BOARD NOTICE 481 OF 2023

THE SOUTH AFRICAN PHARMACY COUNCIL

COMPETENCY STANDARDS FOR SPECIALIST PHARMACISTS IN SOUTH AFRICA

The South African Pharmacy Council intends to publish the **Competency Standards for Industrial Pharmacists, Clinical Pharmacists and Radiopharmacists** in terms of Section 33(o) of the Pharmacy Act, 53 of 1974.

Interested parties are invited to submit, within **60 days** of publication of this notice, substantiated comments on or representation regarding the proposed Competency Standards for Industrial Pharmacists, Clinical Pharmacists and Radiopharmacists. Comments must be addressed to the Registrar, the South African Pharmacy Council by way of email at BN@sapc.za.org (for the attention of the Company Secretary and Legal Services)

SCHEDULE

1. Competency Standards for Industrial Pharmacists

2. Competency Standards for Clinical Pharmacists

3. Competency Standards for Radiopharmacist

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To obtain the full content of this Board Notice, please visit the 'Proposed Legislation' section on the South African Pharmacy Council's website: https://www.sapc.za.org/Legislation_Proposed

South African Pharmacy Council

COMPETENCY STANDARDS FOR A PHARMACIST WHO PROVIDES INDUSTRIAL PHARMACEUTICAL SERVICES IN SOUTH AFRICA

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ACRONYMS AND DEFINITIONS

API: Active Pharmaceutical Ingredient;

CAPA: Corrective Action and Preventative Action;

GxP: Good Practice Guidelines and Regulations, e.g., Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Wholesaling Practice (GWP) and other pharmaceutical practices;

IVDs: *In Vitro* Diagnostics;

"Specialist Pharmacist" means a pharmacist who is registered as such in terms of the Pharmacy Act, 53 of 1974 ("the Act");

"Speciality" means a specialist qualification in one of the fields of pharmacy approved and published in rules made by the South African Pharmacy Council; and

"Industrial Pharmacist" means a pharmacist registered with Council to offer industrial pharmaceutical services.

INTRODUCTION

An Industrial Pharmacist is a pharmacist registered with the South African Pharmacy Council (hereafter "Council") who specialises in *inter alia* the development, manufacturing, registration and distribution of medicines, medical devices, and *in vitro* diagnostics (IVDs) in the pharmaceutical industry.

The Industrial Pharmacist is responsible for developing, monitoring and maintaining compliance with the quality management system. The Industrial Pharmacist must ensure that the quality of medicines and medical devices and IVDs is maintained throughout the distribution chain.

BACKGROUND

In 2018, the South African Pharmacy Council published Competency Standards for Pharmacists. Competency standards had been developed and used as the basis for pharmacy education and practice since 2006. These competency standards for industrial pharmacists are developed to encompass the scope of practice for an industrial pharmacist as a specialist pharmacist.

THE SCOPE OF PRACTICE FOR AN INDUSTRIAL PHARMACIST

In addition to the acts and services which form part of the scope of practice of a pharmacist as prescribed in terms of Regulations 3 and 4 of the Regulations relating to the practice of Pharmacy, a pharmacist who has completed a master's degree in Industrial Pharmacy must be allowed to provide the following services or acts pertaining to the scope of practice of an industrial pharmacist:

(a) Perform acts and services pertaining to the profession of a pharmacist.

(b) Control both intrinsic and extrinsic quality of a product taking into account patient health and safety.

(c) Manage knowledge and transfer of research evidence into practice.

(d) Provide strategic leadership for the manufacture of medicine and warehousing.

(e) Supply chain management.

(f) Design, develop and interpret quality systems for implementation of GMP.

(g) Provide education and training relating to industrial pharmacy.

(h) Provide pharmaceutical leadership and guidance in directing the business.

RATIONALE FOR THE DEVELOPMENT OF COMPETENCY STANDARDS FOR INDUSTRIAL PHARMACISTS

Industrial Pharmacists are required to understand the provision of pharmaceutical services in the pharmaceutical industry and facilitate the enhancement of *inter alia* the manufacture and registration of medicines, medical devices and IVDs.

The competency standards have been developed to encompass the changes and developments including new technologies, work processes, changes in legislation and international trends. Primarily, this is done to ensure the production of quality, safe and efficacious medicines and the promotion of proper medication usage and pharmaceutical care, in the patient's and the public's best interests.

INDUSTRIAL PHARMACISTS' REGISTRATION

Industrial Pharmacists are obliged to be registered with Council for the purposes of offering the acts related to their scope of practice as follows:

(a) Specialist pharmacist student.

(b) Specialist pharmacist resident.

(c) Specialist pharmacist.

INDUSTRIAL PHARMACIST QUALIFICATIONS

For purposes of registration as an Industrial Pharmacist, the qualification shall be-

(a) a professional master's degree in Industrial Pharmacy as determined by Council and published from time to time; or

(b) a qualification deemed to be equivalent or higher than the professional master's degree in Industrial Pharmacy as assessed by Council.

STRUCTURE OF THE COMPETENCY STANDARDS AND DOMAINS

A competency framework consisting of six (6) domains suitable for the South African context was developed, together with several competencies. A domain represents an organised cluster of competencies within a framework and the domains, with associated competencies, are summarised in Table 1. The behavioural statements indicating how individuals working within the competency framework should behave in practice have also been drafted.

Table 1: Summary of industrial pharmacy domains and competencies.

SUMMARY OF INDUSTRIAL PHARMACY COMPETENCY STANDARDS

DOMAIN	COMPETENCY STANDARD
1. Public Health	1.1 Promotion of industrial pharmaceutical services. 1.2 Pharmacoeconomic interventions.
2. Design and maintenance of facilities	2.1 Design of manufacturing facilities. 2.2 Design of warehousing and distribution facilities.
3. Supply of medicines, medical devices and in-vitro diagnostics	3.1 Manufacture and control of medicines, medical devices, IVDs and Inventory control of API. 3.2 Supply chain management.
4. Quality management in Industrial pharmacy	4.1 Compliance with quality assurance principles. 4.2 Pharmaceutical infrastructure management.
5. Governance and regulation of medicines and medical devices	5.1 Development of medicine, medical devices and IVDs dossiers and technical files. 5.2 Medicine registration, medical devices and IVD listing. 5.3 Professional practice.
6. Education, training and research	6.1 Research technologies relevant to improve industrial pharmaceutical services. 6.2 Formulation and development of dosage forms. 6.3 Management of clinical trials.

DOMAIN 1: PUBLIC HEALTH

INTRODUCTION

The domain covers competencies that are required to promote industrial pharmaceutical services. Participation of pharmacists in the promotion of public health utilising industrial pharmacy entails the following competencies:

1.1 Promotion of industrial pharmaceutical services.

1.2 Pharmacoeconomics.

DOMAIN 1: PUBLIC HEALTH	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
1.1 Promotion of industrial pharmaceutical services	1.1.1 Promote access to quality industrial pharmacy services. 1.1.2 Educate other healthcare professionals and the public with technical information related to industrial pharmacy. 1.1.3 Monitor and maintain the development of industrial pharmacy services. 1.1.4 Demonstrate qualities to improve performance and manage industrial pharmacy services. 1.1.5 Encourage the practice of good industrial pharmacy practice. 1.1.6 Advocate for industrial pharmaceutical services by engaging other healthcare professionals, stakeholders and regulatory authorities.
1.2 Pharmacoeconomic interventions	1.2.1 Monitor and maintain inter alia economical production, registration and distribution of medicines, medical devices and IVD as part of a health care team. 1.2.2 Demonstrate the ability to develop, maintain and monitor health systems to ensure that industrial pharmaceutical services are cost effective and in line with the burden of disease.

DOMAIN 2: DESIGN AND MAINTENANCE OF FACILITIES

INTRODUCTION

Industrial Pharmacists must have the knowledge of the procedures and operations to design and maintain pharmaceutical manufacturing and distribution facilities. The competencies required in the domain for design and maintenance of facilities in industrial pharmacy are:

2.1 Design of manufacturing facilities.

2.2 Design of warehousing and distribution facilities.

DOMAIN 2: DESIGN AND MAINTENANCE OF FACILITIES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
2.1 Design of manufacturing facilities	2.1.1 Ensure that the design and maintenance of the manufacturing facility comply with regulatory requirements. 2.1.2 Ensure that the dossier storage facilities comply with regulatory requirements. 2.1.3 Monitor compliance with the health and safety policies.
2.2 Design of warehousing and distribution facilities	2.2.1 Ensure that the design and maintenance of warehousing and distribution facility complies with regulatory requirements. 2.2.2 Monitor compliance with the health and safety policies. 2.2.3 Ensure compliance with the Occupational Health and Safety Act and all other applicable legislations and guidelines.

DOMAIN 3: SUPPLY OF MEDICINES, MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS

INTRODUCTION

The Industrial Pharmacist plays an important role in the supply and distribution of medicines, medical devices and IVDs. The competencies required in this domain are as follows -

3.1 Manufacture and control of medicines, medical devices and IVDs, and inventory control of APIs.

3.2 Supply chain management.

DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
3.1 Manufacture and control of medicines, medical devices and IVDs, and inventory control of APIs.	3.1.1 Manage and control the inventory of APIs. 3.1.2 Maintain the storage conditions for APIs and other excipients. 3.1.3 Verify the quality of finished products before release. 3.1.4 Import and export medicines, medical devices and IVD. 3.1.5 Ensure that storage conditions for API and other excipients are maintained according to the manufacturer's specifications and GMP. 3.1.6 Ensure that the finished products and medical devices meet quality, safety and environmental control requirements. 3.1.7 Manage the storage and transportation of finished products in accordance with GxP. 3.1.8 Perform pharmacokinetic and pharmacodynamic dosing alterations.
3.2 Supply chain management	3.2.1 Develop, maintain and monitor health systems for the import and export of medicines, medical devices and IVD. 3.2.2 Design the warehouse area to ensure compliance with Good Distribution and Warehousing Practice.

DOMAIN 4: QUALITY MANAGEMENT IN INDUSTRIAL PHARMACY

INTRODUCTION

Industrial Pharmacists must have knowledge of procedures and operations to integrate and apply expertise in establishing, evaluating, maintaining and monitoring quality management systems. The competencies required in the domain of quality management in industrial pharmacy are:

4.1 Compliance with quality assurance principles.

4.2 Pharmaceutical infrastructure management.

DOMAIN 4: QUALITY MANAGEMENT IN INDUSTRIAL PHARMACY	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
4.1 Compliance with quality assurance principles.	4.1.1 Demonstrate the ability to make decisions relating to complex quality control issues. 4.1.2 Demonstrate the ability to establish, monitor and manage CAPAs. 4.1.3 Develop and maintain quality management systems for manufacturing and distribution of medicines, medical devices and IVDs. 4.1.4 Develop and maintain quality management systems for the control of equipment.
4.2 Pharmaceutical infrastructure management.	4.2.1 Develop and maintain quality management systems for the design and maintenance of pharmaceutical manufacturing facilities. 4.2.2 Develop and maintain quality management systems for the design and maintenance of pharmaceutical wholesaling facilities. 4.2.3 Develop and monitor compliance with health and safety policies.

DOMAIN 5: GOVERNANCE AND REGULATION OF MEDICINES AND MEDICAL DEVICES

INTRODUCTION

The competencies required in the domain to ensure governance and regulation of medicines and medical devices are:

5.1 Development of medicine, medical devices and IVDs dossiers and technical files.

5.2 Medicine registration, medical devices and IVD listing.

5.3 Professional practice.

DOMAIN 5: GOVERNANCE AND REGULATION OF MEDICINES AND MEDICAL DEVICES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
5.1 Development of medicine, medical devices, IVDs, dossiers and technical files.	5.1.1 Compile and maintain medicine dossiers and technical files in accordance with relevant legislation. 5.1.2 Effectively engage with regulatory authorities.
5.2 Medicine registration and medical devices and IVD listing.	5.2.1 Compile and submit dossiers and technical files for registration of medicines and/or listing of medicines, medical devices and diagnostics. 5.2.2 Demonstrate an in-depth knowledge of all applicable medicines and device regulatory guidelines.

DOMAIN 5: GOVERNANCE AND REGULATION OF MEDICINES AND MEDICAL DEVICES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
5.3 Professional practice	5.3.1 Develop and monitor protocols to ensure that the industrial pharmacy operates in line with the current GxP. 5.3.2 Contribute to the review and development of legislation. 5.3.3 Develop and monitor protocols to ensure post-marketing surveillance and law enforcement can be carried out. 5.3.4 Develop and monitor protocols to ensure ongoing compliance with industrial pharmacy-related legislation, regulations and regulatory bodies. 5.3.5 Develop and monitor protocols to ensure ongoing compliance with surveillance requirements.

DOMAIN 6: RESEARCH AND DEVELOPMENT

INTRODUCTION

Research and development are essential for the initial development of medicines and medical devices and is required throughout a lifetime to maintain control of diseases and establish the treatment of newly discovered diseases. The domain includes behavioural statements relating to research and development in an industrial pharmacy setting. The competencies required in the domain are:

6.1 Research technologies relevant to improve industrial pharmaceutical services.

6.2 Development of dosage forms.

6.3 Management of clinical trials.

DOMAIN 6: EDUCATION, TRAINING AND RESEARCH	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
6.1 Research technologies relevant to improve industrial pharmaceutical services.	6.1.1 Demonstrating a detailed knowledge and understanding of the development of new medicines and medical devices. 6.1.2 Demonstrate the ability to discover new APIs for the development of medicines. 6.1.3 Demonstrate the ability to research new methods of manufacturing, distribution, and dossier development. 6.1.4 Publish articles on research findings. 6.1.5 Develop, implement and maintain the record for training and assessment of healthcare teams, patients and the public. 6.1.6 Demonstrate the ability to provide pharmaceutical advice on specialised nutrition support or any other similar products. 6.1.7 Design and evaluate health technology assessments.
6.2 Formulation and development of dosage forms.	6.2.1 Demonstrate the ability to conduct research and develop formulations for various dosage forms. 6.2.2 Assess the performance and stability of newly developed formulations of dosage forms. 6.2.3 Ensure that the relevant documentation relating to the development of the formulations complies with the applicable standards. 6.2.4 Demonstrate the ability to provide advice regarding the formulation of dosage forms.
6.3 Management of clinical trials	6.3.1 Participate in the development and evaluation of clinical trial protocols in all phases. 6.3.2 Ensure that prior approval is obtained from relevant statutory bodies. 6.3.3 Develop a process to prepare a clinical trial master file and all required documents. 6.3.4 Implement and monitor all the relevant aspects of the clinical trial protocols throughout the respective studies.

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South African Pharmacy Council

COMPETENCY STANDARDS FOR A PHARMACIST WHO PROVIDES RADIOPHARMACEUTICAL SERVICES IN SOUTH AFRICA

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ACRONYMS

The following acronyms have been included however, the list is not exhaustive.

CAPA: Corrective Action and Preventative Action

cGRPP: current Good Radiopharmacy Practice

GMCP: Good Medicine Compounding Practices

GMP: Good Manufacturing Practice

GxP: Good Practice Guidelines and Regulations, e.g., Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Wholesaling Practice (GWP), Good Radiopharmacy Practice (GRPP) and other pharmaceutical practices

IAEA: International Atomic Energy Agency

ISORBE: International Society of Radiolabelled Blood Elements

SOP: Standard Operating Procedure

DEFINITIONS

The following definitions have been included; however, the list is not exhaustive:

"Change control report" is a document that records the process of coordinated activities through which a desired change is implemented in an existing function, process, or product in the pharmaceutical industry.

"Medical Devices" means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings and animals for one or more specific medical purposes.

"Nuclear Medicine" means a medical speciality that uses radioactive tracers (radiopharmaceuticals) to assess bodily functions and to diagnose and treat disease.

"Radionuclides" An unstable form of a chemical element that releases radiation as it breaks down and becomes more stable.

"Radiopharmaceutical" means any medicinal product which when ready for use contains one or more radionuclides included for medicinal purposes.

"Radiopharmacist" means a pharmacist registered with the South African Pharmacy Council (hereafter "Council") to offer radiopharmaceutical services.

"Specialist Pharmacist" means a pharmacist who is registered as such in terms of the Pharmacy Act, 53 of 1974 ("the Act").

"Speciality" means a specialist qualification in one of the fields of pharmacy approved and published in rules made by Council.

1. INTRODUCTION

A radiopharmacist is a pharmacist registered with Council with a designation of "practising", who is a specialist in the field of radiopharmacy and is involved in the manufacturing, formulation, dispensing and distribution of radioactive compounds. These are specialised medicinal items which may be harmful if not correctly used or controlled. Radiopharmacists need to accept responsibility for their self-development and assessment of continued competence throughout their professional working lives and ensure that they train all the individuals involved in the distribution and utilisation of radiopharmaceuticals.

Part of the radiopharmacist's duty is to develop, monitor and maintain the quality management system in the manufacturing, compounding, supply and distribution of radiopharmaceuticals in accordance with Guidelines for Good Manufacturing Practice (GMP) and Good Medicine Compounding Practice (GMCP) as published by the South African Health Products Regulatory Authority (SAHPRA).

2. BACKGROUND

In 2018, Council published the reviewed competency standards for Pharmacists. Competency standards have been developed and used as the basis for pharmacy education and practice since 2006. The competency standards for a pharmacist providing radiopharmaceutical services are based on the competency standards for pharmacists. The scope of practice of a pharmacist providing radiopharmaceutical services was considered in the development of these competency standards.

2.1 THE SCOPE OF PRACTICE OF A RADIOPHARMACIST

In addition to the acts and services which form part of the scope of practice of a pharmacist as prescribed in terms of Regulations 3 and 4 of the *Regulations relating to the practice of pharmacy*, a pharmacist who has completed a master's degree in Radiopharmacy must be allowed to provide the following services or acts pertaining to the scope of practice of a radiopharmacist:

(a) Take a leading pharmaceutical role in protocol and guideline development for the use of radiopharmaceuticals in nuclear medicine.

(b) Act as a leading pharmaceutical partner within a multi-professional health care team in nuclear medicine;

(c) Develop, implement, evaluate and provide strategic leadership for radiopharmaceutical services;

(d) Appraise information, make informed decisions regarding the supply and use of radiopharmaceuticals with the evidence available and be able to justify/defend the decisions;

(e) Develop policies and procedures specifically for the speciality area;

(f) Provide education and training related to radiopharmacy; and

(g) Perform research, teach and publish articles related to radiopharmacy.

3. RATIONALE FOR THE DEVELOPMENT OF COMPETENCY STANDARDS FOR RADIOPHARMACIST

Radiopharmacists are experts in radiopharmaceuticals for diagnostic and therapeutic purposes and are, thus, required to keep abreast with new treatment and diagnostic trends. The competency standards have been developed to encompass the changes and developments including new technologies, work processes, changes in legislation and international trends. This is done to ensure the production of quality, safe and efficacious radiopharmaceuticals and the promotion of proper medicine usage for improved health outcomes.

4. REGISTRATION OF RADIOPHARMACISTS

Radiopharmacists are obliged to be registered with Council for the purposes of offering the acts related to their scope of practice as follows:

(a) Specialist pharmacist student.

(b) Specialist pharmacist resident.

(c) Specialist pharmacist.

5. QUALIFICATIONS OF A RADIOPHARMACIST

For purposes of registration as a radiopharmacist, a pharmacist must have obtained -

(a) a professional master's degree in Radiopharmacy as determined by Council and published from time to time; or

(b) a qualification deemed to be equivalent or higher than the professional master's degree in radiopharmacy as assessed by Council.

6. STRUCTURE OF THE COMPETENCY STANDARDS AND DOMAINS

A competency framework consisting of six (6) domains suitable for the South African context was developed, together with several associated competencies. A domain represents an organised cluster of competencies within a framework and the domains with associated competencies are summarised in Table 1. The behavioural statements indicating how individuals working within the competency framework should behave in practice have also been drafted.

TABLE 1: SUMMARY OF RADIOPHARMACY COMPETENCY STANDARDS

DOMAIN	COMPETENCY STANDARD
4. Public Health	4.1 Promotion of radiopharmaceutical services.
5. Safe and rational use of radiopharmaceuticals and medical devices	5.1 Knowledge and understanding of the pharmacology and biodistribution of radiopharmaceuticals. 5.2 Knowledge and understanding of radiopharmaceuticals and medical device safety.
6. Supply of radiopharmaceuticals and medical devices	3.3 Manufacturing of radiopharmaceuticals. 3.4 Compounding of radiopharmaceuticals. 3.5 Supply chain management. 3.6 Radiopharmaceutical dispensing.
7. Quality management in radiopharmacy	7.1 Quality assurance. 7.2 Pharmaceutical infrastructure management.
8. Professional and personal practice	8.1 Good record keeping. 8.2 Clinical application of radiopharmaceuticals. 8.3 Professional practice.
9. Education, training and research	9.1 Provision of education and training. 9.2 Practice embedded education or workplace education. 9.3 Research.

DOMAIN 1: PUBLIC HEALTH

INTRODUCTION

This domain covers competencies that are required to promote radiopharmaceutical services. Participation of pharmacists in the promotion of public health utilising radiopharmaceuticals requires the following competency:

1.3 Promotion of radiopharmaceutical services.

DOMAIN 1: PUBLIC HEALTH	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
1.3 Promotion of radiopharmaceutical services.	1.3.1 Develop, monitor, and maintain radiopharmaceutical services. 1.3.2 Demonstrate qualities to improve performance and manage radiopharmaceutical services. 1.3.3 Encourage good radiopharmacy practice. 1.3.4 Promote continuous updates of core competencies by other related healthcare professionals.

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

INTRODUCTION

Radiopharmacists must have knowledge of the procedures and operations relating to the safe and rational use of radiopharmaceuticals. The competencies required in the domain for safe and rational use of radiopharmaceuticals are:

2.1 Knowledge and understanding of the pharmacology and biodistribution of radiopharmaceuticals; and

2.2 Knowledge and understanding of radiopharmaceutical and medical device safety.

DOMAIN 2: SAFE AND RATIONAL USE OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
2.3 Knowledge and understanding of the pharmacology and biodistribution of radiopharmaceuticals.	2.3.1 Evaluate the administration of radionuclides and radiopharmaceuticals as part of the holistic patient care, where applicable. 2.3.2 Evaluate the clinical use of radionuclides and radiopharmaceuticals. 2.3.3 Demonstrate an understanding of the different types of radiopharmaceuticals used for diagnosis and therapy. 2.3.4 Understand the pharmacokinetic and pharmacodynamic principles in patient management with radiopharmaceuticals. 2.3.5 Understand the biodistribution of radiopharmaceuticals. 2.3.6 Advise on the provision of effective and cost-effective radiopharmaceuticals. 2.3.7 Understand the various routes of administration of radionuclides and radiopharmaceuticals. 2.3.8 Appraise the clinical use of radionuclides and radiopharmaceuticals.

DOMAIN 2: SAFE AND RATIONAL USE OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
2.4 Knowledge and understanding of radiopharmaceutical and medical device safety.	2.4.1 Promote safe handling of radiopharmaceuticals. 2.4.2 Identify, classify, and analyse the various types of radiopharmaceuticals, their side effects, and toxicities. 2.4.3 Demonstrate and apply principles ensuring the safe use of radionuclides and radiopharmaceuticals. 2.4.4 Demonstrate and apply principles ensuring the safe storage, distribution and disposal of radionuclides and radiopharmaceuticals. 2.4.5 Demonstrate the practical implementation of radiation safety principles. 2.4.6 Manage programmes in the radiopharmacy to minimise risks of radioactive contamination.

DOMAIN 3: SUPPLY OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES

INTRODUCTION

A radiopharmacist plays an important role in the supply of radiopharmaceutical medicines by ensuring that relevant policies, procedures, and legislation are followed in the manufacturing, compounding, and dispensing of radiopharmaceuticals. The competencies required in the domain to supply radiopharmaceuticals and medical devices are as follows:

3.1 Radiopharmaceutical production.

3.2 Radiopharmaceutical compounding.

3.3 Supply chain management.

3.4 Radiopharmaceutical dispensing.

DOMAIN 3: SUPPLY OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
3.3 Radiopharmaceutical production (Large scale manufacturing)	3.3.1 Demonstrate and understand the manufacturing of radiopharmaceuticals. 3.3.2 Manufacture radiopharmaceuticals in accordance with GMP. 3.3.3 Implement a manufacturing process to ensure the stability of radiopharmaceuticals throughout their shelf-life. 3.1.4 Demonstrate and understand how to manufacture radiopharmaceuticals using synthesis modules.
3.4 Medicine compounding (Small-scale manufacturing in centralised and hospital radiopharmacies)	3.2.1 Implement aseptic preparation of radiopharmaceuticals. 3.2.2 Manage the preparation and labelling of radioactive blood products according to prescribed protocols. 3.2.3 Demonstrate and apply the necessary knowledge to perform generator elution. 3.2.4 Demonstrate an in-depth knowledge of the safe compounding of radiopharmaceuticals from kits and generators. 3.2.5 Demonstrate knowledge of the use of synthesis modules in the compounding of radiopharmaceuticals. 3.2.6 Ensure that the radiopharmaceutical product is sterile. 3.2.7 Understand the IAEA operational levels for hospital radiopharmacies.

DOMAIN 3: SUPPLY OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
3.5 Supply chain management	3.3.1 Design a laboratory area for use as a radiopharmacy. 3.3.2 Ensure that the sterility and stability of radiopharmaceuticals are maintained throughout the supply chain. 3.3.3 Maintain an inventory of radiopharmaceuticals. 3.3.4 Maintain an inventory of non-radioactive kits, starting materials and reference standards.
3.6 Radiopharmaceutical dispensing	3.6.1 Evaluate orders and prescriptions and ensure that correct calculations are used to dispense the required radiopharmaceutical quantity or dose. 3.6.2 Manage, organise, and prioritise the dispensing of radiopharmaceuticals according to the relevant legislation. 3.6.3 Manage the preparation and distribution of radiopharmaceuticals in bulk form. 3.6.4 Dispense and distribute individualised patient doses in accordance with GMCP.

DOMAIN 4: QUALITY MANAGEMENT IN RADIOPHARMACY

INTRODUCTION

Radiopharmaceuticals must be handled with care to ensure their safety and efficacy. The competencies required in this domain which relates to the implementation of quality management in radiopharmacy according to the applicable guidelines, are as follows:

4.1 Quality assurance.

4.2 Pharmaceutical infrastructure management.

DOMAIN 4: QUALITY MANAGEMENT IN RADIOPHARMACY	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
4.1 Quality assurance	4.1.1 Develop, implement, and maintain a comprehensive radiopharmaceutical Quality Management System (QMS) to ensure the quality, safety and efficacy of the radiopharmaceuticals including the drafting and review of - (a) SOPs. (b) change control reports, (c) risk assessments, and (d) guidance documents. 4.1.2 Identify and investigate deviations and create CAPAs. 4.1.3 Demonstrate and understand analytical methods and instruments used in the quality control of radiopharmaceuticals. 4.1.4 Develop, implement, and maintain validation processes.
4.2 Pharmaceutical infrastructure management	4.2.1 Design, implement and manage a radiopharmacy environmental monitoring system. 4.2.2 Implement a programme for the maintenance of equipment used in the manufacturing and compounding of radiopharmaceuticals. 4.2.3 Implement a programme for the maintenance of equipment used in the quality control of radiopharmaceuticals. 4.2.4 Implement a programme for the maintenance of the radiopharmacy facility including the air handling unit.

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE

INTRODUCTION

The competencies required in the domain to ensure good personal and professional practice are:

5.4 Good record keeping.

5.5 Clinical application of radiopharmaceuticals.

5.6 Professional practice.

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
5.4 Good record keeping	5.4.1 Develop a patient and prescriber administration and ordering system. 5.4.2 Maintain and review records in accordance with GMCP, GMP, GRPP and relevant legislation. 5.4.3 Manage record systems for the preparation of radiopharmaceuticals. 5.4.4 Manage radiopharmacy cleaning records. 5.4.5 Manage record systems for the manufacturing of radiopharmaceuticals. 5.4.6 Manage records for the quality control of radiopharmaceuticals.
5.5 Clinical application of radiopharmaceuticals	5.2.3 Demonstrate an in-depth knowledge of various radiopharmaceutical drug interactions and contraindications. 5.2.4 Advise other healthcare professionals on adverse drug-drug interactions. 5.2.5 Advise other healthcare professionals on adverse drug-food reactions. 5.2.6 Advise other healthcare professionals on radiopharmaceutical contraindications where applicable. 5.2.7 Demonstrate an in-depth knowledge of the use of radiopharmaceuticals in nuclear medicine.
5.6 Professional practice	5.6.1 Develop and monitor protocols to ensure that the radiopharmacy operates in line with the current GMP or GMCP, as applicable. 5.6.2 Contribute to the review and development of GMP and GMCP. 5.6.3 Demonstrate knowledge of the GMP and GMCP processes for radiopharmaceuticals. 5.6.4 Play an active role as a member of the nuclear medicine healthcare team.

DOMAIN 6: EDUCATION, TRAINING AND RESEARCH

INTRODUCTION

Education is essential for the initial development of pharmacists and is required throughout a pharmacist's career to maintain currency on knowledge, skills, attitudes, and values. Pharmacists should participate in the education and training of patients and other healthcare practitioners.

Pharmacists should critically evaluate information sources, literature and research on medicines and practice in terms of evidence for decision-making and implementation in practice. Pharmacists should participate in practice-based research and, where applicable, publish research in the radiopharmaceutical field. The domain includes behavioural statements relating to education, training, and research in a radiopharmaceutical setting. The competencies required in the domain are:

6.1 Provision of education and training.

6.2 Practice embedded education or workplace education.

6.3 Research.

DOMAIN 6: EDUCATION, TRAINING AND RESEARCH	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
6.1 Practice embedded education or workplace education	6.1.8 Develop training policies on radiopharmacy. 6.1.9 Tutor specialist pharmacist residents in radiopharmacy. 6.1.10 Provide training on the role of radiopharmacy in nuclear medicine, in diagnosis and therapy, to the healthcare team.
6.2 Provision of education and training	6.2.5 Assess the performance and learning needs of the radiopharmacy team members. 6.2.6 Plan a series of effective learning experiences for radiopharmacy team members and other healthcare professionals.
6.3 Research	6.3.1 Contribute scientifically to – (a) clinical and pre-clinical trials; (b) the development of new radiopharmaceuticals; (c) the development of new manufacturing and compounding procedures for radiopharmaceuticals; and (d) the development of new quality control methods for radiopharmaceuticals. 6.3.2 Publish articles on research findings and present research findings at relevant fora.

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South African Pharmacy Council

COMPETENCY STANDARDS FOR A PHARMACIST WHO PROVIDES CLINICAL PHARMACEUTICAL SERVICES IN SOUTH AFRICA

TABLE OF CONTENTS

ACRONYMS

The following acronyms have been included; however, the list is not exhaustive –

CAPA: Corrective Action and Preventative Action

GCP: Good Clinical Practice

GXP: Good Practice Guidelines and Regulations, e.g., Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Wholesaling Practice (GWP) and Good Radiopharmacy Practice (GRPP) and other pharmaceutical practices

HTA: Health Technology Assessment

IPC: Infection, Prevention and Control

IVDs: *In-vitro* Diagnostics

PTC: Pharmacy and Therapeutics Committee

SOP: Standard Operating Procedure

TDM: Therapeutic Drug Monitoring

UHC: Universal Health Coverage

DEFINITIONS

"Change control report" is a document that records the process of coordinated activities through which a desired change is implemented in an existing function, process, or product in the pharmaceutical industry.

"Clinical Pharmacist" a pharmacist registered with the South African Pharmacy Council (hereafter "Council") to offer clinical pharmacy services.

"Specialist pharmacist" means a pharmacist who is registered as such in terms of the Pharmacy Act, 53 or 1974 ("the Act").

"Speciality" means a specialist qualification in one of the fields of pharmacy approved and published in rules made by Council.

For purposes of this document, the terms drug and medicine are used interchangeably.

1. INTRODUCTION

Clinical pharmacy is aimed at the development and promotion of rational and appropriate use of medicines and pharmaceutical care, in the interest of the patient and the community. Patients with advanced disease have multiple symptoms, and treatment becomes complicated. This makes it difficult for patients and/or their carers to manage their medicines which leads to symptoms being inadequately controlled and a low level of therapeutic compliance. Pharmacists have the responsibility to identify, resolve, and prevent each patient's therapeutic problems. These responsibilities are met by using the caring paradigm in a patient-centred manner.

Pharmaceutical care mandates that pharmacists should not only dispense medicines but also assume the responsibility of improving the quality of life of patients and improving therapy outcomes.

Pharmaceutical care within a clinical pharmacy context involves the implementation of the following steps:

- Assessment of patient health and formulation of treatment plans.
- Monitoring of patient's response to therapy to ensure optimum therapeutic outcomes.
- Performing medicine reviews to detect and resolve medicine-related problems.
- Documentation of the care provided and provision of advice to patients in a way that patients understand.

2. BACKGROUND

In 2018, the South African Pharmacy Council published the reviewed competency standards for Pharmacists. Competency standards had been developed and used as the basis for pharmacy education and practice since 2006. The competency standards for a pharmacist providing clinical pharmacy services are based on the competency standards for pharmacists. These competency standards for a clinical pharmacist are developed to encompass the scope of practice of a clinical pharmacist as a specialist pharmacist.

2.1 THE SCOPE OF PRACTICE FOR A CLINICAL PHARMACIST

In addition to the acts and services which form part of the scope of practice of the pharmacist as prescribed in terms of Regulations 3 and 4 of the *Regulations relating to the practice of pharmacy*; a pharmacist who has completed a master's degree in Clinical Pharmacy must be allowed to provide the following services or acts pertaining to the scope of practice of a clinical pharmacist:

(a) Provide advanced clinical services to medical specialities;

(b) Take a pharmaceutical leadership role in clinical protocol and guideline development;

(c) Lead clinical audits of medicine use;

(d) Act as a leading pharmaceutical partner within a multi-professional health care team;

(e) Develop, implement, evaluate and provide strategic leadership for clinical pharmacy services;

(f) Appraise clinical pharmacy information, make informed decisions with the evidence available and be able to justify/defend the decisions;

(g) Develop policies and procedures specifically for clinical pharmacy;

(h) Provide education and training related to clinical pharmacy; or

(i) Perform research, teach, and publish in clinical pharmacy.

3. RATIONALE FOR THE DEVELOPMENT OF COMPETENCY STANDARDS FOR A CLINICAL PHARMACIST

The rationale is to train advanced-level clinical pharmacists who are able to register with Council as specialists. This will contribute to capacity building in the field of clinical pharmacy and create specialists in the field of pharmacy, for the advancement of health care in South Africa in line with Universal Health Coverage (UHC).

In addition, according to Van Mil (2004): "*If we want to try to prove that the structured provision of pharmaceutical care has an effect on outcomes, we must first of all make sure that the care provided matches the needs of the patients in that specific health system".*

Historically, the role of the pharmacist, regardless of the health setting, was to ensure prompt and efficient medicine supply, adequate stock, accurate dispensing, compounding, storage and transport, and to ensure that medicines are easily accessible to patients who need them. The pharmacist is also responsible for the selection of medicines, dosage forms, and monitoring of patient compliance.

Clinical pharmacists are required to understand the provision of pharmaceutical care that matches the patient's specific health needs. These pharmacists focus on disease prevention and treatment, including evidence-based medicine use and related care that improve both short- and long-term outcomes for patients.

The competency standards have been developed to encompass the changes and developments including new technologies, work processes, changes in legislation and international trends, primarily to ensure the production and promotion of prudent and proper medicine usage and pharmaceutical care, in the patient's and the public's best interests.

4. REGISTRATION OF CLINICAL PHARMACISTS

Clinical Pharmacists are obliged to be registered with Council for the purposes of offering the acts related to their scope of practice as follows:

(a) Specialist pharmacist student.

(b) Specialist pharmacist resident.

(c) Specialist pharmacist.

5. QUALIFICATIONS OF A CLINICAL PHARMACIST

For purposes of registration as a clinical pharmacist, a pharmacist must have obtained -

(c) a professional master's degree in clinical pharmacy as determined by Council and published from time to time, or

(d) a qualification deemed to be equivalent or higher than the professional master's degree in clinical pharmacy as assessed by Council.

6. STRUCTURE OF THE COMPETENCY STANDARDS AND DOMAINS

A competency framework consisting of six (6) domains suitable for the South African context was developed together with several associated competencies. A domain represents an organised cluster of competencies within a framework and the domains with associated competencies, are summarised in Table 1. The behavioural statements indicating how individuals working within a competency framework should behave in practice have also been drafted.

TABLE 1: SUMMARY OF CLINICAL PHARMACY COMPETENCY STANDARDS

DOMAIN	COMPETENCY STANDARD
7. Public Health	7.1 Promotion of clinical pharmacy services. 7.2 Pharmacoeconomics.
8. Safe and rational use of Medicine and Medical devices	8.1 Patient consulting. 8.2 Patient medicines review and management. 8.3 Medicines, medical devices and IVD safety.
9. Supply of Medicines and Medical devices	3.7 Medicine compounding. 3.8 Supply chain management. 3.9 Medicine dispensing.
10. Quality management in Clinical Pharmacy	10.1 Quality assurance. 10.2 Pharmaceutical infrastructure management.
11. Professional and Personal Practice	11.1 Good record keeping. 11.2 Patient-centred care. 11.3 Professional practice. 11.4 Continuing professional development.
12. Education, training, and research	12.1 Provision of education and training. 12.2 Practice embedded education or workplace education. 12.3 Clinical Trials. 12.4 Research.

DOMAIN 1: PUBLIC HEALTH

INTRODUCTION

The domain covers competencies that are required to promote clinical pharmacy services. Participation of pharmacists in the promotion of public health utilising clinical pharmacy entails the following competencies:

1.4 Promotion of clinical pharmacy services.

1.5 Pharmacoeconomics.

DOMAIN 1: PUBLIC HEALTH	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
1.4 Promotion of clinical pharmacy services.	1.1.1 Demonstrating an ability to develop, implement and monitor health systems for the promotion of public health through the safe and effective use of medicine and medical devices. 1.1.2 Develop, monitor, and maintain clinical pharmacy services. 1.1.3 Demonstrate qualities to improve the performance of and manage clinical pharmacy services. 1.1.4 Encourage good clinical pharmacy practice.
1.2 Pharmacoeconomics	1.2.1 Monitor and maintain cost-effective utilisation of medicines as part of a healthcare team. 1.2.2 Demonstrate an ability to develop, monitor and maintain health systems to ensure the rational and cost-effective use of medicines in accordance with the burden of disease.

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

INTRODUCTION

Clinical Pharmacists must have the knowledge of procedures and operations relating to the safe and rational use of medicine and medical devices to ensure appropriate therapeutic assessments and decisions including medicine therapy. The competencies required in the domain of safe and rational use of medicines are:

2.3 Patient consultation.

2.4 Patient medicines review and management.

2.5 Medicines, medical devices and in vitro diagnostics (IVDs) safety.

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
2.5 Patient consultation	2.5.1 Demonstrate the ability to - (a) use medical devices and IVDs to evaluate clinical parameters; (b) formulate, maintain and evaluate pharmaceutical care plans; (c) counsel patients to optimise and individualise their treatment outcomes. (d) develop and review patients' medical histories; and (e) develop, monitor and review the pharmaceutical care plan.
2.6 Patient medicines review and management	2.6.1 Demonstrate the ability to - (a) develop, implement and monitor medicine regimens that incorporate the pharmacodynamic, pharmacogenomic and pharmacokinetic properties of medicines. (b) implement health systems that allow for the monitoring of patient treatment plans and assessment of medicine and medical device use. 2.6.2 Ensure safe and effective medicine use with optimal therapy outcomes. 2.6.3 Monitor and report on therapeutic outcomes.
2.7 Medicines, medical devices and IVD safety	2.7.1 Promote safe handling of medicines, medical devices and IVDs. 2.7.2 Demonstrate and apply safe disposal/destruction of medicines and diagnostic equipment. 2.7.3 Manage the infection, prevention and control (IPC) programmes in the clinical pharmacy to minimise risks of contamination.

DOMAIN 3: SUPPLY OF MEDICINES, MEDICAL DEVICES AND IVDS

INTRODUCTION

The Clinical Pharmacist plays an important part in the supply of clinical pharmacy services by ensuring that patients receive individualised doses in accordance with their therapy charts, taking into consideration their disease states, laboratory results and genetics. The competencies required in the domain to supply medicines and medical devices are as follows:

9.1 Medicine compounding.

9.2 Supply chain management.

3.3 Medicine dispensing.

DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
3.7 Medicine compounding	3.7.1 Manage the preparation of individualised patient doses by ensuring accurate dosing calculations. 3.7.2 Ensure safe compounding of medicines to meet individualised patient needs according to GMCP. 3.7.3 Ensure that compounded medicines meet the quality, safety and environmental control requirements. 3.7.4 Monitor the safe and effective use of compounded medicine by patients. 3.7.5 Utilise basic and/or advanced TDM to ensure safe and effective dosing alterations.
3.8 Supply chain management	3.8.1 Develop, maintain and monitor systems for the provision of patient-centred medicine therapy management. 3.8.2 Demonstrate the ability to design the pharmacy area for the provision of clinical pharmaceutical care. 3.8.3 Manage the storage and transportation of compounded medicine in accordance with GxP.
3.9 Medicine dispensing	3.9.1 Evaluate a patient's prescription and ensure that an appropriate pharmaceutical care plan is developed. 3.9.2 Implement and monitor the implementation of the plan (including the monitoring of personalised medicine treatment plans for patients).

DOMAIN 4: QUALITY MANAGEMENT IN CLINICAL PHARMACY

INTRODUCTION

The competencies required in this domain implement quality management in clinical pharmacy according to GxP as follows:

4.3 Quality assurance.

4.4 Pharmaceutical infrastructure management.

DOMAIN 4: QUALITY MANAGEMENT IN CLINICAL PHARMACY	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
4.3 Quality assurance	4.3.1 Develop, implement, and maintain a comprehensive clinical pharmacy system to ensure the quality, safety and efficacy of the pharmaceutical services including writing and reviewing: (e) SOPs; (f) change control reports; (g) risk assessments; and (h) guidance documents. 4.3.2 Raise and investigate deviations and create CAPAs.
4.4 Pharmaceutical infrastructure management	4.4.1 Design, implement and manage a clinical pharmacy monitoring system.

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE

INTRODUCTION

The competencies required in the domain to ensure good personal and professional practice are:

5.7 Good record keeping.

5.8 Patient-centred care.

5.9 Professional practice.

5.10 Continuing professional development.

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
5.7 Good record keeping	5.7.1 Ensure the maintenance and review of patient records in accordance with relevant legislation. 5.7.2 Develop, implement and maintain records for training and assessment of healthcare teams. 5.7.3 Maintain a portfolio of evidence related to clinical pharmacy services.
5.8 Patient-centred care	5.2.8 Review, appraise and evaluate the pharmaceutical care concept against the patient's medical history. 5.2.9 Demonstrate and apply in-depth knowledge of various drug mechanisms of action, indications, adverse reactions and interactions. 5.2.10 Develop, monitor and evaluate patient care plans in line with the patient's ongoing therapy. 5.2.11 Provide direct patient care including the treatment and monitoring of potential adverse drug-food reactions within a multi-disciplinary team. 5.2.12 Provide clinical care to patients receiving specialised nutrition support. 5.2.13 Formulate and implement non-pharmaceutical measures including lifestyle modifications.
5.9 Professional practice	5.9.1 Develop and monitor clinical protocols as required and mandated. 5.9.2 Demonstrate knowledge of the legislation, guidelines, and procedures for clinical pharmacy. 5.9.3 Contribute to the review and development of legislation, policies and guidelines relating to clinical pharmacy. 5.9.4 Perform HTAs and apply rational medicine use at the PTC level. 5.9.5 Demonstrate the ability to assist patients dealing with trauma, death and bereavement. 5.9.6 Effectively communicate with patients within the multidisciplinary team. 5.9.7 Effectively communicate with members of the multidisciplinary team.

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
5.10 Continuing professional development	5.10.1 Develop, implement and maintain continuous professional evidence of training and assessment. 5.10.2 Identify knowledge and skills gaps to advance the role of a clinical pharmacist. 5.10.3 Develop a personal development plan to keep abreast with the provision of pharmaceutical services as a clinical pharmacist. 5.10.4 Keep abreast with the current clinical pharmacy guidelines. 5.10.5 Demonstrate the ability to provide and receive peer reviews.

DOMAIN 6: EDUCATION, TRAINING AND RESEARCH

INTRODUCTION

Education is essential for the initial development of Clinical Pharmacists and is required throughout their careers to maintain currency on knowledge, skills, attitudes, and values. Clinical pharmacists should participate in the education and training of patients and other healthcare practitioners.

Critical evaluation of information sources, literature and research on medicines and practice in terms of evidence for decision-making and implementation in practice. The domain includes behavioural statements relating to education, training, and research in a clinical pharmacy setting. The competencies required in the domain are:

6.1 Practice embedded education or workplace education.

6.2 Provision of education and training.

6.3 Clinical Trials.

6.4 Research.

DOMAIN 6: EDUCATION, TRAINING AND RESEARCH	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
6.3 Practice embedded education or workplace education	6.1.11 Develop, implement and monitor training policies in clinical pharmacy. 6.1.12 Demonstrate the ability to supervise the training of clinical pharmacists in accordance with approved treatment or clinical guidelines. 6.1.13 Provide training on the role of a clinical pharmacist in patient care to the healthcare team, patients, and caregivers.
6.4 Provision and oversight of education and training	6.3.1 Develop, implement and maintain training systems for the clinical pharmacy team. 6.3.2 Assess the performance and learning needs of the clinical pharmacy team. 6.3.3 Plan a series of effective learning experiences for the clinical care team including other health care professionals. 6.3.4 Provide technical coaching, support, and training to the clinical pharmacy team and other health care professionals. 6.3.5 Provide specialist clinical advice on a broad range of clinical pharmacy services.
6.5 Clinical Trials	6.3.1 Identify, develop, implement and monitor all phases of clinical trials. 6.3.2 Develop a clinical trial plan including the identification, screening and selection of the clinical trial participants. 6.3.3 Participate as a member of the clinical trial team.

DOMAIN 6: EDUCATION, TRAINING AND RESEARCH	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
6.6 Research	12.4.1 Critically evaluate information sources, literature and research on medicines and practices in terms of evidence for decision-making and implementation in practice. 12.4.2 Apply the principles of research methodology in the development of a research protocol. Obtain ethical clearance if necessary. 12.4.3 Conduct research in accordance with established research methodology and ethics, as well as GCP where necessary. 12.4.4 Analyse data, interpret findings and/or results and formulate conclusions and recommendations. 12.4.5 Write and submit a technical report, manuscript for publication or minor dissertation based on the research outcomes with the necessary approvals.

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