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SOUTH AFRICAN PHARMACY COUNCIL

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

The South African Pharmacy Council hereby publishes for **implementation**, the **Competency standards for a specialist pharmacist who provides industrial pharmaceutical services in South Africa** in terms of Sections 33(o) of the Pharmacy Act, 53 of 1974.

SCHEDULE

(a) Competency standards for a specialist pharmacist who provides industrial pharmaceutical services in South Africa

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

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ACRONYMS

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;

DEFINITIONS

Specialist Pharmacist:	a pharmacist who is registered as such in terms of the Pharmacy Act, 53 of 1974 (the Act);
Speciality:	a specialist qualification in one of the fields of pharmacy approved and published in rules made by Council; and
Industrial Pharmacist:	a pharmacist registered with Council to offer Industrial pharmaceutical services.

INTRODUCTION

An industrial pharmacist is a pharmacist registered with 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 (hereinafter referred to as “products”). The industrial pharmacist is responsible for developing, monitoring and maintaining compliance to the quality management system. The industrial pharmacist must ensure that the quality of products is maintained throughout the distribution chain.

BACKGROUND

In 2018, the South African Pharmacy Council published Competency Standards for Pharmacists. Competency Standards have 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 manufacture of medicine, warehousing and supply chain management.

(e) Design, develop and interpret quality systems for implementation of Good Manufacturing Practices.

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

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

(h) Take a leading role in pharmaceutical research and development;

(i) Take a leading role in the development of and contribution to regulatory guidelines and relevant legislation; and

(j) Appraise pharmaceutical information, make informed decisions with the evidence available and be able to justify/defend the decision.

RATIONALE FOR 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 to ensure the production of quality, safe and efficacious medicines and 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. 2.3 Pharmaceutical infrastructure management.
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.
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 improving 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 Pharmacoeconomic interventions.

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 products 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. 1.2.3 Manage activities related to the development and submission of value proposition dossiers to applicable stakeholders.

DOMAIN 2: DESIGN AND MAINTENANCE OF FACILITIES

INTRODUCTION

Industrial pharmacists must have 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 the warehousing and distribution facility comply 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.
2.3 Pharmaceutical infrastructure management.	2.3.1 Develop and maintain quality management systems for the design and maintenance of pharmaceutical manufacturing facilities. 2.3.2 Develop and maintain quality management systems for the design and maintenance of pharmaceutical wholesaling facilities. 2.3.3 Develop and monitor compliance with health and safety policies.

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 specification 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 practices.

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.

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.
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 ensure ongoing compliance with post-marketing surveillance requirements.

DOMAIN 6: RESEARCH AND DEVELOPMENT

INTRODUCTION

Research and development are essential for the initial development of medicines and medical devices and are 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 improving 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 improving 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.