

BOARD NOTICE 102 OF 2021
THE SOUTH AFRICAN PHARMACY COUNCIL

PRIMARY CARE DRUG THERAPY PHARMACIST (PCDT)

The South African Pharmacy Council hereby publishes for broad-based stakeholder consultation, the scope of practice for a Primary Care Drug Therapy (PCDT) Pharmacist, the competency standards of such pharmacists and the criteria for the approval of a curriculum of a PCDT 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 Primary Care Drug Therapy (PCDT) pharmacist.

Part 2: Competency standards for a Primary Care Drug Therapy (PCDT) pharmacist.

Part 3: Criteria for accreditation/approval by the South African Pharmacy Council of a curriculum of a PCDT 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.



VM TLALA
REGISTRAR

Address: 591 Belvedere Street, Arcadia, Pretoria, 0083,
Private Bag X40040, Arcadia, 0007. Telephone: 0861 7272 00

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



PRIMARY CARE DRUG THERAPY PHARMACIST

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PART 1: THE SCOPE OF PRACTICE FOR A PRIMARY CARE DRUG THERAPY (PCDT) PHARMACIST

In addition to the acts and services which form part of the scope of practice of the pharmacist as prescribed in terms of Regulation 3 and 4 of the *Regulations relating to the practice of Pharmacy*, a pharmacist who has completed the PCDT supplementary training and who has been issued with the relevant section 22A(15) permit and in offering the PCDT services according to the list of conditions published by the National Department of Health from time to time, may perform the following acts and services:

- (a) consultation with patients, in an approved primary health care setting, which includes:
 - (i) comprehensive patient history taking;
 - (ii) physical examination (excluding internal and external genitourinary examination);
 - (iii) assessment of diagnosed and undiagnosed conditions listed in the Primary Health Care (PHC) Standard Treatment Guidelines (STG) and Essential Medicines List (EML);
 - (iv) ordering, conducting and interpretation of applicable diagnostic and laboratory tests for the purposes of (iii) above;
 - (v) interpretation of the assessment/diagnosis;
 - (vi) decision on safe and appropriate therapy;
 - (vii) prescribing of medicines for the conditions identified for the purposes of PCDT as per PHC STG and EML List published by the National Department of Health from time to time;
 - (viii) monitoring of the outcomes of therapy; and
 - (ix) referral to another health care provider where necessary.

PART 2: DRAFT COMPETENCY STANDARDS FOR PRIMARY CARE DRUG THERAPY PHARMACIST

ACRONYMS

DOH	Department of Health
EML	Essential Medicines List
PCDT	Primary Care Drug Therapy
PHC	Primary Health Care
SA	South Africa
SAPC	South African Pharmacy Council
STG	Standard Treatment Guidelines

DEFINITIONS

Behavioural statement: are statements which describe the activity or outcomes prescribers should be able to demonstrate.

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.

1. INTRODUCTION

Pharmacists have a broad scope of practice which allow them to render additional services provided they meet the prescribed minimum requirements. Primary Care Drug Therapy (PCDT) is one of the services that a pharmacist may provide upon completion of a supplementary training course with an accredited higher education institution. On completion of the course, a certificate of completion should be registered with the South African Pharmacy Council (SAPC) prior to submission of an application for a PCDT permit with the Department of Health (DoH). Following the issuing of the permit by the DoH, Pharmacists are required to record the permit with the SAPC. The permit will authorise a pharmacist to diagnose, prescribe and administer medicine for selected conditions in line with Primary Health Care (PHC) Standard Treatment Guidelines (STG) and Essential Medicine List (EML).

2. BACKGROUND

The main goal of extending prescribing to pharmacists is to improve patient care without compromising patient safety, increase access to health care services, increase patient choice, make better use of the skills of health professionals and contribute to the introduction of a more flexible team working in primary health care settings.

Pharmacists are expected to apply the principles of pharmaceutical care in providing PCDT services. Pharmaceutical care is a patient centred, outcomes orientated pharmacy practice that requires the pharmacist to work in conjunction with the patient and the patient's other healthcare providers to promote health, to prevent disease, and to assess, monitor, initiate and modify medication use to assure that medicine therapy is safe and effective.

The competency standards and scope of practice of PCDT pharmacist prescriber will enable them to practise and develop as prescribers and assist in meeting the health care needs of the country in line with the PHC EML and STG.

3. DEVELOPMENT OF COMPETENCY STANDARDS FOR PCDT PHARMACIST

The following documents form the basis for the development of competency standards for PCDT pharmacist:

- PCDT pharmacist qualification and scope of practice
- The scope of practice and competency standards for pharmacists

Competency standards for a PCDT pharmacist have been developed to supplement the approved pharmacist competency standards, in advanced level of practice. Comparison of international competency standards for prescribing pharmacists was also useful to give guidance in determining both the domains and the standards.

These competency standards were developed to supplement the competency standards for pharmacists at an advanced level of practice pertaining to PCDT.

4. SUMMARY OF COMPETENCY STANDARDS FOR PCDT PHARMACIST

DOMAIN	COMPENTENCY STANDARD
1. Public health	1.1 Medicine information 1.2 Professional and health advocacy 1.3 Primary healthcare 1.4 Pharmacoeconomics
2. Safe and rational use of medicines and medical devices	2.1 Patient consultation 2.2 Patient management 2.3 Patient medicine review and management 2.4 Therapeutic outcome monitoring 2.5 Pharmacovigilance
3. Supply of medicines and medical devices	3.1 Medicine prescribing 3.2 General housekeeping and administrative tasks
4. Organisational and management skills	4.1 Quality assurance 4.2 Record keeping
5. Professional and personal practice	5.1 Professional practice 5.2 Ethical and legal practice 5.3 Continuing professional development 5.4 Collaborative practice
6. Education, critical analysis and research	6.1 Research

DOMAIN 1: PUBLIC HEALTH**INTRODUCTION**

Domain 1 covers public health and includes 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 provision of medicines and healthcare information and education forms an integral part of the scope of practice of a pharmacist. The availability of specialised pharmaceutical knowledge at all levels of care, including primary healthcare (PHC), is an important component for the delivery of effective and efficient pharmaceutical services. The domain covers competencies that are required to promote health, promote and monitor adherence.

The public health domain competencies are:

- 1.1 Medicine information
- 1.2 Professional and health advocacy
- 1.3 Primary healthcare
- 1.4 Pharmacoeconomics

DOMAIN 1: PUBLIC HEALTH	
COMPETENCIES	BEHAVIOURAL STATEMENTS
1.1 Medicine information	1.1.1 Provide the patient/care giver clear, information about their medicines (e.g., what it is for, how to use it, possible unwanted effects and how to report them, expected duration of treatment).
	1.1.2 Ensure that the patient/care giver knows what to do if there are any concerns about the management of their condition, if the condition deteriorates or if there is no improvement in a specific time frame.
	1.1.3 Encourage and support patients/care givers to take responsibility for their medicines and self-manage their conditions.
1.2 Professional and health advocacy	1.2.1 Act in the best interest of the patients and other members of the public
	1.2.2 Provide the best healthcare for the community in partnership with other health professionals
1.3 Primary healthcare	1.3.1 Practise in primary healthcare settings approved by Council
1.4 Pharmacoeconomics	1.4.1 Initiate interventions to improve cost-effective use of medicines.

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES

INTRODUCTION

Domain 2 covers competencies that are required to ensure safe and rational use of medicines 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 medicines are:

- 2.1 Patient consultation
- 2.2 Patient management
- 2.3 Patient medicine review and management
- 2.4 Monitor therapeutic outcome
- 2.5 Pharmacovigilance

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES	
COMPETENCIES	BEHAVIOURAL STATEMENTS
1.1 Patient consultation	2.1.1 Explain and obtain Informed consent from the patient.
	2.1.2 Take an appropriate medical, social and medication history including allergies and intolerances.
	2.1.3 Conduct an appropriate clinical assessment.
	2.1.4 Interpret relevant investigation necessary to inform treatment options
	2.1.5 Interpret all available and relevant patient records to ensure knowledge of the patient's management to date, for effective patient health management.
2.2 Patient management	2.2.1 Apply criteria for patient referral in accordance with primary health care STG.
2.3 Patient medicine review and management	2.3.1 Discuss and agree on the management plan with the patient.
	2.3.2 Review adherence to and effectiveness of current medicines.
	2.3.3 Adjust medicine therapy which has been prescribed previously authorised prescribers.
2.4 Monitor therapeutic outcome	2.4.1 Monitor patient response to therapeutic intervention.
	2.4.2 Review management plan, when necessary, based on patient's response.
2.5 Pharmacovigilance	2.5.1 Understands the potential for adverse effects and takes steps to avoid/minimise, recognise and manage them.

DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES

INTRODUCTION

Domain 3 includes competencies required to address the supply of medicines to patients, the behavioural statement in this domain includes prescribing of medicines

The competencies required for the supply of medicines domain are:

- 3.1 Medicine prescribing
- 3.2 General housekeeping and administrative tasks

DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES	
COMPETENCIES	BEHAVIOURAL STATEMENTS
3.1 Medicine prescribing	3.1.1 Prescribe medicines for the management of conditions listed in PHC STG and EML.
	3.1.2 Prescribe only medicines listed in primary healthcare STG and EML
	3.1.3 Consider patient needs and diversity.
	3.1.4 Prescribe medicines for a patient whom he or she has assessed personally.
3.2 General housekeeping and administrative tasks	3.2.1 Take appropriate action in the event of body fluids spillage and/or contamination.
	3.2.2 Dispose of medical waste and other consumables and devices safely according to applicable protocols.

DOMAIN 4: ORGANISATIONAL AND MANAGEMENT SKILLS

INTRODUCTION

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

The competencies required are:

- 4.1 Quality assurance
- 4.2 Record keeping

DOMAIN 4: ORGANISATIONAL AND MANAGEMENT SKILLS	
COMPETENCIES	BEHAVIOURAL STATEMENTS
4.1 Quality assurance	4.1.1 Develop processes to prevent, detect and manage medication errors.
	4.1.2 Develop processes that support safe prescribing practices.
	4.1.3 Report errors to prescribing healthcare professionals and discuss alternatives.
	4.1.4 Record prescribing errors and critical incidents, and review practice to prevent recurrence.
4.2 Record keeping	4.2.1 Generate and maintain accurate, legible, and unambiguous records of patient care.
	4.2.2 Document and record adverse reactions where applicable.

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 and ability to work collaboratively with other healthcare professionals.

The competencies required are:

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

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE	
COMPETENCIES	BEHAVIOURAL STATEMENTS
5.1 Professional practice	5.1.1 Practise in a pharmacy which has been approved by SAPC to offer primary health care services in line with the primary health care EML and STGs.
	5.1.2 Prescribe medicines which could be dispensed by another pharmacist to allow separation of duties and avoid conflict of interest.
	5.1.3 Responsible for their own safe and efficient practice and are bound by Good Pharmacy Practice standards, ethical rules and the code of conduct.
	5.1.4 Behave with integrity and honesty, and do not engage in any behaviour or activity likely to bring the profession into disrepute and undermine public confidence in the profession.
	5.1.5 Act in the interest of patients and other members of the public and seek to provide the best possible healthcare for the community, in partnership with other health professionals.
	5.1.6 Prescribe medicine to patients and not for own personal use or for use by any person with whom they have close personal or emotional relationship unless under exceptional circumstances.
5.2 Ethical and legal practice	5.2.1 Promote safe and efficient practice bound by Good Pharmacy Practice standards, ethical rules and the code of conduct.
	5.2.2 Practice within legal and regulatory frameworks affecting prescribing and administration of medicines.
5.3 Continuing professional development	5.3.1 Keep abreast with clinical and professional developments.
	5.3.2 Keep abreast with evidence-based medicine and best practices in the management of conditions which they are authorised to treat.
5.4 Collaborative practice	5.4.1 Practise in collaboration with other health care professionals and refer patients to other members of a health care team when necessary.
	5.4.2 Establish peer review, support and mentoring arrangements to enable him/her an opportunity for reflection on prescribing, as well as other aspects of practice.

DOMAIN 6: EDUCATION, CRITICAL ANALYSIS AND RESEARCH**INTRODUCTION**

Domain 6 includes the behavioural statements relating to education and training, critical analysis and research. Pharmacists should participate in practice-based research. The research may include investigations into prescribing practices, patterns of medicine usage, evaluation of medicine use, the monitoring of adverse reactions, the benefits of the pharmacist's advisory role, computerised data handling, health economics, legislation, and aspects of abuse and irrational use of medicines. Practising pharmacists are increasingly participating in health systems and quality improvement research, which must be encouraged as a means of providing databases and information for future policy, guidelines and practice development. Such research is often conducted in collaboration with other healthcare providers.

The education, research and critical analysis competencies are:

6.1 Research

DOMAIN 6: EDUCATION, CRITICAL ANALYSIS AND RESEARCH	
COMPETENCIES	BEHAVIOURAL STATEMENTS
6.1 Research	6.1.1 Design a research protocol and conduct research on relevant aspects related to PCDT.
	6.1.2 Present research findings at relevant fora.

5. References

<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Prescribing%20competency%20framework/prescribing-competency-framework.pdf>.

Royal Pharmaceutical Society. A competency framework for all prescribers. July 2020.

South African Pharmacy Council Board Notice 122 of 2011. Scope Of Practice and Qualification for Authorised Pharmacist Prescriber Published 01 July 2011.

South African Pharmacy Council Board Notice 59 of 2018. The Pharmacy Act (53/1974): Competency Standards for Pharmacists in South Africa. Published on 11 May 2018.

PART 3: CRITERIA FOR ACCREDITATION: PRIMARY CARE DRUG THERAPY

1. RATIONALE FOR THE PCDT SUPPLEMENTARY TRAINING

The Medicines and Related Substances Act 101 of 1965 (Medicines Act) currently permits a pharmacist to dispense Schedule 1 and 2 medicines without a prescription from an authorised prescriber, as defined in the Act. In striving to develop and utilise pharmaceutical services and the pharmacist's expertise optimally in South Africa, pharmacists who have obtained the Primary Care Drug Therapy (PCDT) supplementary training are issued with a permit in terms of Section 22A(15) of the Medicines Act.

Section 22A(15) "Notwithstanding anything to the contrary contained in this section, the Director General may, after consultation with the South African Pharmacy Council Africa as referred to in section 2 of the Pharmacy Act, 1974 (Act No. 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."

The Section 22A(15) permits are issued by the National Department of Health (NDoH) together with a list (referred to as the PCDT medicine list (Appendix A)) of conditions that the PCDT pharmacist may diagnose and a list of medication (schedule 3, 4 and 5) that the PCDT pharmacist may prescribe and dispense to treat these diagnosed conditions. This PCDT medicine list is in line with the NDoH's latest Primary Health Care Standard Treatment Guidelines and Essential Medicines List (PHC STG & EML). Only pharmacists who have recorded their PCDT supplementary training with the SAPC may apply for the Section 22A(15) permit for PCDT.

PCDT pharmacists are expected to apply the principles of pharmaceutical care in providing pharmacist-initiated therapy. Pharmaceutical care is patient centred, outcome orientated pharmacy practice that requires the pharmacist to work in conjunction with the patient and the patient's other healthcare providers to promote health, to prevent disease and to assess, monitor, initiate and modify medication use to assure that medicine therapy is safe and effective.

2. PURPOSE OF THE PCDT SUPPLEMENTARY TRAINING

The purpose of PCDT supplementary training is to equip pharmacists with the essential knowledge in the field of pharmacotherapy and pharmaceutical care and to develop pharmacist's clinical skills in order to provide pharmacist-initiated therapy within the scope of Good Pharmacy Practice (GPP) rules. PCDT pharmacists must act in the interest of patients and other members of the public and seek to provide the best possible healthcare for the community.

PCDT pharmacists should be able to practise and develop as authorised prescribers to meet the health care needs of the country in line with the PHC STG & EML and as stipulated in the PCDT medicine list, as amended from time to time by the NDoH. They are responsible for their own safe and efficient practice and are bound by GPP rules. Minimum standards, Ethical rules and the Code of Conduct for pharmacists and other persons registered in terms of the Act in accordance with section 35A(b)(i) of the Pharmacy Act, 53 of 1974 and must comply with the Medicines Act.

The goal of PCDT pharmacists is to improve patient care without compromising patient safety, increase access to health care services, optimise the skills of health professionals and contribute to the introduction of a more flexible multidisciplinary primary health care (PHC) team. They are expected to practise in collaboration with other health care professionals and refer patients to other members of a health care team when necessary. PCDT pharmacists must ensure that they behave with integrity and honesty, and do not engage in any behaviour or activity likely to bring the profession into disrepute and undermine public confidence in the profession.

PCDT pharmacists have a professional responsibility to keep themselves abreast of clinical and professional developments. They are expected to keep up to date with evidence and best practices in the management of conditions which they are authorised to treat. They must establish peer to peer interaction and discussion or mentoring arrangements providing an opportunity for reflection on prescribing, as well as other aspects of practice. They may only prescribe medicines for a patient whom they have assessed personally and may not prescribe any medicine for their own use or for any person with whom they have close personal or emotional relationship.

3. TARGET GROUP FOR PCDT SUPPLEMENTARY TRAINING

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

4. MINIMUM ENTRANCE CRITERIA TO THE PCDT SUPPLEMENTARY TRAINING

Pharmacists who wish to enrol for the PCDT supplementary training must:

- be in possession of a Bachelor of Pharmacy (BPharm) degree, or recognised equivalent,
- be registered at the SAPC as a Pharmacist, and
- have completed their community service year.

5. DURATION OF PCDT SUPPLEMENTARY TRAINING

This supplementary training comprise 120 credits, 1200 notional hours to be completed on a part-time basis, over 24 months.

6. PCDT SUPPLEMENTARY TRAINING RULES

In order to be credited with PCDT supplementary training, the student must have achieved the specified outcomes in the training.

Note: A PCDT certificate is issued by the SAPC once the pharmacist records their PCDT supplementary training with the SAPC.

After successful completion of the course, the PCDT pharmacist must:

- (a) Record their supplementary training (PCDT) at the SAPC by completing and submitting the application form for SAPC Supplementary Training (online or printable form available at: <http://www.pharmcouncil.co.za>) together with a certified

- copy of the pharmacist's ID, certified copies of the pharmacist's *PCDT certificate* and proof of payment of the SAPC registration fee (refer to SAPC application form).
- (b) After receiving the PCDT certificate from the SAPC the PCDT pharmacist must apply for a Section 22(A)15 permit at the NDoH (the application form can be obtained by sending an e-mail to permits@health.gov.za).
 - (c) Upon receipt of the Section 22(A)15 permit from the NDoH the PCDT pharmacist must record their PCDT permit at the SAPC (form available on the website of the SAPC (<http://www.pharmcouncil.co.za>)).
 - (d) Lastly the PCDT pharmacist must apply for a "Practice Number for a Primary Care Drug Therapist" from the Board of Healthcare Funders of Southern Africa (BHF) (the application form can be obtained by sending an e-mail to clientservices@bhfglobal.com).

7. RECOGNITION OF PRIOR LEARNING

Recognition of prior learning is not applicable.

8. OUTCOMES AND THE ASSOCIATED ASSESSMENT CRITERIA

The minimum outcomes and assessment criteria of the course are tabulated below.

Topic	Specific outcomes	Assessment criteria	No. of credits
History taking and patient interviewing	Learners should have the ability to collect relevant patient information and compile a complete patient history.	<ul style="list-style-type: none"> • Demonstrate effective communication skills. • Demonstrate the correct use of a patient information and history form. • Obtain the relevant information (social, medical, etc.) to the clinical condition. • Ask appropriate questions which are necessary for the completion of a patient information and history form. • Compile a complete patient history. • Appropriately record and store patient information according to GPP. 	10
Clinical examination	Learners should be able to perform physical examinations related to the conditions specified in the PCDT list aligned to current PHC STGs and EML.	<ul style="list-style-type: none"> • Demonstrate relevant and necessary knowledge of human anatomy and physiology. • Identify and describe the processes of performing the relevant physical examinations. • Describe the procedures to be followed and the principles underlying the relevant tests. • Demonstrate knowledge of the relevant clinical conditions, including definitions, classification, etiopathology, signs and symptoms. • Correctly perform the relevant physical examinations. • Perform appropriate screening test. • Interpret the results of the relevant screening tests. 	40
Evaluation, interpretation, and decision making	Learners should be able to critically evaluate and interpret various clinical scenarios related to the conditions specified in the PCDT list aligned to current PHC STGs and EML, and decide on an appropriate intervention.	<ul style="list-style-type: none"> • Evaluate the relevant patient information obtained from history taking and clinical examination. • Describe and distinguish between the signs, symptoms and clinical presentation of the specified conditions. • Demonstrate the ability to use and apply the relevant aspects gained from the patient 	40

Topic	Specific outcomes	Assessment criteria	No. of credits
		<p>history and anamnesis, results of relevant laboratory and/screening tests and findings of physical examinations, to inform the diagnosis and intervention.</p> <ul style="list-style-type: none"> • Consider relevant differential diagnoses and decide on a correct diagnosis. • Decide on an appropriate intervention where applicable, which may include among others, therapy or referral to another health care professionals. 	
Developing a pharmaceutical care plan and monitoring therapeutic outcomes	Learners should be able to understand, conceptualise and develop an appropriate pharmaceutical care plan for the conditions specified in the PCDT list aligned to current PHC STGs and EML.	<ul style="list-style-type: none"> • Draft an appropriate pharmaceutical care plan based on the patient information and a relevant diagnosis. • Develop a plan to monitor and evaluate therapeutic outcomes and make recommendations regarding potential amendments to the pharmaceutical care plan, where necessary. • Identify and anticipate potential medicine-related problems, and generate strategies to prevent and solve problems that may arise. • Analyse and evaluate any prior or current treatment plans for the following: medicine efficacy, safety and rationale for use. • Monitor therapeutic outcomes and make recommendations regarding potential amendments to the pharmaceutical care plan, where necessary. • Analyse and evaluate the relevant therapeutic progress reports and construct correct and concise recommendations in the form of a written report. 	20

Topic	Specific outcomes	Assessment criteria	No. of credits
Providing patient information	Learners should be able to communicate with their patients regarding their diagnosed condition and the relevant pharmaceutical care plan.	<ul style="list-style-type: none"> • Communicate relevant information to the patient relating to the diagnosed condition, the pharmaceutical care plan, and other relevant topics, e.g. lifestyle modification and other preventative measures. • Demonstrate knowledge of national programmes and notifiable diseases, including the guidelines thereto. 	08
Documentation and record keeping	Learner should be able to keep accurate record and draft appropriate documentation.	<ul style="list-style-type: none"> • Document and keep records of all aspects of the consultation session, including patient feedback regarding the information provided. • Draft appropriate referral letters and/or any other relevant documentation. • Develop appropriate informed consent and assent forms and ensure proper documentation thereof. 	01
Legal, professional and ethical practice	Learner should be able to act in a legal, professional and ethical manner in accordance to relevant legislation (e.g. Pharmacy Act 53 of 1974, Medicine and Related Substances Act 101 of 1965, etc.).	<ul style="list-style-type: none"> • Act in a professional and ethical manner when performing any or all of the abovementioned tasks. • Apply GxP principles when taking and handling samples. • Comply with all legal, professional and ethical record keeping and reporting requirements. 	01

LIST OF ABBREVIATIONS

BHF:	Board of Healthcare Funders of Southern Africa
BPharm:	Bachelor of Pharmacy
GPP:	Good Pharmacy Practice
GxP:	Is a general abbreviation for the 'good practice' quality guidelines, regulations, and rules, and includes Good Manufacturing Practice, Good Wholesale Practice, Good Pharmacy Practice, Good Laboratory Practice, Good Clinical Practice, etc.
HEI:	Higher Education Institution
HPCSA:	Health Professions Council of South Africa
MBCChB:	Bachelor of Medicine and Bachelor of Surgery
MCQ:	Multiple Choice Questionnaire
NDoH:	National Department of Health
OSCE:	Objective Structured Clinical Examination
PCDT:	Primary Care Drug Therapy
PHC STG & EML:	Primary Health Care Standard Treatment Guidelines and Essential Medicines List
PHC:	Primary Health Care
SAPC:	South African Pharmacy Council
SAQA:	South African Qualifications Authority

6. CRITICAL CROSS-FIELD OUTCOMES

- Identifying and solving problems in which responses display that responsible decisions using critical and creative thinking have been made.
- Working effectively with others as a member of a team, group, organisation, community.
- Organising and managing oneself and one's activities responsibly and effectively.
- Collecting, analysing, organising and critically evaluating information.
- Communicating effectively using visual, mathematical and/or language skills in the modes of oral and/or written persuasion.
- Using science and technology effectively and critically, showing responsibility towards the environment and health of others.
- Demonstrating an understanding of the world as a set of related systems by recognising that problem-solving contexts do not exist in isolation.
- Contributing to the full personal development of each student and the social and economic development of society at large, by making it the underlying intention of any programme of learning to make an individual aware of the importance of:
 - reflecting on and exploring a variety of strategies to learn more effectively;
 - participating as responsible citizens in the lives of local, national and global communities;

- being culturally and aesthetically sensitive across a range of social contexts.

7. QUALIFICATIONS AND EXPERIENCE OF PRESENTERS/FACILITATORS

The presenters/facilitators of the 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 Pharmacist with the SAPC;
- have completed the PCDT supplementary training;
- have recorded their PCDT supplementary training with the SAPC; and
- preferably be in possession of a valid Section 22A(15) permit issued by the NDoH.

At least one presenter for the practical component must:

- have a MBChB degree, or recognised equivalent; and
- be registered as a medical practitioner at the Health Professions Council of South Africa (HPCSA);

8. STANDARDS FOR PRESENTATION OF THE PCDT SUPPLEMENTARY TRAINING

The PCDT course must be presented by any HEI and accredited provider of the SAPC.

9. MODE OF DELIVERY

PCDT is supplementary training for pharmacists and must be presented in a manner that allow flexible study hours. Any other mode of delivery should allow flexible study hours. The HEI 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 (including study guides, PowerPoint® presentations, video's);
- Submission of work assignments; and
- Online test and examinations.

A comprehensive course reader/study guide must be available for the courses. This must guide the student through the learning process and should integrate all the topics. Additional textbooks and references must also be used.

At least one contact session/workshop (minimum 2 days) must form part of practical component. The purpose of the contact session is to equip the student with the necessary practical examination skills required to examine a patient. The students

must attend the contact session before commencing with their 200 health examinations.

10. ASSESSMENT OF THE PCDT SUPPLEMENTARY TRAINING

The method of assessment for the courses must include both formative and summative assessment. Formative assessment in the form of work assignments and formal summative assessment by means of an examination at the end of the course should be included. The examination must be in the form of a written/online examination. The assessment of the practical component must be in the form of an OSCE. Admission to the examination is obtained through proof of participation, confirming that the learner has met the requirement for admission to the examination.

Practical component

Compilation of a portfolio (containing at least 200 patient examinations on a PCH level) is an integral part of the practical component. The 200 patient examinations must include all the conditions listed in the PHC STG & EML in line with the scope of practice of a PCDT pharmacist.

The portfolio must contain at least 200 patient examinations and should include at least the following number of patient examinations per condition:

Section (as per PHC STG & EML Chapters)	Conditions	Number of health examinations
1	Dental and oral	Min. 5
2	Gastro-intestinal	Min. 20
3	Blood and nutrition	Min. 10
4	Cardiovascular	Min. 20
5	Skin	Min. 5
6	Obstetrics and gynaecology	Min. 10
7	Family planning	Min. 10
8	Kidney and urology	Min. 20
9	Endocrine	Min. 5
10	Infections and related conditions	Min. 10
11	HIV	Min. 10
12	Sexually transmitted diseases ¹	Min. 10
13	Immunisation	Min. 10
14	Musculoskeletal	Min. 5
15	Central nervous system	Min. 5
16	Mental health	Min. 5

¹ Syndromic STI diagnosis and treatment, no genitourinary examination is allowed, as it does not form part of the scope of practice of a PCDT pharmacist.

Section (as per PHC STG & EML Chapters)	Conditions	Number of health examinations
17	Respiratory	Min. 20
18	Eye	Min. 10
19	Ear, nose and throat	Min. 20
20	Pain	Min. 5
21	Trauma and emergencies	Min. 5

Each student's portfolio must be evaluated prior to practical examination at the end of the course. The portfolios must meet at least the following acceptance criteria:

- contain a minimum of 200 valid patient examinations (as per minimum number listed above);
- include intramuscular (IM) and immunisation administrations;
- in cases where the doctor/nurse/health care professional prescribed medicine that is not within the scope of a PCDT pharmacist the student must have made a note on what he/she (as PCDT pharmacist) would have done if this patient came to the pharmacy clinic (including referral to a doctor).
- Each health examination must include the correct medication (that a PCDT pharmacist may prescribe as per the PCDT medicine list), medicine strength, dosage and duration of treatment.
- Health examination which are not on a PHC level do not count as suitable cases for the portfolio. The student must be able to distinguish between (i) medication which is regularly available in the pharmacy as OTC medication, (ii) medication allowed to be prescribed by the PCDT pharmacist (in accordance tot the PCDT medicine list and PH STG & EML) and (iii) medication which may only be prescribed by a medical practitioner (doctor's prescription).

Portfolios that does not meet the requirements may be returned to the student for correction/ additional health examinations and may be submitted by the student before the next practical examination opportunity.

11. PROCESS OF APPEAL

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

12. 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 in serious cases, should be reported to the SAPC.

13. CERTIFICATION METHODS AND PROCEDURES

Procedures must be in place to ensure that certification of the 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 course:

- provider name and/or logo
- name of the course
- student's full name (first names followed by surname)
- date of issue of the certificate
- signatories

14. FACILITIES, EQUIPMENT AND CONSUMABLES

The physical facilities of the HEI must be adequate. Essential physical facilities must include offices for administrative staff and course presenters, lecture rooms and clinical simulation laboratory (for presentation of compulsory contact session/workshops). The facilities must be adequately equipped to at least cover the conditions specified in the PCDT list aligned to current PHC STGs and EML, well maintained and provide a reasonably attractive environment for teaching and learning.

The facilities, including lecture rooms and clinical simulation laboratory, must be sufficient in number and adequate in size to accommodate the number of students. The clinical simulation laboratory must also provide adequate storeroom facilities for housing of equipment and supplies and must include areas for practice simulations and an area(s) where the practical examination can be held.

The equipment in the clinical simulation laboratory must include (in sufficient amounts) at least the following:

- hospital bed/patient examination bed,
- stethoscope,
- otoscope (with different size earpieces),
- sphygmomanometer or calibrated blood pressure apparatus,
- tuning fork,
- blood glucose meter, lancets and test strips,
- cholesterol meter,
- peak flow meter and disposable mouth pieces,
- tongue depressors,
- disposable rubber gloves,
- clinical thermometer,
- alcohol swabs of 70% alcohol solution or surgical spirits,
- towels or paper towels,
- disinfectants for equipment,
- soap and water for washing of hands,
- applicable equipment for approved screening tests,
- mirror,
- scale plus baby scale,
- height chart and tape measure, and
- equipment for first aid, e.g. plaster, gauze, cotton wool, sterile wound dressings, scissors.

15. 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 number,
- cell phone number,
- e-mail address,
- postal address,
- qualifications, and
- past 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 for the course and must include a functionality to generate an "Academic Record" for each student. Confidentiality of personal information must be maintained at all times.

APPENDIX A - PCDT medicine list

 health Department: Health REPUBLIC OF SOUTH AFRICA		DEPARTMENT OF HEALTH AFFORDABLE MEDICINES: LICENSING UNIT Cnr Struben and Thabo Sehume Streets Pretoria Tel: 012 395 8315 Email: permits@health.gov.za	
		V2, 22 March 2017	
PRIMARY CARE DRUG THERAPY LIST ALIGNED TO THE STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST			
NOTE: It is incumbent upon the permit holder to remain abreast of revisions and updates of the Standard Treatment Guidelines and Essential Medicines List			
CONDITION	ICD 10 CODE	NOTES	
PRIMARY HEALTH CARE LEVEL STGS AND EML, 2014			
Gastro-intestinal conditions			
Diarrhoea, chronic, in adults (Giardiasis)	A07.1/ K52.9	This is treatment of Diarrhoea for more than two weeks. The standard treatment guidelines requires that the practitioner provides empiric treatment for giardiasis before referring patients.	
Nausea and vomiting, non-specific	R11		
Dyspepsia, heartburn and indigestion	K30/R12	Practitioner to provide standard treatment as per standard treatment guidelines for 14 days and if symptoms recur after 14 days, refer to a doctor.	
Skin conditions			
Acne vulgaris	L70.0		
Obstetrics and gynaecology			
Dysmenorrhoea	N94.4 - N94.6		
Family planning			
Contraception, injectable	Z30.0/ Z30.4	Injection technique is part of the PCDT training. The administration of injections is routine practice.	
Contraception, oral	Z30.0/ Z30.4		
Kidney and urological disorders: urinary tract infection			
Uncomplicated cystitis (Adults)	N30.0/ N30.9		
Complicated cystitis (Adults)	N30.0-4/ N30.8/ N30.9		
Complicated cystitis for pregnant women	O23.1		
Infections and related conditions			
Pyrexia (= Fever in EDL)	R50.0/ R50.1/ R50.8/ R50.9	Antipyretic agents are not indicated with the sole aim of reducing body temperature in children and adults with fever	
Musculoskeletal conditions			
Gout, acute	M10.00 - 09/ M10.90 - 99		
Osteoarthritis	M13.00-19/M13.80-99/M15.0/M15.3/M15.8/M15.9/ M16.0-9/M18.0-5/M18.9/M19.00-09/M19.20-9/M19.80-M19.99		
Rheumatoid Arthritis	M05.90-99/M06.90-99		
Respiratory conditions			
Acute bronchitis in adults and adolescents	J20.9		
Pneumonia uncomplicated in adults (exclusions paediatrics and over 65 years)	J18.0-2/J18.8-9		
Acute asthma & acute exacerbations of COPD	J46/J45.9		
Chronic Asthma	J45.0/J45.1/J45.8/J45.9	If control is inadequate refer to doctor	

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V2, 22 March 2017		
PRIMARY CARE DRUG THERAPY LIST ALIGNED TO THE STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST		
NOTE: It is incumbent upon the permit holder to remain abreast of revisions and updates of the Standard Treatment Guidelines and Essential Medicines List		
CONDITION	ICD 10 CODE	NOTES
Eye conditions: bacterial eye infections		
Conjunctivitis, bacterial (excluding conjunctivitis of the newborn)	H10.0/H10.2-5/H10.8-9	
Ear, nose and throat conditions		
Otitis externa	H60.0/H60.3/H60.5/H60.9	
Otitis media, acute	H65.0/H65.1/H65.9/H66.0/H66.9	
Sinusitis, acute, bacterial	J01.0-4/J01.8-9	
Tonsillitis and pharyngitis	J02.0/J02.8-9/J03.0/J03.8-9	
Pain		
Acute pain control - Mild Pain	R52.0/ R52.9	
Trauma and emergencies		
Animal and human bites	S01.0-9/S11.0-2/S11.7-9/S21.0-2/S21.7-9/S31.0-5/S31.7-8/S41.0-1/S41.7-8/S51.0/S51.7-9/S61.0-1/S61.7-9/S71.0-1/S71.7-8/S81.0/S81.7-9/S91.0-3/S91.7/ T01.0-3/T01.6/T01.8-9/T09.1/T11.1/T13.1/T14.0-1/A82.0-1/A82.9/Z24.2/Z20.3 + External Cause Code (W,X,Y,Z)	
Insects stings and spider bites	T63.2/3/4 + External Cause Code (V,W,X,Y)	
Anaphylaxis	R57.9/T78.0-3/T80.5/T88.6	
HIV Prophylaxis, Post Exposure (PEP)		
Occupational Post Exposure HIV Prophylaxis for healthcare worker (HCW)	Z20.6 + Z29.8 + S61.0/Z57.8/X58.92/W46.22	
Vaccines		
Immunisation	Z23.2/Z23.5/Z23.8/Z24.0/Z24.4/Z24.6/Z25.1/Z25.8/Z27.8	
Cardiovascular conditions		
Angina pectoris, unstable	I20.0	
Hypertensive emergencies in adults	I10	
Hypertension in adults	I10	Refer to doctor after 6 months
Diabetes and Epilepsy		
Type 1 Diabetes in adults	E.10.9	Refer to doctor after 6 months
Type 2 Diabetes in adults	E11.9	Refer to doctor after 6 months
Central Nervous System Conditions		
Epilepsy in adults	G40.0-9	Refer to doctor after 6 months
ADULT HOSPITAL LEVEL STGS AND EML, 2015		
Systemic and Nosocomial Infections		
Tick bite fever	A79.9	