BOARD NOTICE 101 OF 2021

THE SOUTH AFRICAN PHARMACY COUNCIL

A PHARMACIST WHO PROVIDES PHARMACIST-INITIATED MANAGEMENT OF ANTIRETROVIRAL THERAPY (PIMART) SERVICES IN SOUTH AFRICA: SCOPE OF PRACTICE, COMPETENCY STANDARDS AND THE CRITERIA FOR ACCREDITATION OF A PHARMACIST INITIATED MANAGEMENT OF ANTIRETROVIRAL THERAPY (PIMART) COURSE

The South African Pharmacy Council hereby publishes for **implementation**, the scope of practice of a pharmacist who provides PIMART services, the competency standards of such pharmacists and the criteria for the approval of a curriculum of a PIMART course**.**

SCHEDULE:

Part 1: Scope of practice for a pharmacist who provides pharmacist-initiated management of antiretroviral therapy (PIMART) services.

Part 2: Competency standards for a pharmacist who provides pharmacist-initiated management of antiretroviral therapy (PIMART) services.

Part 3: Criteria for accreditation/approval by the South African Pharmacy Council of a curriculum leading to the awarding of a PIMART 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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PART 1: THE SCOPE OF PRACTICE FOR A PIMART PHARMACIST

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*; a pharmacist who has completed the Pharmacist Initiated Management of Antiretroviral Therapy (PIMART) supplementary training must be allowed to perform consultations with patients at a pharmacy or in an approved primary health care setting, which includes:

(a) history taking, performing of screening and confirmatory tests, ordering, conducting and interpretation of diagnostic and laboratory tests in line with NDoH guidelines (for diagnosis, clinical staging and assessment of an HIV infected patient or those at high risk of contracting HIV);

(b) assess and manage the HIV-infected patients or those at high risk of contracting HIV who require Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP), who are not pregnant or under 15 years of age;

(c) decision on safe and appropriate therapy;

(d) initiate anti-retroviral treatment limited to PrEP, PEP and 1st line Antiretroviral Therapy (ART) plus initiation of TB-Preventative Therapy (TPT) in line with NDoH guidelines;

(e) adjustment of ART (where necessary) which has been prescribed previously;

(f) monitoring of the outcomes of therapy;

(g) referral to another health care provider where necessary, e.g. discordant results; and

(h) confidential and adequate record keeping.

PART 2: COMPETENCY STANDARDS FOR A PHARMACIST WHO PROVIDES PHARMACIST-INITIATED MANAGEMENT OF ANTIRETROVIRAL THERAPY (PIMART) SERVICES

ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CD4	Cluster of Differentiation 4
CD8	Cluster of Differentiation 8
ELISA	Enzyme-Linked Immunosorbent Assay
GP	General Practitioner
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
IRIS	Immune Reconstitution Inflammatory Syndrome
MTCT	Mother-to-Child Transmission
NDoH	National Department of Health
PEP	Post Exposure Prophylaxis
PhICT	Pharmacist-Initiated Counselling and Testing
PIMART	Pharmacist-Initiated Management of Antiretroviral Therapy
PMTCT	Prevention of Mother-to-Child Transmission
PrEP	Pre-Exposure Prophylaxis
TB	Tuberculosis
TPT	TB-preventative treatment
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organisation

DEFINITIONS

Behavioural competency: Typical behaviour observed when effective performers apply motives, traits or skills to job-relevant tasks.

Competency: A quality or characteristic of a person related to effective or superior performance. Competency consists of aspects such as attitudes, motives, traits and skills.

Domain: Represents an organised cluster of competencies within a framework and the domains, with associated competencies.

Fast Track Initiation Counselling: Fast-tracking patients onto ART without delay and providing minimal ART preparation counselling.

HIV Specialist: A practising physician with a background in clinical, internal or family medicine who provides comprehensive primary health care services to patients with HIV on a daily basis.

SUMMARY OF PIMART COMPETENCY STANDARDS

DOMAIN	Competency Standard
1. Conduct testing and diagnosis of HIV	1.1 Understand and perform various HIV testing options. 1.2 Understand and perform CD4 Testing. 1.3 Conduct Pharmacist-Initiated Counselling and Testing (PhICT). 1.4 Provide Risk Reduction Counselling. 1.5 Use immunological and virological parameters in understanding the severity of HIV infection.
2. Initiate pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP) and 1st line antiretroviral therapy (ART) plus the initiation of TB-preventative therapy (TPT) where appropriate and apply protocol adherence measures	2.1 Demonstrate knowledge of ART Principles. 2.2 Prepare patients for ART adherence. 2.3 Identify, classify, and analyse the various types of ARTs and their side effects and toxicities. 2.4 Initiate ART. 2.5 Analyse ART medicine choices in PrEP and PEP, and considerations around pharmacology and drug interactions, including TPT. 2.6 Identify and manage PrEP, PEP and ART contra-indications. 2.7 Conduct PEP in the PIMART environment.
3. Implement processes for the prevention of HIV transmission and infection via PrEP, safer conception and contraception, and prevention of mother to child transmission (PMTCT)	3.1 Implement PrEP in the PIMART environment. 3.2 Conduct pregnancy screening and recommend contraception in the PIMART context. 3.3 Implement pre-conception management for HIV positive couples. 3.4 Demonstrate knowledge of PMTCT and the rationale for PMTCT programmes.
4. Implement processes to identify and manage co-morbidities and opportunistic infections related to HIV	4.1 Manage HIV co-morbidities. 4.2 Identify and manage common opportunistic infections. 4.3 Manage TB and HIV co-infection. 4.4 Promote TB prevention.
5. Implement processes to prevent and manage drug interactions and drug resistance	5.1 Understand the importance of drug interactions, e.g. drug/drug and drug/disease. 5.2 Demonstrate in-depth knowledge of various ART drug interactions. 5.3 Prevent adverse drug interactions and reactions. 5.4 Define the types and consequences of drug resistance.
6. Handle ART data responsibly and use disease management systems appropriately	6.1 Generate reports to assist with clinical governance, programme management and quality improvement. 6.2 Use a Patient Management System. 6.3 Implement the process of care for PIMART. 6.4 Apply minimum package of interventions to support linkage to care.

DOMAIN 1: CONDUCT TESTING AND DIAGNOSIS OF HIV

INTRODUCTION

The domain covers competencies that are required to conduct testing and diagnosis of HIV, provide counselling and understanding the severity of the HIV infection and the mental state of the patient. The NDoH's aspiration is that 90% of people living with HIV will know their status. Participation of pharmacists in conducting testing and diagnosis of HIV will contribute to improved access to quality testing and diagnosis sites. The competencies required in the domain for testing and diagnosis of HIV are:

1.1 Understand and perform various HIV testing options;
1.2 Understand and perform CD4 Testing;
1.3 Conduct Pharmacist-Initiated Counselling and Testing (PhICT);
1.4 Provide Risk Reduction Counselling; and
1.5 Use immunological and virological parameters in understanding the severity of HIV infection.

DOMAIN 1: CONDUCT TESTING AND DIAGNOSIS OF HIV	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
1.1 Understand and perform various HIV testing options	1.1.1 Demonstrating an understanding of the different types of tests available when testing for HIV. 1.1.2 Performing rapid or point of care tests (including HIV Self-tests) to diagnose HIV. 1.1.3 Interpreting HIV test results including reasons for false-negative. 1.1.4 Selecting which tests to use to diagnose HIV in a range of circumstances. 1.1.5 Linking patients with positive, negative, or indeterminate results to care (appropriate referral).
1.2 Understand and perform CD4 Testing	1.2.1 Explaining the role CD4+ T-cells and CD8+ T-cells play. 1.2.2 Knowing when and why CD4 counts are measured. 1.2.3 Interpreting CD4 counts. 1.2.4 Describing the factors that affect CD4 counts.
1.3 Conduct Pharmacist-Initiated Counselling and Testing (PhICT)	1.3.1 Demonstrating an understanding of HTS in general and PIMART in terms of linkage to care and pre-test counselling. 1.3.2 Describing the nature of counselling as it relates to counselling phases, clinical interaction, legal and ethical issues, and confidentiality and disclosure. 1.3.3 Demonstrating an understanding and application of empathic counselling skills. Range: Active listening, mirroring, paraphrasing, the reflection of content and feelings, summarising, responding, and questioning. 1.3.4 Demonstrating an understanding and application of counselling approaches in specified groups Range: Adolescents, strong reactions, couples, serodiscordant couples and suicidal patients. 1.3.5 Describing the basic goals of PEP and PrEP Effective Use counselling.
1.4 Provide Risk Reduction Counselling	1.4.1 Demonstrating an understanding of common risk reduction conditions. 1.4.2 Demonstrating an understanding of risk-taking variables Range: Knowledge, Relationships, Social Context, Structural Factors. 1.4.3 Demonstrating an understanding of the risk reduction behaviour change model. 1.4.4 Applying the seven (7) steps in risk reduction counselling.
1.5 Use immunological and virological parameters in understanding the severity of HIV infection	1.5.1 Demonstrating an understanding of the use and benefits of clinical staging. 1.5.2 Describing the WHO HIV Stages. 1.5.3 Identifying symptoms and common opportunistic infections for stage 1, 2, 3 and 4, i.e. AIDS-defining illness. 1.5.4 Demonstrating an understanding of immunological and clinical staging parameters.

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DOMAIN 2: INITIATE PRE-EXPOSURE PROPHYLAXIS (PrEP), POST-EXPOSURE PROPHYLAXIS (PEP) AND 1ST LINE ANTIRETROVIRAL THERAPY (ART) PLUS INITIATION OF TB-PREVENTATIVE THERAPY (TPT) WHERE APPROPRIATE AND APPLY PROTOCOL ADHERENCE MEASURES

INTRODUCTION

The domain covers competencies that are required to initiate therapy and apply protocol adherence measures. A concept adopted by NDoH which advocates that 90% of people who know their HIV status will receive treatment with at least 90% of those on treatment being virally suppressed.

The competencies required in the domain for testing and diagnosis of HIV are:

2.1 Demonstrate knowledge of ART Principles;
2.2 Prepare patients for ART adherence;
2.3 Identify, classify, and analyse the various types of ARTs and their side effects and toxicities;
2.4 Initiate ART;
2.5 Analyse ART medicine choices in PrEP and PEP, and considerations around pharmacology and drug interactions, including TPT;
2.6 Identify and manage PrEP, PEP and ART contra-indications; and
2.7 Conduct PEP in the PIMART environment.

DOMAIN 2: INITIATE PRE-EXPOSURE PROPHYLAXIS (PrEP), POST-EXPOSURE PROPHYLAXIS (PEP) AND 1ST LINE ANTIRETROVIRAL THERAPY (ART) PLUS INITIATION OF TB-PREVENTATIVE THERAPY (TPT) WHERE APPROPRIATE AND APPLY PROTOCOL ADHERENCE MEASURES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
2.1 Demonstrate knowledge of ART Principles	2.1.1 Describing the objectives of ART. 2.1.2 Describing the HIV life cycle, CD 4 counts, viral load and when to start therapy.
2.2 Prepare patients for ART adherence	2.2.1 Defining ART adherence. 2.2.2 Applying the pre-ART counselling process. 2.2.3 Prepare patients for ART by applying the adherence counselling process. 2.2.4 Interpreting viral load results and monitor for ART adherence. 2.2.5 Conducting laboratory monitoring for antiretroviral therapy efficacy and safety. 2.2.6 Applying the post-ART counselling process.
2.3 Identify, classify, and analyse the various types of ART and their side effects and toxicities	2.3.1 Demonstrating knowledge of the classes of ART. 2.3.2 Describing the pharmacology, dosing, side effects, toxicity monitoring and management of medicines used in 1st line ART, PrEP and PEP according to current national guidelines.
2.4 Initiate ART	2.4.1 Describing first-line treatment pharmacology practicalities in PIMART. 2.4.2 Identifying who is not eligible for therapy via PIMART by analysing initiation limitations in PIMART. Range: TB, IRIS, cryptococcal meningitis, hepatitis B, pregnant woman, patients under 15 years. 2.4.3 Describing ART Initiation steps and implementing the ART initiation algorithm according to current national guidelines. 2.4.4 Transitioning a patient from PrEP to ART if required.
2.5 Analyse ART medicine choices in PrEP and PEP, and considerations around pharmacology and drug interactions, including TPT	2.5.1 Describing and analysing pharmacology, dosing, toxicity, side effects and drug interactions of various regimens as determined by NDoH for PEP and PrEP.
2.6 Identify and manage PrEP, PEP and ART contra-indications	2.6.1 Identifying PEP contraindications. 2.6.2 Analysing and classifying the management of ambiguities in source status, source ART adherence, and patient HIV status. 2.6.3 Referring pregnant and breastfeeding women who require PEP. 2.6.4 Describing Hepatitis B screening and vaccination as set out in the PHC EML for PEP.

DOMAIN 2: INITIATE PRE-EXPOSURE PROPHYLAXIS (PrEP), POST-EXPOSURE PROPHYLAXIS (PEP) AND 1ST LINE ANTIRETROVIRAL THERAPY (ART) PLUS INITIATION OF TB-PREVENTATIVE THERAPY (TPT) WHERE APPROPRIATE AND APPLY PROTOCOL ADHERENCE MEASURES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
2.7 Conduct PEP in the PIMART environment	2.7.1 Describing PEP in the PIMART Context. 2.7.2 Listing PEP Indications. 2.7.3 Identifying at-risk groups in terms of PEP. 2.7.4 Analysing PEP Efficacy. 2.7.5 Describing the steps in the PEP treatment process. 2.7.6 Initiate clients on PEP. 2.7.7 Implementing adherence monitoring and follow-up. 2.7.8 Implementing the PEP to PrEP transition.

DOMAIN 3: IMPLEMENT PROCESSES FOR THE PREVENTION OF HIV TRANSMISSION AND INFECTION VIA PrEP, SAFER CONCEPTION AND CONTRACEPTION, AND PREVENTION OF MOTHER TO CHILD TRANSMISSION

INTRODUCTION

The competencies required in the domain to implement processes for the prevention of HIV transmission and infection.

3.1 Implement PrEP in the PIMART environment.
3.2 Conduct pregnancy screening and recommend contraception in the PIMART context.
3.3 Implement pre-conception management for HIV positive couples.

DOMAIN 3: IMPLEMENT PROCESSES FOR THE PREVENTION OF HIV TRANSMISSION AND INFECTION VIA PrEP, SAFER CONCEPTION AND CONTRACEPTION, AND PREVENTION OF MOTHER TO CHILD TRANSMISSION	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
3.1 Implement PrEP in the PIMART environment	3.1.1 Interpreting and applying the steps in the treatment process. Range: screening, initiation, follow-up, maintenance, adherence support, FAQs and stopping PrEP. 3.1.2 Implementing the PEP to PrEP transition, and the prevention continuum and failure referral. 3.1.3 Describing PrEP administration methods and components. 3.1.4 Describing PrEP regimen options and nomenclature. 3.1.5 Analysing the pharmacology, dosing, safety, toxicity monitoring and side effects of medicines recommended by NDoH for PrEP. 3.1.6 Describing PrEP indications, contra-indications, and practical application in the pharmacy context.
3.2 Conduct pregnancy screening and recommend contraception in the PIMART context	3.2.1 Carrying out a basic fertility intention screen and referring patients who wish to conceive. 3.2.2 Demonstrating an understanding of processing pregnancy test results. Range: positive, STI and HIV screening, negative with pregnancy intent, negative without pregnancy intent. 3.2.3 Listing and describing the types of available contraceptives. Range: classification, dosing, and efficacy. 3.2.4 Describing indications for contraception. Range: women who may wish to conceive in the future, and women who do not wish to conceive at all, contraception eligibility, and general use in South Africa. 3.2.5 Describing the link between contraception and HIV. Range: injectable link to incidence, HIV and contraception choices and safety, contraception impact on risk.
3.3 Implement pre-conception management for HIV positive couples	3.3.1 Describing key aspects to consider ensuring conception occurs safely, and knowledge of how to minimise the risks of partner acquiring HIV. 3.3.2 Describing methods used to ensure safe conception. Range: ART, PrEP, VMMC, STI treatment, timed intercourse without the use of a condom and self-insemination. 3.3.3 Demonstrate application of couple counselling skills when working with discordant couples.
3.4 Demonstrate knowledge of PMTCT and the rationale for PMTCT programmes	3.4.1 Demonstrating knowledge of the MTCT risk and risk factors in South Africa. 3.4.2 Demonstrating knowledge of the ideal treatment pathway for PMTCT. 3.4.3 Demonstrating knowledge of the safety and efficacy of various pharmacological therapies in PMTCT. 3.4.4 Demonstrate knowledge of the factors that improve and impede adherence and retention in PMTCT interventions. 3.4.5 Demonstrating knowledge of appropriate viral load monitoring and responses in PMTCT.

DOMAIN 4: IMPLEMENT PROCESSES TO IDENTIFY AND MANAGE CO-MORBIDITIES AND OPPORTUNISTIC INFECTIONS RELATED TO HIV

INTRODUCTION

The competencies required in the domain implement processes to identify and manage co-morbidities and opportunistic infections related to HIV are:

4.1 Manage HIV co-morbidities;
4.2 Identify and manage common opportunistic infections;
4.3 Manage TB and HIV co-infection; and
4.4 Promote TB prevention.

DOMAIN 4: IMPLEMENT PROCESSES TO IDENTIFY AND MANAGE CO-MORBIDITIES AND OPPORTUNISTIC INFECTIONS RELATED TO HIV	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
4.1 Manage HIV co-morbidities	4.1.1 Describing and applying the management of diseases as HIV co-morbidities. • Type 2 Diabetes as an HIV co-morbidity. • Hypertension as an HIV co-morbidity. • Asthma and COPD as an HIV co-morbidity. • Epilepsy as an HIV co-morbidity. • Hypertriglyceridaemia and hypercholesterolaemia as HIV co-morbidities.
4.2 Identify and manage common opportunistic infections	4.2.1 Demonstrating an understanding to identify and manage opportunistic infections, including: • Pneumocystis Carinii Pneumonia. • Respiratory Distress. • Kaposi Sarcoma. • Cryptococcal meningitis. • Herpes Zoster.
4.3 Manage TB and HIV co-infection	4.3.1 Demonstrating an understanding of TB diagnosis in HIV infected adults. 4.3.2 Demonstrating an understanding of managing TB/HIV co-infection. 4.3.3 Identifying and describing TB/HIV drug interactions and shared side effects. 4.3.4 Promoting adherence to TB treatment and ART.
4.4 Promote TB prevention	4.3.5 Screening for TB in adults and children and know when to refer patients for further care if TB is suspected. 4.3.6 Application of TB-Preventative Therapy (TPT) Range: dosage, eligibility, monitoring, adherence.

DOMAIN 5: IMPLEMENT PROCESSES TO PREVENT AND MANAGE DRUG INTERACTIONS, ADVERSE DRUG REACTIONS AND DRUG RESISTANCE

INTRODUCTION

The competencies required in the domain to implement processes to prevent and manage drug interactions, adverse drug reactions and drug resistance are:

5.1 Understand the importance of drug interactions, e.g. drug/drug and drug/disease;
5.2 Demonstrate in-depth knowledge of various ART drug interactions and reactions;
5.3 Prevent adverse drug interactions and reactions; and
5.4 Define the types and consequences of drug resistance.

DOMAIN 5: IMPLEMENT PROCESSES TO PREVENT AND MANAGE DRUG INTERACTIONS, ADVERSE DRUG REACTIONS AND DRUG RESISTANCE	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
5.1 Understand the importance of drug interactions, e.g. drug/drug and drug/disease	5.1.1 Understanding the basics of drug interactions. 5.1.2 Listing and describing the consequences of drug interactions. Range: therapeutic failure, drug resistance, life-threatening toxicities, poor adherence, increased costs. 5.1.3 Demonstrating knowledge and understanding of how the body processes drugs and of specified pharmacological concepts. Range: pharmacokinetics and pharmacodynamics, therapeutic index, substrate, inhibitor, inducer.
5.2 Demonstrate in-depth knowledge of various ART drug interactions and reactions	5.2.1 Listing the ARVs most involved in drug interactions. 5.2.2 Describing medicines that may interact with ART and understand their mode of interaction and the management of interaction.
5.3 Prevent adverse drug interactions and reactions	5.3.1 Knowing how to prevent drug interactions. Range: Comprehensive patient questioning and accessing useful resources.
5.4 Define the types and consequences of drug resistance	5.4.1 Demonstrating an understanding of the consequences of drug resistance. 5.4.2 Demonstrating an understanding of the mechanism of HIV drug resistance. 5.4.3 Defining acquired drug resistance, transmitted drug resistance, and pre-treatment drug resistance in patients.

DOMAIN 6: HANDLE ART DATA RESPONSIBLY AND USE DISEASE MANAGEMENT SYSTEMS APPROPRIATELY

INTRODUCTION

The competencies required in the domain to handle ART data responsibly and use disease management systems appropriately are:

6.1 Generate reports to assist with clinical governance, programme management and quality improvement;
6.2 Use a Patient Management System;
6.3 Implement the process of care for PIMART; and
6.4 Apply minimum package of interventions to support linkage to care.

DOMAIN 6: HANDLE ART DATA RESPONSIBLY AND USE DISEASE MANAGEMENT SYSTEMS APPROPRIATELY	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
6.1 Generate reports to assist with clinical governance, programme management and quality improvement	6.1.1 Demonstrating an understanding and description of the content, generation, extraction, and verification of reports- • Outstanding laboratory results list. • Data validation list. • Early missed appointment list. • Late missed appointment list. • Unconfirmed lost to follow-up list. • ART regimen line validations list. • Viral load cascade list.
6.2 Use a Patient Management System	6.1.2 Describing the functionality and process flow within a patient management system.
6.3 Implement the process of care for PIMART	6.3.1 Demonstrating a detailed knowledge and understanding of the baseline Clinical Evaluation for HIV+ Adults and Adolescents (>15 years) in terms of clinical evaluation component, purpose, and further actions. 6.3.2 Demonstrating a detailed knowledge and understanding of the Baseline Laboratory Evaluation for Adults and Adolescents (>15 years) in terms of laboratory evaluation, purpose, sex, and referral. 6.3.3 Demonstrating a detailed knowledge and understanding of the Serial HIV Testing Algorithm. 6.3.4 Demonstrating a detailed knowledge and understanding of the REFLEX Laboratory ELISA Testing Algorithm. 6.3.5 Demonstrating an understanding of the Baseline Laboratory Evaluation for Adults and Adolescents (>15 years) (GP/HIV Specialist) in terms of laboratory evaluation, purpose, sex, outcomes. 6.3.6 Demonstrating a detailed knowledge and understanding of TPT in terms of client category, specific eligibility requirements, treatment and duration. 6.3.7 Identifying common 1st line regimens.
6.4 Apply minimum package of interventions to support linkage to care	6.4.1 Demonstrating a detailed knowledge and understanding of PIMART referral criteria. 6.4.2 Demonstrating a detailed knowledge and understanding of Fast Track Initiation Counselling. 6.4.3 Describing the procedure to follow before, during and at the end of each session. 6.4.4 Describing the steps in dealing with substance abuse. 6.4.5 Describing the procedure to follow for scheduling appointments for the next visit and tracing patients not seen for ≥ 90 days. 6.4.6 Describing the procedure for re-integrating patients into care.

REFERENCES

1. Adherence guidelines for HIV, TB and NCDs: Policy and service delivery guidelines for linkage to care, adherence to treatment and retention in care. 2016. National Department of Health.

2. HIV Testing Services: Policy, 2016. National Department of Health.

3. Scope of practice and competency standards for a PIMART pharmacist. 2020. HIV Clinician Society.

PART 3: CRITERIA FOR ACCREDITATION/APPROVAL BY THE SOUTH AFRICAN PHARMACY COUNCIL OF A CURRICULUM LEADING TO THE AWARDING OF A PHARMACIST INITIATED MANAGEMENT OF ANTIRETROVIRAL THERAPY COURSE

A. INTRODUCTION

In terms of Section 3 of the Pharmacy Act, 53 of 1974, one of the objects of the South African Pharmacy Council (Council) is to establish, develop, maintain and control universally acceptable standards of pharmaceutical education.

Council developed these criteria in order to evaluate the Pharmacist Initiated Management of Antiretroviral Therapy (PIMART) course curriculum of each accredited institution.

B. PRINCIPLES

The criteria for the accreditation/approval of a curriculum leading to the awarding of a PIMART course are based on the following principles–

1.1 Use of the criteria should promote the application of the principles of good governance in the process of the evaluation of curricula submitted to Council for approval.

1.2 Any decisions taken with regard to the approval or disapproval of a curriculum must be defensible by Council.

1.3 Compliance with the criteria will be considered to be a minimum requirement for the accreditation/approval of the PIMART curriculum.

1.4 The institutional autonomy of the Higher Education Institution (HEI)/Skills Development Provider (SDP) must be respected.

1.5 Portability will not be used as a basis for approval of courses.

C. CRITERIA FOR ACCREDITATION/APPROVAL OF A CURRICULUM LEADING TO THE AWARDING OF A PIMART COURSE

1. Criteria for entry to the course

1.1 Evidence must be provided by the prospective provider that pharmacists who wish to enter into study towards achieving this course must:

(a) be in possession of a Bachelor of Pharmacy (BPharm) degree, or recognised equivalent,

(b) be registered as a pharmacist with the SAPC, and

(c) have completed their community service year.

2. Criteria for compliance with the requirements of the course

2.1 Evidence must be provided by the prospective provider that –

2.1.1 The curriculum must be on NQF level 8; and

2.1.2 The duration for completion of the course must be at least 160 notional study hours.

3. Requirements for pharmacists who want to provide PIMART services

3.1 In order to provide PIMART services, the pharmacist is required to:

3.1.1 Successfully complete the PIMART course with an accredited provider.

3.1.2 Record the PIMART course with the SAPC.

3.1.3 Apply for a Section 22(A)15 permit at the NDoH.

3.1.4 Upon receipt of the Section 22(A)15 permit from the NDoH the pharmacist must record their permit with the SAPC.

3.1.5 Lastly, the pharmacist may apply for a Practice Code Number from the Board of Healthcare Funders of Southern Africa (BHF).

4. Criteria for compliance with the outcomes

The prospective provider must provide evidence that the topics and the associated outcomes have been with complied with as listed in Table 1:

Table 1: Topics covered in the PIMART course with associated outcomes

Topic	On completion, the student should be able to:
HIV	(a) Apply commonly used medical terminology and acronyms, relevant to this course. (b) Demonstrate a sound understanding of the HIV life cycle, CD4 count and viral load meaning, and when to initiate ART. (c) Order, perform and interpret HIV tests (rapid, self-screening ELISA and CD-4 tests); i.e. diagnose. (d) Describe factors that could influence test results (such as CD-4 count). (e) Perform, order or refer and interpret additional, relevant screening tests (tuberculosis[1], sexually transmitted infections[2], substance abuse and pregnancy tests). (f) Order or refer and interpret additional, relevant laboratory screening tests, e.g. baseline creatinine. (g) Differentiate between the different WHO staging profiles and be able to classify a patient accordingly. (h) Describe the mechanism, clinical presentation and preventative measures relating to Immune Reconstitution Inflammatory Syndrome (IRIS). (i) Effectively consult and accurately document patient history, including but not limited to socio-economic profile, medication history, comorbidity profile etc. (j) Identify opportunistic infections (in line with WHO staging and most recent NDoH standard treatment guidelines). (k) Demonstrate the ability to perform patient assessments based on theoretical guidelines. (l) Demonstrate specialised clinical skills by providing authentic proof of practice-based experience and knowledge of HIV test results. (m) Effectively and professionally communicate with other members of the healthcare team. (n) Identify and professionally refer complicated cases.
Prevention of HIV transmission and infection (PrEP and PEP)	(a) Demonstrate a clear understanding of the importance, role indications, contra-indications and regimen options of PrEP and PEP. (b) Have a thorough knowledge and understanding of basic ARV treatment principles (as applied PMTCT, PrEP or PEP). (c) Describe who is eligible for PMTCT, PrEP or PEP. (d) Appropriately initiate PMTCT, PrEP or PEP. (e) Discuss the general preventative measures against HIV (i.e. condoms, contraceptives). (f) Understand the importance of keeping pregnant women HIV negative. (g) Understand the role and importance of PMTCT, along with the ability to initiate it. (h) Describe methods to ensure safe conception.

[1] Pharmacists may not draw blood or order/interpret X-rays, differential diagnosis will only be made based on symptoms and complaints.

[2] Pharmacists may not perform physical examination of genital area, differential diagnosis will only be made based on symptoms and complaints.

Topic	On completion, the student should be able to:
	(i) Demonstrate ability to screen for pregnancy. (j) Demonstrate a clear understanding of the interactions between ARV and oral contraceptives. (k) Elaborate on the association and interaction between STIs and HIV. (l) Demonstrate a clear understanding of harm reduction programmes in key populations. (m) Demonstrate a clear understanding of the importance, role, and indications of PEP (including the legal requirements in the case of criminal offences) and PrEP.
Pharmacological Management of HIV	(a) Outline and differentiate between the pharmacological and clinical profiles (including, but not limited to mechanisms of action, side effects and interaction profiles, absolute and relative contraindications, antiviral drug resistance implications and dosing) of the various ARV drugs. (b) Have a thorough knowledge and understanding of basic ARV treatment principles (as applied to ART). (c) Identify, classify and analyse the different ARV pharmacological profiles. (d) Implement the most recent NDoH standard treatment guidelines. (e) Apply pre-ART counselling appropriately and initiate ARV treatment regimens. (f) Illustrate sound clinical knowledge by means of recommending evidence-based treatment regimens. (g) Discuss the importance of treatment adherence for general treatment outcome. (h) Effectively and clearly explain the way forward to the patient and what to expect (including, but not limited to expected adverse effects and potential drug-drug interactions, drug allergies, contraindications, and general adherence and risk reduction counselling). (i) List complications in the ART era and describe the general approaches to managing these complications.
Drug interactions and drug resistance	(a) Outline the basic principles of drug interactions and the consequences thereof. (b) List the most significant interactions relating to ARV treatment and explain appropriate measures to accommodate or eliminate these interactions. (c) Demonstrate an understanding of the mechanism of HIV resistance and understand how resistance is determined clinically. (d) Define acquired drug resistance, transmitted drug resistance and pre-treatment drug resistance.
Co-morbidities and opportunistic infections related to HIV	(a) List and describe co-morbidities (including, but not limited to diabetes, hypertension, asthma, epilepsy, hypercholesterolemia, hyperthyroidism, TB) to be considered in ARV initiated patients. (b) Identify opportunistic infections and refer accordingly. (c) Discuss recent anti-TB treatment regimens (according to most recent NDoH standard treatment guidelines), their pharmacological profiles and dosage adjustments required when co-administering with ARVs (Including first-line ART, PMTCT, PrEP or PEP). (d) Demonstrate knowledge of Hepatitis. (e) Demonstrate knowledge of TB prevention.
ART data, disease management and referral network	(a) Record keeping. (b) Data management. (c) Referral pathway.

5. Criteria for compliance with requirements relating to qualifications and experience of course presenters

5.1 Evidence must be provided by the prospective provider that the presenter(s) of the course-

5.1.1 have a Bachelor of Pharmacy (BPharm) degree, or recognised equivalent and be registered as a pharmacist with the SAPC with prior experience or an additional qualification in HIV management; or

5.1.2 have a MBChB degree and be registered as a medical practitioner with the Health Professions Council of South Africa (HPCSA) with prior experience or an additional qualification in HIV management; or

5.1.3 is a nurse practitioner who is providing training for the NIMART course.

6. Criteria for compliance with requirement for prior approval by the relevant structures of the institution

6.1 Evidence must be provided by the prospective provider that the course received prior approval by the relevant structures of the HEI or SDP or providers of short courses.

7. Criteria for compliance with requirements relating to mode of delivery

7.1 Evidence must be provided by the prospective provider that-

7.1.1 the course allows for flexible study hours;

7.1.2 the institution has a reliable electronic platform that makes provision for sharing of study material and resources;

7.1.3 this platform must have access control and at a minimum allow for the following:

(i) General announcements;

(ii) Communication with students;

(iii) Resources and training material (e.g. study guides, PowerPoint presentations and videos);

(iv) Submission of work assignments; and

(v) Online tests and examinations.

7.1.4 there are comprehensive study guides which guide the student through the learning process.

7.1.5 there are additional textbooks and references.

8. Criteria for compliance with requirements relating to assessment and moderation

8.1 Evidence must be provided by the prospective provider that–

8.1.1 both formative and summative forms of assessment are applied appropriately throughout the assessment process.

8.1.2 the student is exposed to a minimum of twenty (20) clinical cases of which ten (10) are observed and ten (10) as part of formal assessment.

8.1.3 admission to the examination of the course is obtained through proof of participation confirming that the student has met the requirement for admission to the examination.

8.1.4 the summative assessment at the end of the course must be in the form of a written/online examination and a formal Objective Structured Clinical Examination (OSCE) with two examination opportunities.

8.1.5 the students must achieve an average mark of at least 60% for the portfolio of evidence (which includes assignments and clinical cases), with a subminimum of 60% for each component, in order to be admitted to the summative assessment (examination).

8.1.6 the subminimum examination mark must be at least 70%. The pass requirements for the course must be a final course mark of at least 70%.

8.1.7 the final course mark is calculated as follows:

(a) Average mark of compulsory portfolio which includes the ten (10) documented clinical cases: 33%

(b) Examination mark (written/oral) and OSCE examination: 67%

(c) Final course mark:100%

9. Criteria for compliance with the process of appeal

9.1 Evidence must be provided by the prospective provider that–

9.1.1 there is a process in place in cases where students are in disagreement regarding the outcome of an assessment (written/practical).

9.1.2 the appeals process against assessment decisions on the demonstration of competence by candidates is described in the study guide.

10. Criteria for compliance with the dishonesty and plagiarism policy

10.1 Evidence must be provided by the prospective provider that there are policies and procedure in place to address dishonesty and plagiarism.

11. Criteria for compliance with the certification methods and procedures

11.1 Evidence must be provided by the prospective provider that–

11.1.1 there are procedures in place to ensure that certification of the students is managed in a secure and safe manner.

11.1.2 the security and accuracy of certificates during printing, filing and distribution must be assured.

11.1.3 the following information is available for certification of the course certificate:

(a) provider name and/or logo;

(b) name of the course;

(c) student's full name (first names followed by surname);

(d) student's identity number;

(e) date of issue of the certificate; and

(f) signatories.

12. Criteria for compliance with facilities and equipment

12.1 Evidence must be provided by the prospective provider that-

12.1.1 If the course is presented in a mode that requires contact sessions with the students then the physical facilities are:

(a) adequate and include lecture rooms;

(b) The lecture rooms are sufficient in number and adequate in size to accommodate the number of students; and

(c) The lecture rooms are adequately equipped, well maintained and provide a reasonably attractive environment for teaching and learning.

12.1.2 If the course is presented as a distance learning course with only contact workshops then the institution must have a reliable electronic platform that makes provision for:

(a) sharing of study material and resources;

(b) submission of work assignments by the students; and

(c) the functionality that allows students to write online tests and/or exams.

12.1.3 there are offices for administrative staff and course presenters;

12.1.4 there are clinical simulation facilities (for presentation of compulsory contact sessions/workshops); and

12.1.5 the clinical simulation facilities are sufficient in number and adequate in size to accommodate the number of students, and must be adequately equipped, well maintained and provide a reasonably attractive environment for teaching and learning.

13. Criteria for compliance with standards for administration and record keeping

13.1 Evidence must be provided by the prospective provider that-

13.1.1 there is a student administration system for maintaining and updating detailed information about each enrolled student.

13.1.2 the student Information includes but is not limited to the following:

(a) student's full names and surname;

(b) maiden name (if applicable);

(c) ID number;

(d) cell phone number;

(e) e-mail address;

(f) postal address; and

(g) qualifications.

13.1.3 the student administration system has a functionality to generate a document that can be used as "Proof of Registration" for each enrolled student.

13.1.4 the student administration system allows for record keeping of the marks that each student has obtained during the course and must include a functionality to generate an "Academic Record" for each student.