



**South African
Pharmacy Council**

**2018 COMPETENCY STANDARDS FOR
PHARMACISTS IN SOUTH AFRICA**

TABLE OF CONTENTS

ACRONYMS	2
DEFINITIONS	4
1. INTRODUCTION	6
2. BACKGROUND	6
2.1 Process for reviewing competence standards.....	6
2.2 Rationale for the development of competency standards	7
2.3 Areas influenced and informed by the competency standards	7
3. THE COMPETENCY STANDARD DEVELOPMENT TEAM	7
4. COMPETENCE STANDARDS VS COMPETENCY STANDARDS	8
4.1 Moving from competence to competency	8
5. DEVELOPMENT PROCESS	9
6. DEVELOPMENT OF THE COMPETENCY STANDARDS	10
7. STRUCTURE OF THE COMPETENCY STANDARDS AND DOMAINS	11
8. COMPETENCY STANDARDS FOR PHARMACISTS IN SOUTH AFRICA	12
9. LEVELS OF PRACTICE FOR PHARMACISTS	13
10. THE 2018 COMPETENCY STANDARDS FOR PHARMACISTS IN SOUTH AFRICA	13
DOMAIN 1: PUBLIC HEALTH	14
DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES	18
DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES	25
DOMAIN 4: ORGANISATION AND MANAGEMENT SKILLS	32
DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE	36
DOMAIN 6: EDUCATION, CRITICAL ANALYSIS AND RESEARCH	41
REFERENCES	44

ACRONYMS

BPharm	Bachelor of Pharmacy
CE	Continuing Education
CPD	Continuing Professional Development
cGMP	Current Good Manufacturing Practice
FIP	International Pharmaceutical Federation
GPP	Good Pharmacy Practice
ICPA	Independent Community Pharmacy Association
IPASA	Innovative Pharmaceutical Association South Africa
NCS	National Core Standards
NDP	National Development Plan
NHI	National Health Insurance
NMU	Nelson Mandela University
NQF	National Qualifications Framework
NWU	North-West University
PCDT	Primary Care Drug Therapy
PHC	Primary Healthcare
PIASA	Pharmaceutical Industry Association of South Africa
PIT	Pharmacist initiated therapy
PLASA	Pharmaceutical Logistics Association of South Africa
PSP	Pharmacy support personnel
PSSA	Pharmaceutical Society of South Africa
PTC	Pharmacy and Therapeutics Committee
RU	Rhodes University
SA	South Africa
SAAHIP	South African Association of Hospital and Institutional Pharmacists
SAPC	South African Pharmacy Council
SAQA	South African Qualifications Authority
SMU	Sefako Makgatho Health Sciences University
SOP	Standard operating procedures
TUT	Tshwane University of Technology
UK	United Kingdom
UKZN	University of KwaZulu-Natal
USA	United States of America
UWC	University of the Western Cape
WITS	University of the Witwatersrand

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DEFINITIONS

Antimicrobial stewardship: A coordinated programme that promotes the appropriate use of antimicrobials, improves patient outcomes, reduces microbial resistance and decreases the spread of infections caused by multidrug resistant organisms.

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

Competence: Ability to carry out a job or task. The evaluation of competence is based on the exit level outcomes (ELO) developed for the pharmacy profession.

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

Continuing education (CE): A structured process of education designed or intended to support the continuous development of pharmacists to maintain and enhance their professional competence. CE does not necessarily equate to adequate learning to attain the competence of the professional, hence the profession increasingly adopts continuing professional development (CPD) worldwide as the way to ensure professional competence.

Continuing professional development (CPD): A process by which registered persons continually ensure and enhance their competence throughout their professional careers. CPD encompasses a range of activities including continuing education and supplementary training.

Culturally sensitive manner: Cultural sensitivity allows a person to respond in a respectful and appropriate manner to different types of people in a way that recognises and affirms their worth, regardless of their cultural background.

Cultural awareness: A person's understanding of the differences between themselves and people from other countries or other backgrounds, especially differences in attitudes and values.

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

Evidence-based practice: The use of good quality evidence to make sound clinical decisions.

Exit level outcome (ELO): A performance indicator based on standards that are measurable; often demonstrated through products or behaviours. The preregistration programme is based on a set of ELOs that describe the knowledge, skills and attitudes required of an entry level pharmacist. These ELOs form the basis for the (new) BPharm curriculum registered with the South African Qualifications Authority (SAQA).

GxP: A general term for guidelines for good manufacturing, clinical, laboratory, storage or distribution practices.

Life-long learning: All learning activities throughout life that improve knowledge, skills and competence within a personal, civic, social and/or employment-related field.

Palliative care: An approach used to improve the quality of life of individuals and their families who face problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and/or physical, psychosocial and spiritual issues.

Sector: A major field of professional activity in a defined environment such as the community, institutional (hospital), manufacturing and wholesale, academia, consultancy and administration areas.

Supply chain management: The management of the flow of goods and services. It involves the movement and storage of raw materials, of work-in-process inventory, and of finished goods from point of origin to point of consumption by the patient.

1. INTRODUCTION

Pharmacy is a diverse and exciting profession with professionals working across very different practice settings which include, but are not limited to, the academic, administration, community, consultancy, institutional (hospital), managed care, manufacturing, research and wholesale settings.

Pharmacists in each practice setting are required to accept responsibility for their self-development and assessment of continued competence throughout their professional working lives. This requires systematic maintenance and development of skills, attitudes and behaviours, broadening of knowledge while maintaining proficiency, providing quality service and/or products, responding to patient needs, and keeping abreast of changes in the profession.

Pharmacists are encouraged to identify the learning needs relevant to their existing and future roles in the profession and, through CPD, to update their knowledge, skills and behaviours. Pharmacists should plan their development as professionals according to these needs and continually assess the impact of their achievements and progress on their practice.

2. BACKGROUND

The South African Pharmacy Council (SAPC or Council) developed the first competence standards for pharmacists in 2006. These competence standards were based on the unit standards specified in the *Regulations Relating to Pharmacy Education and Training* published in terms of the Pharmacy Act 53 of 1074, as amended.

At a meeting on 13 and 14 May 2015, Council resolved that the competence standards and outcomes be reviewed in line with current practice, the revised BPharm qualification 2012/3 to 2018, and the International Pharmaceutical Federation (FIP) global competency framework (2012).

2.1 Process for reviewing competence standards

In reviewing the competence standards, the following were considered:

- (a) the BPharm qualification approved by Council in 2011 and implemented in 2012/3;
- (b) the competence standards developed in 2006;
- (c) emerging trends in pharmacy practice;
- (d) literature on national and international developments in pharmacy education and training;
- (e) literature on competencies and an analysis of global competency frameworks in pharmacy;

- (f) the Global Report on Continuing Professional Development (CPD) and Continuing Education (CE) in Pharmacy published by FIP in 2012¹;
- (g) international benchmarking against the Republic of Ireland, New Zealand, Australia, the European Union, Singapore, Canada, and the United States of America (USA); and
- (h) any other relevant information.

2.2 Rationale for the development of competency standards

The competency standards have been developed to encompass the changes and developments in all sectors of pharmacy and practice, including new technologies, work processes, changes in legislation and international trends, primarily to ensure public safety.

2.3 Areas influenced and informed by the competency standards

The competency standards will influence and inform the following areas:

- (a) education and practice standards;
- (b) BPharm curriculum development and review;
- (c) the SAPC pre-registration policy for pharmacist interns;
- (d) scope of practice of pharmacists;
- (e) identification of learning needs for CPD for pharmacists in practice in different sectors of pharmacy;
- (f) development of short courses to address learning gaps;
- (g) evaluation of courses for advanced practice e.g. Primary Care Drug Therapy (PCDT);
- (h) evaluation of courses for specialisations in pharmacy;
- (i) assessment of pharmacists with foreign qualifications; and
- (j) job descriptions and performance evaluation.

3. THE COMPETENCY STANDARD DEVELOPMENT TEAM

Council appointed a panel of experts to update and develop the competence standards. The panel consisted of one member each from the eight institutions² accredited to offer the BPharm, and members from the Pharmaceutical Society of South Africa (PSSA), the Independent Community Pharmacy Association (ICPA), the South African Association of Hospital and Institutional Pharmacists (SAAHIP), the Pharmaceutical Logistics Association of South Africa (PLASA) and the Innovative Pharmaceutical Association South Africa (IPASA).

¹ FIP competency framework was derived from a comparative study of common behaviours within frameworks used in Australia, Canada, New Zealand, Thailand, United Kingdom, USA and Zambia, which includes third world countries.

² All nine institutions accredited to offer the BPharm were invited to participate in the development of competency standards.

The panel advised that rather than simply developing the existing competence standards, Council should consider a structural approach to competency, one that incorporates both educational outcomes and behaviours instead of a stand-alone competence structure.

The draft competency standards were presented to a task team appointed by Council. The task team comprised two members each from the CPD, the Practice and the Education committees.

4. COMPETENCE STANDARDS VS COMPETENCY STANDARDS

The *competence* of a practitioner refers to the overarching capacity of that individual to perform. From the shared perspectives of patients, civil society and employers, *competence* suggests an expectation of effective, persistent behaviour of that healthcare professional.

A *competence* (plural *competences*) is a deconstructed item or functional task relating to the job of the healthcare professional. Collectively, competences represent the functional, the *what*, of a particular professional's work. The following may be considered to be competence standards:

- (a) qualifications or evidence of subject mastery, literacy or numeracy (academic competence standards);
- (b) mental and physical competence to practice; and
- (c) practical skills, abilities and knowledge.

A *competency* (plural *competencies*) represents the individual qualities or attributes of professional activity, the *how* of performance. These are learned behaviours, and are thus able to be effectively incorporated into developmental programmes that require practitioners to apply learned behaviours. Since competency standards are developed with a focus on performance, they facilitate identification of the aspects of performance in the workplace and provide the best means to deduce professional competence. Competency is a broad concept that includes all aspects of practice, including:

- (a) skills to perform particular tasks;
- (b) managing a number of different tasks/activities within an occupation or profession;
- (c) responding to problems and non-routine events; and
- (d) dealing with all aspects of the workplace including working with others.

4.1 Moving from competence to competency

Competency standards provide a clear statement of what is considered to be important for ongoing competent performance in a profession. Behavioural competency is therefore a typical behaviour observed when effective performers apply motives, traits or skills to job relevant tasks. It is, therefore, implied that competences are acquired

during the early training of an individual in gaining the knowledge and skills to undertake tasks.

Behavioural competency relies on learned behaviours. It incorporates the inherent components of knowledge and skills and embraces attitudes and values; attributes that are necessary for the successful performance of tasks of the profession. Monitoring of behavioural competency permits identification of strengths and weaknesses and is useful for personal development and continuing education. It is, therefore, the basis for identification of appropriate CPD for the pharmacist. The differences between competence and competency are summarised in Table 1.

Table 1: Difference between competence and competency

Competence	Competency
Skills-based	Behaviour-based
Standard attained	Manner of behaving
<i>What is measured</i>	<i>How the standard is achieved</i>

5. DEVELOPMENT PROCESS

The development process consisted of eight phases:

Phase 1: Panel of experts

The proposed competency standards for pharmacists were developed in line with the FIP global competency framework (2012): April to June 2016.

Phase 2: Task team appointed by Council

Council's task team reviewed the draft document on 15 August 2016, 16 to 17 November 2016, and 8 to 9 February 2017.

Phase 3: CPD, Education and Practice Committees

The draft document was presented to the Council committees on 6 to 8 March 2017.

Phase 4: Council

Council approved the reviewed competency standards for public comment: 10 to 11 May 2017.

Phase 5: Publication of competency standards for public comment

The competency standards were published for public comment on 16 August to 16 October 2017.

Phase 6: Task team

Council's task team incorporated comments received from the profession: 6 November and 5 December 2017.

Phase 7: CPD, Education and Practice Committees

Circulate competency standards document to Council's CPD, Education and Practice committees for approval: 2018.

Phase 8: Council

Council approval of new competency standards for implementation in 2018.

6. DEVELOPMENT OF THE COMPETENCY STANDARDS

The 2006 SAPC competence standards were developed using a competence approach that focused only on knowledge and skills. Behavioural aspects and attitudes were not considered.

The 2018 SAPC competency standards for pharmacists were developed in line with the FIP global competency framework (2012).

The SAPC panel of experts held three meetings to develop a draft document. During the first meeting, the panel identified a number of inadequacies in the 2006 SAPC competence standards for pharmacists. The panel identified that:

- (a) cultural aspects were either disregarded or not clearly evident;
- (b) the standards were mostly task driven with a focus on capabilities and outcomes, and behavioural aspects were absent or not apparent;
- (c) no consideration was given to aspects of multidisciplinary practice;
- (d) new developments since 2006 were not addressed, such as preparations for the National Health Insurance, and the National Core Standards;
- (e) the standards failed to provide a process to encourage practising pharmacists to incorporate changes in the undergraduate curriculum into daily practice; and
- (f) there was a general lack of inclusion of pharmacoeconomic principles and practice.

The panel of experts agreed that the competence standards (2006) should be developed into competency standards based on the following principles:

- (a) accommodate all sectors of the profession of pharmacy, including, academia, administration, community, institutional (hospital), managed care, manufacturing and wholesale practice;
- (b) recognise the current BPharm qualification is a four year professional degree;
- (c) inform the ELOs of the BPharm qualification;
- (d) consider the National Qualifications Framework level (NQF) descriptors;
- (e) contextualise the content for South African resources and needs;
- (f) align with South Africa's policies and plans, e.g. the National Health Insurance (NHI) and the National Development Plan (NDP);

- (g) support the implementation of the National Core Standards (NCS) and NHI; and
- (h) guide the CPD of pharmacists.

A mapping tool, developed from documentation from selected countries that had drafted competency standards using the FIP global competency framework (2012), was used for benchmarking purposes. Information from the Republic of Ireland, New Zealand, Australia, the European Union, Singapore, Canada and USA was also used.

7. STRUCTURE OF THE COMPETENCY STANDARDS AND DOMAINS

In 2012, FIP published a global competency framework suitable to use as a mapping tool for the creation of country-specific competency standards. The FIP framework was developed following a comparative study conducted to identify common behaviours within the frameworks used in Australia, Canada, New Zealand, Thailand, United Kingdom, USA and Zambia.

FIP consolidated the information derived from the comparative study into four domains:

- (a) pharmaceutical public health (population focus);
- (b) pharmaceutical care (patient focus);
- (c) organisation and management (system focus); and
- (d) professional/personal (practice focus).

A competency framework consisting of six domains and a number of competencies suitable for the South African context, was developed. A domain represents an organised cluster of competencies within a framework and the domains, with associated competencies, are summarised in Table 2. The behavioural statements indicating how individuals working within a competency should behave in practice have also been drafted.

It is expected that a pharmacist at a higher level of practice, in addition to the behaviours associated with that level, must also exhibit the behaviours from the lower level(s) of practice.

Table 2: Summary of domains and competencies

DOMAINS	COMPETENCIES
1. Public health	1.1 Promotion of health and wellness 1.2 Medicines information 1.3 Professional and health advocacy 1.4 Health economics 1.5 Epidemic and disaster management 1.6 Primary healthcare
2. Safe and rational use of medicines	2.1 Patient consultation 2.2 Patient counselling 2.3 Patient medicine review and management

DOMAINS	COMPETENCIES
and medical devices	2.4 Medicines and medical devices safety 2.5 Therapeutic outcome monitoring 2.6 Pharmacist initiated therapy 2.7 Pharmacovigilance 2.8 Clinical trials
3. Supply of medicines and medical devices	3.1 Medicine production according to GxP 3.2 Supply chain management 3.3 Formulary development 3.4 Medicine dispensing 3.5 Medicine compounding 3.6 Medicine disposal/destruction
4. Organisation and management skills	4.1 Human resources management 4.2 Financial management 4.3 Pharmaceutical infrastructure management 4.4 Quality assurance 4.5 Change management 4.6 Policy development
5. Professional and personal practice	5.1 Patient-centred care 5.2 Professional practice 5.3 Ethical and legal practice 5.4 Continuing professional development 5.5 Leadership 5.6 Decision-making 5.7 Collaborative practice 5.8 Self-management 5.9 Communication
6. Education, critical analysis and research	6.1 Education and training policy 6.2 Provision of education and training 6.3 Practice embedded education or workplace education 6.4 Gap analysis 6.5 Critical analysis 6.6 Research 6.7 Supervision of other researchers 6.8 Collaborative research

8. COMPETENCY STANDARDS FOR PHARMACISTS IN SOUTH AFRICA

Competency standards were developed as a tool to help the professionals assess their own learning needs. Gaps in knowledge, skills, attitudes and values are identified by comparing personal knowledge, skills, attitudes and values with those required by the competency standards. Competency standards have also been structured to assist with identifying areas, within current or future practice, that may require modification and/or improvement in knowledge, skills, attitudes and values.

As pharmacists practise in a variety of practice settings, each professional must evaluate whether or not a specific competency standard applies to their practice.

9. LEVELS OF PRACTICE FOR PHARMACISTS

The 2018 competency standards for pharmacists take into consideration various processes of development and are applicable when a person is registered as a pharmacist and able to practise independently. The competency standards have been developed with three levels of behavioural statements linked to each competency in order to guide pharmacists in progressing from one level of practice to another.

The three levels are:

- (a) **Entry level into practice:** generally recognised as the first three years of practice
- (b) **Intermediate practice:** generally recognised as between three and seven years of practice
- (c) **Advanced practice:** generally recognised as more than seven years of practice

The competency standards for specialisation and pharmacy support personnel will be presented in a separate document.

10. THE 2018 COMPETENCY STANDARDS FOR PHARMACISTS IN SOUTH AFRICA

The competency standards and associated behavioural statements are presented within the six domains.

DOMAIN 1: PUBLIC HEALTH**INTRODUCTION**

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

The provision of medicines and healthcare information and education forms an integral part of the scope of practice of a pharmacist. The availability of specialised pharmaceutical knowledge at all levels of care, including primary healthcare (PHC), is an important component for the delivery of effective and efficient pharmaceutical services.

The domain covers competencies that are required to promote health, promote and monitor adherence and apply pharmacoeconomic principles.

The public health domain competencies are:

- 1.1 Promotion of health and wellness
- 1.2 Medicines information
- 1.3 Professional and health advocacy
- 1.4 Pharmacoeconomics
- 1.5 Epidemics and disaster management
- 1.6 Primary healthcare

DOMAIN 1: PUBLIC HEALTH				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
1.1 Promotion of health and wellness	1.1.1	1.1.1.1 Advise on health promotion, disease prevention and control, and healthy lifestyles.	1.1.1.2 Assess healthcare needs of communities taking into account the cultural and social context and public health priorities in South Africa.	1.1.1.3 Collaborate with other healthcare professionals in the planning, development and implementation of evidence-based public health campaigns.
	1.1.2	1.1.2.1 Participate in public health campaigns.	1.1.2.2 Assist and encourage communities to make use of available health resources.	1.1.2.3 Incorporate national health and medicines policy and guidelines into organisational practices.
	1.2.1	1.2.1.1 Participate in pharmaceutical and therapeutics committees.	1.2.1.2 Play an advisory role in pharmaceutical and therapeutics committees.	1.2.1.3 Play a leading role in pharmaceutical and therapeutics committees.
1.2 Medicines information	1.2.2	1.2.2.1 Participate in antimicrobial stewardship.	1.2.2.2 Play an advisory role in antimicrobial stewardship	1.2.2.3 Play a leading role in an antimicrobial stewardship team.
	1.2.3	1.2.3.1 Apply principles of palliative care for management of patients with life-limiting conditions.	1.2.3.2 Recognise and manage the changing pharmacological and pharmaceutical care needs of patients with life-limiting conditions.	1.2.3.3 Develop and review policies to support the application of the palliative care approach in medicine management.
	1.2.4	1.2.4.1 Identify and use medicine information centres and evidence-based sources of information for medicines.	1.2.4.2 Identify and use medicine information centres and relevant evidence-based sources of information for medicines.	1.2.4.3 Interpret and use relevant evidence-based sources when consulting on advanced medicine information queries.
1.3 Professional and health advocacy	1.3.1	1.3.1.1 Participate as a pharmacist within a healthcare team.	1.3.1.2 Promote the role of the pharmacist within healthcare teams.	1.3.1.3 Act as a patient advocate to ensure that pharmaceutical care is optimised.
	1.3.2	1.3.2.1 Apply health policy and procedures in practice.	1.3.2.2 Participate in the implementation of health policy.	1.3.2.3 Contribute to the development and review of health policy.
1.4 Pharmacoeconomics	1.4.1	1.4.1.1 Monitor and encourage adherence to formularies and guidelines.	1.4.1.2 Report on adherence to formularies.	1.4.1.3 Evaluate reports and develop interventions to improve formularies and guidelines.

DOMAIN 1: PUBLIC HEALTH					
BEHAVIOURAL STATEMENTS					
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice	
1.5 Epidemics and disaster management	1.4.2	1.4.2.1 Apply developed interventions to ensure cost-effective use of medicines.	1.4.2.2 Collate reliable information and conduct analysis to ensure cost-effective use of medicines.	1.4.2.3 Develop interventions to improve cost-effective use of medicines.	
	1.4.3	1.4.3.1 Participate in collecting pharmaceutical data to determine if pharmaceutical use is in accordance with the burden of disease.	1.4.3.2 Compile and analyse reports such as Defined Daily Doses (DDDs) and ABC analysis to determine if pharmaceutical use is in accordance with burden of disease.	1.4.3.3 Develop reporting systems to determine whether pharmaceutical services are in accordance with the burden of disease.	
	1.5.1	1.5.1.1 Assist in the implementation of the outbreak/disaster plan.	1.5.1.2 Participate as a member of a disease outbreak/disaster response team.	1.5.1.3 Implement, monitor and evaluate the roll out of an outbreak/disaster pharmaceutical response plan.	
	1.5.2	1.5.2.1 Identify disease trends in your pharmacy practice setting (patient based).	1.5.2.3 Identify and report disease trends in the community to the relevant authority.	1.5.2.3 Identify and report the incidence and prevalence of disease in the population with detection of source and cause of infectious diseases.	
	1.5.3	1.5.3.1 Identify threats for outbreak/disaster in your pharmacy practice setting (patient based).	1.5.3.2 Identify threats for outbreak of disease/disasters in the community.	1.5.3.3 Identify possible threats for outbreak of disease/disasters in the population.	
	1.5.4	1.5.4.1 Assist in managing outbreaks/disasters.	1.5.4.2 Implement activities aimed at managing outbreaks/disasters.	1.5.4.3 Plan actions and prepare for possible outbreaks/disasters.	
	1.6 Primary healthcare	1.6.1	1.6.1.1 Engage in lifestyle changes, in a multidisciplinary setting, that may prevent communicable and non-communicable diseases and/or improve therapeutic outcomes.	1.6.1.2 Work in a multidisciplinary healthcare team to optimise therapeutic outcomes.	1.6.1.3 Play a leading role in a multidisciplinary healthcare team to optimise therapeutic outcomes.

DOMAIN 1: PUBLIC HEALTH				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
	1.6.2	1.6.2.1 Participate in screening and disease prevention programmes and campaigns.	1.6.2.2 Advocate for lifestyle changes that may prevent communicable and non-communicable diseases and/or improve the outcomes of medicinal therapy.	1.6.2.3 Advocate for lifestyle changes that may prevent communicable and non-communicable diseases and/or improve the outcomes of medicinal therapy.
	1.6.3	1.6.3.1 Advise patients on self-care and adherence to treatment regimens.	1.6.3.2 Implement strategies to encourage patients to take responsibility for their own health and adherence to treatment guidelines.	1.6.3.3 Develop strategies to encourage patients to take responsibility for their own health and adherence to treatment guidelines.

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

Domain 2 covers the rational use of medicines, a concept adopted by the World Health Organization (WHO), which advocates that patients receive medicines and medical devices that are:

- appropriate to their clinical needs;
- in doses that meet individual requirements;
- for an adequate period of time; and
- cost-effective for the patient and community.

Participation of the pharmacist in the promotion of rational use of medicines will contribute to improved access to quality medicines and other pharmaceutical services.

Pharmacists have a professional obligation to the public to ensure an adequate and reliable supply of safe, cost-effective medicines and medical devices of acceptable quality as prescribed in the National Drug Policy (1996). Patients must be educated in respect of the correct use of medical devices that meet all regulatory, safety and performance requirements.

Patients and healthcare workers are encouraged to report all medicine safety related complaints, and pharmacists should monitor, record and process such complaints.

In the domain of safe and rational use of medicines and medical devices, effective verbal and non-verbal methods of communication with patients and other healthcare professionals, are essential competencies. Pharmacists require these competencies to improve patient health outcomes and to build and maintain professional working relationships within a healthcare team. This domain also encompasses activities such as pharmacist initiated therapy (PIT), medicine utilisation reviews and use evaluations, and monitoring of therapeutic outcomes.

The competencies required in the domain for the safe and rational use of medicines and medical devices are:

- 2.1 Patient consultation
- 2.2 Patient counselling
- 2.3 Patient medicines review and management
- 2.4 Medicines and medical devices safety
- 2.5 Therapeutic outcome monitoring
- 2.6 Pharmacist initiated therapy (PIT)
- 2.7 Pharmacovigilance
- 2.8 Clinical trials

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
2.1 Patient consultation	2.1.1	2.1.1.1 Undertake consultations, in an appropriate setting, with minimal interruption, while maintaining verbal, auditory and personal privacy.	2.1.1.2 Undertake more complex consultations, in an appropriate setting with minimal interruption, while maintaining verbal, auditory and personal privacy.	2.1.1.3 Ensure that appropriate facilities are available to permit patient consultation.
	2.1.2	2.1.2.1 Use appropriate communication and questioning techniques to gather relevant patient information on allopathic, complementary and alternative medicines and therapy use.	2.1.2.2 Provide accurate and evidence-based information on allopathic, complementary and alternative medicines and therapy use.	2.1.2.3 Provide guidance to pharmacists and pharmacy support personnel on allopathic, complementary and alternative medicines and therapy use, using evidence-based information.
	2.1.3	2.1.3.1 Consult with a patient and/or caregiver to determine health needs in a culturally sensitive manner.	2.1.3.2 Implement protocols to ensure that all personnel maintain cultural sensitivity in all patient interactions.	2.1.3.3 Develop and review protocols to ensure that all personnel maintain cultural sensitivity in all patient interactions.
	2.1.4	2.1.4.1 Identify the need for further information and/or referral to an appropriate healthcare provider/resource.	2.1.4.2 Implement protocols for referral in consultation with other members of the healthcare team.	2.1.4.3 Develop and review protocols for referral in consultation with other members of the healthcare team.
	2.1.5	2.1.5.1 Where appropriate and after obtaining patient consent, use diagnostic aids and/or tests.	2.1.5.2 Implement protocols to ensure appropriate use/application of diagnostic aids and/or tests.	2.1.5.3 Develop and review protocols to ensure appropriate use/application of diagnostic aids and/or tests.
	2.1.6	2.1.6.1 Where applicable, examine patient records to obtain patient medication and disease history.	2.1.6.2 Implement care plans based on patient records.	2.1.6.3 Develop and review a care plan based on patient records and monitor patient outcomes.

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES				
COMPETENCIES	BEHAVIOURAL STATEMENTS			
	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
2.2. Patient counselling	2.1.7	2.1.7.1 Maintain confidentiality of patient information in line with legislative requirements.	2.1.7.2 Manage the risk assessment plan relating to breach of confidentiality of patient information in line with legislative requirements.	2.1.7.3 Develop and review the risk assessment plan relating to breach of confidentiality of patient information in line with legislative requirements.
	2.1.8	2.1.8.1 Keep and maintain appropriate records.	2.1.8.2 Implement procedures and protocols for document management and recordkeeping.	2.1.8.3 Develop and review procedures and protocols for document management and recordkeeping.
	2.2.1	2.2.1.1 Establish existing understanding and knowledge of health conditions, medicines use for a patient and the need for counselling.	2.2.1.2 Formulate a counselling plan according to the needs of the patient to ensure the safe and effective use of medicines.	2.2.1.3 Ensure that all patients receive appropriate counselling that is in line with facility specific protocols.
	2.2.2	2.2.2.1 Counsel patients on the safe and rational use of medicines and medical devices (including selection, use, contraindications, storage, and side effects).	2.2.2.2 Implement systems to ensure that patient counselling is performed in accordance with GPP.	2.2.2.3 Develop and manage systems to ensure that patient counselling is performed in accordance with GPP.
	2.2.3	2.2.3.1 Listen effectively, using active and reflective listening techniques.	2.2.3.2 Respond appropriately to more challenging or complex scenarios that require attentive listening.	2.2.3.3 Use advanced listening skills to differentiate or distinguish challenging and complex scenarios.
	2.2.4	2.2.4.1 Use an appropriate counselling plan based on patient needs and ensure the safe and effective use of medicine.	2.2.4.2 Respond appropriately to more challenging or complex scenarios requiring patient counselling.	2.2.4.3 Develop and review counselling plan templates to ensure the safe and effective use of medicine.

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
2.3 Patient medicine review and management	2.2.5	2.2.5.1 Maximise opportunities for counselling and the provision of information and advice to patients.	2.2.5.2 Identify opportunities for counselling and the provision of information and advice to patients.	2.2.5.3 Create opportunities for counselling and the provision of information and advice to patients.
	2.2.6	2.2.6.1 Communicate in a manner that demonstrates sensitivity to alternative customs and approaches to healthcare.	2.2.6.2 Implement communication techniques/systems that consider alternative customs and approaches to healthcare.	2.2.6.3 Develop communication techniques/systems that consider alternative customs and approaches to healthcare.
	2.2.7	2.2.7.1 Use language, including verbal and nonverbal cues, that the patient is likely to understand.	2.2.7.2 Implement and monitor the use of a language policy that includes verbal and nonverbal cues that the patient is likely to understand.	2.2.7.3 Develop a language policy that includes verbal and nonverbal cues that the patient is likely to understand.
	2.2.8	2.2.8.1 Where appropriate, use instructional aids.	2.2.8.2 Implement the use of instructional aids appropriately.	2.2.8.3 Develop instructional aids that can be used to maximise counselling.
	2.2.9	2.2.9.1 Obtain feedback from the patient to confirm their understanding of the information provided during the counselling process.	2.2.9.2 Implement processes and procedures to obtain patient feedback regarding counselling.	2.2.9.3 Develop processes and procedures to obtain patient feedback in counselling.
	2.3.1	2.3.1.1 Confirm patient adherence to a medicine regimen or treatment plan.	2.3.1.2 Encourage and facilitate patient adherence to a medicine regimen or treatment plan.	2.3.1.3 Identify, prioritise and resolve medicines management problems.
	2.3.2	2.3.2.1 Assist with medicine utilisation reviews.	2.3.2.2 Perform medicine utilisation reviews, as appropriate, to ensure the rational use of medicine and positive clinical outcomes.	2.3.2.3 Recognise and manage trends associated with inappropriate medicine prescribing behaviour.
	2.3.3	2.3.3.1 Liaise with the prescriber or other healthcare professionals to ensure the optimal use of medicines.	2.3.3.2 Liaise with the prescriber or other healthcare professionals to implement a plan to ensure the optimal use of medicines.	2.3.3.3 Contribute to strategies to optimise patient medication management using clinical tools where appropriate.

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
2.4 Medicine and medical device safety	2.3.4	2.3.4.1 Use appropriate protocols to ensure cost-effective use of medicines and medical devices.	2.3.4.2 Use appropriate protocols to ensure cost-effective use of medicines and medical devices.	2.3.4.3 Develop protocols to ensure the cost-effective use of medicines and medical devices.
	2.3.5	2.3.5.1 Identify patients requiring additional monitoring.	2.3.5.2 Recognise and advise on any additional patient monitoring required.	2.3.5.3 Recognise and advise on any additional patient monitoring required in complex scenarios.
	2.4.1	2.4.1.1 Report dispensing errors, side and adverse effects.	2.4.1.2 Implement developed protocols to avoid common dispensing errors such as 'look-alike' and 'sound-alike' medicines.	2.4.1.3 Develop protocols to avoid common dispensing errors such as 'look-alike' and 'sound-alike' medicines.
	2.4.2	2.4.2.1 Keep abreast of emerging medicine safety information.	2.4.2.2 Implement and maintain a 'near-misses' and error reporting system.	2.4.2.3 Disseminate information relating to medicine safety and alter practice accordingly.
	2.4.3	2.4.3.1 Participate in prevention and resolution of medication errors.	2.4.3.2 Identify, record, act and report medication errors.	2.4.3.3 Review and interpret medication error reports to identify trends and implement appropriate corrective action.
	2.4.4	2.4.4.1 Identify medicines, and medical devices with quality issues and report according to applicable policies.	2.4.4.2 Source medicines and medical devices of an acceptable quality and standard, in accordance with relevant SOPs.	2.4.4.3 Develop SOPs to ensure that medicines and medical devices are of an acceptable quality and standard, and are sourced from licensed and approved suppliers.
	2.4.5	2.4.5.1 Identify medicines and medical devices that are a high risk in respect of medication errors or that exhibit increased safety risks and take steps to minimise and mitigate the risk.	2.4.5.2 Implement developed systems and protocols to minimise and mitigate medication errors and adverse effects.	2.4.5.3 Develop systems and protocols to minimise and mitigate medication errors and adverse effects.

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES			
BEHAVIOURAL STATEMENTS			
Item no.	Entry Level into Practice		
Intermediate Practice	Advanced Practice		
2.4.6	2.4.6.1 Store medicines and medical devices in a safe, secure, organised and systematic manner.	2.4.6.2 Implement developed systems to ensure safe, secure, organised and systematic storage of medicines and medical devices.	2.4.6.3 Develop systems to ensure safe, secure, organised and systematic storage of medicines and medical devices.
2.5	2.5.1.1 Monitor therapeutic outcomes.	2.5.1.2 Monitor and optimise therapeutic outcomes for more complex scenarios.	2.5.1.3 Ensure that protocols are in place to support the optimisation of therapeutic outcomes by pharmacists.
2.5.2	2.5.2.1 Consult with other healthcare professionals to optimise therapeutic outcomes.	2.5.2.2 Contribute to the PTC or at formulary design level to optimise therapeutic outcomes.	2.5.2.3 Participate in optimisation of therapeutic outcomes at PTC/formulary design level.
2.6.1	2.6.1.1 Assess and treat a patient based on objective and subjective signs and symptoms as guided by relevant legislation and within the scope of practice.	2.6.1.2 Ensure all medicine selection and advice provided reflects best evidence and guidance.	2.6.1.3 Ensure that protocols are in place to facilitate supervision of pharmacy support personnel involved in pharmacist initiated therapy (PIT).
2.6.2	2.6.2.1 Discuss the use of appropriate medicines and obtain consensus from the patient, taking into account patient preferences, allergies and medical history.	2.6.2.2 Implement the guidelines and policies on the appropriate use of medicines.	2.6.2.3 Develop guidelines and policies for appropriate use of medicines.
2.6.3	2.6.3.1 Document any intervention, including medicine supply, according to current legislative requirements.	2.6.3.2 Implement the developed pharmacist documentation system.	2.6.3.3 Develop a pharmacist intervention documentation system.
2.6.4	2.6.4.1 Refer patients, when required, to an appropriate healthcare provider/resource.	2.6.4.2 Implement the referral system to an appropriate healthcare provider/resource.	2.6.4.3 Develop a patient referral system.
COMPETENCIES			
2.5	Therapeutic monitoring outcome		
2.6	Pharmacist initiated therapy (PIT)		

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
2.7 Pharmacovigilance	2.7.1	2.7.1.1 Monitor, receive, record and report quality defects, adverse drug reactions and events.	2.7.1.2 Manage pharmacovigilance activities and classify the events accordingly.	2.7.1.3 Design and implement interventions to prevent and minimise adverse drug events.
	2.7.2	2.7.2.1 Perform post marketing surveillance studies.	2.7.2.2 Compile reports of the post marketing surveillance studies.	2.7.2.3 Review pharmacovigilance reports and report to regulatory authority.
	2.8.1	2.8.1.1 Apply master documents (e.g. SOPs) according to GxP.	2.8.1.2 Implement and monitor compliance in line with GxP.	2.8.1.3 Interpret guidelines, legislation and policies in line with GxP.
2.8 Clinical trials	2.8.2	2.8.2.1 Compile master documents.	2.8.2.2 Review master documents.	2.8.2.3 Approve master documents.

DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES

INTRODUCTION

Domain 3 includes competencies required to address the supply of medicines and medical devices, from production processes to the disposal of unused, expired and obsolete medicines and medical devices. The domain encompasses the planning and management of all activities involved in sourcing, procurement, and logistics management and includes coordination and collaboration with suppliers and other healthcare professionals in delivering pharmaceutical services to patients.

The pharmacist plays a critical role in the registration and manufacturing of safe, quality and effective medicines and medical devices. Procurement of safe, quality and effective medicines and medical devices involves the identification and careful selection of suppliers who provide products manufactured in accordance with current Good Manufacturing Practice (cGMP) and relevant legislation. In addition, behavioural statements for Domain 3 pertain to packaging, storage and transport of medicines and medical devices, and the legislation applicable to manufacturing, storage and distribution of medicines and medical devices.

The procurement, storage and distribution of pharmaceutical products are a major determinant in the availability of affordable, quality, safe and effective medicines. Given the impact of procurement activities on the operation and effectiveness of health services, it is essential that these activities are managed by pharmacists capacitated to apply sound procedures and who have access to reliable stock control, consumption and distribution information in order to manage medicine supply.

The dispensing process is also incorporated in the supply of medicines domain. The process in which the pharmacist interprets and evaluates a prescription, from both legal and pharmacological perspectives, selects appropriate medicine(s), prepares, packs and labels the medicine(s), and counsels the patient on the correct use of the medicine(s), are behaviours included in Domain 3. To improve therapeutic outcomes, the supply of medicines should include behaviours encompassing patient care encounters, prescription review, and medicine utilisation review.

In addition, pharmacists are responsible for minimising pharmaceutical waste. This includes the coordination of continuous monitoring of pharmaceutical waste generation, and the destruction or disposal procedures for any unused, unwanted or expired medicine.

The supply of medicines and medical devices competencies are:

- 3.1 Medicine production according to GxP
- 3.2 Supply chain management
- 3.3 Formulary development
- 3.4 Medicine dispensing
- 3.5 Medicine compounding
- 3.6 Medicine disposal/destruction

DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES				
BEHAVIOURAL STATEMENTS				
Item no.	Entry Level into Practice			
Intermediate Practice	Advanced Practice			
3.1 Medicine production according to GxP	3.1.1 Materials receiving	3.1.1.1 Apply SOPs and production documentation for receiving materials.	3.1.1.2 Implement and monitor compliance with regard to materials receiving requirements in accordance with SOPs.	3.1.1.3 Interpret legislation and policies for receiving material.
	3.1.2 Storage of raw materials and finished products	3.1.2.1 Apply SOPs and production documentation for storage requirements.	3.1.2.2 Implement and monitor compliance with storage requirements in accordance with SOPs.	3.1.2.3 Interpret legislation and policies for storage of raw materials and finished products.
	3.1.3 Production	3.1.3.1 Apply SOPs and production documentation according to the manufacturing process.	3.1.3.2 Implement and monitor compliance with production requirements in accordance with SOPs.	3.1.3.3 Manage deviations, investigate production failures, develop, review and update guidelines, SOPs and policies relating to the manufacturing process.
	3.1.4 Packaging	3.1.4.1 Apply SOPs and production documentation to packaging process.	3.1.4.2 Implement and monitor compliance with packaging requirements in accordance with SOPs.	3.1.4.3 Manage deviations, investigate packaging failures, develop, review and update guidelines, SOPs and policies relating to the packaging process.
	3.1.5 Final product release	3.1.5.1 Apply SOPs and review production documentation for final product release.	3.1.5.2 Implement and monitor product with the final release specifications.	3.1.5.3 Review and approve manufacturing records for final product release.
	3.1.6 Quality management systems	3.1.6.1 Review and apply SOPs and production documentation in line with quality management systems.	3.1.6.2 Develop and implement quality management systems to ensure product safety, quality and efficacy.	3.1.6.3 Develop and manage quality management policies.

DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
	3.1.7 Validation	3.1.7.1 Apply principles of validation.	3.1.7.2 Develop validation protocols and reports.	3.1.7.3 Approve validation protocols and reports.
	3.1.8 Regulatory	3.1.8.1 Apply section 15 of Act 101 to compile medicine registration dossiers.	3.1.8.2 Review the dossier for correctness and completeness, and respond to variations from the regulatory authority.	3.1.8.3 Approve the dossier for submission to the regulatory authority.
3.2 Supply chain management	3.2.1	3.2.1.1 Monitor and report stock requirements and shortages.	3.2.1.2 Implement medicines supply chain protocols to ensure access and availability of safe, effective, quality medicines and medical devices.	3.2.1.3 Develop and review protocols to ensure access and availability of safe, effective, quality medicines and medical devices for various supply and distribution models.
	3.2.2	3.2.2.1 Advise consumers/carers of reasons for the delay in supply of medicines and medical devices, and implement the contingency plans to ensure continuity of care.	3.2.2.2 Convey medicine or medical device shortage contingency plan information to the relevant healthcare professionals.	3.2.2.3 Develop, and monitor contingency plans for medicines and medical device shortages.
	3.2.3	3.2.3.1 Use the tools to monitor and review stock levels.	3.2.3.2 Assess and determine suitable stock levels and maintenance thereof.	3.2.3.3 Develop tools to monitor and review stock levels.
	3.2.4	3.2.4.1 Supply suitable alternative medicines and medical devices in emergency and life-threatening situations.	3.2.4.2 Source and obtain suitable alternative medicines and medical devices in emergency and life-threatening situations.	3.2.4.3 Liaise with prescribers and other stakeholders to identify suitable alternative medicines and medicine devices where supply difficulties are likely to occur.

DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
	3.2.5	3.2.5.1 Procure medicines and medical devices in line with approved procurement/supply chain management policies and procedures appropriate to the practice setting.	3.2.5.2 Implement and manage procurement/supply chain management policies and procedures appropriate to the practice setting.	3.2.5.3 Develop and review procurement/supply chain management policies and procedures ensuring no conflict of interest or inappropriate inducements in the sourcing and supply of medicines.
	3.2.6	3.2.6.1 Distribute medicines and medical devices in line with approved protocols and policies developed in accordance with GxP.	3.2.6.2 Communicate policies and protocols for medicine and medical device distribution, developed in accordance with GxP, to other members of the healthcare team.	3.2.6.3 Apply GxP principles and relevant legislation in the development of policies and protocols for medicine supply management.
	3.2.7	3.2.7.1 Supply unregistered medicines in accordance with relevant legislation.	3.2.7.2 Manage the supply of unregistered medicines in accordance with relevant legislation.	3.2.7.3 Develop systems and protocols for the supply of unregistered medicines in accordance with relevant legislation.
	3.2.8	3.2.8.1 Implement an effective stock management and rotation system, including systems for forecasting patient needs and demands and contingency plans for shortages and discontinuations.	3.2.8.2 Work with documented policies and procedures to implement an effective stock management and rotation system, including systems for forecasting patient needs and demands and contingency plans for shortages and discontinuations.	3.2.8.3 Manage sector wide pharmaceutical quantification.

DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES	
BEHAVIOURAL STATEMENTS	
COMPETENCIES	Item no.
	Entry Level into Practice
	Intermediate Practice
	Advanced Practice
3.3 Formulary development	<p>3.3.1</p> <p>3.3.1.1 Contribute to product selection based on systematic evidence-based evaluation criteria, e.g. suitability for intended use, quality and cost of medicines and medical devices, safety profile, reliability of source and bioequivalence.</p> <p>3.3.1.2 Play an advisory role in product selection based on systematic evidence-based evaluation criteria, e.g. suitability for intended use, quality and cost of medicines and medical devices, safety profile, reliability of source and bioequivalence.</p> <p>3.3.1.3 Play a leading role in product selection based on systematic, evidence-based evaluation criteria, e.g. suitability for intended use, quality and cost of medicines and medical devices, safety profile, reliability of source and bioequivalence.</p>
3.4 Medicine dispensing	<p>3.4.1</p> <p>3.4.1.1 Evaluate, interpret and prepare the prescription in line with legislative requirements and inform patients of availability of generic medicines.</p> <p>3.4.1.2 Manage, organise and prioritise the dispensing of prescriptions according to professional judgment, up-to-date clinical knowledge and in line with legislative requirements.</p> <p>3.4.1.3 Manage, organise and prioritise the dispensing of prescriptions according to professional judgment, up-to-date clinical knowledge and in line with legislative requirements.</p> <p>3.4.2</p> <p>3.4.2.1 Maintain, review and update patient history.</p> <p>3.4.2.2 Ensure that patient history is recorded and stored appropriately in accordance with applicable legislation.</p> <p>3.4.2.3 Ensure that patient history is recorded and stored appropriately in accordance with applicable legislation.</p> <p>3.4.3</p> <p>3.4.3.1 Perform a therapeutic review of a prescription to ensure pharmaceutical and clinical appropriateness of the treatment.</p> <p>3.4.3.2 Perform a therapeutic review of more complex prescriptions to ensure pharmaceutical and clinical appropriateness of treatment.</p> <p>3.4.3.3 Undertake therapeutic review of highly complex prescriptions for patients with multiple coexisting conditions to ensure pharmaceutical and clinical appropriateness of the prescribed treatment for the patient.</p>

DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
	3.4.4	3.4.4.1 Apply GPP principles and ensure accurate dispensing in an organised and systematic way, and apply sequential accuracy checks to all phases of dispensing.	3.4.4.2 Apply GPP principles and ensure accurate dispensing in an organised and systematic way, and apply sequential accuracy checks to all phases of dispensing.	3.4.4.3 Put systems in place to ensure that all phases of dispensing as detailed in the GPP are complied with.
	3.4.5	3.4.5.1 Prepare extemporaneous preparations according to GxP.	3.4.5.2 Ensure that extemporaneous preparations are prepared in accordance with GxP.	3.4.5.3 Develop SOPs for preparation of extemporaneous preparations in line with GxP.
	3.4.6	3.4.6.1 Perform pharmaceutical calculations accurately.	3.4.6.2 Ensure that pharmaceutical calculations are accurate.	3.4.6.3 Provide reference sources and develop procedures for pharmaceutical calculations.
	3.4.7	3.4.7.1 Consult prescribers regarding anomalies or potential problems, e.g. incorrect doses, drug interactions.	3.4.7.2 Address anomalies in clinical meetings with healthcare professionals.	3.4.7.3 Advise and guide prescribers on potential problematic treatment regimens.
	3.4.8	3.4.8.1 Document and record all interventions.	3.4.8.2 Implement a recordkeeping system and ensure that all interventions are documented.	3.4.8.3 Develop a recordkeeping system and undertake an analysis of all documented interventions to improve patient care.
	3.4.9	3.4.9.1 Use dispensing technology in line with practice specific protocols.	3.4.9.2 Implement and monitor the use of dispensing technology developed in line with protocols.	3.4.9.3 Develop protocols to ensure accurate use of all dispensing technologies.

DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
3.5 Medicine compounding	3.5.1	3.5.1.1 Apply pharmaceutical knowledge to the formulation and compounding of medicines.	3.5.1.2 Ensure that pharmaceutical formulation and compounding of medicines are in line with legislation.	3.5.1.3 Source appropriate references for formulation and compounding of medicines in line with GPP and GxP.
3.6 Medicine recall, disposal and destruction	3.6.1	3.6.1.1 Request patients to return any unused, unwanted and/or expired medicines to the pharmacy for safe disposal and implement the protocols for any returned, unused, unwanted, expired and recalled medicines, including the assessment of impact on patient care and required patient follow up.	3.6.1.2 Request patients to return any unused, unwanted and/or expired medicines to the pharmacy for safe disposal and implement the protocols for any returned, unused, unwanted, expired and recalled medicines, including the assessment of impact on patient care and required patient follow up.	3.6.1.3 Develop protocols to ensure the proper management of returned, recalled, expired and unusable products for safe disposal taking into consideration environmental legislations.
	3.6.2	3.6.2.1 Quarantine any returned, damaged, expired, recalled or discontinued medicines and implement and monitor the safe destruction and disposal of waste material, pharmaceutical products and cytotoxic products in accordance with relevant legislation.	3.6.2.2 Quarantine any returned, damaged, expired, recalled or discontinued medicines and implement and monitor the safe destruction and disposal of waste material, pharmaceutical products and cytotoxic products in accordance with relevant legislation.	3.6.2.3 Develop a protocol for the safe destruction and disposal of waste material, pharmaceutical products and cytotoxic products in accordance with relevant legislation.
	3.6.3	3.6.3.1 Apply the guidelines for recall of medicines.	3.6.3.2 Apply the guidelines for recall of medicines.	3.6.3.3 Ensure compliance to the guidelines for recall of medicines.

DOMAIN 4: ORGANISATION AND MANAGEMENT SKILLS**INTRODUCTION**

Domain 4 includes competency standards that relate to the manner in which pharmacists apply organisational and managerial skills to ensure the effective and efficient delivery of pharmaceutical services. It includes behavioural statements relating to: the operation and maintenance of facilities and infrastructure; application of sound fiscal principles; and quality assurance to ensure sustainable pharmaceutical services that are adaptive to changing environments.

Human and financial resources are central to planning, delivering and managing pharmaceutical services. In pharmacy, the goal of human resources management is to develop and sustain an adequate supply of skilled professionals motivated to provide effective pharmaceutical services.

The organisation and management competencies are:

- 4.1 Human resources management
- 4.2 Financial management
- 4.3 Pharmaceutical infrastructure management
- 4.4 Quality assurance
- 4.5 Change management
- 4.6 Policy development

DOMAIN 4: ORGANISATION AND MANAGEMENT SKILLS				
COMPETENCIES	BEHAVIOURAL STATEMENTS			
	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
4.1 Human resources management	4.1.1	4.1.1.1 Contribute to the effective management of pharmacy personnel.	4.1.1.2 Effectively manage pharmacy personnel under supervision.	4.1.1.3 Identify human resources requirements and manage human resources effectively.
	4.1.2	4.1.2.1 Undertake continuing professional development.	4.1.2.2 Participate in the provision of staff training and continuing professional development.	4.1.2.3 Identify staff training needs, facilitate appropriate training opportunities and participate in continuing professional development.
	4.1.3	4.1.3.1 Conduct self-assessments or appraisal in line with the performance management policy.	4.1.3.2 Conduct staff assessments or appraisals in line with the performance management policy.	4.1.3.3 Review performance management policies and processes.
	4.1.4	4.1.4.1 Adhere to basic human resources management legislation, e.g. Labour Relations Act and Basic Conditions of Employment Act.	4.1.4.2 Monitor adherence to relevant human resources management legislation, e.g. Labour Relations Act and Basic Conditions of Employment Act.	4.1.4.3 Develop and train pharmacy personnel.
4.2 Financial management	4.2.1	4.2.1.1 Submit patient prescription claims to health funders to ensure optimum use of patient benefits.	4.2.1.2 Monitor patient prescription claims submitted to health funders to ensure optimum use of patient benefits.	4.2.1.3 Determine dispensing and professional fees to be charged in line with legislation.
	4.2.2	4.2.2.1 Work according to the approved budget.	4.2.2.2 Monitor income and expenditure in line with budget prescripts.	4.2.2.3 Develop and effectively analyse and manage financial data and budgets.
	4.2.3	4.2.3.1 Comply with all relevant legislative prescripts.	4.2.3.2 Monitor adherence to all relevant legislative prescripts.	4.2.3.3 Ensure adherence to all relevant legislative prescripts.

DOMAIN 4: ORGANISATION AND MANAGEMENT SKILLS				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
	4.2.4	4.2.4.1 Perform cost benefit analysis.	4.2.4.2 Apply the principles of pharmaco-economic assessments.	4.2.4.3 Apply the principles of pharmaco-economic assessments.
4.3 Pharmaceutical infrastructure management	4.3.1	4.3.1.1 Identify pharmaceutical facility and equipment needs.	4.3.1.2 Identify pharmaceutical facility and equipment needs.	4.3.1.3 Identify pharmaceutical facility and equipment needs and develop a plan to achieve and meet the needs.
	4.3.2	4.3.2.1 Monitor the suitability of pharmaceutical facilities and equipment.	4.3.2.2 Monitor the suitability of pharmaceutical facilities and equipment.	4.3.2.3 Manage pharmaceutical facilities and equipment.
	4.3.3	4.3.3.1 Work according to the approved workplace procedures and policies.	4.3.3.2 Implement and monitor workplace procedures and policies.	4.3.3.3 Develop and review workplace procedures and policies as required.
	4.3.4	4.3.4.1 Prioritise and organise workflow and demonstrate time management skills.	4.3.4.2 Manage, prioritise and organise workflow and demonstrate time management skills.	4.3.4.3 Develop and review workflow systems in order to manage, prioritise and organise daily work and demonstrate time management skills.
	4.3.5	4.3.5.1 Maintain the existing pharmaceutical infrastructure.	4.3.5.2 Contribute to the improvement of the existing pharmaceutical infrastructure.	4.3.5.3 Ensure pharmaceutical infrastructure is in line with legislative requirements.
4.4 Quality assurance	4.4.1	4.4.1.1 Participate in the update of the SOPs and attend training on SOPs.	4.4.1.2 Contribute to the development, implementation, maintenance and training of staff in respect of SOPs.	4.4.1.3 Conduct regular audit activities, report and act upon findings.
	4.4.2	4.4.2.1 Assist with procedures and processes that ensure quality assurance is achieved.	4.4.2.2 Participate in quality assurance audits.	4.4.2.3 Use feedback from complaints and audits to implement improvement strategies, and monitor and evaluate the outcomes.

DOMAIN 4: ORGANISATION AND MANAGEMENT SKILLS				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
	4.4.3	4.4.3.1 Work according to the approved management and recordkeeping systems.	4.4.3.2 Implement a system for documentation and recordkeeping for quality assurance purposes.	4.4.3.3 Develop and update systems for documentation and recordkeeping for quality assurance purposes.
4.5 Change management	4.5.1	4.5.1.1 Participate in change management processes within the team.	4.5.1.2 Manage a change management process for the team.	4.5.1.3 Contribute to and lead a change management process beyond the team/workplace or across disciplines.
	4.5.2	4.5.2.1 Overcome internal barriers and self-limiting beliefs to change by analysing the climate and the readiness for change followed by measures to improve personnel growth and contribute to organisational success and outcomes.	4.5.2.2 Motivate staff to overcome barriers to change in order to drive organisational success and outcomes.	4.5.2.3 Develop strategies to inspire and motivate staff to overcome barriers to change in order to drive organisational success and outcomes.
4.6 Policy development	4.6.1	4.6.1.1 Apply policies and SOPs.	4.6.1.2 Implement and monitor policies and SOPs.	4.6.1.3 Develop a policy framework and SOPs

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE**INTRODUCTION**

Domain 5 is the professional and personal practice domain and includes behavioural statements that relate to the practice of pharmacy in a professional, legal and ethical manner to deliver patient-centred pharmaceutical services in a multidisciplinary setting.

The professional and personal practice competencies are:

- 5.1 Patient-centred care
- 5.2 Professional practice
- 5.3 Ethical and legal practice
- 5.4 Continuing professional development
- 5.5 Leadership
- 5.6 Decision-making
- 5.7 Collaborative practice
- 5.8 Self-management
- 5.9 Communication

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
5.1 Patient-centred care	5.1.1	5.1.1.1 Assist patients to make informed healthcare decisions.	5.1.1.2 Educate and empower patients to manage their own health and medicine use.	5.1.1.3 Act as a patient advocate to ensure that patient care is optimised.
	5.1.2	5.1.2.1 Ensure patient safety and quality of care are at the centre of the pharmacy practice.	5.1.2.2 Monitor pharmacy practice to ensure patient safety and quality of care.	5.1.2.3 Put systems in place, including patient experience feedback, to ensure patient safety and quality of care are at the centre of the pharmacy practice.
	5.1.3	5.1.3.1 Uphold the patients' rights.	5.1.3.2 Monitor that patients' rights are upheld.	5.1.3.3 Champion patients' rights through the implementation of the Patients' Rights Charter.
5.2 Professional practice	5.2.1	5.2.1.1 Practise in a manner that upholds professionalism.	5.2.1.2 Monitor that pharmacy personnel practise in a manner that upholds professionalism.	5.2.1.3 Develop strategies to ensure that pharmacy personnel practise in a manner that upholds professionalism.
	5.2.2	5.2.2.1 Treat all with sensitivity, empathy, respect and dignity.	5.2.2.2 Monitor that patients are treated with sensitivity, empathy, respect and dignity.	5.2.2.3 Develop systems and processes to ensure that patients are treated with sensitivity, empathy, respect and dignity.
	5.2.3	5.2.3.1 Take responsibility for own actions and patient care.	5.2.3.2 Encourage pharmacy personnel to take responsibility for their own actions and patient care.	5.2.3.3 Teach pharmacy personnel to take responsibility for their own actions and patient care.
	5.2.4	5.2.4.1 Maintain a consistently high standard of work.	5.2.4.2 Ensure that pharmacy personnel consistently achieve a high standard of work.	5.2.4.3 Put systems in place to ensure that pharmacy personnel consistently achieve a high standard of work.
	5.2.5	5.2.5.1 Contribute effectively in a multidisciplinary team.	5.2.5.2 Contribute effectively in a multidisciplinary team.	5.2.5.3 Lead and participate effectively in a multidisciplinary team.

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
	5.2.6	5.2.6.1 Maintain appropriate boundaries with patients, staff and other healthcare professionals according to established ethical and professional practice guidelines.	5.2.6.2 Mentor and coach pharmacy personnel on maintenance of appropriate boundaries with patients, staff and other healthcare professionals using established ethical and professional practice guidelines.	5.2.6.3 Develop ethical and professional practice guidelines to establish appropriate boundaries with patients, staff and other healthcare professionals.
	5.2.7	5.2.7.1 Embrace technology and innovation that can improve patient care.	5.2.7.2 Encourage the use of technology and innovation to improve patient care.	5.2.7.3 Develop and establish policies and approaches that support the use of technology and innovation to improve patient care.
5.3 Ethical and legal practice	5.3.1	5.3.1.1 Apply the Pharmacy Act (No. 53 of 1974), the Medicines and Related Substances Act (No. 101 of 1965) and any other applicable legislation in daily practice.	5.3.1.2 Monitor compliance with the Pharmacy Act, the Medicines Act or any other applicable legislation in daily practice.	5.3.1.3 Develop and update protocols to ensure that practice is in line with current legislation.
	5.3.2	5.3.2.1 Practise within the scope of practice of a pharmacist, recognising own limitations of personal competency and expertise.	5.3.2.2 Practise within the scope of practice of a pharmacist, recognising own limitations of personal competency and expertise.	5.3.2.3 Practise within the scope of practice of a pharmacist, recognising own limitations of personal competency and expertise.
	5.3.3	5.3.3.1 Keep abreast of legislation and apply relevant amendments accordingly.	5.3.3.2 Keep abreast of legislation and apply relevant amendments accordingly.	5.3.3.3 Contribute to the development of new and amended pharmacy related legislation, and guidelines.
	5.3.4	5.3.4.1 Comply with professional indemnity requirements.	5.3.4.2 Encourage compliance with professional indemnity requirements.	5.3.4.3 Ensure compliance with professional indemnity requirements.
	5.3.5	5.3.5.1 Practise and adhere to the obligations of a pharmacist in terms of the	5.3.5.2 Apply the principles of ethics in managing ethical dilemmas in a structured manner.	5.3.5.3 Apply the principles of ethics in managing ethical dilemmas in a structured manner.

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE			
BEHAVIOURAL STATEMENTS			
COMPETENCIES	Item no.	Entry Level into Practice	Advanced Practice
		principles of the statutory Code of Conduct for Pharmacists.	
5.4 Continuing professional development	5.4.1	5.4.1.1 Inculcate the principles of life-long learning into daily practice.	5.4.1.2 Inculcate the principles of life-long learning into daily practice.
	5.4.2	5.4.2.1 Take personal responsibility for engaging in CPD to achieve professional development goals, and document CPD activities appropriately.	5.4.2.2 Take personal responsibility for engaging in CPD to achieve professional development goals, and document CPD activities appropriately.
	5.4.3	5.4.3.1 Critically reflect on personal practice and skills and identify and address learning needs.	5.4.3.2 Critically reflect on personal practice and skills and identify and address learning needs.
5.5 Leadership	5.5.1	5.5.1.1 Build professional credibility and portray the profession in a positive light.	5.5.1.2 Apply assertiveness skills to inspire confidence as an accountable leader.
	5.5.2	5.5.2.1 Provide appropriate supervision and mentoring to pharmacy support personnel.	5.5.2.2 Provide appropriate supervision and mentoring to pharmacy support personnel and other pharmacists.
5.6 Decision-making	5.6.1	5.6.1.1 Make considered and timely evidenced-based decisions incorporating consultation if required.	5.6.1.2 Demonstrate attention to detail and accuracy in decision-making.
5.7 Collaborative practice	5.7.1	5.7.1.1 Practice in a multidisciplinary team with cognisance of the roles and services delivered by healthcare and other related professionals.	5.7.1.2 Practice in a multidisciplinary team with cognisance of the roles and services delivered by healthcare and other related professionals.
		5.7.1.3 Advocate for the inclusion of pharmacists in all multidisciplinary healthcare teams.	5.7.1.3 Advocate for the inclusion of pharmacists in all multidisciplinary healthcare teams.
5.8 Self-management	5.8.1	5.8.1.1 Work in an organised and efficient manner.	5.8.1.2 Work in an organised and efficient manner.
			5.8.1.3 Develop systems and processes to ensure that work is carried out in an organised and efficient manner.

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
5.9 Communication	5.8.2	5.8.2.1 Ensure time and work processes are appropriately planned, prioritised and managed.	5.8.2.2 Modify behaviour and practice in response to feedback, experience and critical incidents.	5.8.2.3 Design behavioural and practice models in response to feedback, experience and critical incidents.
	5.8.3	5.8.3.1 Take appropriate responsibility in the workplace.	5.8.3.2 Take responsibility and be accountable for pharmacy practice issues in the workplace.	5.8.3.3 Identify gaps and areas for personal improvement and ensure implementation.
	5.8.4	5.8.4.1 Ensure punctuality and reliability.	5.8.4.2 Implement effective and efficient work methodology.	5.8.4.3 Develop time management strategies.
	5.9.1	5.9.1.1 Use appropriate language and listening skills, and confirm understanding between patient and pharmacist.	5.9.1.2 Use appropriate language and listening skills, and confirm understanding between patient and pharmacist.	5.9.1.3 Determine the appropriate language and develop appropriate listening skills to use, and confirm understanding between patient and pharmacist.
	5.9.2	5.9.2.1 Understand and demonstrate respect, sensitivity, empathy and cultural awareness.	5.9.2.2 Embody and promote the principles of respect, sensitivity, empathy and cultural awareness.	5.9.2.3 Educate pharmacy personnel on the principles of respect, sensitivity, empathy and cultural awareness.
	5.9.3	5.9.3.1 Convey accurate and relevant information.	5.9.3.2 Demonstrate the principles of accurate, concise and relevant information.	5.9.3.3 Educate pharmacy personnel on the principles of accurate, concise and relevant information.
	5.9.4	5.9.4.1 Apply problem solving and conflict management skills.	5.9.4.2 Apply advanced problem solving and conflict management skills.	5.9.4.3 Educate pharmacy personnel on problem solving and conflict management skills.
	5.9.5	5.9.5.1 Build trust relationships to ensure effective communication with patients, healthcare professionals and relevant staff.	5.9.5.2 Advance trust relationships to ensure effective communication with patients, healthcare professionals and relevant staff.	5.9.5.3 Educate pharmacy personnel on the importance of trust relationships to ensure effective communication with patients, healthcare professionals and relevant staff.

DOMAIN 6: EDUCATION, CRITICAL ANALYSIS AND RESEARCH

INTRODUCTION

Domain 6 includes the behavioural statements relating to education and training, critical analysis and research.

Education is essential for the initial development of pharmacists and is required throughout a pharmacist's career to keep abreast of knowledge, skills, attitudes and values. Pharmacists should participate in the education and training of patients, interns, pharmacy support personnel and other healthcare practitioners.

Critical analysis competencies provide the link between practice and research by assisting in the identification of areas where research is required. Pharmacists should participate in practice-based research. The research may include investigations into prescribing practices, patterns of medicine usage, evaluation of medicine use, the monitoring of adverse reactions, the benefits of the pharmacist's advisory role, computerised data handling, health economics, legislation, and aspects of abuse and irrational use of medicines.

Practising pharmacists are increasingly participating in health systems and quality improvement research, which must be encouraged as a means of providing databases and information for future policy, guidelines and practice development. Such research is often conducted in collaboration with other healthcare providers.

The education, research and critical analysis competencies are:

- 6.1 Education and training policy
- 6.2 Provision of education and training
- 6.3 Practice embedded education or workplace education
- 6.4 Gap analysis
- 6.5 Critical analysis
- 6.6 Research
- 6.7 Supervision of other researchers
- 6.8 Collaborative research

DOMAIN 6: EDUCATION, CRITICAL ANALYSIS AND RESEARCH				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
6.1 Education and training policy	6.1.1	6.1.1.1 Apply national policy relating to pharmaceutical education.	6.1.1.2 Interpret national policy in order to design strategic approaches for pharmaceutical education.	6.1.1.3 Shape and contribute to national education policy.
6.2 Provision of education and training	6.2.1	6.2.1.1 Teach effectively according to an agreed training plan with guidance from a more experienced colleague.	6.2.1.2 Mentor and assist with implementation of training plans.	6.2.1.3 Design and manage a course of study, with appropriate use of teaching approaches, assessment and study methods.
	6.2.2	6.2.2.1 Perform self-assessment and identify own learnings needs.	6.2.2.2 Assess the performance and learning needs of others.	6.2.2.3 Shape, contribute to and be accountable for the performance and learning needs of others.
	6.2.3	6.2.3.1 Participate in developing the learning activities.	6.2.3.2 Plan a series of effective learning experiences for others.	6.2.3.3 Shape, contribute to and be accountable for the creation and/or development of pharmacy education qualification(s).
6.3 Practice embedded education or workplace education	6.3.1	6.3.1.1 Participate in the formal education of students in a practice environment.	6.3.1.2 Design and manage a study programme, based in a practice environment.	6.3.1.3 Shape, contribute to, or be accountable for the creation and/or development of practice-based components of pharmacy education qualification(s).
6.4 Gap analysis	6.4.1	6.4.1.1 Identify gaps in the practice of pharmacy and education based on research.	6.4.1.2 Formulate appropriate and rigorous research questions to address gaps in the practice of pharmacy and education.	6.4.1.3 Design an appropriate research strategy to address research questions.
6.5 Critical analysis	6.5.1	6.5.1.1 Critically evaluate literature in the context of practice of pharmacy and education.	6.5.1.2 Apply critical evaluation skills in the context of practice of pharmacy and education.	6.5.1.3 Undertake peer review activities in the practice of pharmacy and education.

DOMAIN 6: EDUCATION, CRITICAL ANALYSIS AND RESEARCH				
BEHAVIOURAL STATEMENTS				
COMPETENCIES	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
6.6 Research	6.6.1	6.6.1.1 Describe the core features of research protocols.	6.6.1.2 Design a research protocol to address previously formulated research questions.	6.6.1.3 Critically review research protocols.
	6.6.2	6.6.2.1 Conduct research according to approved protocol.	6.6.2.2 Present research findings at relevant fora.	6.6.2.3 Publish an article on research findings.
6.7 Supervision of other researchers	6.7.1	6.7.1.1 Apply research governance principles.	6.7.1.2 Supervise research at undergraduate level.	6.7.1.3 Supervise research at postgraduate level.
6.8 Collaborative research	6.8.1	6.8.1.1 Work as a member of a research team.	6.8.1.2 Establish multidisciplinary links to conduct research projects.	6.8.1.3 Lead a multidisciplinary research team.

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