

Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 553

Pretoria, 1 July
Julie 2011

No. 34428

IMPORTANT NOTICE

The Government Printing Works will not be held responsible for faxed documents not received due to errors on the fax machine or faxes received which are unclear or incomplete. Please be advised that an "OK" slip, received from a fax machine, will not be accepted as proof that documents were received by the GPW for printing. If documents are faxed to the GPW it will be the sender's responsibility to phone and confirm that the documents were received in good order.

Furthermore the Government Printing Works will also not be held responsible for cancellations and amendments which have not been done on original documents received from clients.

CONTENTS • INHOUD

<i>No.</i>		<i>Page No.</i>	<i>Gazette No.</i>
BOARD NOTICES			
122	Pharmacy Act (53/1974): The South African Pharmacy Council: Scope of practice and qualification for Authorised Pharmacist Prescriber.....	3	34428
123	do.: do.: Scope of practice, supervision of pharmacy support personnel and qualifications.....	16	34428

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', written over a horizontal line.

**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

BOARD NOTICE 123 OF 2011

South African
Pharmacy Council

BOARD NOTICE**THE SOUTH AFRICAN PHARMACY COUNCIL****SCOPE OF PRACTICE, SUPERVISION OF PHARMACY SUPPORT
PERSONNEL AND QUALIFICATIONS**

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 three categories of pharmacy support personnel namely pharmacist's assistant, pharmacy technical assistant and pharmacy technician;
- (b) publish amendments to the *Regulations relating to the practice of pharmacy* to provide for the Scopes of Practice of the abovementioned categories of pharmacy support personnel; and
- (c) publish amendments to the *Regulations relating to pharmacy education and training* published in terms of Sections 33 and 34 of the Pharmacy Act to provide the required qualifications for the pharmacist's assistant, pharmacy technical assistant and pharmacy technician.

Furthermore the Council intends to amend the Good Pharmacy Practice Rules published in terms of Section 35A(b)(ii) to include rules for the supervision of such pharmacy support personnel.

The qualifications, proposed scopes of practice and principles relating to the supervision of these cadres are published herewith for public comment prior to the said request/s to the Minister of Health. Please note that the pharmacist's assistant qualification is excluded for publication later.

SCHEDULE

1. **Proposed scopes of practice for pharmacy support personnel in manufacturing, wholesale, institutional and community pharmacies**
2. **Minimum standards for the supervision of pharmacy support personnel**
3. **Qualification for Pharmacy Technical Assistant**
4. **Qualification for Pharmacy Technician**

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 on or representations 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).



**TA MASANGO
REGISTRAR**

PROPOSED SCOPE OF PRACTICE FOR PHARMACY SUPPORT PERSONNEL IN MANUFACTURING, WHOLESALE, INSTITUTIONAL AND COMMUNITY PHARMACIES

INTRODUCTION

A need has been identified to revise the scope of practice of the current categories of pharmacy support personnel. It is proposed that there are three categories viz. pharmacist's assistants, pharmacy technical assistants and pharmacy technicians. After consultation with the various sectors in pharmacy and the National Human Resources Task Team, the proposed scope of practice has been revised. The principles listed below were taken into consideration in the revision of the scope.

GENERAL PRINCIPLES

- (a) A pharmacy as defined in the Pharmacy Act 53 of 1974 must be conducted under the continuous personal supervision of a pharmacist who is physically present in a pharmacy (Refer relevant sections of the Pharmacy Act 53 of 1974 as amended).
- (b) Pharmacy technicians, pharmacy technical assistants and pharmacist's assistants must not be able to work in a pharmacy in which a pharmacist is not physically present.
- (c) The scope of practice of pharmacy technicians and pharmacy technical assistants should enable these cadres of health care workers to be more useful than the current categories of pharmacy support personnel in both the public and the private sector.
- (d) International trends should be taken into account in the development of the scope of practice of new categories of pharmacy support personnel.
- (e) The standards applicable in the public and private sector should be the same.
- (f) Provision must be made for continuing professional development for pharmacy support personnel.
- (g) It must be clearly stated that pharmacy technicians, pharmacy technical assistants and pharmacist's assistants are bound by the ethical rules, the code of conduct, the marketing code and all relevant legislation.
- (h) There is a need to change the Medicines and Related Substances Act 101 of 1965 in order to authorise pharmacy technicians and pharmacy technical assistants to handle medicine in terms of this Act.

PRINCIPLES IN COMMUNITY AND INSTITUTIONAL PHARMACIES

- (a) The scope should be such that the pharmacist is freed from product orientated tasks to perform more patient orientated tasks. Particularly in the public sector the pharmacist should be freed to play a greater role in management, supervision, oversight and monitoring and evaluation of the supply of medicine. This is particularly important in the light of the large number of patients on ARVs and the increasing involvement of lay counsellors and community health workers assisting in patient care at the level of the community.

- (b) There is a need to prevent pharmacy support personnel from working beyond their scope of practice.
- (c) There is a need for pharmacy technicians to work under the direct supervision of a pharmacist (pharmacist is physically present) in pharmacies as well as under the indirect supervision of a pharmacist in a primary health care clinic.
- (d) The details of 'how' pharmacy technicians will practise under supervision of pharmacist will be included in the Good Pharmacy Practice rules published by Council in terms of Section 35A of the Pharmacy Act 53 of 1974. Areas which should be addressed would include the role of the pharmacy technician in generic substitution, the receipt of telephonic prescriptions, the capturing of prescriptions on electronic dispensing systems and the checking of calculations by a pharmacist.
- (e) The scope of practice of the pharmacy technician under supervision of a pharmacist who is physically present in a pharmacy as opposed to one working under supervisory support of a pharmacist who is not physically present in primary health care clinic dispensary can differ.
- (f) Provision should be made for down referrals to primary health care clinics and where the prescription is prepared at a pharmacy and sent down to a primary health care clinic or other site (e.g. a community pharmacy) for dispensing by a pharmacy technician and collection by the patient.
- (g) Different criteria could be used to demarcate the scope of practice of the pharmacy technician. Mechanisms that could be used include the type of medicine that can be dispensed, the disease being treated, the level of care being provided at the facility. Another option would be to base the limitation on an authorisation provided by the responsible pharmacist as is the case with Section 56 authorisations provided to nurses in terms of the Nursing Act 33 of 2005. A combination of the above options could be considered. The mechanism chosen must be easy to implement in the practice setting and easy to monitor from a compliance point of view.
- (h) A combination of the principles included in (g) above be used to delineate the scope of practice.
- (i) It is thus proposed that when practising under supervision of a pharmacist who is physically present in a pharmacy the role of pharmacy technician be as follows –
 - (i) All prescriptions coming into a pharmacy be seen and triaged by a pharmacist;
 - (ii) Prescriptions which contain medicines which fall into Schedules 1 and 2 be dispensed by a pharmacy technician without the further involvement of a pharmacist (Phases 1, 2 and 3);
 - (iii) Any prescription which contains medicines which fall into Schedule 3 of higher must be evaluated by a pharmacist (Phase 1 of the dispensing process);
 - (iv) Data capturing can be done by a pharmacy technician with authorisation by a pharmacist;
 - (v) The preparation of all prescriptions be done by the pharmacy technician or pharmacy technical assistant (Phase 2);

- (vi) The pharmacist would be able to decide which patients require counselling by a pharmacist e.g. patients with complicated regimens, patients receiving a supply of chronic medicine for the first time, patients with co-morbidities, adherence problems etc (Phase 3 of the dispensing process);
 - (vii) In the case of prescriptions containing Schedule 5 and 6 medicines the pharmacist must be involved in the dispensing process.
- (j) Under indirect supervision, consideration could be given to checking of prescriptions prepared by a pharmacy technician by another technician.
 - (k) Pharmacy technicians should be able to work under supervision of a pharmacist who is not physically present in a primary health care clinic dispensary. When working under supervision of a pharmacist who is not physically present in a primary health care clinic dispensary the pharmacy technician should be able to dispense prescriptions which contain medicines appearing in the Primary Health Care Essential Medicines List and which are prescribed in accordance with the Standard Treatment Guidelines. In the case of patients with co-morbidities consultation (could be telephonic) with a pharmacist should take place when the prescription is dispensed.
 - (l) All cadres of pharmacy support personnel must be accommodated in the Occupation Specific Dispensation (OSD).

PRINCIPLES IN WHOLESALE AND MANUFACTURING PHARMACIES

- (a) The responsible pharmacist takes overall responsibility for the pharmacy in which he/she is registered as the responsible pharmacist. This includes all functions performed in the pharmacy. (Refer Pharmacy Act 53 of 1974, Medicines and Related Substances Act 101 of 1965, Good Pharmacy Practice rules and GMP and GWDP guidelines). In a manufacturing pharmacy the responsible pharmacist must ensure that management runs the factory in accordance with Good Manufacturing Practice.
- (b) The scope of the pharmacy technician should be such that the pharmacist is freed from non-critical stages in the manufacturing process and is free to focus on critical stages in the process. Key tasks which the pharmacy technician can perform must be defined.
- (c) Functions in a manufacturing pharmacy and a wholesale pharmacy must be conducted in accordance with Good Manufacturing Practices (GMP), or Good Wholesaling and Distribution Practices (GWDP), determined by the Medicines Control Council, and the Pharmaceutical Inspection Convention (PIC) guidelines, as applicable. The functions performed by pharmacy support personnel must be in line with the requirements of these guidelines refer in particular Section 16.2 of GMP guidelines. The pharmacy support personnel must have the necessary competence.
- (d) Pharmacy support personnel may perform certain procedures independently in accordance with the scope of practice and standard operating procedures approved by the responsible pharmacist of the pharmacy.
- (e) The role of pharmacy support personnel will be process orientated. A pharmacist must always be available to perform all critical functions in the manufacturing and wholesale pharmacy.

- (f) A pharmacist is responsible for checking the authenticity of all suppliers and persons/entities to whom medicines and scheduled substances are sold/supplied or from whom they are procured.
- (g) A pharmacy technician should be able to supervise the activities of pharmacy technical assistants. Such supervision would be determined at an organisational level and not be a legal requirement.

PHARMACIST'S ASSISTANT

This category of pharmacy support personnel would be able to practise in any sector of pharmacy i.e. manufacturing, wholesale, community or institutional pharmacy in either the public or the private sector. The main functions of this category of support personnel would be to assist with functions relating to medicine supply management. This category of support personnel may only work under the personal supervision of a pharmacist who is physically present in a pharmacy. All functions must be performed in accordance with the relevant legislation and standard operating procedures approved by the responsible pharmacist of the pharmacy (refer GPP).

This category of pharmacy support personnel will have no direct role in the interaction with other health care professionals or patients.

The scope of practice must be read together with services which may be provided in the various categories of pharmacies as contained in the *Regulations relating to the practice of pharmacy (GNR 1158 of 20 November 2000)*.

PROPOSED SCOPE OF PRACTICE FOR A PHARMACIST'S ASSISTANT

A pharmacist's assistant may perform the following services or acts in any category of pharmacy under the personal supervision of a pharmacist who is physically present in a pharmacy and in accordance with standard operating procedures approved by the responsible pharmacist:

- (a) assist with packaging and re-packaging of medicines or scheduled substances;
- (b) picking and packing of orders for Schedule 0 to Schedule 5 medicines or scheduled substances provided that orders that contain medicines which fall into schedule 5 and above are validated by a pharmacist prior to release thereof; (Note 'order' will be defined in the regulations);
- (c) assist with the management of stock of Schedule 1 to Schedule 5 medicines or scheduled substances; and
- (d) assist with general housekeeping and administrative tasks in the pharmacy as specified by the responsible pharmacist.

PHARMACY TECHNICAL ASSISTANT

This category of pharmacy support personnel would be able to practise in any sector of pharmacy i.e. manufacturing, wholesale, community or institutional pharmacy in either the public or the private sector. In the wholesale, community and institutional sectors the main functions of this category of support personnel would be to assist with functions relating to the medicine supply management cycle. In community and institutional pharmacies pharmacy technical assistants would also be able to assist with Phase 2 of the dispensing process. In manufacturing pharmacies this category

of person would be involved in assisting in the manufacturing of non-sterile medicines as well as general housekeeping functions.

This category of support personnel may only work under the personal supervision of a pharmacist who is physically present in a pharmacy. All functions must be performed in accordance with the relevant legislation and standard operating procedures approved by the responsible pharmacist of the pharmacy (refer GPP).

This category of pharmacy support personnel will have no direct role in the interaction with other health care professionals.

The scope of practice must be read together with services which may be provided in the various categories of pharmacies as contained in the *Regulations relating to the practice of pharmacy (GNR 1158 of 20 November 2000)*.

PROPOSED SCOPE OF PRACTICE FOR PHARMACY TECHNICAL ASSISTANT

A pharmacy technical assistant may perform the following services or acts in any category of pharmacy under the personal supervision of a pharmacist who is physically present in a pharmacy and in accordance with standard operating procedures approved by the responsible pharmacist:

- (a) assist with the compounding, manipulation, preparation and manufacturing of a non-sterile medicine or scheduled substance; provided that the pharmacy technical assistant is not involved in planning of the production process, interpretation and evaluation, validation and quality assurance;
- (b) assist with packaging and re-packaging of medicines or scheduled substances;
- (c) picking, packing and despatch of orders for Schedule 1 to Schedule 5 medicines or scheduled substances (subject to amendments to Section 22A(14)(a) of the Medicines Act) provided that orders that contain medicines which fall into schedule 5 and above are validated by a pharmacist prior to release thereof; (Note 'order' will be defined in the regulations);
- (d) the checking of orders containing Schedule 1 to 4 medicines in closed packs, prior to the packing and despatch thereof, which have been picked by a pharmacist's assistant, as well as the supervision of such persons provided that this function may only be performed in a manufacturing pharmacy, wholesale pharmacy or bulk store of an institutional pharmacy;
- (e) assist with the management of stock of Schedule 1 to Schedule 5 medicines or scheduled substances (subject to amendments to Section 22A(14)(a) of the Medicines Act); and
- (f) assist with the selection or preparation of a Schedule 1 to Schedule 5 medicine or scheduled substance prescribed by an authorised prescriber and the labelling of an appropriate container, following the interpretation and evaluation of the prescription by a pharmacist; and
- (g) assist with general housekeeping and administrative tasks in the pharmacy as specified by the responsible pharmacist.

PHARMACY TECHNICIAN

This category of pharmacy support personnel would be able to practise in any sector of pharmacy i.e. manufacturing, wholesale, community or institutional pharmacy in either the public or the private sector. Pharmacy technicians would be able to work under supervision of a pharmacist who is physically present in a pharmacy and under the supervision of a pharmacist who is not physically present in the dispensary of a primary health care clinic. All functions would have to be performed in accordance with standard operating procedures approved by the responsible pharmacist or supervising pharmacist. In community and institutional pharmacies, this category of pharmacy support personnel will have direct role with patients and health care professionals.

Functions will include general housekeeping and administrative functions, stock control, manufacturing and compounding of sterile and non-sterile medicines as well as providing assistance with the dispensing of prescriptions. In community and institutional pharmacies, in the case of prescriptions containing only medicines which fall in Schedules 1 and 2 the technician would be able to function semi-autonomously as each prescription would not have to be checked by a pharmacist after dispensing. Oversight by a pharmacist would be required for prescriptions containing medicines which appear in Schedules 3 and higher. The technician would be able to provide instructions to the patient on the use of the medicine on the prescription. The pharmacist would, however, decide when the involvement of a pharmacist is needed.

In manufacturing and wholesale pharmacies, pharmacy technicians will be able to perform certain defined functions without the direct oversight of a pharmacist. Such functions will be performed in accordance with the Batch Manufacturing Documents and standard operating procedures approved by the responsible pharmacist.

The scope of practice must be read together with services which may be provided in the various categories of pharmacies as contained in the *Regulations relating to the practice of pharmacy (GNR 1158 of 20 November 2000)*.

PROPOSED SCOPE OF PRACTICE FOR PHARMACY TECHNICIAN

- (1) A pharmacy technician may provide or perform the following services or acts under the supervision of a pharmacist who is physically present in a pharmacy and in accordance with minimum standards as prescribed in Rules relating to Good Pharmacy Practice published in terms of Section 35A of the Pharmacy Act, and where applicable the Good Manufacturing Principles and the Good Wholesale and Distribution Principles as applied by the Medicines Control Council in terms of the Medicines and Related Substances Act 101 of 1965:
 - (a) assist with the manufacturing, compounding, manipulation or preparation of a non-sterile or sterile medicine or scheduled substance, in accordance with the Medicines Act, by performing the following functions:
 - (i) the weighing of materials including schedule 1 to 6 substances;
 - (ii) the checking and signing of the addition of materials to the mix after the pharmacist has checked each mass or volume and signed for each dispensed material in accordance with the Batch Manufacturing Document or prescription and in compliance with standard operating procedures;

- (iii) checking the identity of the bulk product and its identity label after the pharmacist has checked and signed in accordance with the Batch Manufacturing Document or prescription and in compliance with standard operating procedures;
 - (iv) start-up line clearance and opening of the line as per documented procedure and detailed checklist, provided that the pharmacist has provided the necessary signed authorisation therefore;
 - (v) in process control during manufacture of Schedule 0 to 6 medicines or scheduled substances, provided that the pharmacist does periodic checks in accordance with standard operating procedures and that final line closure is signed off by the pharmacist;
 - (vi) reconciliation of documents of Schedule 0 to 6 medicines or scheduled substances provided that the final release of the product is performed by a pharmacist;
- (b) the packaging and re-packaging of Schedule 0 to Schedule 5 (excluding Specified Schedule 5) medicines or scheduled substances, in accordance with the Medicines Act, provided that the functions of the pharmacy technician may include -
- (i) checking and signing the identity of the bulk product and printed packaging material in accordance with the Batch Manufacturing Document and in compliance with standard operating procedures;
 - (ii) start-up line clearance and opening of the packaging line in accordance with the Batch Manufacturing/Packaging Document and in compliance with standard operating procedures; and detailed checklist, provided that the pharmacist has provided the necessary signed authorisation therefore;
 - (iii) in process control during packaging and re-packaging of Schedule 0 to Schedule 5 (excluding Specified Schedule 5) medicines or scheduled substances, provided that the pharmacist does periodic checks in accordance with standard operating procedures and that final line closure is signed off by the pharmacist;
- (c) the sampling, or supervision of the sampling of medicines or scheduled substances in accordance with Good Manufacturing Practice;
- (d) picking, packing and despatch of orders for Schedule 1 to Schedule 5 medicines or scheduled substances (subject to amendments to Section 22A(14)(a) of the Medicines Act) provided that orders that contain medicines which fall into schedule 5 are validated by a pharmacist prior to release thereof; (Note 'order' will be defined in the regulations);
- (e) the checking of orders containing Schedule 1 to 4 medicines in closed packs, prior to the packing and despatch thereof, which have been picked by a pharmacy technical assistant or pharmacist's assistant, as well as the supervision of such persons provided that this function may only be performed in a manufacturing pharmacy, wholesale pharmacy or bulk store of an institutional pharmacy;

- (f) assist with the management of stock of Schedule 1 to Schedule 5 medicines or scheduled substances (subject to amendments to Section 22A(14)(a) of the Medicines Act), provided that orders that contain medicines which fall into schedule 5 are validated by a pharmacist (Note 'order' will be defined in the regulations);
- (g) the ordering and receipt of Schedule 1 to Schedule 5 medicines or scheduled substances, provided that orders that contain medicines which fall into schedule 5 are validated by a pharmacist (Note 'order' will be defined in the regulations);
- (h) the sale of Schedule 1 and 2 medicines without the prescription from an authorised prescriber, provided that the supply of a Schedule 2 medicine takes place in consultation with a pharmacist; (Note: need to include definition of 'prescription' in the regulations);
- (i) the dispensing of Schedule 1, 2, 3 and 4 medicines or scheduled substances (i.e. the selection, manipulation or compounding of the medicine, the labelling and packing of the medicine in an appropriate container and the provision of information to a patient, caregiver or the agent of a patient regarding the correct use of medicine to optimise therapeutic outcomes) on the prescription of an authorised prescriber, provided that in the case of prescriptions containing Schedule 3 and 4 medicines, this must be preceded by the interpretation and evaluation of the prescription by a pharmacist;
- (j) the selection or preparation of a Schedule 5 medicine or scheduled substance prescribed by an authorised prescriber and the labelling of an appropriate container, following the interpretation and evaluation of the prescription by a pharmacist;
- (k) general housekeeping and administrative tasks in the pharmacy as specified by the responsible pharmacist;
- (l) supervision of pharmacist's assistants, pharmacy technical assistants, and trainee pharmacist's assistants, pharmacy technical assistants and pharmacy technicians, as specified by the responsible pharmacist;
- (m) the provision of technical support in the provision of screening tests provided that where an interpretation of results is required this is done by a pharmacist;
- (2) A pharmacy technician may provide or perform the following services or acts under the supervision of a pharmacist who is physically not present in the dispensary in a primary health care clinic and in accordance with minimum standards as prescribed in the *Rules relating to Good Pharmacy Practice* (GGN 27112, published on 17 December 2004 as amended):
 - (a) the ordering and receipt of Schedule 1 to Schedule 5 medicines or scheduled substances, provided that orders that contain medicines which fall into schedule 5 and above are validated by a pharmacist (Note 'order' will be defined in the regulations);
 - (b) the management of stock of Schedule 1 to Schedule 5 medicines or scheduled substances provided that orders that contain medicines which fall

into schedule 5 and above are validated by a pharmacist (Note 'order' will be defined in the regulations);

- (c) the assessment of a prescription for medicine which appears on the Primary Health Care Essential Medicines List and which is prescribed in accordance with Standard Treatment Guidelines, the selection, manipulation or compounding of the medicine, the labelling and packing of the medicine in an appropriate container and the provision of information to a patient, caregiver or the agent of a patient to optimise therapeutic outcomes;
- (d) the provision of information to a patient, caregiver or the agent of a patient to optimise therapeutic outcomes resulting from the use of medicines which have been dispensed at a pharmacy and sent to the primary health care clinic for supply to the patient or the patient's agent or caregiver;
- (e) management of the dispensary, where the dispensary is designated as a dispensary in terms Rule 1.6.2(a) of the *Rules relating to Good Pharmacy Practice* (GGN 27112, published on 17 December 2004 as amended);
- (f) general housekeeping and administrative tasks in the dispensary as specified by the supervising pharmacist.

MINIMUM STANDARDS FOR THE SUPERVISION OF PHARMACY SUPPORT PERSONNEL

Introduction

Pharmacy support personnel form part of the integral system in the delivery of pharmaceutical services. The functions performed by a pharmacist can be categorised as either product orientated or patient orientated. In efforts to improve service delivery and develop the concept of comprehensive pharmaceutical care, it is essential that the pharmacist as far as possible devolves responsibility and functions related to product supply to pharmacy technicians, pharmacy technical assistants and pharmacist's assistants thus allowing pharmacists more time for patient orientated activities. It is the responsibility of the pharmacist to supervise pharmacy support personnel with regard to the control, purchase, sale, manufacturing, pre-packaging, dispensing and supply of all medicines.

Purpose

The purpose of these rules is to give guidance to pharmacists and pharmacy support personnel on how to manage the supervision. The standard will further expand on the independent role of a pharmacy technician based at a primary health care clinic.

General Considerations applicable to all sectors

1. Pharmacy support personnel may practise in any sector of pharmacy i.e. manufacturing, wholesale, community or institutional pharmacy in either the public or the private sector provided that they are competent to practise and are appropriately registered with Council to practise in that sector.
2. All pharmacy support personnel are responsible for their own safe and efficient practice and are bound by the applicable legislation, the ethical rules, the code of conduct as well as guidelines published in terms of the legislation.
3. Clear and detailed job descriptions must be in place describing the role and responsibilities of all pharmacy support personnel.
4. A pharmacy as defined in the Pharmacy Act 53 of 1974 must be conducted under the continuous personal supervision of a pharmacist. A pharmacist must thus be physically present in the pharmacy.
5. A pharmacy technician, pharmacy technical assistant or pharmacist's assistant may only work in a pharmacy under the supervision of a pharmacist(s) who is physically present in the pharmacy.
6. A pharmacy technician may work independently in a dispensary in a primary health care clinic. Supervisory support must be provided by a pharmacist who is not necessarily physically present at all times in the primary health care clinic.
7. When working in a primary health care clinic with supervisory support of a pharmacist, the pharmacy technician may dispense prescriptions which contain medicines appearing in the Primary Health Care Essential Medicines List and which are prescribed in accordance with the Standard Treatment Guidelines. In

- addition he/she may dispense prescriptions which are in accordance with such other protocols which may be approved by the Pharmacy and Therapeutics Committee of the province, municipal or other competent authority under which the primary health care clinic falls provided that such protocols are publicly available.
8. A pharmacy technician may have direct interaction with patients and health care professionals.
 9. In a community pharmacy or an institutional pharmacy in a private health facility a pharmacy technician may explain the benefits of generic substitution to a patient as required in terms of Section 22F of the Medicines and Related Substances Act 101 of 1965. A pharmacist must, however, be involved in the *final substitution decision* as to which brand of medicine should be dispensed for the patient in cases where such a choice must be made.
 10. A pharmacy technician may not dispense prescriptions containing Schedule 5 and 6 medicines except in the case of a pharmacy technician working under the supervisory support of a pharmacist in a primary health care clinic. The pharmacy technician may, however, issue Schedule 5 medicines on prescriptions which have been prepared and are in a patient ready pack e.g. in the case of down-referrals. He/she may also perform Phase 2 of the dispensing process for prescriptions containing Schedule 5 medicines.
 11. A pharmacy technician may not receive verbal instructions e.g. a telephonic order from an authorised prescriber for a new prescription for a patient.
 12. All calculations relating to the patient's dosage or the volume of liquids to be supplied must be validated by a pharmacist before dispensing takes place.
 13. A pharmacist may only provide supervisory support to a pharmacy technician working in the dispensary in a primary health care clinic which falls under the jurisdiction of the same competent authority e.g. district or metropolitan council by whom he/she is employed. In cases where a pharmacist has been seconded from one authority to another he/she may support pharmacy technicians working in primary health care clinics falling under the jurisdiction of the authority to whom he/she has been seconded.

Supervision of pharmacy support personnel in manufacturing and wholesale pharmacy

The pharmacist involved in the supervision of pharmacy support personnel in a manufacturing or wholesale pharmacy must ensure that he/she is at all times readily available to directly supervise the activities taking place in a pharmacy. The pharmacist must randomly check all activities taking place in a pharmacy. The following approach must be used:

1. A manufacturing or a wholesale pharmacy must be conducted under the supervision of a pharmacist who is physically present in the pharmacy.
2. The pharmacist must be involved at all critical stages in the manufacturing, packaging and distribution process. Pharmacist involvement is needed but is not limited to the control of scheduled substances, the conducting of independent dispensing checks, the conducting of mix checks, line clearance and product

release onto the market. Pharmacists must also be responsible for dealing with product complaints and product recalls.

3. Pharmacy support personnel may be involved in the performance of 'non critical' functions so that pharmacists can focus on the 'critical' functions required to produce products as per Good Manufacturing Practice (GMP) guidelines.
4. These 'non – critical' functions must be identified and formally agreed upon by the responsible pharmacist of the manufacturing or wholesale pharmacy and the pharmacists responsible for each area of the pharmacy and then suitably documented and measured.

L5 PHARMACY TECHNICAL ASSISTANT

Qualification Title:		
Higher Certificate: Pharmacy: Support		
Field	Sub-field	SGB Name
Health Sciences and Social Services (09)	Curative Health	Pharmacy
Minimum Credits	NQF Level	Qualification Class
130	5	Non-Unit Standard based

RATIONALE FOR THE QUALIFICATION

The National Human Resources for Health Planning Framework 2006 identified the need for mid-level workers in all professional areas in order to meet the ever increasing needs of the country for healthcare services. In particular, an absolute need for increased production of pharmacy mid-level workers was identified as being a priority area for implementation. This qualification, Higher Certificate: Pharmacy: Support, has been developed to enable the achievement of this objective.

The Higher Certificate: Pharmacy: Support, NQF Level 5, is designed to meet the needs of learners who are either currently involved in the pharmaceutical field, particularly those who have qualified as pharmacist's assistants (post-basic), or those who wish to enter this profession. The Higher Certificate will allow access to the pharmaceutical environment, and may also open up opportunities for adult learners who wish to develop their careers in one or more of the related categories. 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 reflects the core needs of the pharmaceutical environment. It aims to address these needs by capacitating learners with the scientific knowledge and interpersonal skills required in the workplace.

Qualifying learners, who meet all necessary requirements, will be able to register as a Pharmacy Technical Assistant (PTA) with the South African Pharmacy Council. The Higher Certificate will also allow access to studies leading to the Advanced Certificate: Pharmacy: Technical Support.

The Pharmacy Technical Assistant will be able to practise in any sector of pharmacy, i.e. manufacturing, wholesale, community or institutional pharmacy, in either the public or the private sector. In the wholesale, community and institutional sectors the main functions of this category of support personnel will be to assist with functions relating to the medicine supply management cycle. In community and institutional pharmacy, pharmacy technical assistants will also be able to assist with the selection and preparation of products for dispensing by the pharmacist. In manufacturing pharmacies, this category of person will be involved in assisting in the manufacturing of non-sterile medicines and stock management, as well as general housekeeping functions.

This category of support personnel may only work under the direct personal supervision of a pharmacist in a pharmacy. All functions must be performed in accordance with the relevant legislation and standard operating procedures approved by the responsible pharmacist of the pharmacy.

This category of pharmacy support personnel will have no direct role in the interactions with patients and other health care professionals.

Qualifying learners will be able to:

1. Apply scientific knowledge in the provision of basic pharmaceutical support services.
2. Provide functional support to compound, manipulate and prepare medicines (non-sterile) for specific patients in compliance with Standard Operating Procedures (SOPs) under the supervision of a Pharmacist.
3. Provide functional support in the manufacture, package and/or re-package of non-sterile Scheduled substances/medicines in compliance with Good Manufacturing Practice (GMP) guidelines under the supervision of a pharmacist.
4. Provide functional support in the management of medicine stock, Scheduled substances, medical supplies and devices in compliance with Good Wholesale and Distribution Practice (GWDP) and legal requirements under the supervision of a pharmacist.
5. Provide functional support in Phase 2 of dispensing under the supervision of a pharmacist.
6. Perform general housekeeping and administrative tasks in a pharmacy and/or dispensary.
7. Provide information to promote health and wellness, or
8. Demonstrate the use of Information and Communication Technology (ICT) in the management of inventory in a manufacturing or wholesale or community or institutional pharmacy/dispensary (either the public or the private sector).

QUALIFICATION RULES

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

- Fundamental Component: 20 Credits are compulsory (Exit level outcome 1).
- Core component: 100 Credits are compulsory (Exit level outcomes 2, 3, 4, 5, 6).
- Elective component: a minimum of 10 Credits are required (Select Exit level outcome 7 or 8).

ACCESS TO THE QUALIFICATION

Learners who wish to enter into study towards achieving this qualification must be in possession of a Grade 12 qualification or FETC or National Senior Certificate or recognised equivalent.

LEARNING ASSUMED TO BE IN PLACE

- Mathematics Literacy at NQF level 4 or recognised equivalent.
- Life Science at NQF level 4 or recognised equivalent.

NOTE

It is strongly recommended that all learners accessing this qualification are able to read, write and communicate in English as most learning material is available only in the English medium. Furthermore, Computer literacy, level 3 or equivalent is recommended.

EXIT LEVEL OUTCOMES AND ASSOCIATED ASSESSMENT CRITERIA**Exit level outcome 1**

Apply scientific knowledge in the provision of basic pharmaceutical support services.

(Range of basic pharmaceutical support services include, but is not limited to: weighing of active ingredients, mixing, packing, labelling etc. and excluding any functions related to interpretation, evaluation, validation and Quality Assurance.)

Assessment criteria

- 1.1 Legislation related to the relevant scope of practice in pharmaceutical support services is described in the South African context.
(Range of current legislation includes, but is not limited to: Medicines Act, Pharmacy Act and related regulations and rules etc.).
- 1.2 Ethical and professional conduct related to the relevant scope of practice is demonstrated in the provision of pharmaceutical support services.
(Range of aspects related to professional conduct includes, but is not limited to: values, practices, attitudes and confidentiality etc.).
- 1.3 Basic pharmaceutical terms and concepts are explained in relation to different dosage forms and their route of administration.
- 1.4 Basic scientific principles are explained as applied to non-sterile pharmaceutical preparations.
- 1.5 Basic principles of pharmacology are explained in terms of the treatment of conditions identified in the Primary Health Care Standard Treatment Guidelines (STG) and Essential Medicines List (EML).

Exit level outcome 2

Provide functional support to compound, manipulate and prepare medicines (non-sterile) for specific patients in compliance with Standard Operating Procedures (SOPs) under the supervision of a Pharmacist.

Assessment criteria

- 2.1 The different dosage forms and their route of administration are explained in terms of extemporaneous preparation.
- 2.2 The principles of GPP are explained in relation to compounding, manipulating and preparing of non-sterile medicines.
- 2.3 Non-sterile medicines are compounded in accordance with SOPs, ethical principles and relevant legislation.
- 2.4 Non-sterile medicines are manipulated in accordance with SOPs, ethical principles and relevant legislation.
- 2.5 Non-sterile medicines are prepared and packed in accordance with SOPs authorised by a pharmacist.
- 2.6 Records are compiled and filed for medicines prepared for specific patients in accordance with legal requirements and organisational policies and procedures.

Exit level outcome 3

Provide functional support in the manufacturing, packaging and/or re-packaging of non-sterile and scheduled substances/medicines in compliance with Good Manufacturing Practice (GMP) guidelines under the supervision of a pharmacist.

Assessment criteria

- 3.1 The principles of GMP are explained in relation to the manufacturing, packaging and re-packaging of non-sterile medicines and scheduled substances.
- 3.2 Non-sterile medicines and scheduled substances are manufactured and packaged in accordance with GMP, SOPs, ethical principles and relevant legislation.
- 3.3 Non-sterile medicines and scheduled substances are re-packaged in accordance with GMP, ethical principles, relevant legislation and SOPs authorised by a pharmacist.
- 3.4 Line opening and closing is performed, after line clearance, according to GMP.
- 3.5 Relevant documentation for manufactured, packaged and re-packaged medicines and scheduled substances is completed in accordance with legal requirements and organisational policies and procedures.

Exit level outcome 4

Provide functional support in the management of medicine stock, scheduled substances, medical supplies and devices in compliance with Good Wholesale and Distribution Practice (GWDP) and legal requirements under the supervision of a pharmacist.

Assessment criteria

- 4.1 The principles of GWDP are explained in relation to the management of stock.
(Range of principles include, but is not limited to: FIFO and FEFO, storage and shrinkage, where shrinkage refers to loss, theft, damage, expired and obsolete medicines).
- 4.2 Orders for medicines are assembled according to GWDP and SOPs.
(Range of activities for order assembly include: picking, packing and checking).
- 4.3 Orders for medicines are dispatched according to GWDP and SOPs.
- 4.4 Procedures for stock count (cyclic, monthly, quarterly and annually), stock rotation, storage and shrinkage are explained according to GWDP.
- 4.5 Expired, obsolete and damaged medicines, scheduled substances, medical supplies and devices are identified and disposed of according to GWDP, SOPs, current relevant legislation and guidelines.
- 4.6 All relevant documents and records for management of stock are filed in accordance with relevant legislation, guidelines and SOPs.

Exit level outcome 5

Provide functional support in Phase 2 of dispensing under the supervision of a pharmacist.

Assessment criteria

- 5.1 All phases of the dispensing process are explained in accordance with legal requirements, including GPP.
- 5.2 Phase 2 of the dispensing process is demonstrated in accordance with legal requirements, including GPP.
- 5.3 Medicines are packed in an appropriate container and labelled in accordance with legal requirements, including GPP.
- 5.4 Mechanisms to avoid and identify errors are explained in relation to Phase 2 of the dispensing process.
- 5.5 Records of selecting, preparing and labelling of prescribed medicines are completed according to SOPs.

Exit level outcome 6

Perform general housekeeping and administrative tasks in a pharmacy and/or dispensary.

Assessment criteria

- 6.1 Administrative tasks are performed according to SOPs.

- 6.2 General housekeeping procedures are applied and documented according to SOP and in compliance with all relevant guidelines.
- 6.3 Application of the principles of time management is explained in relation to the scope of work.
- 6.4 Effective lines of communication are established and maintained to facilitate team work in the workplace.

The learner must select ONE of the following two electives

Exit level outcome 7

Provide information to promote health and wellness.

Assessment Criteria

- 7.1 The concepts of health and wellness are explained in terms of disease and disability.
- 7.2 Socio-economic factors that contribute to health and wellness dysfunction are identified with examples.
- 7.3 Preventative measures and lifestyle modification options are explained in relation to the identified condition.

Exit level outcome 8

Demonstrate the use of Information and Communication Technology (ICT) in the management of inventory in a manufacturing or wholesale or community or institutional pharmacy/dispensary (either the public or the private sector).

Assessment criteria

- 8.1 Relevant computer peripherals are installed, configured and operated in accordance with manufacturer's specifications and instructions.
- 8.2 Relevant computer software applications are installed, configured and operated in accordance with manufacturer's specifications and instructions.
- 8.3 Relevant inventory reports are produced in the required format according to the software functions and applications.
- 8.4 Inventory projections and quantification is generated in the required format according to the software functions and applications.
- 8.5 Orders are generated in the required format using the relevant report application.
- 8.6 Inventory expenditure is tracked and produced using the relevant software application.

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 assess information in a chosen topic to develop a pharmaceutical product or enhance pharmaceutical services for patients.
- Communicate effectively using visual, mathematical and/or language skills in the modes of oral, written and/or practical presentation in a sustained discourse and in a manner that demonstrates professionalism and sensitivity towards diversity.
- Use science and technology in pharmacy 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.
 - respecting confidentiality and ethics related to all tasks and responsibilities.

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 Higher Certificate Pharmacy Support and Advanced Certificate Pharmacy Technical Support have been designed and generated with these standards and guidelines in mind. Due to the nature of the Higher Education Qualification Framework (HEQF), both these qualifications must be acquired to

achieve the Pharmacy Technician designation. The two qualifications are equivalent to two full years of study.

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. New Zealand
2. Singapore
3. United Kingdom
4. United States of America
5. Kenya
6. Namibia

While the overall structure of the qualifications on offer varies across countries investigated (New Zealand and United Kingdom offer unit standards based programmes and USA and Singapore use modules of learning), the purpose of the qualifications remain exactly the same. Another common feature is the stipulation that registration as a pharmacy technician with the respective pharmacy authority requires a period of workplace exposure. Furthermore, the duration of study as well as internship, is very similar; approximately three years.

New Zealand

The equivalent New Zealand qualification is the current Diploma in Pharmacy Technician, Level 5 (No. 112499 [237 credits]). This qualification is registered by the New Zealand Qualifications Authority and satisfies legislative requirements for working as a pharmacy technician.

The course covers community based pharmacy services, retail sales for technicians, communication, self-management, health and safety and internship for pharmacy technicians. Training for this course may be completed by full time training. The full time courses are 2 years in length and include on the job work experience. Areas of study include:

- dispensing procedures
- legislation requirements
- providing advice to patients on the use of their medicines
- handling of hazardous substances
- body systems and functions
- compounding
- pharmaceutical dose forms and accessories
- misuse and dependence of drugs
- written and oral advice
- stock management and professionalism.

The strand chosen by the candidate will depend on whether the candidate is employed in a hospital or community pharmacy. Community pharmacy technicians will complete an elective (minimum of 10 credits) in the treatment of minor health disorders and hospital pharmacy technicians will complete an elective in ward medicine management and procedures for repacking.

While there is a major overlap between the South African qualifications and this New Zealand equivalent, the essential difference being that the South African equivalent does not cover the "handling of hazardous substances".

Singapore

National University Hospital (NUH) in Singapore offers the Diploma in Pharmacy Science (N73) over three years. The Diploma in Pharmacy Science provides a broad-based training which opens doors to careers in hospitals, retail pharmacies, pharmaceutical industry and research and development.

Core learning is in pharmaceuticals, clinical trials, pharmaceutical analysis, good manufacturing practices, pharmaceutical microbiology, drug discovery and pharmacology and will culminate in positions, including pharmacy technicians in the health-care industry. The elective options are Complementary Medicine & Traditional Chinese Medicine or Nutraceuticals & Functional Foods. The modules are reflected below:

Year One

Level 1.1	Level 1.2
Introduction to Pharmacy Organic & Biological Chemistry Cell & Molecular Biology Creativity & Applied Thinking Skills Sports & Wellness	Anatomy & Physiology Inorganic & Physical Chemistry Information technology for Life Sciences Mathematics & Statistics Communication tool kit

Year Two

Level 2.1	Level 2.2
Microbiology & Infectious Diseases Pharmacology Clinical Biochemistry Pharmaceuticals	Clinical Immunology Pathology Pharmaceutical Legislation & cGMP Medicinal Chemistry & Drug Discovery Pharmaceutical Analysis Innovation & Enterprise in Action

Year Three

Level 3.1	Level 3.2
Clinical Pharmacy Pharmacotherapeutics Clinical Trials Management Research Project A World Issues A: Singapore Perspective	Pharmacy Practice Pharmacy Management Logistics Aseptic Dispensing Compounding Research Project B

This offering in Singapore includes a greater range of subjects as the duration is an additional year. These additional subjects include, amongst others, Creativity & Applied Thinking Skills, Mathematics & Statistics, Innovation & Enterprise in Action, Research Projects and Clinical Trials Management.

Both the electives here also feature in the equivalent South African qualification, with the obvious replacement of Traditional Chinese Medicine with Traditional African Medicine.

United Kingdom

According to the National Pharmacy Association (NPA) in the United Kingdom, "Pharmacy Technicians must successfully complete a NVQ Level 3 in Pharmacy Services and then apply for registration with the General Pharmaceutical Council (GPhC) Statutory Register for Pharmacy Technicians. Pharmacy Technicians work in the dispensary supporting the pharmacist in the dispensing process."

This course equips the learner with the essential skills needed to become a registered pharmacy technician. This course consists of two separate qualifications both of which are needed to become a registered pharmacy technician. The first is the new Level 3 Diploma in Pharmacy Service Skills which is a work based qualification which requires the candidate to collect evidence to demonstrate competence in essential pharmacy skills such as dispensing medicines, counselling patients, receiving and maintaining pharmaceutical stock and providing pharmaceutical advice. The course is assessed through the completion of a portfolio of work-based evidence.

The second qualification is the Technical Certificate (accredited underpinning knowledge). This course provides the learner with all the theoretical knowledge needed to carry out day to day activities as a pharmacy technician. Learners have the opportunity to learn about the various aspects of pharmacy including pharmaceutical science, pharmacy practice, pharmaceuticals, laws and ethics, actions and uses of drugs and disease management. The course is assessed through the completion of multiple choice questions and written assignments.

To achieve the Level 3 Diploma in Pharmacy Service Skills (NVQ), learners must complete all 14 units in Group A (Mandatory Units) plus 3 units from Group B (Optional Units) as shown below:

<i>Group A</i>	–	<i>Mandatory Units (must complete all 14 mandatory units)</i>
R/600/9413	–	Ensure your own actions reduce risks to health and safety
L/601/3461	–	Provide an effective and responsive pharmacy service
Y/601/3463	–	Process pharmaceutical queries
H/601/3465	–	Reflect on and develop your practice
T/601/3468	–	Receive prescriptions from individuals
M/601/3470	–	Confirm prescription validity
A/601/3472	–	Assemble prescribed items
L/601/3475	–	Issue prescribed items
A/600/9373	–	Prepare extemporaneous medicines for individual use
F/600/9374	–	Order pharmaceutical stock
M/600/9385	–	Receive pharmaceutical stock
T/600/9386	–	Maintain pharmaceutical stock
A/600/9387	–	Issue pharmaceutical stock
Y/600/9395	–	Undertake an in-process accuracy check of assembled prescribed items prior to the final accuracy check

Group B - Optional Units (must complete 3 optional units)

L/601/3430	–	Contribute to the effectiveness of teams
M/600/9371	–	Assist in the sale of medicines and products
H/601/3448	–	Prepare documentation, materials, components and other items for the preparation of aseptic products
M/600/9368	–	Provide advice on symptoms and the actions and uses of medicines
R/601/3476	–	Manufacture and assembly of medicinal products

D/601/3478	–	Prepare aseptic products and carry out in-process checking
D/601/3481	–	Prepare documentation, materials and other items for manufacture and assembly of medicinal products
A/601/3486	–	Check documentation, starting materials, components and other consumables for the production of aseptic products
F/600/9388	–	Provide an effective service in a setting outside of the pharmacy
A/600/9390	–	Assist in the supply of pharmaceutical appliances
J/600/9392	–	Process prescriptions for payment
M/600/9399	–	Prepare to conduct a review of an individual's medicines
M/600/9726	–	Enable learning through demonstrations and instructions

The units of learning listed above indicate a "task" oriented approach to the training of pharmacy technicians with the clear omission of the underpinning scientific knowledge required for pharmaceutical practice. The core components of learning seem to focus mainly on dealing with prescriptions (4 units) and stock (4 units). The South African equivalent reflects learning that provides a necessary theoretical basis for pharmaceutical practice.

United States of America

The course content in a pharmacy technician program (two years) across the USA varies slightly from school to school, but overall concepts are typically the same. Here are some of the more common subjects studied by pharmacy technician students:

- Pharmacology
- Chemistry
- Anatomy
- Physiology
- Medical and pharmaceutical terminology
- Pharmaceutical calculations
- Pharmacy law
- Dosage forms
- Drug preparation
- Compounding medications
- Pharmacy administration
- Pharmacy computing
- Medical billing

After graduation, a pharmacy technician may choose to become certified by taking an exam from either the Pharmacy Technician Certification Board (PTCB) or the Institute for the Certification of Pharmacy Technicians (ICPT).

The learning components of the American approach to Pharmacy Technician training are very similar to the South African equivalent, with more emphasis on scientific knowledge and less on Pharmaceutical practice.

Kenya

Pharmaceutical technologists are required to undertake a three year diploma in Pharmaceutical Technology prior to their registration with the Pharmacy and Poisons Boards. Candidates have to pass a pre-registration examination in order to register.

There are currently 22 institutions (11 public, 10 private and one mission owned) registered with the PPB to offer this qualification.

The Kenya Medical Training College in Nairobi is the leading trainer of middle level manpower in pharmacy the East African region with the Diploma and Higher Diploma in Pharmacy. The Diploma compares with the South African equivalent in terms of its purpose, duration (2 years full-time study and 1 year practice), learning areas and depth of study as evident from the course list below:

First year

Physical Chemistry 120
Inorganic Chemistry 60
Organic Chemistry 120
Biochemistry 120
Medical Physiology & Nutrition 200
Pharmaceutics I 120
Human Anatomy 120
Psychology and Communication 120
Dispensing 60
Analytical Chemistry 60

Second year

Pharmaceutical Chemistry I 120
Medical Microbiology 120
Clinical Pharmacy 120
Pharmaceutics II 120
Pharmacology I 200
Medicinal Chemistry 120
Pharmacognosy 120
Management and Drug Supply Management 30
Research Methods 30
Dispensing 30
Pharmaceutical Analysis 30
First Aid 30

Third year

Research Project 700 hrs
Field Practice 660 hrs
Pharmaceutics III 60
Pharmacology II 60
Pharmaceutical Chemistry II 60
Medicinal Chemistry II 60
Pharmacy Law & Ethics 45
Clinical Pharmacy 60
Pharmaceutical Analysis 30
Dispensing 30

"The graduates of the programme constitute 90% of the pharmaceutical workforce in the country. They work in public hospitals, private hospitals, mission hospitals, and pharmaceutical industries. They also work in community pharmacies, research institutions and with regulatory bodies while others seek self employment."

Namibia

Pharmacist's Assistants are expected to undertake a two year training programme which includes in-service training (2 year pre-service residential training with field attachments).

The National Qualification Authority has accredited the National Health Training Centre (NHTC) as provider of the PA course. The PA course is classified as a certificate qualification at the NQF level 4 as per Namibia's NQF.

Core Modules

1. Demonstrate knowledge of Primary Health Care (PHC) as part of pharmacy operations
2. Describe and demonstrate management skills, demonstrate knowledge of information communication technology (ICT) and describe and apply basic research methodology

Generic Modules

1. Follow workplace safety procedures in an office environment
2. Provide Basic First Aid
3. Demonstrate knowledge of HIV and AIDS
4. Demonstrate knowledge of HIV and AIDS in the workplace

Specialised Modules

1. Demonstrate knowledge of basic human anatomy and physiology as part of pharmacy operations
2. Demonstrate knowledge of microbiology and parasitology as part of pharmacy operations
3. Describe the theory and practice of standard operating procedures of various pharmacy operations
4. Demonstrate knowledge, skills and attitudes in pharmaceuticals practicals
5. Apply principles and procedures on pharmacy stock management as part of pharmacy operations
6. Demonstrate knowledge of basic pharmacology as part of pharmacy operations
7. Describe and comply with the requirements of the law governing practice of pharmacy in Namibia
8. Demonstrate knowledge of basic chemistry in pharmacy operations
9. Describe the services provided under "Over The Counter" prescriptions of pharmacy practice
10. Demonstrate practical experience in pharmacy operations

It is evident that this example is a qualification for a Pharmacy Assistant and is the equivalent of the South African Higher Certificate: Pharmacy: Support, NQF level 5. However, there is no currently available equivalent to the Advanced Certificate: Pharmacy: Technical Support, NQF level 6 for the Pharmacy Technician.

Conclusion

It is evident from the international examples of qualifications for the education and training of Pharmacy Technicians cited above that there are some differences, but a great deal of similarity in comparison to the South African equivalent. One such difference is that the management of the dispensary is included only in the South African equivalent. Another difference is that the South African equivalent does not include First Aid as is the case with many International examples.

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 underpin 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

Examples of horizontal articulation:

- Certificate: Nursing (SAQA ID 23353), Level 5, 120 credits
- Higher Certificate: Clinical Technology (SAQA ID 64969), Level 5, 120 credits

Examples of vertical articulation with this Qualification:

- Advanced Certificate: Pharmacy: Technical Support, Level 6 (Proposed)
- University Diploma: Health Services Management (SAQA ID 19730), Level 6, 240 credits

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 qualification at a minimum of one level higher than the level of the qualification in a relevant field of study.

NOTES

- All learners must be registered with the South African Pharmacy Council for the duration of the study 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 as a guideline.

Institution-based practice

- 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, commonly referred to as practicals. (minimum of 80 hours).

Workplace-based practice

- Once the qualifying learner has completed the requirements of the qualification and wishes to be registered with the SAPC as a designated Pharmacy Technical Assistant (PTA), the learner must have completed a period of 3 months workplace experience at an approved site. The learner may proceed on this learning pathway directly (without having to complete 3 months workplace experience) to achieve the Advanced Certificate: Pharmacy: Technical Support and then complete 6 months workplace experience.

Learning Area	Exit Level Outcome	Credits
Fundamental	1. Apply scientific knowledge in the provision of basic pharmaceutical support services	20
Core	2. Provide functional support to compound, manipulate and prepare medicines (non-sterile) for specific patients in compliance with Standard Operating Procedures (SOPs) under the supervision of a pharmacist.	25
	3. Provide functional support in the manufacturing, packaging and/or re-packaging of non-sterile Scheduled substances/medicines in compliance with Good Manufacturing Practice (GMP) guidelines under the supervision of a pharmacist.	25
	4. Provide functional support in the management of medicine stock, Scheduled substances, medical supplies and devices in compliance with Good Wholesale and Distribution Practice (GWDP) and legal requirements under the supervision of a pharmacist.	20
	5. Provide functional support in Phase 2 of dispensing under the supervision of a pharmacist.	20
	6. Perform general housekeeping and administrative tasks in a pharmacy and/or dispensary	10

Elective	7. Provide information to promote health and wellness, or 8. Demonstrate the use of Information and Communication Technology (ICT) in the management of inventory in a manufacturing, wholesale, community or institutional pharmacy/dispensary (either the public or the private sector).	10
	TOTAL CREDITS	130

L6 PHARMACY TECHNICIAN

Qualification Title:		
Advanced Certificate: Pharmacy: Technical Support		
Field	Sub-field	SGB Name
Health Sciences and Social Services (09)	Curative Health	Pharmacy
Minimum Credits	NQF Level	Qualification Class
140	6	Non-Unit Standard based

Rationale for the qualification

The Advanced Certificate: Pharmacy: Technical Support was developed to meet the requirements of the National Human Resources for Health Plan, with specific reference to the need for mid-level workers in provision of pharmaceutical services to the people of South Africa. The qualification is aimed at developing the core technical knowledge and personal skills acquired during qualification for the Higher Certificate: Pharmacy: Support, Level 5. In this way, it contributes towards development of a career path for mid-level workers.

The Advanced Certificate: Pharmacy: Technical Support, NQF Level 6, is designed to meet the needs of learners who have completed the Higher Certificate: Pharmacy: Support 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

Pharmacy technicians will be able to work under supervision of a pharmacist who is physically present in a pharmacy or, under specified circumstances, under the supervision of a pharmacist who is physically not present in the dispensary of a primary health care clinic. All functions would have to be performed in accordance with standard operating procedures approved by the responsible pharmacist or supervising pharmacist.

Functions will include general housekeeping and administrative functions, stock control, manufacturing and compounding of sterile and non-sterile medicines. In manufacturing and wholesale pharmacies, pharmacy technicians will be able to perform certain defined functions without the direct oversight of a pharmacist. Such functions will be performed in accordance with the Batch Manufacturing Documents and standard operating procedures approved by the responsible pharmacist.

Qualifying learners will be able to:

1. Apply scientific knowledge to provide technical support in pharmaceutical services.
2. Provide technical support to compound, manipulate and prepare sterile and non-sterile medicines and scheduled substances in compliance with standards as described in Good Pharmacy Practice (GPP) rules and Good Manufacturing Practice (GMP) guidelines under the supervision of a pharmacist.

3. Provide technical support to manufacture, package and re-package sterile and non-sterile medicines and scheduled substances in compliance with GMP guidelines under the supervision of a pharmacist.
4. Provide technical support to order, manage, despatch and dispose of medicines, scheduled substances, medical supplies and devices in compliance with Good Wholesale and Distribution Practice (GWDP) and legal requirements.
5. Provide technical support to dispense prescriptions for patients in compliance with applicable legislation, including GPP.
6. Provide schedule 1 and 2 medicines in accordance with legal requirements, including GPP.
7. Manage the dispensary in a Primary Health Care Clinic under the indirect supervision of a pharmacist.
8. Demonstrate an understanding of the principles of management of common chronic conditions, or
9. Demonstrate an understanding of principles of traditional African medicines, or
10. Demonstrate an understanding of principles of complementary medicines, or
11. Demonstrate an understanding of nutraceuticals and functional foods.

QUALIFICATION RULES

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

- Fundamental Component: 20 Credits are compulsory (Exit level outcome 1).
- Core component: 110 Credits are compulsory (Exit level outcomes 2, 3, 4, 5, 6 and 7).
- Elective component: a minimum of 10 Credits are required (Minimum of one of Exit level outcome 8, 9, 10 or 11).

ACCESS TO THE QUALIFICATION

Learners that wish to enter into study towards achieving this qualification must be in possession of a Higher Certificate: Pharmacy: Support, Level 5 or recognised equivalent.

LEARNING ASSUMED TO BE IN PLACE

- Mathematical Literacy at NQF level 4 or recognised equivalent.
- Life Sciences at NQF level 4 or recognised equivalent.

EXIT LEVEL OUTCOMES AND ASSOCIATED ASSESSMENT CRITERIA:

Exit level outcome 1

Apply scientific knowledge to provide technical support in pharmaceutical services.

Assessment criteria

- 1.1 Legislation related to the relevant scope of practice in pharmaceutical services is explained in the South African context.

(Range of legislation includes, but is not limited to: Medicines and Related Substance Act, Pharmacy Act and related regulations and rules etc.).

- 1.2 Ethical and professional conduct related to the relevant scope of practice is demonstrated in the provision of pharmaceutical technical support services.
(Range of aspects related to professional conduct includes, but is not limited to: values, practices, attitudes and confidentiality etc.).
- 1.3 Basic Pharmaceutical terms and concepts are explained in relation to sterile drug delivery systems.
- 1.4 Basic scientific principles are applied to sterile pharmaceutical preparations.
- 1.5 Pharmacology and Biopharmaceutics principles that are used in the treatment of common chronic conditions are explained in relation to the current National Health Strategic Plan.
(Range of chronic conditions includes, but is not limited to: TB, HIV and AIDS, hypertension, diabetes, asthma, arthritis, epilepsy, mental disorders etc.)
- 1.6 Screening tests are performed in accordance with GPP .

(Note: no interpretation of the test result is done)

Exit level outcome 2

Provide technical support to compound, manipulate and prepare sterile and non-sterile medicines and scheduled substances in compliance with standards as described in GPP rules and GMP guidelines under the supervision of a pharmacist.

Assessment criteria

- 2.1 The principles of GPP are explained in relation to compounding, manipulating and preparing of sterile medicines.
- 2.2 Sterile admixtures are compounded, manipulated and prepared according to SOPs and in accordance with aseptic techniques and principles of GMP and/or GPP for specific patients.
- 2.3 Records are generated for each of the preparations produced in accordance with legal requirements and organisational policies and procedures.

Exit level outcome 3

Provide technical support to manufacture, package and re-package sterile and non-sterile medicines and scheduled substances in compliance with GMP guidelines under the supervision of a pharmacist.

Assessment criteria

- 3.1 Pharmaceutical and GMP principles are explained in relation to the manufacturing, packaging and re-packaging of sterile medicines and scheduled substances.

- 3.2 Resources, materials and equipment for preparation of specific medicines are organised and prepared in accordance with process documentation.
- 3.3 Line-clearance (Schedule 1 to 4) is performed according to GMP and process documentation.
- 3.4 The manufacturing process is maintained and controlled in accordance with GMP and relevant SOPs.
- 3.5 Related documents are completed and records maintained in accordance with GMP.

Exit level outcome 4

Provide technical support to order, manage, despatch and dispose of medicines, Scheduled substances, medical supplies and devices in compliance with GWDP and legal requirements.

Assessment criteria

- 4.1 Ordering and receipt of medicines, Scheduled substances, medical supplies and devices are organised and managed in accordance with GMP, GPP and GWDP.
- 4.2 Stock is organised, managed and secured in accordance with legal requirements, including GMP, GPP and GWDP.
- 4.3 Despatch of medicines, Scheduled substances, medical supplies and devices is organised and managed in accordance with GMP, GPP and GWDP.
- 4.4 Disposal of expired and unwanted medicines, scheduled substances, medical supplies and devices is managed according to current relevant legislation and guidelines.
- 4.5 Documents are completed and records maintained in accordance with applicable legislation and SOPs.

Exit level outcome 5

Provide technical support to dispense prescriptions for patients in compliance with applicable legislation, including GPP.

Assessment criteria

- 5.1 Communication with patients/caregivers is conducted in a professional manner in terms of sensitivity to patients' needs and diversity.
- 5.2 Prescriptions are assessed for compliance with the Primary Health Care Essential Medicines List (EML)/Standard Treatment Guidelines and other approved protocol/s.
- 5.3 Prescriptions are dispensed according to organisational procedures and in accordance with current legislation and GPP.

- 5.4 Patient and/or prescription is/are referred to a pharmacist for further management as needed or in relation to problems relating to medicine use.
- 5.5 Relevant records are maintained in accordance with the current legislative requirements, including GPP.

Exit level outcome 6

Provide schedule 1 and 2 medicines in accordance with legal requirements, including GPP.

Assessment criteria

- 6.1 Communication with patients/caregivers is conducted and relevant information and history is obtained in a professional manner in terms of sensitivity to patients' needs and diversity.
- 6.2 A suitable course of action is decided in consultation with a pharmacist in terms of the presented information, including the history.
- 6.3 Medicines and/or appropriate advice is/are provided according to GPP and principles of pharmaceutical care.
- 6.4 Patient is referred to a pharmacist for further management as needed or in relation to problems relating to medicine use.
- 6.5 Appropriate records are completed and filed in accordance with GPP.

Exit level outcome 7

Manage the dispensary in a Primary Health Care Clinic under the indirect supervision of a Pharmacist.

Assessment criteria

- 7.1 Resources are managed according to operational and legal requirements (including GPP). *(Range of resources include, but is not limited to: equipment, infrastructure, personnel, stock and funds). (Range of legal requirements include, but is not limited to: relevant provisions of PFMA, Labour Relations Act and Basic Conditions of Employment Act).*
- 7.2 Application of the principles of supervision is explained in pharmaceutical practice.
- 7.3 Application of the principles of time management is explained in pharmaceutical practice.
- 7.4 Application of the principles of team building is explained in pharmaceutical practice.
- 7.5 Effective lines of communication are established and maintained to facilitate supervision in the workplace.

The learner must select ONE of the following four electives**Exit level outcome 8**

Demonstrate an understanding of the principles of management of common chronic conditions.

Assessment Criteria

- 8.1 Aetiology and Epidemiology of common chronic conditions are explained in relation to the current National Health Strategic Plan.
(Range of chronic condition includes: TB, HIV and AIDS, hypertension, diabetes, asthma, arthritis, Epilepsy and mental disorders.)
- 8.2 Preventative measures and lifestyle modification options are explained in relation to common chronic conditions.
- 8.3 Circumstances under which a patient with a chronic condition is referred to another Health Care Provider/facility are described as related to the information presented and the profile of the patient.

Exit level outcome 9

Demonstrate an understanding of principles of traditional African medicines.

Assessment criteria

- 9.1 The philosophies of traditional African medicines and principles of therapies are explained in terms of how they complement those of conventional medicine.
- 9.2 The sale of traditional African medicines are described in terms of the associated responsibilities, limitations, benefits and potential risks.
- 9.3 The regulation and use of traditional African medicines are explained in terms of legislation.

Exit level outcome 10

Demonstrate an understanding of principles of complementary medicines.

Assessment criteria

- 10.1 The philosophies of complementary medicines and principles of therapies are explained in terms of how they complement those of conventional medicine.
- 10.2 The sale of complementary medicines is described in terms of the associated responsibilities, limitations, benefits and potential risks.
- 10.3 The regulation and use of complementary medicines are explained in terms of legislation.

Exit level outcome 11

Demonstrate an understanding of principles of nutraceuticals and functional foods.

Assessment criteria

- 11.1 The philosophies of nutraceuticals and functional foods and principles of therapies are explained in terms of how they complement those of conventional medicine.
- 11.2 The sale of nutraceuticals and functional foods are described in terms of the associated responsibilities, limitations, benefits and potential risks.
- 11.3 The regulation and use of nutraceuticals and functional foods are explained in terms of legislation.

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 in a chosen topic to develop a pharmaceutical product or enhance pharmaceutical services for 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 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 embed these standards and guidelines in their learning programmes.

The South African Higher Certificate and Advanced Certificate in Pharmacy has been designed and generated with these standards and guidelines in mind. Due to the nature of the Higher Education Qualification Framework (HEQF), both these qualifications must be acquired to achieve the Pharmacy Technician designation.

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. New Zealand
2. Singapore
3. United Kingdom
4. United States of America
5. Kenya
6. Namibia

While the overall structure of the qualifications on offer varies across countries investigated (New Zealand and United Kingdom offer unit standards based programmes and USA and Singapore use modules of learning), the purpose of the qualifications remain exactly the same. Another common feature is the stipulation that registration as a pharmacy technician with the respective pharmacy authority requires a period of workplace exposure. Furthermore, the duration of study as well as internship, is very similar; approximately three years.

New Zealand

The equivalent New Zealand qualification is the current Diploma in Pharmacy Technician, Level 5 (No. 112499 [237 credits]). This qualification is registered by the New Zealand Qualifications Authority and satisfies legislative requirements for working as a pharmacy technician.

The course covers community based pharmacy services, retail sales for technicians, communication, self-management, health and safety and internship for pharmacy technicians. Training for this course may be completed by full time training. The full time courses are 2 years in length and includes on the job work experience. Areas of study include:

- dispensing procedures
- legislation requirements
- providing advice to patients on the use of their medicines
- handling of hazardous substances
- body systems and functions
- compounding

- pharmaceutical dose forms and accessories
- misuse and dependence of drugs
- written and oral advice
- stock management and professionalism.

The strand chosen by the candidate will depend on whether the candidate is employed in a hospital or community pharmacy. Community pharmacy technicians will complete an elective (minimum of 10 credits) in the treatment of minor health disorders and hospital pharmacy technicians will complete an elective in ward medicine management and procedures for repacking.

While there is a major overlap between the South African qualifications and this New Zealand equivalent, the essential difference being that the South African equivalent does not cover the "handling of hazardous substances".

Singapore

National University Hospital (NUH) in Singapore offers the Diploma in Pharmacy Science (N73) over three years. The Diploma in Pharmacy Science provides a broad-based training which opens doors to careers in hospitals, retail pharmacies, pharmaceutical industry and research and development.

Core learning is in pharmaceuticals, clinical trials, pharmaceutical analysis, good manufacturing practices, pharmaceutical microbiology, drug discovery and pharmacology and will culminate in positions, including pharmacy technicians in the health-care industry. The elective options are Complementary Medicine & Traditional Chinese Medicine or Nutraceuticals & Functional Foods. The modules are reflected below:

Year One

Level 1.1	Level 1.2
Introduction to Pharmacy Organic & Biological Chemistry Cell & Molecular Biology Creativity & Applied Thinking Skills Sports & Wellness	Anatomy & Physiology Inorganic & Physical Chemistry Information technology for Life Sciences Mathematics & Statistics Communication tool kit

Year Two

Level 2.1	Level 2.2
Microbiology & Infectious Diseases Pharmacology Clinical Biochemistry Pharmaceutics	Clinical Immunology Pathology Pharmaceutical Legislation & cGMP Medicinal Chemistry & Drug Discovery Pharmaceutical Analysis Innovation & Enterprise in Action

Year Three

Level 3.1	Level 3.2
Clinical Pharmacy Pharmacotherapeutics Clinical Trials Management Research Project A World Issues A: Singapore Perspective	Pharmacy Practice Pharmacy Management Logistics Aseptic Dispensing Compounding Research Project B

This offering in Singapore includes a greater range of subjects as the duration is an additional year. These additional subjects include, amongst others, Creativity & Applied Thinking Skills, Mathematics & Statistics, Innovation & Enterprise in Action, Research Projects and Clinical Trials Management.

Both the electives here also feature in the equivalent South African qualification, with the obvious replacement of Traditional Chinese Medicine with Traditional African Medicine.

United Kingdom

According to the National Pharmacy Association (NPA) in the United Kingdom, "Pharmacy Technicians must successfully complete a NVQ Level 3 in Pharmacy Services and then apply for registration with the General Pharmaceutical Council (GPhC) Statutory Register for Pharmacy Technicians. Pharmacy Technicians work in the dispensary supporting the pharmacist in the dispensing process."

This course equips the learner with the essential skills needed to become a registered pharmacy technician. This course consists of two separate qualifications both of which are needed to become a registered pharmacy technician. The first is the new Level 3 Diploma in Pharmacy Service Skills; which is a work based qualification which requires the candidate to collect evidence to demonstrate competence in essential pharmacy skills such as dispensing medicines, counselling patients, receiving and maintaining pharmaceutical stock and providing pharmaceutical advice. The course is assessed through the completion of a portfolio of work-based evidence.

The second qualification is the Technical Certificate (accredited underpinning knowledge). This course provides learners with all the theoretical knowledge they will need to carry out your day to day activities as a pharmacy technician. Learners will have the opportunity to learn about the various aspects of pharmacy including pharmaceutical science, pharmacy practice, pharmaceuticals, laws and ethics, actions and uses of drugs and disease management. The course is assessed through the completion of multiple choice questions and written assignments.

To achieve the Level 3 Diploma in Pharmacy Service Skills (NVQ), learners must complete all 14 units in Group A (Mandatory Units) plus 3 units from Group B (Optional Units) as shown below:

Group A - Mandatory Units (must complete all 14 mandatory units)

R/600/9413	–	Ensure your own actions reduce risks to health and safety
L/601/3461	–	Provide an effective and responsive pharmacy service
Y/601/3463	–	Process pharmaceutical queries
H/601/3465	–	Reflect on and develop your practice
T/601/3468	–	Receive prescriptions from individuals
M/601/3470	–	Confirm prescription validity
A/601/3472	–	Assemble prescribed items
L/601/3475	–	Issue prescribed items
A/600/9373	–	Prepare extemporaneous medicines for individual use
F/600/9374	–	Order pharmaceutical stock
M/600/9385	–	Receive pharmaceutical stock
T/600/9386	–	Maintain pharmaceutical stock
A/600/9387	–	Issue pharmaceutical stock

Y/600/9395 – Undertake an in-process accuracy check of assembled prescribed items prior to the final accuracy check

Group B - Optional Units (must complete 3 optional units)

L/601/3430	–	Contribute to the effectiveness of teams
M/600/9371	–	Assist in the sale of medicines and products
H/601/3448	–	Prepare documentation, materials, components and other items for the preparation of aseptic products
M/600/9368	–	Provide advice on symptoms and the actions and uses of medicines
R/601/3476	–	Manufacture and assembly of medicinal products
D/601/3478	–	Prepare aseptic products and carry out in-process checking
D/601/3481	–	Prepare documentation, materials and other items for manufacture and assembly of medicinal products
A/601/3486	–	Check documentation, starting materials, components and other consumables for the production of aseptic products
F/600/9388	–	Provide an effective service in a setting outside of the pharmacy
A/600/9390	–	Assist in the supply of pharmaceutical appliances
J/600/9392	–	Process prescriptions for payment
M/600/9399	–	Prepare to conduct a review of an individual's medicines
M/600/9726	–	Enable learning through demonstrations and instructions

The units of learning listed above indicate a "task" oriented approach to the training of pharmacy technicians with the clear omission of the underpinning scientific knowledge required for pharmaceutical practice. The core components of learning seem to focus mainly on dealing with prescriptions (4 units) and stock (4 units). The South African equivalent reflects learning that provides a necessary theoretical basis for pharmaceutical practice.

United States of America

The course content in a pharmacy technician program (two years) across the USA varies slightly from school to school, but overall concepts are typically the same. Here are some of the more common subjects studied by pharmacy technician students:

- Pharmacology
- Chemistry
- Anatomy
- Physiology
- Medical and pharmaceutical terminology
- Pharmaceutical calculations
- Pharmacy law
- Dosage forms
- Drug preparation
- Compounding medications
- Pharmacy administration
- Pharmacy computing
- Medical billing

After graduation, a pharmacy technician may choose to become certified by taking an exam from either the Pharmacy Technician Certification Board (PTCB) or the Institute for the Certification of Pharmacy Technicians (ICPT).

The learning components of the American approach to Pharmacy Technician training are very similar to the South African equivalent, with more emphasis on scientific knowledge and less on Pharmaceutical practice.

Kenya

Pharmaceutical technologists are required to undertake a three year diploma in Pharmaceutical Technology prior to their registration with the Pharmacy and Poisons Boards. Candidates have to pass a pre-registration examination in order to register. There are currently 22 institutions (11 public, 10 private and one mission owned) registered with the PPB to offer this qualification.

The Kenya Medical Training College in Nairobi is the leading trainer of middle level manpower in pharmacy the East African region with the Diploma and Higher Diploma in Pharmacy. The Diploma compares with the South African equivalent in terms of its purpose, duration (2 years full-time study and 1 year practice), learning areas and depth of study as evident from the course list below:

First year

Physical Chemistry 120
Inorganic Chemistry 60
Organic Chemistry 120
Biochemistry 120
Medical Physiology & Nutrition 200
Pharmaceutics I 120
Human Anatomy 120
Psychology and Communication 120
Dispensing 60
Analytical Chemistry 60

Second year

Pharmaceutical Chemistry I 120
Medical Microbiology 120
Clinical Pharmacy 120
Pharmaceutics II 120
Pharmacology I 200
Medicinal Chemistry 120
Pharmacognosy 120
Management and Drug Supply Management 30
Research Methods 30
Dispensing 30
Pharmaceutical Analysis 30
First Aid 30

Third year

Research Project 700 hrs
Field Practice 660 hrs
Pharmaceutics III 60
Pharmacology II 60
Pharmaceutical Chemistry II 60
Medicinal Chemistry II 60
Pharmacy Law & Ethics 45
Clinical Pharmacy 60
Pharmaceutical Analysis 30

Dispensing 30

"The graduates of the programme constitute 90% of the pharmaceutical workforce in the country. They work in public hospitals, private hospitals, mission hospitals, and pharmaceutical industries. They also work in community pharmacies, research institutions and with regulatory bodies while others seek self employment."

Namibia

Pharmacist's Assistants are expected to undertake a two year training programme which includes in-service training (2 year pre-service residential training with field attachments).

The National Qualification Authority has accredited the National Health Training Centre (NHTC) as provider of the PA course. The PA course is classified as a certificate qualification at the NQF level 4 as per Namibia's NQF.

Core Modules

1. Demonstrate knowledge of Primary Health Care (PHC) as part of pharmacy operations
2. Describe and demonstrate management skills, demonstrate knowledge of information communication technology (ICT) and describe and apply basic research methodology

Generic Modules

1. Follow workplace safety procedures in an office environment
2. Provide Basic First Aid
3. Demonstrate knowledge of HIV and AIDS
4. Demonstrate knowledge of HIV and AIDS in the workplace

Specialised Modules

1. Demonstrate knowledge of basic human anatomy and physiology as part of pharmacy operations
2. Demonstrate knowledge of microbiology and parasitology as part of pharmacy operations
3. Describe the theory and practice of standard operating procedures of various pharmacy operations
4. Demonstrate knowledge, skills and attitudes in pharmaceuticals practicals.
5. Apply principles and procedures on pharmacy stock management as part of pharmacy operations
6. Demonstrate knowledge of basic pharmacology as part of pharmacy operations
7. Describe and comply with the requirements of the law governing practice of pharmacy in Namibia
8. Demonstrate knowledge of basic chemistry in pharmacy operations.
9. Describe the services provided under "Over The Counter" prescriptions of pharmacy practice
10. Demonstrate practical experience in pharmacy operations

It is evident that this example is a qualification for a Pharmacy Assistant and is the equivalent of the South African Higher Certificate: Pharmacy: Support, NQF level 5.

However, there is no currently available equivalent to the Advanced Certificate: Pharmacy: Technical Support, NQF level 6 for the Pharmacy Technician.

Conclusion

It is evident from the international examples of qualifications for the education and training of Pharmacy Technicians cited above that there are some differences, but a great deal of similarity in comparison to the South African equivalent. One such difference is that the management of the dispensary is included only in the South African equivalent. Another difference is that the South African equivalent does not include First Aid as is the case with many International examples.

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 underpin 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

Examples of horizontal articulation:

- University Diploma: Health Services Management (SAQA ID 19730), Level 6, 240 credits
- Advanced Certificate: Diagnostic Radiography (SAQA ID 65069), Level 6, 240 credits

Examples of vertical articulation with this Qualification:

- Bachelor of Pharmacy, Level 8 (SAQA ID 65130)
- Advanced University Diploma: HIV and AIDS Health Care, Level 7 (SAQA ID 80706)

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 qualification at a minimum of one level higher than the level of the 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 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 as a guideline only.

Institution-based practice

- 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, summing up to a minimum of 80 hours in their curricula for this purpose, commonly referred to as integrated practical learning.

Workplace-based practice

- Once the qualifying learner has completed the requirements of the qualification and wishes to be registered with the SAPC as a designated Pharmacist Technical Assistant (PTA), the learner must have completed a period of 3 months workplace experience at an approved site. The learner may proceed on this learning pathway directly (without having to complete 3 months workplace experience) to achieve the Advanced Certificate: Pharmacy: Technical Support and then complete 6 months workplace experience in order to register as a Pharmacy Technician. Where a learner is enrolled for the Advanced Certificate: Pharmacy: Technical Support after completing 3 months workplace-based training, he/she must complete 3 months workplace experience prior to registration as a Pharmacy Technician.

Learning Area	Exit Level Outcome	Credits
Fundamental	1. Apply scientific knowledge to provide technical support in pharmaceutical services.	20
Core	2. Provide technical support to compound, manipulate and prepare sterile and non-sterile medicines and Scheduled substances in compliance with standards as described in Good Pharmacy Practice (GPP) rules and Good Manufacturing Practice (GMP) guidelines under the supervision of a pharmacist.	15
	3. Provide technical support to manufacture, package and re-package sterile and non-sterile medicines and Scheduled substances in compliance with GMP guidelines under the supervision of a Pharmacist.	15
	4. Provide technical support to order, manage, despatch and dispose of medicines, Scheduled substances, medical supplies and devices in compliance with Good Wholesale and Distribution Practice (GWDP) and legal requirements.	15
	5. Provide technical support to dispense prescriptions for patients in compliance with applicable legislation, including GPP.	25
	6. Provide Schedule 0 and 1 medicines in accordance with legal requirements, including GPP.	20
	7. Manage the dispensary in a Primary Health Care Clinic under the supervision of a pharmacist.	20
	Elective	8. Demonstrate an understanding of the principles of management of common chronic conditions, or
9. Demonstrate an understanding of principles of traditional African medicines, or		
10. Demonstrate an understanding of principles of complementary medicines, or		
11. Demonstrate an understanding of principles of nutraceuticals and functional foods.		
	Minimum Total Credits	140