
BOARD NOTICES • RAADSKENNISGEWINGS

BOARD NOTICE 100 OF 2021

THE SOUTH AFRICAN PHARMACY COUNCIL

PHARMACIST WHO PROVIDES IMMUNISATION SERVICES

The South African Pharmacy Council hereby publishes for broad-based stakeholder consultation, the scope of practice of a pharmacist who offers IMMUNISATION SERVICES, the competency standards of such pharmacists and the criteria for the approval of a curriculum of an immunisation and injection technique and delivering immunisation services course.

Interested parties are invited to submit, within **60 days** of publication of this notice, substantiated comments on or representation. Comments must be addressed to the Registrar, the South African Pharmacy Council c/o Ms Debbie Hoffmann, via email BN@sapc.za.org.

SCHEDULE:

Part 1: Scope of practice for a pharmacist who provides immunisation services.

Part 2: Competency standards for a pharmacist who provides immunisation services.

Part 3: Criteria for accreditation/approval by the South African Pharmacy Council of a curriculum of an immunisation and injection technique and delivering immunisation services course.

In this notice "the Act" shall mean the Pharmacy Act, 53 of 1974 (as amended), and any expression to which a meaning has been assigned in the Act shall bear such meaning.



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REGISTRAR

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https://www.pharmcouncil.co.za/Legislation_Proposed



DRAFT COMPETENCY STANDARDS FOR A PHARMACIST PROVIDING IMMUNISATION SERVICES, SCOPE OF PRACTICE OF A PHARMACIST OFFERING SUCH SERVICES AND CRITERIA TO ACCREDIT A GENERIC SHORT COURSE FOR PHARMACISTS IN IMMUNISATION AND INJECTION TECHNIQUES, AND DELIVERING IMMUNISATION SERVICES.

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PART 1 SCOPE OF PRACTICE FOR A PHARMACIST OFFERING IMMUNISATION SERVICES

In addition to the acts and services which form part of the scope of practice of the pharmacist as prescribed in terms of Regulations 3 and 4 of the *Regulations relating to the practice of Pharmacy* (GNR 1158, published on 20 November 2000), a pharmacist who has completed the supplementary training on immunisation and injection techniques; and has obtained a section 22A(15) permit, 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 of the outcomes of the immunisation;
- (d) treating of adverse events following immunisation and anaphylactic shock; and reporting of adverse events;
- (e) referral to another health care provider where necessary; and
- (f) record keeping and maintaining confidentiality.

PART 2: COMPETENCY STANDARDS

1. Introduction

The South African Pharmacy Council is committed to its mandate to ensure that pharmacists and pharmacy support personnel have the necessary knowledge and skills to deliver the best possible pharmaceutical services to the people of South Africa. This is achieved by monitoring trends in education and practice, both nationally and internationally. FIP report (2016) acknowledges the fact that the role of pharmacists in immunisation and vaccination varies across the world. Pharmacists are involved in ensuring the safe supply and dispensing of vaccines, as well as advocating for immunisation, while in other countries, pharmacist are also empowered to organise vaccinations activities and campaigns as well as actual administrations of vaccines to those in need.

In recent years, competency mapping has been identified as a way of ensuring that pharmacy professionals are equipped with the specific skills, knowledge, abilities, and behaviours that are needed to work effectively.

2. Background

Regulation 18(6)(b) of the Regulations relating to the practice of pharmacy indicates the provision of immunisation as part of the scope of practice of a pharmacist which can be provided in a community or institutional pharmacy provided that the pharmacist is competent to provide the service and is in possession of section 22A (15) permit. Rule 2.14 of the *Rules relating to good pharmacy practice* further support pharmacist's involvement in activities related to immunisation as well as the actual administration of vaccines to members of the public and acknowledge the fact that the involvement of pharmacists to immunisation activities would vary depending on the practice setting.

FIP outlines the role of pharmacists in vaccination as follows:

- (a) Advocacy Activities
- (b) Regulatory Frameworks
- (c) Vaccine administration
- (d) Training and certification
- (e) Keeping vaccination records

3. Summary of competency standards for pharmacist providing immunisation services.

DOMAIN	Competency Standard
1. Public health	1.1 Professional advocacy 1.2 Pandemic management
2. Safe and rational use of vaccine and administration device	2.1 Patient consultation 2.2 Communication with patient, caregiver, and agent of a patient 2.3 Patient management 2.4 Vaccine and administration device safety
3. Supply of vaccines	3.1 Vaccine administration 3.2 Vaccine storage and control 3.3 General housekeeping and administrative tasks in the pharmacy
4. Organisational and management skills	4.1 Quality assurance 4.2 Record keeping 4.3 Policy development
5. Professional and personal practice	5.1 Professional practice 5.2 Ethical and legal practice 5.3 Continuing professional development

DOMAIN 1: PUBLIC HEALTH

INTRODUCTION

Domain 1 covers competencies that are required in both the public and private healthcare sectors to promote health and wellness through the provision of healthcare information and education to the public and other members of the healthcare team.

The domain covers competencies that are required to advocate vaccination and promote health.

The public health domain competencies are:

- 1.1 Professional advocacy
- 1.2 Pandemic management

DOMAIN 1: PUBLIC HEALTH			
COMPETENCIES		BEHAVIOURAL STATEMENTS	
1.1	Professional advocacy	1.1.1	Understand the epidemiology of and patient populations at risk for vaccine-preventable diseases.
		1.1.2	Understand public health goals for immunisation.
		1.1.3	Contribute to the development and distribution of vaccines.
1.2	Pandemic management	1.2.1	Assist in the implementation of vaccine schedules for any pandemic management.

DOMAIN 2: SAFE AND RATIONAL USE OF VACCINE AND ADMINISTRATION DEVICE

INTRODUCTION

Domain 2 covers competencies that are required to ensure safe and rational use of vaccines and administration devices, in this domain effective verbal and non-verbal methods of communication with patients are essential competencies.

The competencies required in the domain for the safe and rational use of vaccines are:

- 2.1 Patient consultation
- 2.2 Communication with patient, caregiver, and agent of a patient
- 2.3 Patient management
- 2.4 Vaccine and administration device safety

DOMAIN 2: SAFE AND RATIONAL USE OF VACCINES AND ADMINISTRATION DEVICES	
COMPETENCIES	BEHAVIOURAL STATEMENTS
2.1 Patient consultation	2.1.1 Ensure that there is a consultation/private area appropriate for administration of vaccines.
	2.1.2 Ensure that all necessary equipment is available in the consultation area.
	2.1.3 Obtain an informed written/electronic patient consent.
	2.1.4 Establish if a person meets the vaccination criteria.
	2.1.5 Undertake a thorough pre-vaccination assessment.
	2.1.6 Maintain patient privacy.
2.2 Communication with patient, caregiver, and agent of a patient	2.2.1 Explain the procedure to the patient.
	2.2.2 Establish an effective and robust communication system.
	2.2.3 Advise consumers on any boosters and post-administration care.

	2.2.4 Describe the service to the patient.
	2.2.5 Communicate the benefits of vaccination versus the risk of disease.
	2.2.6 Have knowledge of the relevant diseases and vaccines to be able to explain the vaccination to the individual, parent or guardian of the individual who is to consent to the vaccination on behalf of the individual, to ensure that the individual or parent or guardian of the individual can give informed consent to the vaccination.
	2.2.7 Provide reassurance to the patient/parent/carer-giver.
	2.2.8 Provide advice on potential adverse events.
2.3 Patient management	2.3.1 Screen patients for contraindications.
	2.3.2 Identify the signs and symptoms of adverse reactions to vaccines.
	2.3.3 Monitor the patient for adverse events following immunisation including anaphylactic shock.

	2.3.4 Provide management of adverse events following immunisation including the performance of cardio-pulmonary resuscitation and refer to an appropriate healthcare professional where necessary.
	2.3.5 Provide the patient with post vaccination care.
2.4 Vaccine and administration device safety	2.4.1 Manage the logistics (including cold chain management), administration and post vaccination care of both on and off-site vaccination.
	2.4.2 Take appropriate action in the event of a needle stick injury or spillage of blood or vaccine.
	2.4.3 Have knowledge of the safe and effective handling of immunisation products, administration device, and equipment.

DOMAIN 3: SUPPLY OF VACCINES

INTRODUCTION

Domain 3 includes competencies required to address the supply of vaccines of patients, the behavioural statement in this domain includes management of the adverse effects of the vaccine.

The competencies required for the supply of vaccines domain are:

- 3.1 Vaccine administration
- 3.2 Vaccine storage and control
- 3.3 General housekeeping and administrative tasks in the pharmacy

DOMAIN 3: SUPPLY OF VACCINES	
COMPETENCIES	BEHAVIOURAL STATEMENTS
3.1 Vaccine administration	3.1.1 Administer the vaccine in accordance with protocol.
	3.1.2 Display understanding of Immunological drug interactions.
	3.1.3 Deliver vaccination services.
	3.1.4 Demonstrate vaccine reconstitution and dosing knowledge.
	3.1.5 Demonstrate the correct administration technique and site of administration for the vaccine.
	3.1.6 Display understanding of the pharmacotherapy for the vaccine.
3.2 Vaccine storage and control	3.2.1 Demonstrate knowledge of vaccine stability and storage requirements.
	3.2.2 Manage the transportation, storage, and administration of vaccines according to cold chain requirements.
	3.2.3 Demonstrate the ability to handle temperature excursion.
3.3 General housekeeping and administrative tasks in the vaccination site	3.3.1 Take appropriate action in the event of vaccine spillage.
	3.3.2 Demonstrate the ability to source and utilise relevant reference material.
	3.3.3 Take appropriate action in the event of a needle stick injury.
	3.3.4 Take appropriate action in the event of blood spillage.

	3.3.5 Understand how to dispose of sharps, vials, and other vaccine equipment safely.
	3.3.6 Understand the importance of the safe disposal of clinical waste created during provision of vaccinations.
	3.3.7 Take responsibility for and comply with the relevant waste legislation.

DOMAIN 4: ORGANISATIONAL AND MANAGEMENT SKILLS

INTRODUCTION

Domain 4 includes competencies required to ensure effective and efficient delivery of vaccination services including amongst other behavioral statements development of the required processes and procedures.

The competencies required are:

- 3.1 Quality assurance
- 3.2 Record keeping
- 3.3 Policy development

DOMAIN 4: ORGANISATIONAL AND MANAGEMENT SKILLS	
COMPETENCIES	BEHAVIOURAL STATEMENTS
4.1 Quality assurance	4.1.1 Contribute to the development of vaccine management Standard Operating Procedures (SOPs) and ensure adherence to the SOPs.
	4.1.2 Perform self-assessment of the vaccine management processes.
	4.1.3 Perform pharmacovigilance.
4.2 Record Keeping	4.2.1 Develop systems for recording of services and deviations.
	4.2.2 Record errors and relevant incidents.
	4.2.3 Document, record, and report adverse reactions if any.
	4.2.4 Reconcile the documentation and report any identified discrepancies.
4.3 Policy development	4.3.1 Develop a vaccine management policy framework.
	4.3.2 Establish systems for the professional management and clinical governance of vaccination services.
	4.3.3 Implement and monitor vaccine management policies and SOPs.

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE

INTRODUCTION

Domain 5 includes behavioural statements that focuses on professional practice, code of conduct and adhering to legal requirements.

The competencies required are:

- 5.1 Professional practice
- 5.2 Ethical and legal practice
- 5.3 Continuing professional development

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE	
COMPETENCIES	BEHAVIOURAL STATEMENTS
5.1 Professional practice	5.1.1 Support and develop the pharmacy team in the provision of a safe and effective service.
	5.1.2 Demonstrate clinical and interpersonal skills.
5.2 Ethical and legal practice	5.2.1 Understand legal implications and professional responsibility.
	5.2.2 Adhere to the Acts and regulations related to the supply of vaccines.
5.3 Continuing professional development	5.3.1 Reflect on personal practice skills.
	5.3.2 Identify and address learning needs.

4. References

ASHP (American Society of Health System Pharmacists). Guidelines on the Pharmacist's Role in Immunization. <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/pharmacists-role-immunization.ashx> Date of access: 26 January 2021.

Association of State and Territorial Health Officials (ASTHO) 2012 Guidance And Templates For State And Territorial Health Agencies When Establishing Effective Partnerships With Pharmacies During Routine And Pandemic Influenza Seasons <https://www.astho.org/Infectious-Disease/Pharmacy-Legal-Toolkit/> Date of access 09 February 2021

FIP (Federation Internationale Pharmaceutique). 2020. An overview of current pharmacy impact on immunisation, A global report. <https://www.fip.org/file/4751> Date of access: 26 January 2021.

Ministry of Health – Manatu Hauro, 2020. Authorisation of vaccinators and criteria for pharmacist vaccinators. <https://www.health.govt.nz/our-work/immunisation-handbook-2020/appe> Date of access: 25 January 2021.

NSW Government, 2020. <https://www.health.nsw.gov.au/immunisation/Pages/pharmacist-vaccination-expansion.aspx> Date of access: 25 January 2021.

The Pharmaceutical society of Ireland (PSI) .2020. Practical Guidance when Providing a Pharmacy Vaccination Service during the COVID-19 Pandemic https://www.thepsi.ie/gns/Pharmacy_Practice/practice-guidance/PharmacyServices/Vaccination_Service.aspx Date of access: 08 February 2021.

PART 3: CRITERIA TO ACCREDIT A GENERIC SHORT COURSE FOR PHARMACISTS IN IMMUNISATION AND INJECTION TECHNIQUES, AND DELIVERING IMMUNISATION SERVICES.

1. RATIONALE FOR TRAINING ON IMMUNISATION AND INJECTION TECHNIQUE

Pharmacists are accessible, as they are well placed within communities as the first point of contact with the health care system. Pharmacists are also well trained, offer cost-effective pharmaceutical services to the public, hence play a pivotal role in the delivery of primary health care services.

Pharmacists can promote public health through immunisations and increase immunisation coverage. Pharmacists acting as educators, facilitators, vaccinators and advocates fulfil important roles during a pandemic.

The South African Pharmacy Council identified the need for pharmacists to be trained as vaccinators and be skilled in practical immunisation and injection techniques. Firstly, this is in line with the National Department of Health's Strategic Plan 2020/2021 - 2024/25, specifically to increase life expectancy from birth, reduce infant and child mortality rates and achieve the sustainable development goal of ensuring healthy lives and promote wellbeing for all at all ages. Secondly in response to the COVID-19 pandemic, to ensure sufficient workforce capacity to vaccinate the entire South African population. Hence, as lifelong learners, pharmacists need to improve their knowledge and skills in order to strengthen immunisation

services across all vaccination programmes and reduce the burden of vaccine preventable diseases.

2. PURPOSE OF THE IMMUNISATION AND INJECTION TECHNIQUE TRAINING

The purpose of the short course on immunisation and injection techniques is to equip pharmacists with the theoretical knowledge and practical expertise necessary to provide safe immunisation services of the highest standard.

This training would allow pharmacists to become vaccinators, vaccine advocates, promote the importance of immunisation in reducing vaccine-preventable diseases, help with dispelling myths associated with vaccines and improve public confidence in vaccines. This would require pharmacist vaccinators to be able to read and interpret immunisation schedules, and safely administer vaccines via all prescribed routes of administration. They should also have the ability to operate an immunisation service in compliance with legal and regulatory standards. Furthermore, these pharmacists may also be required to collaborate with other immunisation stakeholders to improve the availability and access to immunisation services, aimed at reaching herd immunity.

3. TARGET GROUP FOR IMMUNISATION AND INJECTION TECHNIQUE TRAINING

Practicing Pharmacists as defined in the Regulations relating to Continuing Professional Development.

4. MINIMUM ENTRANCE CRITERIA TO THE IMMUNISATION AND INJECTION TECHNIQUE TRAINING

Pharmacists who wish to enrol for the short course on immunisation and injection technique must be:

- in possession of a Bachelor of Pharmacy (BPharm) degree, or recognised equivalent qualification; and
- registered with the SAPC as a Practicing Pharmacist.

5. DURATION OF THE IMMUNISATION AND INJECTION TECHNIQUE TRAINING

The recommended duration of the short course is approximately 6 days and is worth 5 credits.

	Credits	Hours
Interactive Sessions	1.95	19 hours 30 minutes
Practical sessions	1.4	14 hours
Assessments and self-study	1.65	16 hours 30 minutes
Total	5	50 hours

6. IMMUNISATION AND INJECTION TECHNIQUE TRAINING RULES

To successfully complete the short course on immunisation and injection technique, a learner must complete all the training modules and achieve all objectives.

Learners should attend practical sessions and demonstrate competence in all immunisation and injection techniques in a summative practical assessment. In addition, learners must perform the following under supervision of a competent pharmacist, registered nurse or medical practitioner: a minimum of twenty (20) intramuscular immunisations and five (5) subcutaneous immunisations for successful completion of the course. The practical session should also include relevant components of first aid to handle anaphylactic shock.

Vaccination can be done where immediate access to a nursing or medical practitioner is available, in the absence thereof, the vaccinator should have appropriate qualifications to handle anaphylactic shock and adverse events following immunisation.

After successful completion of the short course on immunisation and injection techniques, a pharmacist must comply with the following procedures:

- Record their immunisation and injection technique certificate with the SAPC by completing and submitting the application form for immunisation and injection technique (online or printable form available at: <http://www.pharmcouncil.co.za>) together with a certified copy of the pharmacist's ID, evidence of competence in cardio-pulmonary resuscitation techniques, certified copies of the pharmacist's certificate(s) of successful completion of the short course on immunisation and injection technique and proof of payment of the SAPC registration fee (refer to SAPC application form),
- After receiving the recording certificate from the SAPC the pharmacist must apply to the NDoH for a Section 22(A)15 permit (the application form can be obtained by sending an e-mail to permits@health.gov.za),
- Upon receipt of the Section 22(A)15 permit from the NDoH the pharmacist must record their permit on immunisation and injection techniques at the SAPC (form available on the website of the SAPC (<http://www.pharmcouncil.co.za>)).

7. RECOGNITION OF PRIOR LEARNING

Recognition of prior learning is not applicable to the short course.

8. OUTCOMES AND ASSOCIATED ASSESMENT CRITERIA

STAGES	TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	No. of credits (Interactive Sessions = IS Practical Sessions = P)
Non-specific	1.1 General immunisation principles.	1.1.1 The learner should be able to apply the principles of immunology to vaccination.	1.1.1.1 Explain the concept of vaccine immunology and immunisation. 1.1.1.2 Differentiate between individual and herd immunity. 1.1.1.3 Describe the different types of vaccines.	IS = 0.2 P = 0

STAGES	TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	No. of credits (Interactive Sessions = IS Practical Sessions = P)
		1.1.2 The learner should be able to understand and apply vaccination schedules and strategies for protecting different population groups from vaccine preventable diseases.	<p>1.1.2.1 Interpret and apply South Africa's public and private sector immunisation schedules.</p> <p>1.1.2.2 Describe the vaccination strategy for trauma victims.</p> <p>1.1.2.3 List vaccines that can be given to pregnant woman, when they should be given, and those that cannot be given.</p> <p>1.1.2.4 Explain the vaccination strategies for vaccinating HIV positive babies, pre-term infants, immunocompromised patients, adolescents, healthcare workers, and the elderly.</p> <p>1.1.2.5 Describe the vaccination-catch-up strategy for babies/children who missed scheduled vaccines.</p> <p>1.1.2.6 Describe the importance and the use of immunisation data collection.</p>	

STAGES	TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	No. of credits (Interactive Sessions = IS Practical Sessions = P)
	1.2 Vaccination advocacy, communication, and social mobilisation.	1.2.1 The learner should be able to effectively communicate the risks and benefits of vaccination to their clients to build confidence and demand for vaccination, thereby increasing vaccination coverage.	1.2.1.1 Identify and critically reflect on the factors and behaviours associated with vaccine hesitancy. 1.2.1.2 Apply effective communication strategies to address vaccine hesitancy in practice. 1.2.1.3 Actively promote immunisation. 1.2.1.4 Elaborate on how to involve communities and the public in the planning of immunisation activities.	IS = 0.1 P = 0
2. Pre -vaccination	2.1 Preparation of vaccination station	2.1.1 The learner should be able to operate effectively and efficiently within immunisation programmes.	2.1.1.1 Describe the minimum criteria for the vaccination station, equipment, and material according to Good Pharmacy Practice to ensure the facility is appropriate and ready for immunisation. 2.1.1.2 Describe the relevant data management systems for immunisation and demonstrate their use.	IS = 0.05 P = 0.1

STAGES	TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	No. of credits (Interactive Sessions = IS Practical Sessions = P)
	2.2 Cold chain management and storage.	2.2.1 The learner should be able to list, describe and demonstrate all key aspects of cold chain management and storage.	<p>2.2.1.1 Explain the requirements for storage and monitoring of vaccines and diluents.</p> <p>2.2.1.2 Demonstrate how to pack the vaccine refrigerator.</p> <p>2.2.1.3 Identify alternative cold chain equipment to cater for vaccine storage outside the refrigerator e.g., emergencies, transportation.</p> <p>2.2.1.4 Demonstrate the packing of vaccines and diluents in cold boxes for transportation, campaign site storage and power failures according to the rules relating to Good Pharmacy Practice and the manufacturer's specifications.</p> <p>2.2.1.5 Describe the quality assurance processes, including checking expiry dates, reading and interpreting of Vaccine Vial Monitor (VVM) and using the shake test when appropriate for maintaining vaccine stability.</p>	IS = 0.2 P = 0.2

STAGES	TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	No. of credits (Interactive Sessions = IS Practical Sessions = P)
			<p>2.2.1.6 Describe the process of cleaning a vaccine refrigerator.</p> <p>2.2.1.7 Explain and apply the multidose vial policy.</p>	
	2.3 Patient history taking	2.3.1 The learner should be able to take an appropriate patient history.	<p>2.3.1.1 Identify the correct vaccine recipient.</p> <p>2.3.1.2 Take an appropriate patient history and identify individuals at risk.</p> <p>2.3.1.2.1 Identify medicines currently taken.</p> <p>2.3.1.2.2 Identify current medical conditions.</p> <p>2.3.1.2.3 Identify all possible and potential vaccine-medicine interactions.</p> <p>2.3.1.2.4 Identify all possible and potential vaccine – disease interactions.</p> <p>2.3.1.3 Identify any contraindications or special precautions to vaccination.</p>	IS = 0.1 P = 0

STAGES	TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	No. of credits (Interactive Sessions = IS Practical Sessions = P)
	2.4 Pre-vaccination counselling	2.4.1 The learner should be able to perform appropriate pre-vaccination counselling.	<p>2.4.1.1 Apply effective and culturally sensitive communication skills in pre-vaccination counselling of the vaccinee/caregiver.</p> <p>2.4.1.2 Explain the importance of immunisation, which vaccines are needed, immunisation schedules and dose intervals.</p> <p>2.4.1.3 Explain the risks and benefits of immunisation, including potential adverse events following immunisation.</p> <p>2.4.1.4 Describe the process of obtaining written informed consent, where applicable.</p> <p>2.4.1.5 Respond appropriately to questions and concerns regarding immunisation.</p> <p>2.4.1.6 Provide accurate and relevant information to the vaccinee/ caregiver regarding administration of the vaccine at a specific site.</p>	IS = 0.1 P = 0.1

STAGES	TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	No. of credits (Interactive Sessions = IS Practical Sessions = P)
	2.5 Infection prevention and control (IPC).	2.5.1 The learner should be able to practice appropriate IPC.	2.5.1.1 Demonstrate the processes involved in IPC necessary for a vaccination station including - 2.5.1.1.1 Use of the appropriate personal protective equipment (PPE). 2.5.1.1.2 Clean, hygienic, and well-ventilated environment. 2.5.1.1.3 Maintaining physical distancing where appropriate. 2.5.1.1.4 Regular hand washing and/or sanitising.	IS = 0.1 P = 0.1
3. Vaccine administration	3.1 Preparing to vaccinate	3.1.1 The learner should be able to safely prepare the different types of vaccines for vaccination.	3.1.1.1 Identify principles which should be adhered to in practice, to prevent any immunisation error related AEFI. 3.1.1.2 Demonstrate the steps involved in the preparation of a vaccine including:	IS = 0.1 P = 0.3

STAGES	TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	No. of credits (Interactive Sessions = IS Practical Sessions = P)
			<p>3.1.1.2.1 Identify the correct route of administration and specific injection site for the vaccine according to age, pre-existing condition and current medication taken.</p> <p>3.1.1.2.2 Position the vaccinee in an enabling and comfortable position.</p> <p>3.1.1.2.3 Identify/choose/select the appropriate vaccine, needle-, and syringe size for the individual and the specific vaccine.</p> <p>3.1.1.2.4 Check the expiry date of the vaccine and all products used and the lifespan of multidose vials.</p> <p>3.1.1.2.5 Prepare (reconstitute where applicable) the vaccine as per the EPI guidelines, and GPP and manufacturer's specifications.</p>	

STAGES	TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	No. of credits (Interactive Sessions = IS Practical Sessions = P)
			3.1.1.2.6 Draw the accurate dose for administration according to the manufacturer's specifications.	
	3.2 Administering the vaccine	3.2.1 The learner should be able to safely administer the different types of vaccines.	3.2.1.1 Demonstrate appropriate preparation of the injection site. 3.2.1.2 Demonstrate the ability to safely administer the different types of vaccines, according to the appropriate route of administration, as per EPI guidelines, GPP, and manufacturer's specifications 3.2.1.3 Demonstrate how to safely discard the needle and the syringe into a sharps container. 3.2.1.4 Record the vaccine specific information in the vaccinee's immunisation record, whether electronic or paper-based.	IS = 0.1 P = 0.4
4. Post-vaccination	4.1 Counselling and observation	4.1.1 The learner should be able to provide suitable post-vaccination counselling and observation.	4.1.1.1 Apply effective and culturally sensitive verbal and written communication in the post-vaccination counselling of the vaccinee/caregiver.	IS = 0.15 P = 0

STAGES	TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	No. of credits (Interactive Sessions = IS Practical Sessions = P)
			<p>4.1.1.2 Select relevant information to reinforce with the vaccinee / caregiver either verbally or in writing post-vaccination, including potential vaccine responses, what to do if these occur and how to report.</p> <p>4.1.1.3 Describe the appropriate post-vaccination observation procedures to follow.</p>	
	4.2 Anaphylaxis and emergency management	4.2.1 The learner must be able to provide supportive care for the management of anaphylaxis.	<p>4.2.1.1 Describe the signs and symptoms of anaphylaxis.</p> <p>4.2.1.2 Distinguish between the signs and symptoms of anaphylaxis, general acute stress response and vasovagal reaction with syncope or fainting, brought on by anxiety or stress, related to immunisation.</p> <p>4.2.1.3 Demonstrate the safe and timeous administration of emergency medicines.</p> <p>4.2.1.4 Manage the transfer of the vaccinee to a nearby health care</p>	IS = 0.3 P = 0.1

STAGES	TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	No. of credits (Interactive Sessions = IS Practical Sessions = P)
			facility for further management or observation.	
	4.3 Adverse events following immunisation (AEFI).	4.3.1 The learner must be able to identify, manage and advise the vaccinee / caregiver regarding AEFI.	<p>4.3.1.1 Differentiate between adverse events resulting from the vaccine or the immunisation process, and coincidental events not due to the vaccine or the immunisation process, but temporally associated with immunisation.</p> <p>4.3.1.2 Describe potential underlying causes for each type of AEFI and understand the link between the AEFI and its cause.</p> <p>4.3.1.3 Distinguish between minor and severe (serious and non-serious) AEFI.</p> <p>4.3.1.4 Identify and describe local and systemic signs and symptoms of AEFI and the appropriate management thereof.</p>	IS = 0.1 P = 0
	4.4 Waste disposal.	4.4.1 The learner must be able to discard biohazardous and general waste in a safe and appropriate manner	<p>4.4.1.1 Demonstrate the procedures for disposing of sharps waste.</p> <p>4.4.1.2 Manage the safe disposal of biohazardous and general waste.</p>	IS = 0.05 P = 0.05

STAGES	TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	No. of credits (Interactive Sessions = IS Practical Sessions = P)
5. Monitoring vaccine safety	5.1 Vaccine pharmacovigilance	5.1.1 The learner should be able to explain and apply the principles of pharmacovigilance specific to vaccines.	5.1.1.1 Identify and describe the correct procedures for the timely reporting of AEFI including using the appropriate tools.	IS = 0.1 P = 0
6. Data management	6.1 Record keeping and documentation	6.1.1 The learner should be able to record and document the required/pertinent information specified for vaccine administration.	6.1.1.1 Appropriately record and store vaccinee- and vaccination details according to GPP. 6.1.1.2 Demonstrate knowledge of the vaccination programme, the specific data that needs to be recorded and reported to the appropriate authorities.	IS = 0.1 P = 0.05
7. Stakeholder interactions	7.1 Expanding access to immunisation services	7.1.1 The learner should be able to interact appropriately with relevant stakeholders to expand access to immunisation services.	7.1.1.1 Describe the requirements for establishing a working agreement with relevant stakeholders to render immunisation services in line with written terms and conditions (or service level agreement).	IS = 0.1 P = 0

Abbreviations

AEFI: Adverse events following immunisation

EPI: Expanded Programme on Immunisation

GPP: Good Pharmacy Practice

9. CRITICAL CROSS-FIELD OUTCOMES

- Identify, analyse and solve problems related to the provision of immunisation services.
- Work effectively with others as a member of a team of health care professionals in applying immunisation principles to avert vaccine preventable diseases.
- Collect, analyse, organise and critically evaluate information in using evidence-based approaches in the provision of pharmaceutical services and information to enhance Healthcare and pharmacovigilance activities.
- Communicate effectively using visual, and/or language skills in the modes of oral, written and/or practical presentation in a sustained discourse.
- Use science and technology, including informatics, in pharmacies effectively and critically, showing responsibility towards the environment and health of others by promoting ethical conduct in all contexts.
- Educating healthcare workers, the public and patients in an effective way to promote public health.

10. QUALIFICATIONS AND EXPERIENCE OF PRESENTERS/FACILITATORS

The presenters of the immunisation and injection techniques course must -

- have an undergraduate pharmacy qualification, i.e., Bachelor of Pharmacy (BPharm) degree, or recognised equivalent, plus a relevant postgraduate qualification;
 - be registered as a Practising Pharmacist with the SAPC; and
 - have a minimum of 5 years' experience as a Practising Pharmacist and a minimum of three years' experience in the field of study at a higher education training institution.
- In collaboration with a qualified clinician i.e. a medical practitioner or professional nurse (registered with the relevant professional body) with a minimum of three years' practical experience in the practical skills training offered, where required.

11. STANDARDS FOR PRESENTATION OF THE IMMUNISATION AND INJECTION TECHNIQUE TRAINING

The short course on immunisation and injection techniques must be presented by a Higher Education Institution or a Skills Development Provider accredited by the South African Pharmacy Council to offer the course.

12. MODE OF DELIVERY

The short course on immunisation and injection technique should be presented to practising pharmacists who are employed full-time or part-time. The interactive sessions of the short course should be presented using an online platform or face to face and must be presented in a manner that allows flexible study hours. There should be face to face contact sessions for practical sessions. The Higher Education Institution or the Skills Development Provider must have a reliable electronic platform that makes provision for sharing of study material and resources. This platform must have access control and at a minimum allow for the following:

- General announcements,
- Communication with students,
- Resources and training material (For example study guides, PowerPoint® presentations, video's),
- Submission of work assignments; and
- Online assessments.

A comprehensive study guide(s) must be available. The study guide(s) must guide the learners through the learning process and should integrate all the topics which form part of each module. Additional textbooks and references must also be used. Reference to additional textbooks and references must also be supplied.

13. ASSESSMENT OF THE IMMUNISATION AND INJECTION TECHNIQUE TRAINING

The methods of assessment for the course must include both formative and summative assessments. A learner should obtain 70% for the formative assessments on the theory part of the course to be able to write the summative assessment. Formative assessments should include work assignments and summative assessment should include an examination at the end of the course. The examination at the end of the theory part of the course must be in the form of a written/online examination. The assessment at the end of the practical session of the course must be in the form of a practical examination i.e., an objective structured clinical examination. A learner should be able to demonstrate full competence in all techniques, otherwise they should redo the practical assessment.

14. PROCESS OF APPEAL

An appeal process must be in place in cases where students disagree with the outcome of an assessment (written or practical). The process for appeals against assessment decisions on the demonstration of competence by candidates must be described in the study guide of the course.

15. PROCESS IN CASE OF DISHONESTY AND PLAGIARISM

Students must be warned against dishonesty and plagiarism. A procedure must be in place to address this kind of misconduct and should be reported to the South African Pharmacy Council.

16. STANDARDS FOR ADMINISTRATION AND RECORD KEEPING

A student administration system must be available for maintaining and updating detailed information about each enrolled student. Information must include but not be limited to the following:

- Student's full names and surname
- Maiden name (if applicable)
- Identification or passport number
- Contact numbers (cell phone and landline)
- E-mail address

- Postal address
- Qualifications
- Past and current employment (indicating work experience in a clinical environment)

The system must include a functionality to generate a document that can be used as “Proof of Registration” for each enrolled student.

The student administration system must also allow for record keeping of the marks that each student has obtained in each of the assessments.

Confidentiality of personal information must be maintained at all times.

17. CERTIFICATION METHODS AND PROCEDURES

Procedures must be in place to ensure that certification of students is managed in a secure and safe manner. The security and accuracy of certificates during printing, filing and distribution must be assured. The following minimum information is required for certification of the immunisation and injection technique course:

- Provider name and/or logo
- Name of the course
- Student’s full name (first names followed by surname)
- Student identification
- Date of issue of the certificate
- Signatories

18. FACILITIES, EQUIPMENT AND CONSUMABLES

The physical facilities must be adequate to deliver the theoretical and practical components of the training. For the theoretical training, facilities must include an online teaching and learning platform and suitable venues for lectures where applicable. For the practical training, facilities must include a skills laboratory adequate in size to accommodate the number of learners trained per session. The venue must be suitable to be able to practice and demonstrate competence in the education and counselling of vaccinees and caregivers. The skills laboratory must also provide adequate storeroom facilities for keeping equipment and consumables and must include an area(s) for practice simulations and an area(s) where practical assessments can be conducted.

The equipment in the skills laboratory to deliver practical training must include but not limited to adequate numbers of the following:

- Intramuscular immunisation training pads
- Subcutaneous immunisation training pads
- Cold chain equipment and temperature monitoring devices (e.g., training refrigerator, cold boxes and conditioned ice packs)
- Injectate (e.g. water for injection) in vials and containers representative of the different vaccines to be administered.
- Thermometer to monitor continuous temperature in the cold box and outside refrigerator
- Different needles and syringes suitable for vaccination
- Alcohol swabs, cotton wool balls, gauze swabs, plasters
- Biohazardous materials and sharps disposal containers
- Personal protective equipment i.e., masks and gloves

- Chlorine or alcohol-based disinfectant for cleaning vaccine spills
- Kidney tray
- Emergency tray.

19. APPENDIX A- MEDICINE LIST

- (a) All vaccines for children and adults, including Expanded Programme on Immunisation (EPI) vaccines and COVID-19 vaccines.
- (b) Emergency tray medicines and supplies for the management of adverse events following immunisation (AEFI) and anaphylaxis, in compliance with the required minimum standards, including the following:
- Adrenalin (epinephrine) 1 mg/ml (1:1000) 1 ml ampoule
 - Hydrocortisone (100 mg/ml 200mg/2ml vial)
 - Nebuliser
 - Salbutamol 0.5% 20ml nebulising solution OR 2.5mg/2.5ml OR 5mg/2.5ml unit dose vial for nebulisation OR salbutamol 100 mcg metered dose inhaler
 - Ipratropium 0.25mg/2ml OR 0.5mg/2ml unit dose vial for nebulisation
 - Promethazine 25mg/2ml 2ml ampoule
 - Sodium chloride 0.9% 1L solution
 - 2 sets of disposable syringes with 0.01 ml graduations and 26 G IM needles
 - 2 sets of disposable syringes (5 ml) and 24/ 26 G IM needles
 - IV drip set
 - AEFI case reporting form
 - Drug dosage tables for adrenaline and for hydrocortisone
 - Adhesive dressing

Note: Consult with the National Department of Health Standard Treatment Guidelines and Essential Medicines List for the latest updates