMUNISATION SERVICES

Permit issued in terms of Section 22A(15) of the Medicines and Related Substances Act 101 of 1965

Ms. [REDACTED]
South African Pharmacy Council
Pharmacist

Commencement Date: 24/Nov/2023
Valid Until: 24/Nov/2028

The permit holder is authorised in terms of Section 22A(15) of the Medicines and Related Substances Act 101 of 1965 to acquire, possess, use and supply any vaccine which forms part of the Expanded Programme on Immunisation (EPI), essential vaccines identified in the Standard Treatment Guidelines (STG) and Essential Medicines List (EML), vaccines for COVID-19 vaccine, and any other medicines which may be required in conjunction with the administration of such vaccines.

The permit is subject to the following conditions:

- EPI vaccines and other medicines that may be required in conjunction with the administration of such vaccines may only be administered at or from a registered pharmacy;
- Covid-19 vaccines and other medicines that may be required in conjunction with the administration of such may only be administered at or from a health establishment which is the holder of a permit issued in terms of Section 22A(15) to acquire, possess, use and supply Covid-19 vaccines;
- The permit holder must be registered with, and in good standing with his/her statutory council and competent to provide such services;
- The permit holder must provide services in accordance with all relevant laws, regulations and rules; utilising medicines on the applicable list provided by the National Department of Health;
- The licence does not exempt you from compliance to other relevant laws applicable to you.

For Director General Health: [Signature] Date: 24/Nov/2023

Printed on 24/Nov/2023



health
Department:
Health
REPUBLIC OF SOUTH AFRICA

AB Xuma Building
1112 Voortrekker Road
Pretoria Townlands 351-JR
Pretoria, 0187
Email: rdohpermits@health.gov.za
Website: www.health.gov.za

This list is an annexure to a permit issued to a pharmacist providing Immunisation Services in terms of Section 22A(15) of the Medicines and Related Substances Act 101 of 1965 to acquire, possess, use and supply medicines

Permit number: [REDACTED]
Name: [REDACTED]
P number: [REDACTED]

This list is in accordance with the latest version of the Standard Treatment Guidelines /Essential Medicines List (STGs/EML) as approved by the National Essential Medicines List Committee.

This list is not valid without a valid Permit Number.

Immunisation:

Note: The permit holder will be expected to provide data pertaining to EPI and other vaccine coverage

Condition	ICD10 Code	INN	Schedule	Dosage	Route of Administration	Note
EPI childhood immunization schedule	Z32.2	BCG (Bacillus Calmette-Guérin) Vaccine	S2	0.05 ml	Intradermal	At birth

A list of
conditions
&
medicines



South African Pharmacy Council
Registration certificate issued under the Pharmacy Act, 53 of 1974

Registration of vaccination services Permit
(Issued in terms of Section 22 A (15) of the Medicine and Related Substances Control Act, 101 of 1965)

This is to certify that
[REDACTED]
Reg No: [REDACTED]

EPI and COVID-19 permit, number [REDACTED] issued in terms of Section 22 A (15) of the Medicine and Related Substance Act, 101 of 1965 has been registered in the register of pharmacist in accordance with the provision of the Pharmacy Act, 53 of 1974.

EPI and COVID-19 Permit is valid from 24 November 2023 to 24 November 2028

24 November 2023
Date issued
Pretoria

VM TLALA
Registrar

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Accredited Providers

- Health Sciences Academy (Pty) Ltd
- Nelson Mandela University
- University of the Witwatersrand
- Sefako Makgatho Health Sciences University
- Tshwane University of Technology

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Do you have any questions?



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