
BOARD NOTICES RAADSKENNISGEWINGS

BOARD NOTICE 122 OF 2011



South African
Pharmacy Council

THE SOUTH AFRICAN PHARMACY COUNCIL

SCOPE OF PRACTICE AND QUALIFICATION FOR AUTHORISED PHARMACIST PRESCRIBER

The South African Pharmacy Council (the Council) intends to request the Minister of Health to:

- (a) publish amendments to the *Regulations relating to the registration of persons and the maintenance of registers* to make provision for a new category of pharmacist namely the authorised pharmacist prescriber;
- (b) publish amendments to the *Regulations relating to the practice of pharmacy* to make provision for the scope of practice of the authorised pharmacist prescriber; and
- (c) publish regulations in terms of Sections 33 and 49(mA) to provide the required qualifications for the authorised pharmacist prescriber.

The qualification and the proposed scope of practice are published herewith for public comment prior to the said request/s to the Minister of Health.

SCHEDULE

1. Scope of practice of Authorised Pharmacist Prescriber

2. Qualification for Authorised Pharmacist Prescriber

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.

Interested persons are invited to submit, within 30 days of publication of this notice, substantiated comments or representations on the qualification and scope of practice to the Registrar, The South African Pharmacy Council, Private Bag X40040, Arcadia, 0007, or Fax 086 5063010 or email: debbie.hoffmann@sapc.za.org (for the attention of the Senior Manager: Legal Services and Professional Conduct).

A handwritten signature in black ink, appearing to be 'TA Masango', with a stylized flourish at the end.

**TA MASANGO
REGISTRAR**

AUTHORISED PHARMACIST PRESCRIBER

INTRODUCTION

In striving to develop and utilise pharmaceutical services and the pharmacist's expertise optimally in South Africa (RSA), pharmacists who obtained the Primary Care Drug Therapy qualification were, under specific conditions, issued with permits in terms of Section 22A(15) of the Medicines and Related Substances Act 101 of 1965, as amended (the Medicines Act) to diagnose and treat patients with a specified list of Schedule 3 and Schedule 4 medicines.

A need has been identified to improve the current pharmacist prescriber's scope of practice and qualification to improve service delivery in the provision of prescribing services to the people of South Africa in line with the Primary Health Care Essential Medicines List (EML) and Standard Treatment Guidelines

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.

The Medicines Act currently permits a pharmacist to dispense Schedule 1 and 2 medicines without a prescription.

Pharmacists are expected to apply the principles of pharmaceutical care in providing pharmacist initiated therapy. 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 proposed scope of practice of an authorised 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 Primary Health Care EML and Standard Treatment Guidelines.

Pharmacist prescribers are, amongst other things, expected to assist in:

- (a) filling geographical or skills gaps in services;
- (b) meeting the needs of patient groups who find it hard to access services, e.g. people with busy lifestyles;
- (c) managing long-term conditions;
- (d) managing co-morbidities and complex medication regimens.

GENERAL PRINCIPLES

Authorised pharmacist prescribers -

1. Are expected to practise in primary health care settings as approved by Council.
2. Will only be allowed to practise in a pharmacy which has been accredited to offer primary health care services in line with the Primary Health Care Essential Medicines List and Standard Treatment Guidelines (PHC EML/STGs).
3. May only diagnose conditions listed in the PHC EML/STGs.
4. May only prescribe medicines listed in the PHC EML/STGs.
5. Would as far as possible only prescribe medicines which would be dispensed by another pharmacist or pharmacy technician in order to allow separation of duties and avoid conflict of interest.
6. Are expected to practise in collaboration with other health care professionals and refer patients to other members of a health care team when necessary.
7. May practise in both the private and public sector.
8. Are responsible for their own safe and efficient practice and are bound by Good Pharmacy Practice standards, ethical rules and the code of conduct.
9. 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.
10. Must 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.
11. 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.
12. Must at all times adhere to pharmaceutical care principles.
13. Are accountable for all aspects of their prescribing decisions and may only prescribe medicines they know are safe for the patient and effective for the condition being treated.
14. May not prescribe medicines which are required to be registered and are not registered.
15. May only prescribe medicines for a patient whom he or she has assessed personally.
16. Must not prescribe any medicine for their own use or for any person with whom they have close personal or emotional relationship unless under exceptional circumstances.
17. Must establish peer review, support and mentoring arrangements to enable him/her an opportunity for reflection on prescribing, as well as other aspects of practice.
18. Are required to keep accurate, legible, unambiguous and up to date records of a patient's care.

19. Must have appropriate professional indemnity.
20. Are expected to successfully complete a diploma offered by a provider registered with council accredited to provide the relevant qualification.
21. Are expected to at least have two years experience in a clinical environment (hospital/ community setting) post community service, prior to being registered as a learner for a diploma to qualify as an authorised pharmacist prescriber.

SCOPE OF PRACTICE OF AN AUTHORISED PHARMACIST PRESCRIBER

In addition to the acts and services which form part of the scope of practice of the pharmacist as prescribed in terms of Section 35A of the Pharmacy Act, 53 of 1974, an authorised pharmacist prescriber may perform the following acts and services:

- (a) consultation with patients, in an approved primary health care setting, which includes:
 - (i) 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;
 - (v) interpretation of the assessment/diagnosis;
 - (vi) decision on safe and appropriate therapy;
 - (vii) prescribing of medicines for the management of potential or existing health needs listed in the Primary Health Care (PHC) Standard Treatment Guidelines (STG) and Essential Medicines List (EML);
 - (viii) adjustment of medicine therapy which has been prescribed previously by an authorised prescriber;
 - (ix) monitoring of the outcomes of therapy; and
 - (x) referral to another health care provider where necessary.

AUTHORISED PHARMACY PRESCRIBER

Qualification Title:		
Post Graduate Diploma: Pharmacy: Authorised Prescribing		
Field	Sub-field	SGB Name
Health Sciences and Social Services (09)	Curative Health	Pharmacy
Minimum Credits	NQF Level	Qualification Class
120	8	Non-Unit Standard based

RATIONALE FOR THE QUALIFICATION

The Post Graduate Diploma: Pharmacy: Authorised Prescribing was developed to meet the requirements of the National Human Resources for Health Plan, with specific reference to the need to improve service delivery in the provision of prescribing services to the people of South Africa. In addition, the Primary Health Care Standard Treatment Guidelines and Essential Medicines List were developed *inter alia* to build capacity in all health care workers at the Primary Health Care level. It is expected that these changes will result in improved health outcomes by optimising drug therapy for patients in an enhanced health care system.

The qualification is aimed at extending the core clinical and pharmaceutical knowledge and skills acquired during qualification for the BPharm degree: Level 8 to include the diagnosis and treatment of common conditions in line with the Primary Health Care Standard Treatment Guidelines and Essential Medicines List.

The Post Graduate Diploma: Pharmacy: Authorised Prescribing, NQF Level 8, is designed to meet the needs of learners who have completed the BPharm. degree and who wish to further their competencies in this field while developing their careers in one or more practice area. While the sub-field at present is listed as Curative Health the qualification also includes Preventative Health, Promotive Health, and Development Services and Rehabilitative Health Services.

PURPOSE OF THE QUALIFICATION

This qualification will enable pharmacists to practise and develop as prescribers and to meet the health care needs of the country in line with the Primary Health Care (PHC) Standard Treatment Guidelines (STG) and Essential Medicines List (EML).

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.

Pharmacist prescribers are amongst other things expected to assist in filling geographical or skills gaps in services, meeting the needs of patient groups who find it hard to access services, managing long-term conditions and managing co-morbidities and complex medication regimens.

Qualifying learners will be able to:

1. Demonstrate clinical and pharmaceutical knowledge to diagnose and treat conditions commonly encountered in primary health care settings.
2. Ensure quality prescribing practice.
3. Perform clinical assessment to make a diagnosis.
4. Formulate a treatment management plan.
5. Implement treatment plan and monitor therapeutic outcome.
6. Evaluate the patient assessment and management processes of selected cases to ensure quality prescribing practice.

QUALIFICATION RULES

In order to be credited with this qualification, the learner is required to achieve the following combination of credits:

- Fundamental component: 45 credits are compulsory (Exit level outcome 1 & 2).
- Core component: 60 credits are compulsory (Exit level outcomes 3, 4 & 5).
- Elective component: a minimum of 15 credits are required (Exit level outcome 6).

ACCESS TO THE QUALIFICATION

Learners who wish to enter into study towards achieving this qualification must be in possession of a Bachelor of Pharmacy, Level 8 or recognised equivalent.

LEARNING ASSUMED TO BE IN PLACE

The learner entering into this programme must be in possession of the Bachelor of Pharmacy degree or equivalent with at least two years experience in dealing with patients as a pharmacist in a clinical environment excluding community service.

EXIT LEVEL OUTCOMES AND ASSOCIATED ASSESSMENT CRITERIA:

Exit level outcome 1

Demonstrate clinical and pharmaceutical knowledge to diagnose and treat conditions commonly encountered in primary health care settings.

Assessment criteria

- 1.1 The pathophysiology of conditions, as listed in the Primary Health Care (PHC) Standard Treatment Guidelines (STG) and Essential Medicines List (EML), is described to inform clinical diagnosis and treatment.
- 1.2 The signs and symptoms of common conditions are identified and described in relation to the pathophysiology.
- 1.3 Knowledge of the primary health care system is explained in relation to the National Health Strategic Plan.

- 1.4 Accountability and responsibility in relation to diagnosis and treatment is explained in terms of legal and professional requirements, and ethical considerations.

Exit level outcome 2

Ensure quality prescribing practice.

Assessment criteria

- 2.1 Principles embedded in the Patients Rights Charter are applied in interactions with patients.
- 2.2 Communication with patients/caregivers is conducted in a professional manner in terms of sensitivity to patients' needs and diversity.
- 2.3 Collaboration and/or consultation with other health care professionals is initiated and maintained in the patient's best interest.
- 2.4 Current evidenced-based sources of information and professional advice are identified and utilised in order to improve patient care.
- 2.5 Local resources are identified and utilised for patient referral and support.
- 2.6 Relevant records are generated and maintained in accordance with legal requirements and organisational policies and procedures.

Exit level outcome 3

Perform clinical assessment to make a diagnosis.

Assessment criteria

- 3.1 Informed consent is explained and obtained in accordance with best practice and relevant legislation.
- 3.2 Patient history is taken to inform clinical decisions.
- 3.3 Signs, symptoms and disease risk factors are interpreted to inform clinical decisions.
- 3.4 Appropriate diagnostic interventions are employed with attention to safety, cost, invasiveness, simplicity and acceptability.
- 3.5 Physical examination, which is problem focused and age specific, is performed to inform clinical decisions.

(Range aspects of physical examination to be excluded: internal and external genitourinary examination.)
- 3.6 Sources of information and advice are identified and assessed for use in patient care.
- 3.7 History, presenting symptoms and diagnostic information are analysed and interpreted to develop the appropriate differential diagnoses.

- 3.8 Acute and long-term conditions are diagnosed by taking cognisance of the patient's response to the illness.

Exit level outcome 4

Formulate a treatment management plan.

Assessment criteria

- 4.1 Appropriate therapeutic interventions and regimens are identified and selected within the scope of the Primary Health Care Standard Treatment Guidelines and Essential Medicines List.
- 4.2 Non-pharmacological interventions are identified and selected according to the condition and the patient's health status.
- 4.3 Medicines are prescribed safely, appropriately and cost effectively within the primary health care standard treatment guidelines and Essential Medicines List.
- 4.4 Criteria for referral are applied appropriately and in accordance with PHC STGs.
- 4.5 An integrated action plan is formulated to achieve the desired therapeutic outcomes within a determined timeframe.

Exit level outcome 5

Implement treatment plan and monitor therapeutic outcome.

Assessment criteria

- 5.1 The management plan is discussed and agreement reached with the patient.
- 5.2 Results of interventions are evaluated using accepted outcome criteria.
- 5.3 Patient response to therapeutic intervention(s) is monitored according to the management plan.
- 5.4 The diagnosis and management plan is reviewed and revised, as needed, based on the patient's response.

Exit level outcome 6

Evaluate the patient assessment and management processes of selected cases to ensure quality prescribing practice.

Assessment criteria

- 6.1 A portfolio of the required number of cases is compiled in order to provide evidence of prescribing competence.

(Range of evidence for the portfolio must include, but is not limited to: case records, treatment plans, verification by a Designated Authorised Prescriber (DAP).)

(Range of cases includes, but is not limited to the following conditions: Hypertension in adults, Diabetes, Respiratory Conditions, Asthma, HIV/AIDS, Skin conditions, Contraception, Urinary Tract Infection, Sexually Transmitted Infections, Immunisation, Tuberculosis.)

- 6.2 Critical reflection on management of four cases is demonstrated to provide evidence of application of knowledge in practice.
- 6.3 Any four conditions as listed in the PHC EML/STGs are selected and critically evaluated for the improvement of case management in terms of evidence based medicine, rational medicine use and pharmaco-economic factors.

CRITICAL CROSS-FIELD OUTCOMES

- Identify, analyse and solve problems related to the provision of pharmaceutical services legally, responsibly and ethically.
- Work effectively with others as a member of a team of health care professionals in applying pharmaceutical principles.
- Organise and manage oneself and one's activities responsibly and effectively in participating in and contributing to the education and training institution and broader community.
- Collect, analyse, organise and critically evaluate information on a chosen topic to ensure effective clinical assessment, diagnosis and management of patients.
- Communicate effectively using visual, mathematical and/or language skills in the modes of oral, written and/or practical presentation in a sustained discourse.
- Use science and technology in pharmacy prescribing effectively and critically, showing responsibility towards the environment and health of others by promoting ethical conduct in all contexts.
- Demonstrate an understanding of the world as a set of related systems by recognising that problem-solving contexts do not exist in isolation.
- Contribute to the personal development of each learner and the social and economic development of society by making learners aware of the importance of:
 - reflecting on and exploring a variety of strategies to learn more effectively.
 - participating as responsible citizens in the life of local, national and global communities.
 - being culturally and aesthetically sensitive across a range of social contexts.
 - exploring education and career opportunities by drawing on various knowledge, skills and attitudes acquired in the attainment of this qualification.
 - developing entrepreneurial opportunities by drawing on the knowledge, skills and attitudes acquired in the attainment of this qualification.

INTERNATIONAL COMPARABILITY

The International Pharmaceutical Federation (FIP) represents two million pharmacists around the world through Member Organisations and Individual Members. FIP sets global pharmacy standards through professional and scientific guidelines, policy statements and declarations, as well as through its collaboration with other international organizations, including the World Health Organization (WHO) and other United Nations (UN) agencies. The South African Pharmacy Council ensures that approved pharmacy schools and providers embed these standards and guidelines in their learning programmes.

The South African Post Graduate Diploma: Pharmacy: Authorised Prescriber has been designed and generated with these standards and guidelines in mind. Although all member countries offer pharmacy training in line with FIP and their offerings are therefore comparable, institutions from the following countries were considered for the purpose of this benchmarking exercise:

1. United Kingdom
2. Canada

United Kingdom

In April 2006, the Department of Health in the United Kingdom added independent prescribing rights to the official scope of practice of pharmacists. The following requirements are listed by the General Pharmaceutical Council (GPC):

- (a) a pharmacist must have at least two years experience appropriate patient-orientated experience in a UK hospital, community or primary care setting as a pharmacist, following their pre-registration year after graduation before they can enrol in a programme accredited by the GPC to become an independent prescriber;
- (b) as part of the training programme, pharmacists are required to do a minimum period equivalent to 12 X 7½ days of learning in practice under the supervision of a designated medical practitioner;
- (c) the medical practitioner will be responsible for assessing whether the learning outcomes have been met and whether the trainee has acquired the necessary competencies as identified by the higher education institution providing the individual course;
- (d) the designated medical practitioner and the higher education institution will collaborate in conducting the accredited programme for the non-medical prescriber;
- (e) the duration of theoretical training is expected to be at least 26 days including sufficient face to face time to enable pharmacists to work with other students, share and consolidate their learning and learn about common diagnostic aids and assess patients' health status;
- (f) the training programme of training and preparation may be spread over a period of 3 to 6 months;
- (g) pharmacists must identify an area of clinical practice and need, in which to develop their prescribing skills;

- (h) pharmacists must have an up to date clinical pharmacological and pharmaceutical knowledge relevant to their intended area of prescribing practice;
- (i) pharmacists must demonstrate how they reflect on their own performance and take responsibility for their own CPD;
- (j) pharmacists must demonstrate how they will develop their own networks for support, reflection and learning including prescribers from other professions;
- (k) pharmacists who successfully complete an accredited programme will be awarded a practice diploma in independent prescribing and thereafter can register with the GPC;
- (l) the accredited programme can only be offered by Higher Education Institutions and programme is at first degree level(QAA level 3);
- (m) the training programme, for both pharmacists and nurses, includes an assessment of theory and practice which must be passed before the practitioner is annotated on the register.

Canada

In Canada, pharmacists in some jurisdictions have had the ability to independently prescribe emergency contraception (now a Schedule II product), but not other prescription medications, since early 2000. The Canadian Pharmacists Association indicates that pharmacists who have completed orientation to new practice standards can adapt existing prescriptions and prescribe in emergency situations, when immediate treatment is required, but another prescriber is not accessible. Pharmacists who have been evaluated and granted additional prescribing privileges may initiate, modify, and extend (manage) medicine therapy for acute and chronic conditions when working interdependently or collaboratively with other health professionals.

INTEGRATED ASSESSMENT

Integrated assessment at the level of the qualification provides an opportunity for learners to show that they are able to integrate concepts, ideas and actions across exit level outcomes to achieve competence that is grounded and coherent in relation to the purpose of the qualification. Integrated assessment should show how already demonstrated competence in individual areas can be linked and applied for the achievement of a holistic outcome as described in the exit level outcomes. Both formative and summative forms of assessment should be applied appropriately throughout the assessment process.

Integrated assessment must judge the quality of the observable performance, and also the quality of the thinking that lies behind it. Assessment tools must encourage learners to give an account of the thinking and decision-making that underpins their demonstrated performance. Some assessment practices will demand practical evidence while others may be more theoretical, depending on the type of outcomes to be assessed. The ratio between action and interpretation is not fixed, but varies according to the demands of the particular exit level outcome of the qualification. A broad range of task-orientated and

theoretical assessment tools may be used, with the distinction between practical knowledge and disciplinary knowledge maintained so that each takes its rightful place.

RECOGNITION OF PRIOR LEARNING

This qualification may be achieved in whole or in part through the process of recognition of prior learning at the request of the learner and the discretion of the education and training institution.

ARTICULATION POSSIBILITIES

Example of vertical articulation with this qualification: Masters in Clinical Pharmacy, level 9.

MODERATION OPTIONS AND MODERATING BODY/BODIES

- Any institution offering learning that will enable achievement of this qualification must be accredited by the relevant ETQA.
- External moderation of assessment will take place.
- The accredited training provider will oversee internal and external moderation of assessment.
- Moderation should encompass achievement of competence described in exit level outcomes, critical cross-field outcomes and the integrated competence described in the qualification.

CRITERIA FOR THE REGISTRATION OF ASSESSORS

- Assessors must be registered as assessors with a relevant ETQA or an ETQA that has a Memorandum of Understanding with the relevant ETQA.
- Assessors must be in possession of a similar or higher qualification in a relevant field of study.

NOTES

- All learners must be registered as learners with the South African Pharmacy Council for the duration of the period of learning as specified in current relevant legislation and in agreement with the relevant QC.
- The range of elective learning areas offered will be dependent on the approval of the provider and ETQA.
- Credit values reflected for each exit level outcome in the table below should be regarded only as a guideline.
- The respective Assessment Criteria aim to test the achievement of the specific learning outcomes. As many of these criteria are practice-based, providers are required to include periods in their curricula for this purpose.
- Practice must take place under the supervision of a medical practitioner or an Authorised Pharmacist Prescriber.

Learning Area	Exit Level Outcome	Credits
Fundamental	1. Demonstrate clinical and pharmaceutical knowledge to diagnose and treat conditions commonly encountered in primary health care settings.	25
	2. Ensure quality prescribing practice.	20
Core	3. Perform clinical assessment to make a diagnosis.	20
	4. Formulate a treatment management plan.	20
	5. Implement treatment plan and monitor therapeutic outcome.	20
Elective	6. Evaluate the patient assessment and management processes of <u>selected cases</u> to ensure quality prescribing practice.	15
	Minimum Total Credits	120