BOARD NOTICES • RAADSKENNISGEWINGS

BOARD NOTICE 814 OF 2025

SOUTH AFRICAN PHARMACY COUNCIL

QUALIFICATIONS FOR SPECIALIST PHARMACISTS IN SOUTH AFRICA

The South African Pharmacy Council hereby publishes, in terms of Section 33(1)(e) and 31(1)(p) of the Pharmacy Act, 53 of 1974, the **Professional Master's Degree Qualifications and Curriculum Outlines for Specialists in Pharmacy**.

SCHEDULE

(a) Specialist in Pharmacy: Radiopharmacy

(b) Specialist in Pharmacy: Clinical Pharmacy

(c) Specialist in Pharmacy: Industrial Pharmacy

(d) Specialist in Pharmacy: Public Health Pharmacy

VM TLALA
REGISTRAR/CEO

Address: 591 Belvedere Street, Arcadia, Pretoria, 0083,
Private Bag X40040, Arcadia, 0007. Telephone: 0861 7272 00

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

South African
Pharmacy Council

Professional Master's Degree
Qualification and Curriculum Outline

for the

Specialist in Pharmacy: Radiopharmacy

CONTENTS

SYNOPSIS: 1

QUALIFICATION OUTLINE: 2

1. QUALIFICATION TITLE: 2

2. QUALIFICATION TYPE: 2

3. FIELD AND SUB-FIELD: 2

4. LEVEL: 2

5. CREDITS: 2

6. RATIONALE FOR THE QUALIFICATION: 2

7. PURPOSE: 3

8. RULES OF COMBINATION: 4

9. ACCESS TO THE QUALIFICATION: 4

10. LEARNING ASSUMED TO BE IN PLACE: 4

11. EXIT LEVEL OUTCOMES AND THEIR ASSOCIATED ASSESSMENT CRITERIA: 4

12. CRITICAL CROSS-FIELD OUTCOMES: 16

13. INTERNATIONAL COMPARABILITY: 16

14. INTEGRATED ASSESSMENT: 18

15. CREDIT ACCUMULATION AND TRANSFER: 18

16. ARTICULATION (PROGRESSION): 19

17. MODERATION OPTIONS: 19

18. CRITERIA FOR THE APPOINTMENT OF ASSESSORS: 19

19. NOTES: 19

APPENDIX A 20

LIST OF TABLES

Table 1: Summary of the proposed qualification 1

Table 2: Curriculum Outline 5

SYNOPSIS:

To provide a curriculum for a professional Master's Degree in Radiopharmacy, to enable students to register with the South African Pharmacy Council (hereafter referred to as "Council") as specialists with a post-qualification that complies with Council's requirements.

Table 1: Summary of the proposed qualification

	Professional Master's Degree in Radiopharmacy
Duration:	Two (2) years
Entry criteria:	Bachelor's Degree in Pharmacy
HEQF-level:	Level 9
Field (CESM):	09 Health Sciences and Social Services
Sub-field:	Curative Health
SAQA credits:	360 credits
Qualification type:	Professional, exit-level, career-orientated, whole qualification
Final assessment and evaluation:	• Final, exit-level examination(s) will need to be passed in accordance with the relevant Higher Education provider's rules and regulations. • In addition, a comprehensive portfolio of evidence will need to be submitted and successfully passed by the accredited provider. • Requirements for registration as a specialist after obtaining the professional Master's Degree are presented in Appendix A to this document.
CPD requirements for annual re-registration:	As required by Council
Professional status:	Registration with Council as a practising Radiopharmacist
Articulation:	DPharm/Doctoral Degree

QUALIFICATION OUTLINE

1. QUALIFICATION TITLE

Master of Pharmacy in Radiopharmacy

Abbreviation: MPharm (Radiopharmacy)

2. QUALIFICATION TYPE

Professional Master's Degree

3. FIELD AND SUB-FIELD

Field: [09] Health Sciences and Social Services

Sub-field: Curative Health

4. LEVEL

NQF/HEQF Level 9 (Master's Degree)

5. CREDITS

Total credits: 240

6. RATIONALE FOR THE QUALIFICATION

A shortage of Radiopharmacists has been identified in South Africa and in Africa as a whole. Currently, there are only two (2) Council-registered specialist Radiopharmacists in South Africa.

Radiopharmaceuticals are used in the diagnosis and treatment of many end-stage organ diseases and life-threatening conditions such as major cardiac, renal, endocrine and cerebral disorders, as well as cancers and obscure infections. Their use is growing as they are key agents in the newer diagnostic modalities such as Single Photon Emission Computed Tomography and Computed Tomography (SPECT-CT) and Positron Emission Tomography (PET) scintigraphy. Radiopharmaceuticals must be handled with care for both safety and efficacy. Their dosage form design, production and manipulation are often highly technical and sensitive to poor handling techniques, which render them ineffective or dangerous. Hence, Radiopharmacy is a specialised area which is key to the diagnostic and treatment services offered in Nuclear Medicine.

There is a need for a qualified Radiopharmacist in every academic hospital Nuclear Medicine department, as well as in many private hospitals. Currently, there are no posts for these professionals in the public sector, which presents a major obstacle. In addition, South Africa has major production centres for radiopharmaceuticals, which are sold and used throughout Africa, yet not one of these facilities has a qualified Radiopharmacist. Inappropriate role substitution, therefore, occurs in most facilities which handle radiopharmaceuticals. In hospitals, some of the tasks that should be performed by Radiopharmacists are performed by radiographers, whilst other radiopharmacy tasks are simply not performed at all. In production facilities, there is role-substitution by radiochemists, medical physicists and pharmacists who have been trained in the workplace.

The existence of this speciality does not preclude the current practice of pharmacists already dispensing radiopharmaceuticals. Pharmacists should continue to perform the acts pertaining to the scope of practice of a pharmacist.

Radiopharmacists should perform a leading pharmaceutical role in all activities which relate to radiopharmaceuticals. The role includes:

(a) Procurement: Order, receipt, storage and inventory control of radiopharmaceuticals, ancillary drugs, supplies and related materials.

(b) Compounding: Generator elution, kit reconstitution, preparation of products not commercially available and other radiolabelling procedures.

(c) Manufacture: Radionuclide production and quality control of radiopharmaceuticals according to *Good Manufacturing Practice* in an industrial setting.

(d) Quality assurance: Functional checks of instruments, equipment and devices and determination of radiopharmaceutical quality and purity (e.g. radionuclidic purity, radiochemical purity, chemical purity, particle size, sterility, apyrogenicity).

(e) Dispensing: Preparation of bulk vials or individual patient doses for delivery to the user.

(f) Distribution: Packaging, labelling and transport of radiopharmaceuticals to the user.

(g) Health and safety: Radiation protection practices and proper handling of hazardous chemicals and biological specimens.

(h) Provision of information and consultation: Communication of radiopharmaceutical-related information to others, i.e., general applicability (e.g. teaching), organisational (e.g. policies and procedures), or information concerning the care of specific patients.

(i) Monitoring patient outcomes: Activities to assure optimal outcomes for individual patients, which include patient preparation before radiopharmaceutical administration; prevention, recognition, investigation and rectification of clinical problems, such as drug interactions.

(j) Research and development: Laboratory testing of new radiopharmaceuticals, new compounding procedures, or new quality control methods, and participation in clinical trials of radiopharmaceuticals.

The rationale for the Radiopharmacy postgraduate qualification is to train Radiopharmacists who are able to register with Council as specialists in order to ensure safe and effective production and use of radiopharmaceuticals.

7. PURPOSE

The purpose of this professional **Master's Degree** is to provide pharmacists who meet the minimum entry requirements (Bachelor's Degree in Pharmacy) with the opportunity to become specialists in the field of radiopharmacy by expanding their basic knowledge, skills, values, and attitudes and, therefore, enabling them

to meet the minimum requirements of Council. The degree is inherently a practice-based degree with a large component of work-integrated learning.

Council's Scope of Practice for Radiopharmacists

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

(b) Take a leading pharmaceutical role in protocol and guideline development in radiopharmacy and nuclear medicine.

(c) Take a leading pharmaceutical role in compounding and/or manufacturing radiopharmaceuticals

(d) Act as a leading pharmaceutical partner within a multi-professional healthcare team in nuclear medicine departments and in industry.

(e) Develop, implement, evaluate and provide strategic leadership for radiopharmacy services.

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

(g) Develop policies and procedures specifically for the speciality area.

(h) Develop a quality and an evaluative culture within radiopharmaceutical services.

(i) Perform pharmaceutical risk management.

(j) Provide education and training related to radiopharmacy.

(k) Research, teach and publish in the field of radiopharmacy.

8. RULES OF COMBINATION

Fundamental credits:	**72**
Core credits:	**156**
Elective credits:	**12**
Total:	**240**

9. ACCESS TO THE QUALIFICATION

The minimum admission requirement is a four-year Degree in Pharmacy (NQF Level 8) or equivalent, registration with Council as a pharmacist post-community service, and placement in the area of specialisation**.**

10. LEARNING IS ASSUMED TO BE IN PLACE

A four-year Degree in Pharmacy (NQF Level 8), assuming the following is in place:

(a) Professional and ethical practice;

(b) Communication (collaboration with members of the healthcare team) and self-management;

(c) Optimal use of medicines (therapeutic decision-making) and medication management;

(d) Anatomy and physiology;

(e) Pharmaceutics;

(f) Pharmacy practice (including aseptic experience, standard operating procedures, Good Manufacturing Practice (GMP) and quality assurance);

(g) Pharmacology; and

(h) Research methodology.

Candidates have to comply with all of the theoretical requirements set by Council for registration as a specialist pharmacist, as well as annual registration and must have a thorough understanding and working knowledge of South African *Good Pharmacy Practice* rules.

11. EXIT-LEVEL OUTCOMES AND THEIR ASSOCIATED ASSESSMENT CRITERIA

See Table 2.

Table 2: Curriculum Outline

Learning Area	Exit-Level Outcome	Credits	Notional Hours
Fundamental	*Exit-Level Outcome 1*: Apply scientific knowledge in radiopharmacy services	42	420
Fundamental	*Exit-Level Outcome 2*: Promote safe handling of radiation sources and radiopharmaceuticals in compliance with relevant South African legislation	14	140
Fundamental	*Exit-Level Outcome 3*: Institute quality management in radiopharmacy according to current *Good Radiopharmacy Practice* (cGRPP [1]) and in compliance with GMP[2] in radiopharmaceutical production	16	160
Core	*Exit-Level Outcome 4*: Produce, procure, distribute and dispose of radiopharmaceuticals according to cGRPP and in compliance with GMP in radiopharmaceutical production	10	100
Core	*Exit-Level Outcome 5*: Compound and dispense radiopharmaceuticals and radiolabelled blood elements according to GPP, cGRPP and recognised international standards and applicable legislation	18	180
Core	*Exit-Level Outcome 6*: Conduct and monitor quality management for radiopharmaceuticals and instrumentation in the radiopharmacy	14	140
Core	*Exit-Level Outcome 7*: Monitor and promote diagnostic accuracy and successful treatment outcomes as an active member of the nuclear medicine team	26	260
Core	*Exit-Level Outcome 8*: Act as part of a multidisciplinary team to provide information and consultation on radiopharmaceuticals and good radiopharmacy practice in clinical trials	8	80
Core	*Exit-Level Outcome 9*: Conduct research and prepare for publication in the field of radiopharmacy	80	800
Elective	*Exit-Level Outcome 10*: Choose an elective topic	12	120
MPharm (Radiopharmacy)	**TOTAL**	**240**	**2400**

[1] Guidelines on current Good Radiopharmacy Practice (cGRPP) in the preparation of radiopharmaceuticals (most current version). EANM Radiopharmacy Committee
[2] Republic of South Africa. [Department of Health] (most current version). Medicines Control Council: South African Guide to GMP. Pretoria: Government Printers.

Specific Exit-level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Radiopharmacy (MPharm)	Fundamental	*Exit-Level Outcome 1:* Apply scientific knowledge in radiopharmacy services Range statement: The range of scientific knowledge will include, but is not limited to: • Radiation physics and radiation detection instrumentation • Production and properties of radionuclides • Radiopharmaceutical localisation, mode of action, half-life and dosimetry • Aseptic preparation and quality control of radiopharmaceuticals **[64 credits]**	*Assessment Criteria for Exit-Level Outcome 1:* 1. Discuss the role of Radiopharmacy in Nuclear Medicine in diagnosis and therapy. 2. Medical physics: Explain atomic theory, decay processes, mathematics of radioactivity decay, interaction of radiation with matter, types of radioactivity and radiation detection (instrumentation and cameras at a basic level only). 3. Radiochemistry: Describe and explain the production of radionuclides (natural, reactor, cyclotron, generators). Explain properties of commonly used diagnostic and therapeutic radionuclides, their chemistry and the principles of the use of ligands and chelating agents. 4. Radiopharmacology: Explain the localisation and mode of action of common radionuclides and radiopharmaceuticals, physical and biological half-life and dosimetry. 5. Radiopharmaceutics: Explain and demonstrate aseptic radiolabelling techniques and quality control for radiopharmaceuticals.	420

Specific Exit-level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Radiopharmacy (MPharm)	Fundamental	*Exit-Level Outcome 2:* Promote safe handling of radiation sources and radiopharmaceuticals in compliance with relevant South African legislation. **[20 credits]**	*Assessment Criteria for Exit-Level Outcome 2:* 1. Explain and apply legislation relevant to radiopharmacy services in the South African context[3]. 2. Discuss and apply local and international guidelines relevant to the production, distribution, use and disposal of radionuclides and radiopharmaceutical products. 3. Describe and demonstrate the principles of the "as low as reasonably achievable" (ALARA) concept and the importance of distance, shielding and time in radiation protection and radiation exposure limits. 4. Demonstrate the practical implementation of radiation protection principles.	140

[3] Department of Minerals and Energy (most current version). Radioactive Waste Management Policy and Strategy for the Republic of South Africa, Pretoria, South Africa AND Department of Health (most current version). Directorate Radiation Control. Code of Practice for the Management and Disposal of Non-Nuclear Radioactive Waste.WSCP91-1, Pretoria, South Africa AND Republic of South Africa. [Department of Health]. 1965. Medicines and Related Substances Control Act, 101 of 1965. Pretoria.

Specific Exit-level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Radiopharmacy (MPharm)	Fundamental	*Exit-Level Outcome 3:* Institute quality management in radiopharmacy according to current *Good Radiopharmacy Practice* (cGRPP) and in compliance with GMP in radiopharmaceutical production **[24 credits]**	*Assessment Criteria for Exit-Level Outcome 3:* 1. Introduce and maintain a quality management system. 2. Design and implement environmental requirements for a radiopharmacy, including choice, operation and maintenance requirements of laminar flow hoods and isolators. 3. Undertake facility inspections and audits. 4. Prepare, apply and monitor standard operating procedures (SOPs) for radiopharmacy processes. 5. Assure radiopharmacy equipment calibration and implement maintenance and cleaning programmes. 6. Complete documents and maintain and review records in accordance with applicable legislation and SOPs. 7. Discuss the role of international organisations in training and standards. 8. Describe the GMP approach for radiopharmaceuticals and explain validation processes.	160

Specific Exit-level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Radiopharmacy (MPharm)	Core	*Exit-Level Outcome 4:* Produce, procure, distribute and dispose of radiopharmaceuticals according to cGRPP and in compliance with GMP in radiopharmaceutical production **[16 credits]**	*Assessment Criteria for Exit-Level Outcome 4:* 1. Describe the legislative status of key radiopharmaceuticals and radionuclides. 2. Explain and apply the production principles of radiopharmaceuticals in nuclear reactors, cyclotrons and generators. 3. Order, receive, store and maintain the inventory of radiopharmaceuticals, ancillary drugs, supplies and related materials according to cGRPP. 4. Distribute radiopharmaceuticals to the user according to cGRPP (packaging, labelling and transport). 5. Conduct radionuclide and radiopharmaceutical waste management according to current South African legislation[4] and cGRPP. 6. Manage the ordering of and record-keeping for Section 21 radiopharmaceuticals.	100

[4] Department of Minerals and Energy. (most current version). Radioactive Waste Management Policy and Strategy for the Republic of South Africa. Pretoria. South Africa. AND South African Health Products Regulatory Authority Radiation Council (most current version) . Code of Practice for the Management and Disposal of Non-Nuclear Radioactive Waste.WSCP91-1, Pretoria, South Africa.

Specific Exit-level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Radiopharmacy (MPharm)	Core	*Exit-Level Outcome 5:* Compound and dispense radiopharmaceuticals, radiolabelled blood elements, biologicals and other novel radiopharmaceutical dosage forms according to GPP, cGRPP and recognised international standards and applicable legislation[5] **[28 credits]**	*Assessment Criteria for Exit-Level Outcome 5:* 1. Compound radiopharmaceuticals according to GPP and cGRPP. Perform generator elution, kit reconstitution, preparation of products not commercially available and other radiolabelling procedures. 2. Dispense radiopharmaceuticals according to GPP and cGRPP, including evaluation of the prescription, preparation of bulk vials or individual patient doses for delivery to the user, and prepare and reconstitute cold kits. 3. Blood products: Prepare radiolabelled red and white cells and other blood elements according to local or International Society of Radiolabeled Blood Elements (ISORBE) protocols. 4. Compound, manipulate and prepare sterile admixtures according to SOPs, in accordance with aseptic techniques and principles of GMP and/or GPP. 5. Appraise sterilisation methods for commonly used radiopharmaceuticals. 6. Manage radiopharmacy cleaning programmes so that sources and risks of microorganism contamination are reduced. 7. Manage record systems for radiopharmaceutical preparations	180

[5] South African Health Products Regulatory Authority (Most current version). Guidelines for similar biological medicines (biosimilar medicines). Non-clinical and clinical requirements. AND The National Health Act, 61 of 2003. Chapter 8. Control of use of blood, blood products, tissue and gametes in humans. Sections 53-68 and all relevant Regulations thereunder.

Specific Exit-level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
			produced in accordance with legal requirements and organisational policies and procedures.	

Specific Exit-level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Radiopharmacy (MPharm)	Core	*Exit Level Outcome 6:* Conduct and monitor quality management for radiopharmaceuticals and instrumentation in the radiopharmacy. **[20 credits]**	*Assessment Criteria for Exit Level Outcome 6:* 1. Describe in detail the principles of radiopharmacy quality management in hospitals and in production facilities. 2. Conduct functional checks of instruments, equipment and devices. 3. Determine radiopharmaceutical quality and purity requirements for radionuclidic, radiochemical and chemical purity. 4. Evaluate and ensure particle size, sterility and apyrogenicity of radiopharmaceuticals. 5. Ensure the completion and filing of appropriate records in accordance with cGRPP.	140

Specific Exit-level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Radiopharmacy (MPharm)	Core	*Exit-Level Outcome 7:* Monitor and promote diagnostic accuracy and successful treatment outcomes as an active member of the nuclear medicine team. Range statement: The range of conditions includes but is not limited to disorders and diseases, commonly seen in nuclear medicine, of the following systems: • Cardiovascular • Central Nervous System • Endocrine • Gastrointestinal • Hepatobiliary • Lymphatic • Pulmonary • Renal • Skeletal **[40 credits]**	*Assessment Criteria for Exit-Level Outcome 7:* 1. Describe the pathophysiology of key disease states seen in nuclear medicine. 2. Apply the principles of pharmaceutical care and patient monitoring. 3. Interpret clinical laboratory results. 4. Interpret laboratory tests associated with the identification and quantification of pathogens. 5. Explain the mode of action of common radionuclides and radiopharmaceuticals. 6. Analyse the rationale for the choice of specific radiopharmaceuticals in common conditions (disease or suspected diagnosis, age and gender of the patient, contra-indications, radio-pharmaceutical availability and cost-containment issues). 7. Evaluate patient preparation with regard to prevention or recognition of drug or food interactions before radiopharmaceutical administration. 8. Appraise the administration and clinical use of commonly used radionuclides and radiopharmaceuticals. 9. Demonstrate active participation in decision-making in the nuclear medicine team.	260

Specific Exit-level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Radiopharmacy (MPharm)	Core	*Exit-Level Outcome 8:* Act as part of a multidisciplinary team to provide information and consultation on radiopharmaceuticals and *Good Radiopharmacy Practice* in clinical trials. **[12 credits]**	*Assessment Criteria for Exit-Level Outcome 8:* 1. Communicate radiopharmacy information (e.g. teaching, policies and procedures for the care of specific patients) to members of the healthcare team. 2. Record, identify and address radiopharmaceutical causes of scintigraphic anomalies. 3. Explain and demonstrate clinical trial methodology and *Good Clinical Practice*.	80
Master's Degree in Radiopharmacy (MPharm)	Core	*Exit-Level Outcome 9:* Conduct research and prepare for publication in the field of radiopharmacy. Range statement: Research may include, but is not limited to, the following areas: • Development of new radiopharmaceuticals, • Laboratory testing of radiopharmaceuticals, • Compounding procedures, • Quality assurance or quality control methods, • Clinical use of radiopharmaceuticals, • Radiopharmaceuticals management. **[120 credits]**	*Assessment Criteria for Exit-Level Outcome 9:* 1. Critically evaluate information sources, literature and research on medicines and practices in terms of evidence for decision-making and implementation in practice. 2. Apply the principles of research methodology in the development of a research protocol. Obtain ethical clearance if necessary. 3. Conduct research in accordance with established research methodology and ethics, as well as *Good Clinical Practice,* where necessary. 4. Analyse data, interpret findings and/or results and formulate conclusions and recommendations. 5. Write and submit a technical report, manuscript for publication or minor dissertation and obtain approval.	800

Specific Exit-level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Radiopharmacy (MPharm)	Elective	*Exit-Level Outcome 10:* Choose an elective topic. Topics for electives may include, but are not limited to: • Hospital radiopharmacy • Radiopharmaceutical manufacture, production or compounding • Radiopharmaceutical clinical trials • Regulation of radiopharmaceuticals **[16 credits]**	*Assessment Criteria for Exit-Level Outcome 10:* Demonstrate a deep knowledge of the chosen elective field of radiopharmacy for transition to independent practice.	120

12. CRITICAL CROSS-FIELD OUTCOMES

The following critical cross-field outcomes will form an integral part of the exit-level outcomes of this programme:

(a) Identify and solve problems in which responses display that responsible decisions using critical and creative thinking have been made;

(b) Work effectively with others as a member of a team, group, organisation and community;

(c) Organise and manage oneself and one's activities responsibly and effectively;

(d) Collect, analyse, organise and critically evaluate information;

(e) Communicate effectively using visual, mathematical and/or language skills in the modes of oral and/or written persuasion;

(f) Use science and technology effectively and critically, show responsibility towards the environment and health of others;

(g) Demonstrate an understanding of the world as a set of related systems by recognising that problem-solving contexts do not exist in isolation;

(h) Promote the personal and professional development of each learner in the programme, and the social and economic development of the society at large, by creating an awareness of the importance of:

  (i) reflecting on and exploring a variety of strategies to learn more effectively;

  (ii) participating as responsible citizens in the life of local, national and global communities;

  (iii) being culturally and aesthetically sensitive across a range of social contexts;

  (iv) exploring education and career opportunities; and

  (v) developing entrepreneurial opportunities.

13. INTERNATIONAL COMPARABILITY

The following examples are provided to illustrate the proposed curriculum's competitiveness and comparability among both developed and developing countries.

Radiopharmaceuticals fall into two major groups – those used for scintigraphy and single photon emission computed tomography (SPECT) and those used for positron emission tomography (PET). PET radiopharmaceuticals are often produced in cyclotrons. Cyclotron operation necessitates specialised training. In Sub-Saharan Africa, there are very few cyclotrons. In other parts of the world, some radiopharmaceutics degrees deal only with cyclotron-produced radiopharmaceuticals. South Africa has four cyclotrons (two in Pretoria and two in Cape Town). In the Southern African context, a degree that deals with

cyclotron-produced radiopharmaceuticals as well as SPECT radiopharmaceuticals is required.

In addition, South Africa has a need for radiopharmacists in the clinical setting, hence, the clinical use of diagnostic and therapeutic radiopharmaceuticals is an essential area for postgraduate study.

Few Radiopharmacy/nuclear pharmacy postgraduate degrees are listed internationally. Some qualifications for nuclear medicine are stated to lead to radiopharmacy careers.

Radiopharmacy/Nuclear Pharmacy Degrees

The following degree courses have been identified and are summarised below.

United Kingdom (King's College Cambridge MSc Radiopharmaceutics and PET Radiochemistry)

Core programme content:

(a) Module 1 – Introduction to Medical Imaging Sciences
Module 2 – Radiopharmacology Formulation and Manufacture

(b) Module 3a – Radiopharmaceutical Chemistry
or

(c) Module 3b – Radiopharmaceutical Chemistry and Radiopharmaceutical Design

(d) Module 4a – Cyclotron Engineering and Nuclear Chemistry
or
Module 4b – Radiopharmaceuticals in Practice

(e) Module 5 – Research Project

FORMAT AND ASSESSMENT

Written examinations (modules 1, 2, 3a, 3b and 4a); practical laboratory work and reports (modules 1, 2, 3a, 3b, 4a, and 5); case studies and oral presentations (module 4b); workshops (all modules); audio-visual presentations (all modules); laboratory or library-based research project (module 5).

Iran (Tehran University of Medical Sciences)

The course includes the following topics:

(a) Health physics and radiobiology

(b) Radiochemistry

(c) Instrumental and analytical methods

(d) Synthesis of radiolabelled compounds

(e) Pharmacology

(f) Medical statistics

Macedonia (University of Goce Delcev – Stip)

(a) Basic applied pharmacy

(b) Radiopharmaceutical chemistry

(c) Radiopharmaceutical preparation

(d) Quality control of radiopharmaceuticals

(e) Nuclear physics, radiation safety and regulations

(f) Nuclear medicine – aspects of clinical practice

(g) Radiopharmaceutical preparation – SPECT, PET and therapeutic

(h) Operation of a GMP facility

(i) Quality control of radiopharmaceuticals

(j) Clinical application of radiopharmaceuticals in nuclear medicine

(k) Master's thesis

United States of America (USA)

Radiopharmacy (nuclear pharmacy) services in the USA are often centralised.

A radiopharmacist must possess an active pharmacist licence and have received didactic instruction (200 hours) and/or supervised professional experience in the practice of nuclear pharmacy (500 hours). (APhA-APPM Section on Nuclear Pharmacy: Nuclear Pharmacy Practice Guidelines).

(a) **University of Purdue** – 200 hours of clerkships in industry, centralised radiopharmacy or nuclear medicine. The coursework covers: radiation physics, radiation safety, regulatory issues, proper use of equipment, and radiation biology. The advanced clinical clerkship includes information resources pertaining to nuclear medicine and nuclear pharmacy practice, information services, centralised unit dose radiopharmacy service and nuclear medicine department-based hot labs, the receipt of orders, preparation of prescriptions, compounding of radiopharmaceuticals, performance of quality control and quality assurance tests of compounded radiopharmaceuticals and the compounding environment, and the packaging and delivery of nuclear pharmacy products. Also, knowledge of the risks associated with administered radiopharmaceuticals and radiation exposure.

(b) **University of New Mexico.** The certificate course has 200 hours of didactic learning and 500 hours of experiential training. It includes an introduction to radiopharmacy, nuclear pharmacy instrumentation, radiopharmaceutical chemistry, radiopharmacy health and radiation biology, and radiopharmacology. Experiential training is in clinical and institutional radiopharmacy.

(c) **Nuclear Education Online (NEO)** offers an online course for certification purposes. The course covers: nuclear physics, instrumentation, radiation safety and regulations, radiation biology and radiochemistry.

European specialisation certificate in radiopharmacy
The Radiopharmacy Committee of the European Association of Nuclear Medicine (EANM) has established a European postgraduate specialisation certificate in radiopharmacy. A certificate after successful attendance may be awarded to participants who, in the view of the European Society of Neurogastroenterology and Motility (ESNM) Radiopharmacy Board, are suitably qualified, in that they have:

(a) acquired a university postgraduate diploma through attendance at appropriate courses teaching the theoretical components of the radiopharmacy syllabus;

(b) completed a two-year period of experience in a radiopharmacy department during which they have completed the practical components of the syllabus; and

(c) completed a nationally acceptable course on radiation safety.

14. INTEGRATED ASSESSMENT

A combination of integrated assessment strategies, which will combine both formative and summative assessment and evaluation, will be used to ensure that the purpose of the qualification is achieved. Assessments may include, but are not limited to, the following strategies:

(a) Portfolios of evidence;

(b) Practical experience workplace assessments;

(c) Written and oral assessments and examinations;

(d) Written assignments;

(e) Objective Structured Practical Examinations (OSPEs);

(f) Case studies;

(g) Journal clubs; and

(h) Self-assessment strategies, peer-group assessment and preceptor evaluation.

15. CREDIT ACCUMULATION AND TRANSFER

Candidates may apply for recognition of credits obtained as part of an incomplete qualification at the same or a different institution, depending on individual institutional policies.

16. ARTICULATION (PROGRESSION)

Completion of a Master's Degree meets the minimum entry requirement for admission to a Doctoral Degree, usually in the area of specialisation in the Master's Degree.

Articulation may also be horizontal to entries into other Master's Degrees in a similar or related field, or area of specialisation.

17. MODERATION OPTIONS

Suitable moderating options should be included in each application for accreditation to provide this qualification in accordance with the stipulations of the Council on Higher Education (CHE), as well as the relevant Education and Training Quality Assurance (ETQA) body (i.e. Council). Both internal and external moderation should form an integral part of the provision of this qualification.

18. CRITERIA FOR THE APPOINTMENT OF ASSESSORS:

Assessors in the field of radiopharmacy must have a suitable background with a proven track record and relevant experience to enable them to make sound judgements through their expert application of the assessment criteria specified for this qualification.

19. NOTES:

(a) All candidates must, in addition to their current registration as academic interns or pharmacists, be registered with Council for study towards the specialisation for the duration of the period of learning as specified in the current relevant legislation.

(b) The range of elective learning areas offered will be dependent on the approval of the provider and ETQA.

(c) Credit values reflected for each exit-level outcome in Table 2 should be regarded only as a guideline.

(d) The respective assessment criteria aim to test the achievement of the specific learning outcomes. Some of these criteria are practice-based. Thus, providers are required to include periods in their curricula for this purpose.

(e) After attaining the Master's Degree, the candidate may commence with the process for registration as a specialist pharmacist in radiopharmacy with Council. Requirements for this registration process will be determined by Council.

See Appendix A

APPENDIX A

Requirements for registration as a specialist after obtaining the Professional Master of Pharmacy in Radiopharmacy

The prospective candidate should be a registered pharmacist with Council

Training Site

A site registered with the Council as a training institution, pharmacy, health or manufacturing facility where radiopharmaceuticals are routinely handled.

Tutor or supervisor

A postgraduate pharmacist or specialist medical practitioner in nuclear medicine, with at least two years' experience in the field.

Practical training

As stipulated by Council

Evaluation and panel

As stipulated by Council.

South African
Pharmacy Council

Professional Master's Degree Qualification and Curriculum Outline

for the

Specialist in Pharmacy: Clinical Pharmacy

CONTENTS

SYNOPSIS: 1
QUALIFICATION OUTLINE: 2
QUALIFICATION TITLE: 2
QUALIFICATION TYPE: 2
FIELD AND SUB-FIELD: 2
LEVEL: 2
CREDITS: 2
RATIONALE FOR THE QUALIFICATION: 2
PURPOSE: 3
RULES OF COMBINATION: 4
ACCESS TO THE QUALIFICATION: 5
LEARNING ASSUMED TO BE IN PLACE: 5
EXIT-LEVEL OUTCOMES AND THEIR ASSOCIATED ASSESSMENT CRITERIA: ..5
CRITICAL CROSS-FIELD OUTCOMES: 20
INTERNATIONAL COMPARABILITY: 20
INTEGRATED ASSESSMENT: 23
CREDIT ACCUMULATION AND TRANSFER: 23
ARTICULATION (PROGRESSION): 24
MODERATION OPTIONS: 24
CRITERIA FOR THE APPOINTMENT OF ASSESSORS: 24
NOTES: 24
APPENDIX A 25

LIST OF TABLES

Table 1: Summary of the proposed qualification 1
Table 2: Curriculum Outline 6

SYNOPSIS:

The aim is to provide a curriculum for a Professional Master's Degree in Clinical Pharmacy, to enable students to register with the South African Pharmacy Council (hereafter referred to as "Council") as specialists.

Table 1: Summary of the proposed qualification

	Professional Master's Degree in Clinical Pharmacy
Duration:	Two (2) years
Entry criteria:	Bachelor's Degree in Pharmacy (Level 8)
HEQF-level:	**Level 9**
Field:	09 Health Sciences and Social Services
Sub-field:	Curative Health
SAQA-credits:	360 credits
Qualification type:	Professional, exit-level, career-orientated, whole qualification
Final assessment and evaluation:	• Final exit-level examination(s) will need to be passed in accordance with the relevant Higher Education provider's rules and regulations. • In addition, a comprehensive portfolio of evidence will need to be submitted and successfully passed by the accredited provider. • Requirements for registration as a specialist after obtaining the professional Master's Degree are presented in Appendix A to this document.
CPD requirements for annual re-registration:	As required by Council
Professional status:	Registration with Council as a practising clinical pharmacist
Articulation:	DPharm / Doctoral Degree

QUALIFICATION OUTLINE:

1. QUALIFICATION TITLE:

Master of Pharmacy in Clinical Pharmacy

Abbreviation: MPharm (Clinical Pharmacy)

2. QUALIFICATION TYPE:

Professional Master's Degree

3. FIELD AND SUB-FIELD:

Field: [09] Health Sciences and Social Services

Sub-field: Curative Health

4. LEVEL:

NQF/HEQF **Level 9** (Master's Degree)

5. CREDITS:

Total credits: 360

6. RATIONALE FOR THE QUALIFICATION:

The rationale for the qualification is to train advanced-level clinical pharmacists who are able to register with Council as specialists who contribute to capacity building in the field of clinical pharmacy, and to create specialists in the field of pharmacy for the advancement of healthcare in South Africa.

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".[1]

Historically, the role of the pharmacist, regardless of the health setting, was to ensure prompt and efficient medication supply, adequate stock, accurate dispensing, compounding, storage and transport, and to ensure that medicines were easily accessible to patients who needed them. The pharmacist was also responsible for the selection of medicines, dosage forms, and the monitoring of patient compliance.[2]

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.[3]

---

[1] Van Mil F. 2004. Proving the benefits of pharmaceutical care. *Pharmacy World and Science,* 26:123.

[2] Hepler CD, and Strand LM.1990. Opportunities and responsibilities in pharmaceutical care. American Journal of Hospital Pharmacy, 47:533–43.

[3] The South African Society of Clinical Pharmacy (SASOCP). 2011. Constitution of the South African Society of Clinical Pharmacy. Available from: http://www.sasocp.co.za. (Accessed: 01/08/2014).

Patients with advanced diseases have multiple symptoms, and treatment becomes complicated[4]. This makes it difficult for carers to manage their patients' medication, which leads to patients' symptoms being inadequately controlled and a low level of compliance[5]. Pharmacists have the responsibility to identify, resolve, and prevent each patient's medicine therapy problems. These responsibilities are met by using the caring paradigm in a patient-centred manner.

Pharmaceutical care mandates that pharmacists should not only dispense medication but also assume the responsibility of improving the quality of life of patients and improving therapy outcomes[6].

Pharmaceutical care involves the implementation of the following steps[7]:

(a) The assessment of patient health and formulation of a treatment plan to treat disease and symptoms

(b) Monitoring of patient response to therapy to ensure optimum therapeutic effects

(c) Performing medication reviews to detect and resolve medication-related problems

(d) Documentation of the care provided and provision of advice to patients in a way that patients understand.

In South Africa, clinical pharmacists are currently not part of the traditional ward staff, as seen in the United States (US) or the United Kingdom (UK)[1]. This situation may be due to a lack of human resources, and inadequate training and the occupational levels of pharmacists. There is a need to develop and accredit formal qualifications which will enable qualifying pharmacists to render professional services within a recommended scope of practice, and under the auspices of the statutory body, namely Council.

7. PURPOSE:

The primary purpose of a professional Master's Degree is to educate and train graduates who can contribute to the development of knowledge at an advanced level, so they are prepared for specialised professional employment.

In some cases, a professional Master's Degree may be designed in consultation with a professional body or fulfil all or part of the requirements for professional registration or recognition, and may include appropriate forms of work-integrated learning.

Successful completion of a programme requires a high level of theoretical engagement and intellectual independence as well as a demonstration of the ability to relate knowledge to the resolution of complex problems in appropriate areas of professional practice. In addition, a professional Master's Degree must include an independent study component that comprises at least a quarter of the credits at NQF Level 9, consisting of either a single research or technical project or a series of smaller projects demonstrating innovation or professional expertise.

---

[4] MacRobbie A, Addie S, & Grant E. 2009. The pharmacist in palliative care. Scottish Palliative Care Pharmacists Association (SPCPA). Available from: http://www.nes.scot.nhs.uk/media/347752/14551_20nes_20pall_care_20dl_20v9_20final.pdf(Accessed: 01/08/2014).

[5] MacRobbie A, Addie S, & Grant E. 2009. The pharmacist in palliative care. Scottish Palliative Care Pharmacists Association (SPCPA). Available from: http://www.nes.scot.nhs.uk/media/347752/14551_20nes_20pall_care_20dl_20v9_20final.pdf(Accessed: 01/08/2014).

[6] Hughes CM, Hawwa AF, Scullin C, Anderson C, Bernsten CB, Bjo¨rnsdo´ttir I, Cordina MA, Alves da Costa M, De Wulf I, Eichenberger P, Foulon V, Henman MC, Hersberger KE, Schaefer MA, Sondergaard M , Tully MP, Westerlund T & McElnay JC. 2010. Provision of pharmaceutical care by community pharmacists: a comparison across Europe. Springer science & business media. Available from: http://upload.sitesystem.ch/B2DBB48B7E/EE929BDFA5/4D7608D543.pdf. (Accessed: 01/08/2014).

[7] Minnesota Senate. 2005. Medication management care. 8th Legislative session, No. 973,1st Engrossment. Available from: https://www.revisor.leg.state.mn.us/bin/bldbill.php?bill=SO973.1&session=ls84. (Accessed: 01/08/2014).

Master's graduates must be able to deal with complex issues both systematically and creatively, design and critically appraise analytical writing, make sound judgements using data and information at their disposal and communicate their conclusions clearly to specialist and non-specialist audiences, demonstrate self-direction and originality in tackling and solving problems, act autonomously in planning and implementing tasks with a professional orientation, and continue to advance their knowledge, understanding and skills relevant to a particular profession.

The purpose of this professional **Master's Degree** is to provide pharmacists who meet the minimum requirements for entry (Bachelor's Degree in Pharmacy) with the opportunity of becoming **specialists in the field of clinical pharmacy** by expanding their basic knowledge, skills, values and attitudes, and, therefore, enabling them to meet the minimum requirements of Council. The degree is inherently a practice-based degree with a large component of work-integrated learning.

Council's Scope of Practice for Clinical Pharmacists

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

(b) Provide advanced clinical pharmacy services to a variety of specialities.

(c) Act as a leading pharmaceutical partner within a multi-professional healthcare team.

(d) Develop, implement, evaluate and provide strategic leadership for clinical pharmacy services.

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

(f) Take a pharmaceutical leadership role in clinical protocol and guideline development.

(g) Lead clinical audits of medicine use.

(h) Develop policies and procedures specifically for clinical pharmacy.

(i) Provide education and training related to clinical pharmacy.

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

(k) Initiate and participate in pharmacovigilance related to clinical practice.

8. RULES OF COMBINATION:

Fundamental credits:	**60**
Core credits:	**284**
Elective credits:	**16**
Total:	**360**

9. ACCESS TO THE QUALIFICATION:

The minimum admission requirement is a four-year Degree in Pharmacy (NQF Level 8) or equivalent, registration with Council as a pharmacist post-community service, and placement in the area of specialisation.

10. LEARNING ASSUMED TO BE IN PLACE:

A four-year Degree in Pharmacy (NQF Level 8) or equivalent, assuming the following is in place:

(a) Professional and ethical practice

(b) Communication (collaboration with members of the healthcare team) and self-management

(c) Optimal use of medicines (therapeutic decision-making) and medication management

(d) Pharmacology

(e) Research methodology.

Candidates have to comply with all of the theoretical requirements set by Council for registration as a specialist pharmacist, as well as annual registration, and must have a thorough understanding and working knowledge of South African *Good Pharmacy Practice* rules.

11. EXIT-LEVEL OUTCOMES AND THEIR ASSOCIATED ASSESSMENT CRITERIA:

See Table 2.

Table 2: Curriculum Outline

Learning Area	Exit-Level Outcome	Credits	Notional Hours
Fundamental	*Exit-Level Outcome 1:* Formulate pharmaceutical care plans and interpret prescriptions to guide treatment for individual patients, and counsel patients to improve treatment outcomes	20	200
Fundamental	*Exit-Level Outcome 2:* Use clinical information, laboratory and diagnostic tests and results to assist with or support therapeutic assessments and decisions, including medicine therapy	20	200
Fundamental	*Exit-Level Outcome 3:* Apply basic and clinical pharmacokinetics, pharmacogenomics and pharmacodynamics in medicine therapy for individualised patient care	20	200
Core	*Exit-Level Outcome 4:* Optimise therapy for infectious diseases	28	280
Core	*Exit-Level Outcome 5:* Optimise therapy for disorders related to the endocrine system, including obstetric, gynaecological and urological conditions	20	200
Core	*Exit-Level Outcome 6:* Optimise therapy for disorders related to the gastrointestinal system	20	200
Core	*Exit-Level Outcome 7* Optimise therapy for disorders related to the cardiovascular system	28	280
Core	*Exit-Level Outcome 8:* Optimise therapy for disorders related to the renal system	20	200
Core	*Exit-Level Outcome 9:* Optimise therapy for neurological and psychiatric disorders	28	280
Core	*Exit-Level Outcome 10:* Optimise therapy for disorders related to the respiratory system	20	200
Core	*Exit-Level Outcome 11:* Conduct research and prepare for publication in the field of clinical pharmacy	120	1 200
Elective	*Exit-Level Outcome 12:* Optimise therapy for disorders and/or optimise clinical pharmacy practice related to any one (1) chosen elective topic	16	160
MPharm (Clinical Pharmacy)	**TOTAL**	**360**	**3 600**

Specific Exit Level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Fundamental	*Exit-Level Outcome 1:* Formulate pharmaceutical care plans and interpret prescriptions to guide treatment for individual patients, and counsel patients to improve treatment outcomes Range statement: The range of pharmaceutical care topics will include, but is not limited to, the following points: • The pharmaceutical care concept • The concept and coping skills needed for dealing with death and bereavement as encountered in clinical practice • The basic skills necessary to communicate and act in a professional and assertive manner within the multi-disciplinary team • Essential patient information collection and organisation • Patient medical charts • Patient database establishment • Drug therapy problem list construction and resolution of problems • Pharmacist care plan design and recommendation • Pharmacist's care plan monitoring **[20 credits]**	*Assessment Criteria for Exit Level Outcome 1:* 1. Define, review, appraise and evaluate the pharmaceutical care concept against the patient's medical and/or surgical history. 2. Evaluate patient medical charts. 3. Construct, analyse, appraise and maintain a patient database. 4. Identify and explain the different stages of the bereavement process. 5. Display and apply the necessary communication skills to function effectively with patients and as a member of the multidisciplinary team in the clinical practice setting. 6. Construct, describe, categorise and appraise patients' medicine therapy problem lists and make suggestions for resolving the identified problems. 7. Plan and construct care plans and recommend interventions. 8. Monitor and evaluate care plans against the changing environment of the patient's ongoing therapy. 9. Conduct the process within the ethical and legal framework as defined by the legislation.	200

Specific Exit Level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Fundamental	*Exit-Level Outcome 2:* Use clinical information, laboratory and diagnostic tests and results to assist with or support therapeutic assessments and decisions, including medicine therapy. Range statement: The range of topics will include, but is not limited to, the following points: • Vital signs and clinical condition • Urea and electrolytes • Medical microbiology, immunology • Genetics • Full blood count • Organ function tests • Pathology and pathophysiology as related to these tests **[20 credits]**	*Assessment Criteria for Exit-Level Outcome 2*: 1. Describe, analyse, review and apply normal/reference ranges for commonly used tests. 2. Appraise and explain the possible aetiology of, and pathology related to, clinical laboratory results which are outside these ranges. 3. Interpret and apply the impact of the aetiology of, or pathology related to, clinical laboratory test results on medicine therapy of individual patients.	200

Specific Exit Level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Fundamental	*Exit-Level Outcome 3:* Apply basic and clinical pharmacokinetics, pharmacogenomics and pharmacodynamics in medicine therapy for individualised patient care. Range statement: The range of topics will include, but is not limited to, the following points: • Principles of pharmacokinetics, pharmacogenomics and pharmacodynamics • Individualised dosing calculations • Patient disease state and the interpretation of laboratory values and its influence on medicine therapy **[20 credits]**	*Assessment Criteria for Exit-Level Outcome 3:* 1. Explain pharmacokinetic and pharmacodynamic definitions and terminology. 2. Describe basic genetic/genomic concepts and nomenclature. 3. Identify medicine and disease-associated genetic variations that facilitate the development of prevention, diagnostic and treatment strategies. 4. Calculate individualised dosing calculations, including loading dose, maintenance dose and dosing intervals, when appropriate patient information is interpreted (e.g., clearance, volume of distribution and half-life). 5. Relate patient disease states and laboratory results to alterations in medicine therapy and perform appropriate calculations where necessary. 6. Manage disease states using appropriate blood levels and interpret to make appropriate recommendations. 7. Use pharmacodynamic endpoints to make appropriate therapeutic decisions using alterations in pharmacokinetic and pharmacodynamic dosing alterations.	200

Specific Exit Level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Core	*Exit-Level Outcome 4:* Optimise therapy for infectious diseases Range statement: The range of topics will include, but is not limited to, the following points: • Pathogens and laboratory tests • Pathophysiology of the conditions • Medication-related problems • Evidence-based, patient-specific medication treatment plans • Treatment plans, including assisting the patient • Patient response to and modification of pharmacotherapy • Patient interventions and antimicrobial stewardship **[28 credits]**	*Assessment Criteria for Exit-Level Outcome 4:* 1. Classify common pathogens and describe mechanisms related to the development of acquired resistance. 2. Interpret and understand laboratory tests associated with the identification and quantification of pathogens and the use of antimicrobials. 3. Identify, describe and implement antimicrobial stewardship principles as applicable to clinical practice. 4. Define, discuss and appraise the pathophysiology of the diseases induced by microorganisms. 5. Use pharmacodynamic principles to guide and ensure effective antimicrobial therapy. 6. Define, discuss and apply infectious disease principles to the various infective conditions. 7. Appraise, organise and evaluate patient information. 8. Recognise, categorise and interpret medication-related problems and make appropriate interventions. 9. Formulate patient-specific, evidence-based medication treatment plans. 10. Formulate and implement treatment plans (including non-medicine treatment) and assist the patient with implementation.	280

			11. Monitor and evaluate pharmacotherapy to assess patient response. 12. Document patient interventions in accordance with professional and legal requirements.	

Specific Exit Level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Core	*Exit-Level Outcome 5:* Optimise therapy for disorders related to the endocrine system, including obstetric, gynaecological and urological conditions. Range statement: The range of topics will include, but is not limited to, the following conditions: • Diabetes mellitus • Diabetes insipidus • Thyroid disorders • Disorders of the pituitary gland • Medicine use during pregnancy and lactation • Contraception (including emergency contraception) • Hormone replacement therapy • Erectile dysfunction • Benign prostatic hyperplasia • Urinary incontinence **[20 credits]**	*Assessment Criteria for Exit-Level Outcome 5:* 1. Define, discuss and appraise the pathophysiology of the diseases related to the endocrine system, including gynaecological and urological conditions. 2. Appraise, organise and evaluate patient information. 3. Recognise, categorise and interpret medication-related problems and carry out appropriate interventions. 4. Formulate and apply patient-specific, evidence-based medication treatment plans. 5. Formulate and implement treatment plans (including non-medicine treatment) and assist the patient with implementation. 6. Monitor and evaluate pharmacotherapy to assess patient responses. 7. Document patient interventions in accordance with professional and legal requirements.	200

Specific Exit Level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Core	*Exit-Level Outcome 6:* Optimise therapy for disorders related to the gastrointestinal system Range statement: The range of topics will include, but is not limited to, the following matters: • Anatomy and physiology of the gastrointestinal tract • Gastro-oesophageal reflux (GORD) • Peptic ulcer disease • Inflammatory bowel disease • Treatment of nausea and vomiting • Irritable bowel syndrome • Treatment of constipation and diarrhoea • Hepatic medicine metabolism • Alcoholic liver disease • Drug-induced liver disease • Pancreatitis • Hepatitis (viral, acute and chronic) • Identify and manage diseases related to nutritional disorders (including a basic understanding of clinical nutrition) **[20 credits]**	*Assessment Criteria for Exit-Level Outcome 6:* 1. Define, discuss and appraise the pathophysiology of disorders related to the gastrointestinal system. 2. Appraise, organise and evaluate patient information. 3. Identify, categorise and interpret medication-related problems and make appropriate interventions. 4. Formulate and apply patient-specific, evidence-based medication treatment plans. 5. Monitor and evaluate clinical nutrition when required according to patient-specific disease states. 6. Formulate and implement treatment plans (including non-medicine treatment) and assist the patient with implementation. 7. Monitor and evaluate pharmacotherapy to assess patient response. 8. Document patient interventions in accordance with professional and legal requirements.	200

Specific Exit Level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Core	*Exit-Level Outcome 7*: Optimise therapy for disorders related to the cardiovascular system Range statement: The range of topics will include, but is not limited to, the following conditions: • Hypertension • Heart failure • Ischaemic heart disease • Myocardial infarction (MI) • Arrhythmias • Dyslipidaemia • Thromboembolic disease • Acute coronary syndrome • Tests used to evaluate the cardiovascular system **[28 credits]**	*Assessment Criteria for Exit-Level Outcome 7:* 1. Define, discuss and appraise the pathophysiology of various cardiac disorders. 2. Appraise, organise and evaluate patient information, including laboratory tests specific to the cardiac system. 3. Recognise, categorise and interpret medication-related problems and make appropriate interventions. 4. Formulate and apply patient-specific, evidence-based medication treatment plans. 5. Formulate and implement treatment plans (including non-medicine treatment) and assist the patient with implementation. 6. Monitor and evaluate pharmacotherapy to assess patient response. 7. Document patient interventions in accordance with professional and legal requirements.	280

Specific Exit Level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Core	*Exit-Level Outcome 8:* Optimise therapy for disorders related to the renal system Range statement: The range of topics will include, but is not limited to, the following points: • Assessment and quantification of renal function • Acute renal failure • Chronic renal failure and end-stage renal failure • Drug-induced renal disease • Appropriate calculations in the adjustment of medicine therapy in renal failure • Assessment and management of the hydration status of a hospitalised patient **[20 credits]**	*Assessment Criteria for Exit-Level Outcome 8:* 1. Define, discuss and appraise the pathophysiology of disorders related to the renal system. 2. Appraise, organise and evaluate patient information. 3. Recognise, categorise and interpret medication-related problems and make appropriate interventions. 4. Formulate and apply patient-specific, evidence-based medication treatment plans. 5. Formulate and implement treatment plans (including non-medicine treatment) and assist the patient with implementation. 6. Monitor and evaluate pharmacotherapy to assess patient response. 7. Document patient interventions in accordance with professional and legal requirements.	200

Specific Exit Level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Core	*Exit-Level Outcome 9:* Optimise therapy for neurological and psychiatric disorders Range statement: The range of topics will include, but is not limited to, the following conditions: Psychiatric Disorders • Assessment of psychiatric illness • Schizophrenic disorders • Depression • Bipolar disorders • Anxiety • Obsessive-compulsive disorders • Pharmacological involvement in intellectual disabilities Neurological Disorders • Epilepsy syndromes • Parkinson's disease • Alzheimer's disease • Stroke • Multiple sclerosis • Attention deficit hyperactivity disorder **[28 credits]**	*Assessment Criteria for Exit-Level Outcome 9:* 1. Define, discuss and appraise the pathophysiology of disorders related to the central nervous system (including neurologic and psychiatric disorders). 2. Appraise, organise and evaluate patient information. 3. Recognise, categorise and interpret medication-related problems and make appropriate interventions. 4. Formulate and apply patient-specific, evidence-based medication treatment plans. 5. Formulate and implement treatment plans (including non-medicine treatment) and assist the patient with implementation. 6. Monitor and evaluate pharmacotherapy to assess patient response. 7. Document patient interventions in accordance with professional and legal requirements.	280

Specific Exit Level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Core	*Exit-Level Outcome 10:* Optimise therapy for disorders related to the respiratory system Range statement: The range of topics will include, but is not limited to, the following points: • The assessment of pulmonary function • Asthma • Chronic obstructive pulmonary disease • Drug-induced lung disease • Pulmonary hypertension • Occupational pulmonary diseases **[20 credits]**	*Assessment Criteria for Exit-Level Outcome 10:* 1. Define, discuss and appraise the pathophysiology of the disorders related to the respiratory system. 2. Appraise, organise and evaluate patient information. 3. Recognise, categorise and interpret medication-related problems and make appropriate interventions. 4. Formulate and apply patient-specific, evidence-based medication treatment plans. 5. Formulate and implement treatment plans (including non-medicine treatment) and assist the patient with implementation. 6. Monitor and evaluate pharmacotherapy to assess patient response. 7. Document patient interventions in accordance with professional and legal requirements.	200

Specific Exit Level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Core	*Exit-Level Outcome 11:* Conduct research and prepare for publication in the field of clinical pharmacy Range statement: The range of topics will encompass any suitable postgraduate research study in the field of clinical pharmacy. **[120 credits]**	*Assessment Criteria for Exit-Level Outcome 11* 1. Critically evaluate information sources, literature and research on medicines and practices in terms of evidence for decision-making and implementation in practice. 2. Apply the principles of research methodology in the development of a research protocol. Obtain ethical clearance if necessary. 3. Conduct research in accordance with established research methodology and ethics, as well as *Good Clinical Practice,* where necessary. 4. Analyse data, interpret findings and/or results and formulate conclusions and recommendations. 5. Write and submit a technical report, manuscript for publication or minor dissertation based on the research outcomes and obtain approval.	1 200

Specific Exit Level	Learning Area	Exit-Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Elective	*Exit-Level Outcome 12:* Optimise therapy for disorders and/or optimise clinical pharmacy practice related to any one (1) chosen elective topic. Range statement: The range of topics may include, but is not limited to, the following selected examples: • Paediatrics • Clinical drug development • Critical care in adults • Oncological pharmacy • Pharmacovigilance • Dermatology • Geriatrics • Pharmacogenomics • Pharmacoeconomics **[16 credits]**	*Assessment Criterion for Exit-Level Outcome 12:* Demonstrate extensive knowledge of the chosen elective field of clinical pharmacy for transition to independent practice.	160

12. CRITICAL CROSS-FIELD OUTCOMES:

The following critical cross-field outcomes will form an integral part of the exit-level outcomes of this programme:

(a) Identify and solve problems in which responses display that responsible decisions using critical and creative thinking have been made;

(b) Work effectively with others as a member of a team, group, organisation and community;

(c) Organise and manage oneself and one's activities responsibly and effectively;

(d) Collect, analyse, organise and critically evaluate information;

(e) Communicate effectively using visual, mathematical and/or language skills in the modes of oral and/or written persuasion;

(f) Use science and technology effectively and critically, show responsibility towards the environment and health of others;

(g) Demonstrate an understanding of the world as a set of related systems by recognising that problem-solving contexts do not exist in isolation;

(h) Promote the personal and professional development of each learner in the programme, and the social and economic development of the society at large, by creating an awareness of the importance of:

(i) reflecting on and exploring a variety of strategies to learn more effectively;

(ii) participating as responsible citizens in the life of local, national and global communities;

(iii) being culturally and aesthetically sensitive across a range of social contexts;

(iv) exploring education and career opportunities; and

(v) developing entrepreneurial opportunities.

13. INTERNATIONAL COMPARABILITY:

The following examples are provided to illustrate the proposed curriculum's competitiveness and comparability among both developed and developing countries.

Africa: Example Ethiopia

An Eastern African country classified as a low-income country with a high prevalence of infectious diseases. Ethiopia has similar health-related issues to South Africa and is also experiencing an epidemiological transition with diabetes, hypertension and other cardiovascular diseases.[8]

As in South Africa, Ethiopia is experiencing a shortage of pharmacists and pharmacy support staff, and has also identified the need for pharmaceutical care services to meet

[8] Odegard PS, Tadeg H, Downing D, Suleman S, Bedada W, Paulos, G, Mekonnen H, Negussu M, Barlein R and Stergachis A. Strengthening Pharmaceutical Care Education in Ethiopa through collaboration. American Journal of Pharmaceutical Education. 2011;75 (7)134

and respond to healthcare needs. In 2009, the School of Pharmacy of Jimma University launched its first postgraduate programme, a Master of Science in Clinical Pharmacy. The initiative was started as part of a partnership with the Ethiopian Pharmaceutical Association, Strengthening Pharmaceutical Systems Programme of Management Sciences for Health, and the University of Washington.

The following points pertain to Ethiopia's training and education:

(a) Undergraduate and postgraduate students and faculty members are trained. In South Africa, an emphasis on introducing clinical pharmacy in undergraduate programmes to train true specialists has been made, and postgraduate programmes similar to this programme exist.

(b) The objectives and priority areas of their Master's Degree include a strong emphasis on pharmaceutical care and pharmacovigilance – in South Africa, pharmaceutical care is a core component of the curriculum. However, due to the disease burden in South Africa, strong emphasis is placed on a disease-driven Master's Degree. Pharmacovigilance is included as an elective. Pharmacovigilance is part of the Master's Degree in Medicines Management. Other courses are available.

Europe: Example Germany

In Europe, general specialisation towards clinical pharmacy follows the same route as that proposed in South Africa – a basic BPharm degree (in some countries it is three years, in others four years), followed by an internship plus a final examination by a competent entity. Formal education in a university, with a practical component, allows entrance to a specialisation. Special degrees for pharmacists are possible after advanced training of at least three years in specialities such as clinical pharmacy (as proposed in this document). Clinical pharmacy, as part of the basic undergraduate programme in Germany, has also been included in recent years, as in South Africa.[9]

United States of America (USA)

Pharmacy practice has shifted to include more clinical services. This has been supported in the schools of pharmacy by education and training. The USA has moved from a Bachelor of Science in Pharmacy to a Doctor of Pharmacy, with additional years of training, from four years of training (Bachelor of Science in Pharmacy) to a minimum of six years of training.

The core curriculum is comparable with the subjects presented in a Master's Degree in Clinical Pharmacy, as the basic pharmacy degree presented in South Africa is still very reliant on natural sciences. The Doctor of Pharmacy core curriculum includes:

(a) Pathophysiology

(b) Pharmacology

(c) Therapeutics

(d) Clinical problem solving

(e) Laboratory monitoring

[9] Buschauer A. Pharmacy Education in Germany. Presentation. 2011.

(f) Physical assessment skills for many diseases.

This curriculum is supported by practical clinical rounds with medical students accompanying physicians. The latest curricular guidelines from the Accreditation Council for Pharmacy Education (ACPE) mandates early pharmacy practice experience through training/shadowing in a physician's office and clinical hospital setting, exposing the pharmacist student to collaborative practice environments. Master's and Doctoral-level training are still being undertaken in clinical pharmacy, with additional residencies to encourage advanced-level practice and specialisation, similar to the proposal in this document.

Clinical speciality certifications, endorsed by the Board of Pharmacy Specialties (BPS), are available for pharmacists in the following areas:

(a) Pharmacotherapy Specialist (BCPS)

(b) Nuclear Pharmacist (BCNP)

(c) Nutrition Support Pharmacist (BCNSP)

(d) Oncology Pharmacist (BCOP)

(e) Psychiatric Pharmacist (BCPP)

(f) Ambulatory Care Pharmacist (BCACP)

The board certification is NOT required for pharmacists and is different from that required for specialist physicians – this is different from the proposed South African degree outlined in this document.[10]

Australia

The principal pharmacy degree in Australia remains the four-year Bachelor of Pharmacy, but some universities have started offering an entry-level Master's Degree in Pharmacy. The curricula for the two degrees remain the same, and one has no advantage/disadvantage over the other. As in South Africa, no pharmacy school currently offers a Doctor of Pharmacy (PharmD) as the entry point for registration as a pharmacist. However, clinical pharmacy is being offered as part of postgraduate degrees such as the Master of Clinical Pharmacy, Doctor of Clinical Pharmacy, graduate diploma or graduate certificate awards, in addition to research degrees such as research master's and PhD degrees. The emphasis in the curricula for these postgraduate programmes in clinical pharmacy differs from institution to institution. What is similar to the proposal in this document is that they generally include components of therapeutics and, at the master's level and beyond, completion of a practice-based research project.[11]

India

The Master of Pharmacy in Clinical Pharmacy is offered as a two-year degree programme by seventeen institutions across India. Students who have passed their Bachelor of Pharmacy are eligible to enrol. In India, clinical pharmacy is the branch of pharmacy in which pharmacists provide patient care that optimises the use of medicines and promotes health, wellness and disease prevention. The degree is designed to

[10] Office of the Chief Pharmacist. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice: A Report to the U.S. Surgeon General. 2011.

[11] Marriot JL, Nation RL, Roller L, Costelloe M, Galbraith K, Stewart P & Charman WN. Pharmacy Education in the Context of Australian Practice. American Journal of Pharmaceutical Education. 2008;72 (6):131

prepare pharmacists for expanded roles as providers of direct patient care with emphasis on physiology, applied therapeutics and pharmacy practice skills.

The subjects in the first year include clinical pharmacy practice, clinical pharmacokinetics, pharmacotherapeutics, biostatistics and research methods. Second-year studies include a research project, a general medicine clerkship and biotechnology. Specialisation areas include clinical trials, new medicine discovery and hospital pharmacy.

The role of a clinical pharmacist in India is to support and provide the best quality medicine therapy for patients. This role may include:

(a) Prescription monitoring to maximise medicine efficiency, minimise medicine toxicity and promote cost effectiveness;

(b) Therapeutic medicine monitoring of medicines with a narrow therapeutic index;

(c) Medicine information services;

(d) Patient services and counselling;

(e) Improving patient compliance through collecting past medical history; and

(f) Offering recommendations to the physician for an optimised medical treatment that is completely patient-oriented.[12]

14. INTEGRATED ASSESSMENT:

A combination of integrated assessment strategies, which will combine both formative and summative assessment and evaluation, will be used to ensure that the purpose of the qualification is achieved. Assessments may include, but are not limited to, the following strategies:

(a) Portfolios of evidence

(b) Simulations, role play and workplace assessments

(c) Written and oral assessments and examinations

(d) Written assignments

(e) Case studies

(f) Journal clubs

(g) Self-assessment strategies, peer-group assessment and preceptor evaluation

(h) Objective structured clinical examination (OSCEs).

15. CREDIT ACCUMULATION AND TRANSFER:

Candidates may apply for recognition of credits obtained as part of an incomplete qualification at the same or a different institution, depending on individual institutional policies.

---

[12] Viswanad V, Prabhakar V. 2011. The emergence of the clinical pharmacist and the Indian scenario. Inventi Rapid: Pharmacy Practice 2, (1). Published on Web 21/02/2011, www.inventi.in

16. ARTICULATION (PROGRESSION):

Completion of a Professional Master's Degree meets the minimum entry requirement for admission to a Doctoral Degree, usually in the area of specialisation in the Master's Degree.

Articulation may also be horizontal to entries into other Master's Degrees in a similar or related field or area of specialisation.

17. MODERATION OPTIONS:

Suitable moderation options should be included in each application for accreditation to provide this qualification in accordance with the stipulations of the Council on Higher Education (CHE), as well as the relevant ETQA (i.e. Council). Both internal and external moderation should form an integral part of the provision of this qualification.

18. CRITERIA FOR THE APPOINTMENT OF ASSESSORS:

Assessors in the field of clinical pharmacy must have a suitable background with a proven track record and relevant experience to enable them to make sound judgements through their expert application of the assessment criteria specified for this qualification.

19. NOTES:

(a) All candidates must, in addition to their current registration as academic interns or pharmacists, be registered with Council for study towards the specialisation for the duration of the period of learning as specified in the current relevant legislation.

(b) The range of elective learning areas offered will be dependent on the approval of the provider and ETQA.

(c) Credit values reflected for each exit-level outcome in Table 2 should be regarded only as a guideline.

(d) The respective assessment criteria aim to test the achievement of the specific learning outcomes. Some of these criteria are practice-based. Thus, providers are required to include periods in their curricula for this purpose.

(e) After attaining the professional Master's Degree, the candidate may commence with the process for registration as a specialist pharmacist in clinical pharmacy with Council. Requirements for this registration process will be determined by Council.

See Appendix A

APPENDIX A

Requirements for registration as a specialist after obtaining the professional Master of Pharmacy in Clinical Pharmacy

The prospective candidate should be a registered pharmacist with Council.

Training Site

A site registered with Council as a training institution, pharmacy or health facility where clinical pharmacy is routinely practised.

Tutor or supervisor

A registered clinical pharmacist or postgraduate pharmacist tutor/trainer with at least two years' experience in clinical pharmacy.

Practical training

As stipulated by Council.

Evaluation and panel

As stipulated by Council

South African
Pharmacy Council

Professional Master's Degree Qualification and Curriculum Outline

for the

Specialist in Pharmacy: Industrial Pharmacy

CONTENTS

SYNOPSIS 3
QUALIFICATION OUTLINE: 4
1. QUALIFICATION TITLE: 4
2. QUALIFICATION TYPE: 4
3. FIELD AND SUB-FIELD: 4
4. LEVEL: 4
5. CREDITS: 4
6. RATIONALE FOR THE QUALIFICATION: 4
7. PURPOSE: 5
8. RULES OF COMBINATION: 6
9. ACCESS TO QUALIFICATION: 7
10. LEARNING ASSUMED TO BE IN PLACE: 7
11. EXIT LEVEL OUTCOMES (ELO) AND THEIR ASSOCIATED ASSESSMENT CRITERIA: 8
12. CRITICAL CROSS-FIELD OUTCOMES: 14
13. INTERNATIONAL COMPARABILITY: 14
14. INTEGRATED ASSESSMENT: 18
15. CREDIT ACCUMULATION AND TRANSFER: 18
16. ARTICULATION (PROGRESSION): 18
17. MODERATION OPTIONS: 18
18. CRITERIA FOR THE APPOINTMENT OF ASSESSORS: 19
19. NOTES: 19
APPENDIX A 20

SYNOPSIS

The South African Pharmacy Council (hereafter referred to as "Council") envisages designing and developing a curriculum for a professional master's degree in Industrial Pharmacy for the purposes of enabling registration as a specialist with a postgraduate qualification in compliance with Council requirements.

Table 1: Summary of the proposed qualification

Master of Pharmacy in Industrial Pharmacy	
Duration:	Two (2) years
Entry criteria:	Bachelor's Degree in Pharmacy or Equivalent
HEQSF-level:	**Level 9**
Field (CESM)	**09** Health Sciences and Social Services
Sub-field:	0911 Curative Health
SAQA credits:	240 credits
Qualification type:	Professional, exit-level, career-orientated, whole qualification
Final assessment and evaluation:	1. The following components of the curriculum must be passed in accordance with the rules and regulations specific to the relevant Higher Education provider: (a) All course modules (compulsory and electives) (b) Work-Based Learning components (WBL) (c) Relevant research project (d) A comprehensive portfolio of evidence for each candidate to be submitted to the accredited provider. 2. To register as a specialist after obtaining the professional master's degree, candidates must complete two (2) years of practical exposure/experience in a relevant environment, e.g. Research and Development Institution, Manufacturing Facility, Regulatory Affairs which may be waivered or shortened on application for qualifying persons with at least three (3) years of relevant experience.
CPD requirements for annual re-registration:	As required by Council
Professional status:	Registration with Council as a practising Industrial Pharmacist
Articulation:	PhD or Professional Doctoral Degree

QUALIFICATION OUTLINE:

1. QUALIFICATION TITLE

Master of Pharmacy in Industrial Pharmacy

Abbreviation: MPharm (Industrial Pharmacy)

2. QUALIFICATION TYPE

Professional Master's Degree

3. FIELD AND SUB-FIELD

Field: [09] Health Sciences and Social Services

Sub-field: [0911] Curative Health

4. LEVEL:

NQF **Level 9** (Master's Degree)

5. CREDITS

Total credits: 240

6. RATIONALE FOR THE QUALIFICATION

The South African Pharmacy Council (SAPC), as the statutory body regulating pharmacists and pharmacy support personnel, seeks to develop a speciality in Industrial Pharmacy at an intermediate postgraduate level.

In line with Sustainable Development Goals (SDGs), 3, 8, and 9 as well as the National Development Plan that requires the diversification of manufactured commodities in the country to boost economic growth, the Master's degree in Pharmacy (Industrial Pharmacy) was developed to meet the requirements of the pharmaceutical industry in South Africa to facilitate enhancement of local production of pharmaceuticals (LPPs) and registration of health products, food supplements and cosmetics. These products are required to meet relevant quality, safety, efficacy, and performance standards and are manufactured under applicable regulations promulgated and administered by health authorities/regulators, which set minimum standards for activities involved in all stages of the lifecycle of health products and materials. Furthermore, the intention is that this will contribute positively to the South African government's Industrial Policy Action Plan.

From the perspective of the Department of Health, the pharmaceutical industry should be viewed as central to the so-called industrial health complex, i.e. economic activities which form the basis for goods production and services related to the provision of health services. Therefore, the development of the sector will contribute to the development of skilled industrial pharmacy professionals.

The SAPC has recognised the need for the development of a specialisation for pharmacists at MPharm level to ensure that the growth of the industry is accommodated and to create career opportunities for pharmacists in the pursuit of the SAPC Vision 2030, the National Skills Development Strategy (NSDS), the Human Resource Development Strategy for South Africa, the requirements of the

New Growth Path, the Industrial Policy Action Plan, and the outcomes of the Medium-Term Strategic Framework.[1]

The existence of this specialisation does not preclude pharmacists with a Bachelor of Pharmacy degree practising in the areas of manufacture and registration of health products. Pharmacists should continue to perform the acts pertaining to the scope of practice of a pharmacist. Industrial pharmacists should be competent to take a leading responsibility in all activities that relate to the practice of industrial pharmacy and must do so in compliance with the requirements of the Medicines and Related Substances Act, 101 of 1965, the Pharmacy Act, 53 of 1974, and other applicable legislations.

The rationale for the Master of Industrial Pharmacy postgraduate qualification is to educate and train industrial pharmacist postgraduates who, on completion of a qualification, would be able to register with the South African Pharmacy Council as specialists in order to improve industrial pharmacy practice in South Africa and take up leadership roles based on their well-rounded industrial pharmacy education (e.g. Responsible Pharmacist). Postgraduates must be holders of a Bachelor of Pharmacy (or equivalent qualification) and, following completion of a professional master's degree, may articulate to a Doctoral Degree. Graduates will be skilled to work in the pharmaceutical industry at a technical and leadership level. It is envisaged that the graduates will have sufficient knowledge and competencies to drive innovation and competitiveness within the industry and thus enhance pharmaceutical production in South Africa and the rest of our continent, with associated positive economic and social spin-offs for industrial growth as well as human social development. The graduates will also have competencies to ensure the quality, safety, efficacy and performance of healthcare products according to national and international regulatory frameworks.

7. PURPOSE

The Master of Pharmacy in Industrial Pharmacy is a 240-credit degree at NQF level 9. The purpose of this Professional Master's Degree is to educate and train highly specialised pharmacists for the pharmaceutical industry in accordance with National Skills Development Strategy (NSDS) Phase III[2], the Human Resource Development Strategy for South Africa[3] and the requirements of the Industrial Policy Action Plan[4]. Following completion of the qualification, learners should have the requisite attributes, skills and knowledge to contribute to the development and advancement of pharmaceutical knowledge at an innovative level in the core areas of industrial pharmacy and practice and successfully integrate all essential elements into the practice of industrial pharmacy.

The core fields of study identified as the basis of the envisaged curriculum include:

(a) Research & Development

(b) Formulation

(c) Manufacturing

(d) Distribution/wholesale

Regulatory/compliance and then apply systematically to the requirements and scope.

(a) Pharmaceutical Quality Management Systems

(b) Manufacturing of products, quality assurance and quality control of raw materials and final finished products

(c) Supply chain management, i.e. control, export, import and distribution of health products to ensure cold chain and product life cycle management

(d) Regulatory Compliance, governance, regulation, quality assurance and control, post-marketing surveillance and law enforcement

(e) Facility management

(f) Research and Development (R&D) of new products or reformulation of existing products

(g) Design and maintenance of pharmaceutical, medical device and *in vitro* device (IVD) manufacturing facilities

Graduates of this degree must be able to systematically and creatively deal with complex issues, design and critically appraise analytical writing, make judgements using data and information at their disposal and communicate their conclusions clearly to both specialist and lay audiences, demonstrate self-direction and originality in tackling and solving problems, act autonomously in planning and implementing tasks with a professional orientation, and continue to advance their knowledge, understanding and skills relevant to industrial pharmacy. The Master's degree may articulate vertically with a doctoral-level degree.

8. RULES OF COMBINATION

This qualification has been designed by the South African Pharmacy Council and will be registerable with Council as a specialisation.

Due to the competency-based nature of the curriculum, work-based learning will be integrated into the curriculum.

Successful completion of the degree will require:

(a) Completion of compulsory and elective coursework requiring a high level of theoretical engagement and intellectual independence. Candidates must demonstrate an ability to apply knowledge to complex and appropriate industrial pharmacy problems.

(b) An independent study component comprised of credits at NQF Level 9 (90 credits minimum) of either a single research or technical project (mini thesis/dissertation) or a series of smaller projects (case studies) demonstrating innovation or professional expertise. One credit equals 10 notional hours.

The knowledge mix required for the envisaged programme is listed in Table 2. The different types of learning are integrated across Exit-Level Outcomes (ELO) with the purpose of ensuring the design of an integrated and multidisciplinary curriculum to meet the requirements of post-modern educational programme design. All learning areas are compulsory except disciplinary learning or elective courses that can be offered to the value of 18 credits. Disciplinary learning integrated within professional development (18 credits) should be informed by the field of study of the specific elective course to be studied.

Table 1: *Knowledge Mix*

LEARNING TYPES	ELO01 Pharmaceutical knowledge and knowledge production	ELO02 Specialised Pharmaceutical and Research Skills	ELO03 Professional Development	ELO04 Pharmaceutical Ethics and Statutory Responsibilities and Accountability	TOTAL CREDITS
Compulsory learning	72				**72**
Disciplinary learning (Elective)	18		20		**38**
Practical learning	30				**30**
Situational Learning				10	**10**
Research		90			**90**
TOTAL	**120**	**90**	**20**	**10**	**240**

9. ACCESS TO QUALIFICATION

The minimum admission requirement is a four-year Degree in Pharmacy (NQF Level 8) or equivalent, registration with Council as a pharmacist post-community service, and placement in the area of specialisation.

10. LEARNING ASSUMED TO BE IN PLACE

A four-year degree in Pharmacy (NQF Level 8) in which the knowledge mix is listed in Sections 10.1 – 10.8 are covered:

(a) Professional and ethical practice

(b) Communication skills and self-management

(c) Anatomy and physiology

(d) Pharmaceutics (including aseptic experience, standard operating procedures, Good Manufacturing Practice [GMP] and quality assurance)

(e) Chemistry and Pharmaceutical Chemistry

(f) Forensic Pharmacy

(g) Pharmacy practice

(h) Pharmacology

(i) Clinical Pharmacy

(j) Research methodology

Candidates must comply with all theoretical requirements set by Council for registration as a specialist industrial pharmacist.

11. EXIT-LEVEL OUTCOMES (ELOs) AND THEIR ASSOCIATED ASSESSMENT CRITERIA

11.1 The envisaged ELOs were framed against the Level Descriptors of the South African Qualifications Authority (SAQA) and formulated by integrating the scope of practice as indicated in below, with the scope and depth of the level descriptors on level 9 of the NQF.

The envisaged Scope of Practice of an Industrial Pharmacist includes:

(a) Pharmaceutical Quality Management Systems (QMS) including, but not limited to:

(i) Policy Management: Quality Manual for the implementation and maintenance of the Pharmaceutical Quality Systems (PQS) as per the applicable/GXP/International Organisation for Standardisation (ISO) requirements, Master Validation Plan, Product Life Cycle Management and Continuous Improvement and Proficiency Management;

(ii) Non-Compliance Management and Control Strategy;

(iii) Data Integrity and Computerised Systems Management;

(iv) Adherence to quality by design principles for pharmaceutical products and devices;

(v) Quality risk management;

(vi) Management Responsibility;

(vii) Business Risk Management; and

(viii) Finished Product Release and Distribution.

(b) Manufacturing of products, QA and quality control (QC) of raw materials and final finished products; Production and quality control of pharmaceuticals products and devices according to GxP [good practice standards, where X-represents Manufacturing (GMP), Laboratory (GLP), Wholesaling (GWP) and many other practices] or ISO standards;

(c) Material management: receipt, storage and inventory control of active pharmaceutical ingredients (API) and related materials (including excipients and packaging) and finished product;

(d) Supply chain management (including cold chain management), i.e. procurement control, export, import and distribution of medicine, medical devices, *In Vitro* Devices (IVDs), food supplements and cosmetics, health products to ensure cold chain and product life cycle management;

(e) Regulatory Compliance and governance of health products, including:

(i) governance, regulation

(ii) quality assurance and control, post-marketing surveillance and law enforcement

(iii) Compilation and filing of registration dossiers or Technical Files for marketing authorisation, and engaging with the regulatory authorities

(iv) Ongoing compliance with regulation and post-marketing surveillance requirements

(v) Product dossier of Technical File Life Cycle Management, Health Care Products Regulatory Compliance Management

(vi) Contract and Agreements

(vii) Self-Inspections (Audits and External Audits

(viii) Training

(f) Facility, equipment and utility management;

(g) Research and Development (R&D) of new products or reformulation of existing products;

(h) Design and maintenance of pharmaceutical, medical device and IVD manufacturing facility;

(i) Health and safety, including but not limited to implementation and compliance with the Occupational Health and Safety Act, 85 of 1993;

(j) Provision of information and consultation, including but not limited to communication of technical information to various stakeholders, including other professionals, policymakers and lay people;

(k) Advocacy and lobbying, including but not limited to promoting access to high-quality health products for patients through interaction with other pharmacists, healthcare professionals and regulatory authorities;

(l) Business management and entrepreneurship, including but not limited to starting up and managing a pharmaceutical enterprise;

(m) Research and development, including but not limited to research into improved processes and processing, technologies (PAT) and/or methods relevant to industrial practice and adoption and application of best practice;

(n) Development and testing of formulations and dosage forms, including commonly used dosage forms and/or novel;

(o) Technologies relevant to the market; and

(p) Implementation, conducting and monitoring of all phases of clinical trials.

11.2 EXIT-LEVEL OUTCOMES

ELO 0109 (120 Credits): Develop, integrate and apply specialist pharmaceutical knowledge in the establishment, critical evaluation, monitoring and management of Corrective and Preventative Action (CAPA), problem solving and change control.

Such activities should be performed by making autonomous decisions relating to complex organisational or professional issues including, but not limited to:

(a) Manufacture, export, import and distribution of medicines, medical devices and IVDs;

(b) Design and maintenance of pharmaceutical manufacturing plants;

(c) Quality management systems;

(d) Governance of health products (Regulation, control, post-marketing surveillance and law enforcement);

(d) Business Management; and

(e) Research and development of new products and reformulation of existing products.

Assessment Criteria

The achievement of these competencies will be evident when/if specialist knowledge and advanced scholarship of research and enquiry, and knowledge production are demonstrated within the context of integrated assessment and practice, within fields of learning, including, but not limited to:

ACC010109: Manufacturing, export, import and distribution of health products including, but not limited to:

(a) Raw materials;

(b) Final products;

(c) Plant, equipment and environment;

(d) Manufacturing procedures and processes;

(e) Non-compliance management;

(f) Quality assurance and Quality Control;

(g) Import, export and distribution; and

(h) Cold Chain Management.

ACC020109: Design and maintenance of pharmaceutical plants including, but not limited to:

(a) Manufacturing facilities;

(b) Utilities;

(c) Equipment;

(d) Qualification and validation; and

(e) Access control.

ACC030109: Quality management systems including, but not limited to:

(a) Quality Assurance and Quality Control;

(b) Standard operating procedures (SOPs);

(c) Quality Risk Management (QRM);

(d) Quality by Design (QbD);

(d) Management responsibilities;

(e) Technical agreements;

(f) Audits and Inspections;

(g) Policy management; and

(h) Training.

ACC040109: Health products governance including, but not limited to:

(a) Product Life Cycle Management;

(b) Licensing;

(c) Product registration and dossier/technical file maintenance;

(d) Law enforcement (compliance issues, e.g. substandard and counterfeit products, advertising, management of controlled substances);

(e) Post-marketing surveillance (e.g. recalls, vigilance, pharmacovigilance, field action alert); and

(f) Provision of medical information.

ACC050109: Pharmaceutical Business Management including, but not limited to:

(a) Operations management, including production planning and resource management (e.g. human resources);

(b) Role of the responsible pharmacist in the leadership team;

(c) Business risk management;

(d) Commercial operations management (marketing, finance and forecasting); and

(e) Pharmacoeconomics and health technology assessment.

ACC060109: Research and development including, but not limited to;

(a) Clinical trials;

(b) Formulations development;

(c) Use of unregistered medicines in clinical trials and pre-license programmes, e.g. named patient programmes; and

(d) Research ethics.

ELO0209 (90 Credits): Demonstrate and apply a wide range of specialised skills to address complex and challenging, practical and theoretical problems within the field of industrial pharmacy and be able to design and implement cutting-edge research strategies to address problems.

Candidates should be able to design and implement appropriate and creative solutions in addition to addressing intended and unintended consequences of all potential interventions. They should be able to conduct comprehensive and critical reviews of current research and practices, utilise a range of specialised skills, discourses and technologies to produce insights and knowledge in the field of Industrial Pharmacy, be able to defend ideas generated during their research and communicate such ideas to a wide audience. Such specialised skills may include, but are not limited to:

(a) Root cause analysis (quality management, business management, operations and logistics, risk management, medicines government);

(b) Corrective and Preventative Action (CAPA);

(c) Monitoring and re-evaluation;

(d) Quality management system; and

(e) Clinical trials and governance of medicines.

Assessment Criteria

The achievement of these attributes will be evident when/if:

ACC010209: Specialised skills are used to investigate and identify complex and challenging problems

ACC020209: A situational analysis of a practical and/or theoretical problem in industrial pharmacy is undertaken

ACC030209: Solutions to practical and/or theoretical problems are designed and implemented

ACC040209: Monitoring, evaluation and re-evaluation of proposed solutions are performed in order to generate insight and understand intended and unintended consequences of interventions

ACC050209: Insights/lessons learnt, and knowledge produced are documented and reported

ACC060209: Appropriate literature resources (i.e. reports, legislation, guidelines, policies and technical documentation) informing research and problem solving are identified and used. A comprehensive and critical review of current research and/or practice is conducted and reported

ACC0701209: Appropriate research strategies are designed and implemented in order to produce insight and knowledge

ACC080209: Specialised skills and technologies are applied appropriately in research and problem solving

ACC090209: Communication of research findings is undertaken to audiences of diverse expertise

ELO0309 (20 Credits): Develop and enhance self-directed learning strategies to sustain independent learning, professional development and interactions

As such, the graduate should be able to operate independently and take full responsibility/accountability for their own work, and be able to lead, initiate, and implement systems while ensuring efficient resource management and good governance practice. Such specialised strategies include, but are not limited to:

(a) independent learning;

(b) accountability and responsibility;

(c) leadership;

(d) creativity;

(e) innovation;

(f) project management; and

(g) entrepreneurship.

Assessment Criteria

The achievement of these attributes will be evident when/if:

ACC010309: Independent learning, professional development and interaction are developed and enhanced as demonstrated by learning activities including, but not limited to:

(a) Reviewing personal competencies;

(b) Case studies;

(c) Presentations;

(d) Report writing; and

(e) Simulated learning.

ACC020309: Systems are initiated and implemented to ensure efficient resource and project management and good governance of practice. Such systems must demonstrate that the candidate has an understanding of the necessary accountability, responsibility and leadership attributes required.

ELO0409 (10 Credits): Demonstrate an understanding of ethical standards and the legislation relevant to the pharmaceutical and healthcare industries.

The candidate should take full responsibility and accountability for their decisions and actions. Such understanding may include, but is not limited to, the areas of ethical and statutory responsibility.

Assessment Criteria

Achievement of these attributes will be evident when/if:

ACC010409: An understanding of ethical behaviour and pharmaceutical legislation is demonstrated and implemented.

ACC020409: The role of the Responsible Pharmacist in Industry, with respect to statutory responsibility and accountability, is appreciated, understood and applied at all times.

12. CRITICAL CROSS-FIELD OUTCOMES

(a) The following critical cross-field outcomes form an integral part of the exit-level outcomes for this qualification. Candidates must be able to identify and solve problems, and their responses must display responsible decision making following critical and creative thinking in the field of Industrial Pharmacy

(b) Work effectively with others as a member of an industrial pharmacy team, group, organisation and/or community of practice

(c) Organise and manage their activities responsibly and effectively

(d) Collect, analyse, organise, and critically evaluate information in the field of industrial pharmacy

(e) Communicate effectively using visual, graphical, mathematical and/or language skills for oral and/or written presentations

(f) Critically evaluate pharmaceutical science and technology and show responsibility towards the environment and health of all

(g) Demonstrate an understanding of the world as a set of related systems by recognising that problem-solving contexts do not exist in isolation.

(h) Promote the personal and professional development of each candidate in the programme and the social and economic development of society at large by creating awareness of the importance of:

(i) exploring and reflecting on strategies to learn effectively

(ii) participating as responsible citizens in local, national and global communities

(iii) being culturally and aesthetically sensitive across all social contexts

(iv) exploring education and career opportunities efficiently and

(v) development of entrepreneurial skills

13. INTERNATIONAL COMPARABILITY

The following examples are provided to illustrate the proposed competitiveness and comparability of the proposed curriculum with those of developed and developing countries.

13.1 UNITED KINGDOM

(a) **University of London**

The University of London has three (3) programmes, of which two (2) are discussed here.

(i) Drug Discovery and Development Master of Science

(aa) This programme provides a broad overview of the drug discovery and development process and is designed for graduates of science-based curricula as preparation for either PhD-level research studies or a career in the pharmaceutical industry or a regulatory body.

(bb) Students gain hands-on experience in molecular modelling and computer-based drug design, analytical and synthetic techniques. They are also exposed to modern platforms of drug discovery and methods of synthesis.

The programme consists of 180 credits made up of three core modules (90 credits), two optional modules (30 credits) and a dissertation (60 credits). The core modules are offered in medicinal chemistry, drug discovery and development. The dissertation is written following a laboratory-based research project, which is assessed at the end of the year as a written report and by oral presentation.

(cc) The programme is delivered through a combination of lectures, tutorials and seminars supported by e-learning and practical classes. Assessment is undertaken through a combination of written examinations and continuous coursework submission and assessment.

(ii) Drug Discovery and Pharma Management Master of Science

(aa) This is a recently introduced programme started as a spin-off from a Drug Discovery Master of Science (MSc) degree in response to increasing opportunities that exist for research scientists to evaluate the business potential of their generated science.

(bb) This MSc is comprised of the scientific core of the Drug Discovery MSc and combines a broad overview of the drug discovery and development process with specialisation in management training and awareness, strategic partnering and business development skills. The programme consists of 180 credits, comprised of five core modules (120 credits) and a dissertation (60 credits). The core modules are medicinal chemistry, pharma management, drug discovery and development. The dissertation is undertaken as a business development project based on an aspect of science from drug discovery, which is assessed at the end of the year as a written report and via oral presentation.

(cc) The programme is delivered through a combination of lectures, tutorials, seminars and practical classes. Assessment is achieved through a combination of written examinations and coursework. The business development project is assessed by

a written report and an oral presentation to the class and a panel of judges comprised of scientists and business managers.

(dd) The entry requirements are a second-class UK Bachelor's degree or higher in a related subject such as pharmacy, pharmaceutical science, pharmacology, physiology, physical science, biochemistry, biotechnology, chemistry, chemical engineering, genetics, material sciences, or a medical degree (MBBS), or an overseas qualification of an equivalent standard.

(b) **University of Central Lancashire**

(i) *Master of Science Industrial Pharmaceutics:* This MSc programme develops the skills required for prospective employees in the pharmaceutical industry and has been developed following extensive discussions with the industry. The emphasis of the programme is on dosage form development and manufacture.

The programme is open to students with an undergraduate degree in chemistry, pharmacy, biology, related subjects or experience equivalent to the above. The course is offered as a one-year full-time course taught over three terms. A research project is undertaken for the whole of the third term. Practical, industry and research skills are incorporated in all aspects of the programme.

(c) **University of Strathclyde**

(i) *Master of Science Advanced Pharmaceutical Manufacturing*: This course trains graduates in key aspects of modern manufacturing approaches suitable for pharmaceuticals and high-value chemicals. This course is designed to produce highly skilled graduates well-versed in continuous manufacturing science and technology to meet the growing demands for expertise in this area. Candidates are trained to take up jobs in the food, chemical and pharmaceutical industries. The course consists of 180 credits, 120 credits (six 20-credit taught modules) of which are taught in combination with practical classes, after which they complete a research project at the University or at an external company or organisation.

Compulsory classes include materials in which research skills, Process Analytical Technology (PAT), Quality by Design (QbD) in Continuous Pharmaceutical Manufacturing, Continuous Manufacturing of Pharmaceutical Particles and Products, and Pharmaceutical Project Management are covered. Theory and applications are taught through lectures, tutorials, seminars and web-based learning approaches.

13.2 UNITED STATES

(a) **University of Ephos**

(i) *Master's Degree in Industrial Pharmacy and Regulatory Affairs*: This degree in industrial pharmacy and regulatory affairs provides students with technical know-how and allows them to develop skills such as analysis and problem solving, organisation and sound application of methodology as required by the pharmaceutical industry so as to be

able to enter areas of drug manufacturing and control, distribution and regulatory affairs.

Modules offered in this degree include professional skills, legal framework for drugs, drug manufacture and control, regulatory affairs and pricing, reimbursement and access and a thesis on planning for the registration and manufacture of a drug in the American context.

13.3 AFRICA

(a) **Kilimanjaro School of Pharmacy (KSP) / Purdue University**

(i) *Advanced Industrial Pharmacy Training Programme*: The Advanced Industrial Pharmacy Training Programme is offered at KSP in close collaboration with lecturers from Purdue and Howard Universities, USA and aims at filling a void on the continent *viz.* the lack of a well-educated and qualified workforce that is a key factor constraining the growth and development of the local pharmaceutical industry.

Modules covered include Drug Development, Good Regulatory Practices and Documents and Dialogues of Drug Development and Registration. Students are able to work towards a master's degree conferred by Purdue University.

13.4 INDIA

(a) Pharmacy education in India, both at the BPharm and MPharm levels, is taught as an industry- and product-oriented profession with a focus on the basic sciences. Six (6) National Institutes of Pharmaceutical Education and Research (NIPER) in India offer MS (Pharm), MTech (Pharm) and higher-level degrees. The NIPER were created with the vision of providing excellence in pharmacy and pharmacy-related education. The MPharm degree is offered in many disciplines, including pharmaceutics and pharmacology. The curriculum is divided into two parts. The first is one (1) year of didactic theory and laboratory course work, and the second involves completion of a research project under the supervision of a faculty member in pharmacy in a selected discipline. Students who pursue an MPharm in industrial pharmacy may undertake research projects in the pharmaceutical industry during the second year of the course and an industrial expert is appointed as a co-supervisor who is responsible for this part of the research.

(b) The JSS College in Mysore offers a two-year MPharm degree in one of twelve (12) areas of specialisation, including but not limited to Industrial Pharmacy, Pharmaceutical Analysis, Pharmaceutical Quality Assurance and Regulatory Affairs. Candidates who have passed a BPharm degree at any recognised University are eligible for admission to the qualification. The course is offered as a two-year full-time degree with taught modules, a dissertation and an oral examination. No work-based or experiential components apart from laboratory-based practicals are included.

13.5 BRAZIL

(a) The School of Pharmaceutical Sciences (FCF) at "Júlio de Mesquita Filho" São Paulo State University – UNESP offers a teaching-based course founded on the principle of integration of teaching, research and community service that are considered indissociable. The Graduate School offers three

stricto sensu programmes at the master's and Doctoral levels in the Food and

Nutrition area focusing on Food and Nutritional Science, Clinical Analysis and Pharmaceutical Sciences, including research and development of pharmaceuticals and drugs, and Bioprocessor and Biotechnology Engineering.

14. INTEGRATED ASSESSMENT

A combination of integrated assessment strategies, including formative and summative assessment and evaluation, must be used to ensure that the purpose of the qualification is achieved. Assessment may include, but is not limited to, any or all of the following approaches:

(a) Portfolio of evidence;

(b) Mini dissertation;

(c) Practical experience workplace assessment;

(d) Written and oral assessments and examinations;

(e) Written assignments;

(f) Objective Structured Practical Examination (OSPE);

(g) Case studies;

(h) Journal clubs; and/or

(i) Self-assessment strategies, peer-group assessment and preceptor evaluation.

15. CREDIT ACCUMULATION AND TRANSFER

Candidates may apply for recognition of credits obtained as part of an incomplete qualification at the same or a different institution, depending on the admission and articulation policies of individual institutions.

16. ARTICULATION (PROGRESSION)

Achievement of a master's degree is an indication that the minimum entry requirement for admission to a doctoral degree, usually in the area of specialisation of the master's degree, has been achieved.

Articulation may also be horizontal, and entry into other master's degrees in a similar or related field or area of specialisation, may be considered.

17. MODERATION OPTIONS

Suitable moderating options should be included in each application for accreditation so as to ensure this qualification complies with the stipulations of the Council on Higher Education (CHE), as well as the relevant Standards Generating Body (SGB) (i.e. Council). Both internal and external moderation should form an integral part of quality assurance for the provision of this qualification. External moderators are selected based on their expertise in the particular field of study.

18. CRITERIA FOR THE APPOINTMENT OF ASSESSORS

Assessors in the field of Industrial Pharmacy must have a suitable background with a proven track record and relevant experience to enable them to make sound judgements through their expert application of the assessment criteria specified for the qualification.

19. NOTES

(a) All candidates must, in addition to their current Council registration as academic interns or pharmacists, be registered with Council for the MPharm for the duration of the period of learning as specified in current relevant legislation

(b) The range of elective learning areas offered will be dependent on the approval of the provider and SGB

(c) Credit values reflected for each exit-level outcome listed in Table 2 should be regarded as a guideline only

(d) The respective assessment criteria should aim to assess the achievement of specific learning outcomes for modules. Some of these criteria are likely to be practice-based, therefore, providers are required to include time and space in their curriculum design for this purpose

(e) Following completion of the master's degree, a candidate may commence with the process of registration as a specialist pharmacist in Industrial Pharmacy with Council. Requirements for this registration process will be as determined by Council (see Annexure A).

References

---

[1] Medium Term Strategic Framework: 2014-2019 - DPME www.dpme.gov.za/keyfocusareas/outcomesSite/Pages/default.aspx

[2] http://led.co.za/sites/default/files/cabinet/orgname-raw/document/2012/nsds_3.pdf

[3] http://www.hrdcsa.org.za/sites/default/files/documents/Microsoft%20Word%20-%20HRDSA%20stra tegy.doc.pdf

[4] http://www.thedti.gov.za/news2013/ipap_2013-2016.pdf

ANNEXURE A

Requirements for registration as a specialist after obtaining the Master of Pharmacy in Industrial Pharmacy

The prospective candidate should be a registered pharmacist or Pharmacist Intern with Council.

Training Site

A site registered with Council as a training institution, pharmacy or health facility where industrial pharmacy is routinely practised.

Mentor or supervisor

A registered industrial pharmacist or postgraduate pharmacist mentor /supervisor with at least two years' experience in industrial pharmacy.

Practical training

Two (2) years as stipulated by Council.

Evaluation and panel

As stipulated by Council

South African
Pharmacy Council

Professional Master's Degree Qualification and Curriculum Outline

for the

Specialist in Pharmacy: Public Health Pharmacy

CONTENTS

SYNOPSIS: 2

QUALIFICATION OUTLINE: 3

1. QUALIFICATION TITLE: 3
2. QUALIFICATION TYPE: 3
3. FIELD AND SUBFIELD: 3
4. LEVEL: 3
5. CREDITS: 3
6. RATIONALE FOR THE QUALIFICATION: 3
7. PURPOSE: 5
8. RULES OF COMBINATION: 6
9. ACCESS TO THE QUALIFICATION: 6
10. LEARNING ASSUMED TO BE IN PLACE: 6
11. EXIT LEVEL OUTCOMES AND THEIR ASSOCIATED ASSESSMENT CRITERIA: 7
12. CRITICAL CROSS-FIELD OUTCOMES: 19
13. INTERNATIONAL COMPARABILITY: 19
14. INTEGRATED ASSESSMENT: 25
15. CREDIT ACCUMULATION AND TRANSFER: 25
16. ARTICULATION (PROGRESSION): 25
17. MODERATION OPTIONS: 26
18. CRITERIA FOR THE REGISTRATION OF ASSESSORS: 26
19. NOTES: 26

APPENDIX A 27

LIST OF TABLES

Table 1: Summary of the proposed qualification 2

Table 2: Curriculum Outline 8

SYNOPSIS:

To provide a curriculum for a professional Master's Degree in Public Health Pharmacy and Management to enable students to register with the South African Pharmacy Council (hereafter referred to as Council) as specialists with a post-qualification that complies with Council's requirements.

Table 1: Summary of the proposed qualification

	Professional Master of Pharmacy in Public Health Pharmacy and Management
Duration:	Two years
Entry criteria:	Bachelor's Degree in Pharmacy (NQF Level 8)
NQF-level:	**Level 9**
Field:	09 Health Sciences and Social Services
Sub-field:	Curative Health
SAQA-credits:	240 credits
Qualification type:	Professional, exit-level, career-orientated, whole qualification
Final assessment and evaluation:	• Final, exit level examination(s) will need to be passed in accordance with the relevant Higher Education provider's rules and regulations. • In addition, a comprehensive portfolio of evidence will need to be submitted and successfully passed by the accredited provider. • Requirements for registration as a specialist after obtaining the Professional Master's Degree will be determined by Council.
CPD requirements for annual re-registration:	As required by Council
Professional status:	Registration with Council as a Pharmacist Specialist in Public Health Pharmacy and Management
Articulation	DPharm/Doctoral Degree

QUALIFICATION OUTLINE

1. QUALIFICATION TITLE

Master of Pharmacy in Public Health Pharmacy and Management

Abbreviation: MPharm (Public Health Pharmacy)

2. QUALIFICATION TYPE

Professional Master's Degree

3. FIELD AND SUBFIELD

Field: [09] Health Sciences and Social Services

Subfield: Curative Health

4. LEVEL

NQF/HEQF **Level 9** (Master's Degree)

5. CREDITS:

Total credits: 240

6. RATIONALE FOR THE QUALIFICATION

There is a need in South Africa, especially with the implementation of the National Health Insurance (NHI) and the re-engineering of primary healthcare, for pharmacists to have the necessary skills and expertise to implement public health standards and management principles in the delivery of pharmaceutical services to the population. This need is in line with current local and international efforts to stop the increase of chronic non-communicable diseases. The commitment of pharmacists to combat non-communicable diseases (including cardiovascular diseases, diabetes, chronic respiratory diseases and cancers) was noticeably evident in 2011 when the Durban Declaration was issued at a conference jointly hosted by the Commonwealth Pharmacists Association, the Pharmaceutical Society of South Africa and the South African Pharmacy Council (SAPC).[1]

Internationally, the professional practice role of the pharmacist in public health, and the increasing contribution pharmacists should be making to the provision of public health, has been highlighted.

Postgraduate specialisation for pharmacists in pharmaceutical public health was advocated at the 9th International Conference on Life-Long Learning in Pharmacy in New Zealand in 2011.[2] Having specialist public health pharmacists within the profession would be in line with the progressive towards a more patient-oriented focus.

In March 2014, the Royal Pharmaceutical Society in the United Kingdom published *Professional Standards for Public Health Practice for Pharmacy*, which sets out a best practice framework for the delivery of public health services across all pharmacy settings

[1] Commonwealth Pharmacists' Association. The Durban Declaration. S Afr Pharm J. 2011; 78:10.

[2] Shaw.J. 20:20 Vision Focusing on the Future of Pharmacy Practice and Education. School of Pharmacy. Life Long Learning in Pharmacy Conference, Rotorua, New Zealand, 29 June 2011.

in England and Wales.[3] These standards emphasise the pharmacy profession's integral part in public health and the public health workforce aimed at delivering a service that will improve the health and well-being of the public health community.

The professional Master's Degree in Public Health Pharmacy and Management, NQF Level 9, was developed to meet the requirements of Council, the statutory body for the pharmacy profession, for specialists in pharmacy with specific reference to public health pharmacy and management. With this qualification, specialist pharmacist training is aligned with the needs of the health system and will contribute to capacity building for better management of pharmaceutical services, provide for the professional recognition of the pharmacist's role in public health activities and preserve pharmacists, as a scarce resource, in South Africa.

'Public health' is defined as *the science and art of promoting and protecting health and well-being, preventing ill health and prolonging life through the organised efforts of society*.[4] The World Health Organisation (WHO)[5] further states that public health refers to all organised measures, whether **public or private**, to prevent disease, promote health, and prolong life among the population as a whole. Public health activities are therefore aimed at improving health for entire populations and not only individual patients or a particular disease. The WHO[5] and the Royal Pharmaceutical Society[3] identified three main public health functions or domains. The pharmacy profession has a role to play across all three:

(a) Health protection, which entails the assessment and monitoring of the health of communities and populations at risk to identify health problems and priorities. This includes infectious diseases, environmental hazards and emergency preparedness.

(b) Health service delivery and quality, including service planning, efficiency, audit, evaluation and the formulation of public policies designed to solve identified local and national health problems and priorities.

(c) Health improvement, which includes health promotion and disease prevention services, to ensure that all populations have access to appropriate and cost-effective care.

'Public health pharmacy' and **'pharmaceutical public health'** are terminology commonly used to describe the role or involvement of the pharmacist in public health. Pharmaceutical public health has been defined as the *application of pharmaceutical knowledge, skills and resources to the science and art of preventing disease, prolonging life, promoting, protecting and improving health for all through organised efforts of society*.[6]

The focus of pharmaceutical public health is on the development of pharmacy services and expertise to enhance the health and well-being of the whole population. This definition does not, however, cover all the key aspects and potential roles of pharmacists in public health, categorised previously as micro- and macro-level activities.[7] **Micro-level activities** focus on individual health promotion and disease prevention services,

[3] Royal Pharmaceutical Society. Professional Standards for Public Health Practice for Pharmacy. March 2014.
[4] Adapted from the original definition in the Public Health in England report by Sir Donald Acheson, 1988. In: Royal Pharmaceutical Society. Professional Standards for Public Health Practice for Pharmacy. March 2014.
[5] World Health Organisation (WHO). Public health. Trade, foreign policy, diplomacy and health. Available from: http://www.who.int/trade/glossary/story076/en/.
[6] Walker R. Pharmaceutical public health: the end of pharmaceutical care? Pharmaceutical Journal. 2000; 264:340-341.
[7] Rappaport H, et al. Assessment of realistic public health roles for pharmacists. Journal of Social and Administrative Pharmacy. 1984; 2(2):57-66.

while **macro-level activities** comprise population-wide approaches, including policy formulation, planning and management functions.[8] The specialist qualification in public health pharmacy and management will predominantly be appropriate for pharmacists involved in macro-level activities in the public and private sectors.

This professional Master's Degree is designed to meet the needs of pharmacists who have completed the BPharm degree and who wish to further their competencies in the field of pharmaceutical services and develop their careers in the public health pharmacy and management practice area. An increase in the number of pharmacists with specialised knowledge in public health pharmacy and management will contribute to capacity building in this field, for the overall development of healthcare in South Africa. Pharmacists with this qualification will practise at a higher level and hold senior positions within the health system. Positions of practice would include, for example, pharmaceutical management in the public sector (facility pharmacy manager, sub-district or district pharmacist, provincial head office, policy or human resources, medical depot, national level positions), academia (especially pharmacy practice or public health), private sector (medical aid schemes, community pharmacy), non-profit organisation (including global health-sector non-profit organisations), general management positions in health systems or hospital management (public, private, non-profit) and public-private partnerships (part of non-governmental organisations (NGOs) and NHI).

The development and introduction of this qualification and curriculum outline will assist higher education institutions in the training of these specialist pharmacists who can register with Council as specialists in public health pharmacy and management. Although the sub-field for this qualification is currently listed as curative health, it also includes preventative health, health promotion, health education, environmental health and occupational health.

7. PURPOSE

The purpose of this professional **Master's Degree** is to extend the public health and pharmaceutical management competencies of pharmacists to become **specialists in the field of public health pharmacy and management,** apply their expertise in this field and add value to the provision of pharmaceutical services within the health system. Successful completion of this qualification will enable specialist pharmacists to contribute to public health outcomes and pharmaceutical services management. The degree is inherently a practice-based degree with a large component of work-integrated learning.

Council's Scope of Practice for Public Health Pharmacy and Management Pharmacists

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

(b) Lead and manage surveillance and assessment of the pharmaceutical services.

(c) Lead projects to protect and promote health and well-being, including communicable disease control and environmental health.

(d) Manage, analyse and interpret information and statistics.

[8] Bradley H, Sanders D, Bheekie A. Public health: every pharmacist's business! S Afr Pharm J. 2011; 78(10):34-36.

(e) Develop and analyse pharmaceutical public health policy for the better use of existing and new medicines/technologies and rational use of all medicines, to improve health services.

(f) Provide strategic leadership for medicine supply management.

(g) Provide education and training related to public health and management.

(h) Manage knowledge and transfer research evidence into practice.

(i) Develop policies and procedures for public health and management.

(j) Manage, analyse, interpret and advise on pharmacoeconomic information for the rational use of medicines.

(k) Perform research, teach and publish in the field of public health and management.

8. RULES OF COMBINATION

Fundamental credits:	43
Core credits:	176
Elective credits:	21
Total:	240

9. ACCESS TO THE QUALIFICATION

The minimum admission requirement is a four-year Degree in Pharmacy (NQF level 8) or equivalent, registration with Council as a pharmacist post-community service, and placement in the area of specialisation.

10. LEARNING ASSUMED TO BE IN PLACE

A four-year Degree in Pharmacy (NQF Level 8), assuming the following are in place:

(a) Professional and ethical practice;

(b) Communication (collaboration with members of the healthcare team) and self-management;

(c) Optimal use of medicines (therapeutic decision-making) and medication management;

(d) Basic knowledge of healthcare and pharmaceutical management;

(e) Pharmacology; and

(f) Research methodology.

Candidates have to comply with all of the theoretical requirements set by Council for registration as a specialist pharmacist, as well as annual registration, and must have a thorough understanding and working knowledge of South African *Good Pharmacy Practice* rules.

11. EXIT-LEVEL OUTCOMES AND THEIR ASSOCIATED ASSESSMENT CRITERIA

See Table 2.

Table 2: Curriculum Outline

Learning Area	Exit-Level Outcome	Credits	Notional Hours
Fundamental	*Exit-Level Outcome 1:* Practise as a specialist pharmacist within the regulatory and policy framework of public health pharmacy	19	240
Fundamental	*Exit-Level Outcome 2:* Apply basic epidemiology and biostatistics in disease prevention, health promotion, healthcare delivery and policy development	24	240
Core	*Exit-Level Outcome 3:* Apply strategic management and leadership to ensure an effective and efficient health system	24	200
Core	*Exit-Level Outcome 4:* Implement the concepts and principles of public health to protect and promote general health and well-being	24	300
Core	*Exit-Level Outcome 5:* Provide strategic leadership for pharmaceutical management in the health system	24	260
Core	*Exit-Level Outcome 6:* Design and implement strategies for the rational use of pharmaceuticals to improve health services	24	280
Core	*Exit-Level Outcome 7:* Conduct research and prepare for publication in one of the specialisation fields of public health pharmacy and management	80	80
Elective	*Exit-Level Outcome 8:* Deepen knowledge of work in research interest area for transition to independent work in public health pharmacy and management	21	160
MPharm (Public Health Pharmacy and Management)	**TOTAL**	**240**	**2 400**

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Public Health Pharmacy and Management (MPharm)	Fundamental	*Exit-Level Outcome 1:* Practise as a specialist pharmacist within the regulatory and policy framework of public health pharmacy. **[16 credits]**	*Assessment Criteria for Exit-Level Outcome 1:* 1. Interpret and explain the sources of South African law, how it is developed and the interrelationship between the constitution, legislation and the functioning of the courts. 2. Identify, analyse and interpret relevant legislation and policy in the delivery and management of public health pharmacy services. 3. Examine and evaluate the implementation of National Health Insurance within the regulatory and policy framework of public health. 4. Analyse the Bill of Rights (equity), Patient Rights Charter and Batho Pele Principles and appraise their application to the health sector. 5. Appraise and apply the process of development and amendment of legislation and policies. 6. Identify, appraise and apply professional responsibilities and obligations within an ethical framework in providing optimal care to communities.	190

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Public Health Pharmacy and Management (MPharm)	Fundamental	*Exit-Level Outcome 2:* Apply basic epidemiology and biostatistics in disease prevention, health promotion, healthcare delivery and policy development. **[24 credits]**	*Assessment Criteria for Exit-Level Outcome 2:* 1. Critically evaluate and use the common causes of death, disease and disability in a particular community in the planning and design of health programmes. 2. Identify, analyse and evaluate the main determinants of health for potential implementation into health policy and health services. 3. Conduct and interpret community health needs assessment to plan healthcare and public health programmes. 4. Apply the principles and methods of epidemiology in public health. 5. Use epidemiological data to appraise the effectiveness and efficiency of healthcare delivery. 6. Design appropriate studies to determine causes of disease, prognosis, prevention and the evaluation of therapy. 7. Design and demonstrate the ability to implement in-practice interventions to prevent and control disease. 8. Apply key biostatistical concepts and methods to summarise, display, evaluate and interpret medical and healthcare data.	240

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Public Health Pharmacy and Management (MPharm)	Core	*Exit-Level Outcome 3:* Apply strategic management and leadership to ensure an effective and efficient health system. **[20 credits]**	*Assessment Criteria for Exit-Level Outcome 3:* 1. Identify, appraise and adhere to principles of good corporate governance. 2. Apply appropriate management styles and skills at the different managerial levels to ensure efficient and effective service. 3. Appraise and practise effective leadership in a healthcare environment. 4. Analyse and apply concepts and principles of change management in areas of organisational development. 5. Evaluate and apply coaching, mentoring and counselling skills to improve organisational performance. 6. Apply motivational theories in performance management and the development of human resources. 7. Establish and maintain effective organisational and interdisciplinary teams to ensure quality patient care. 8. Apply strategic management in the design of a public health project to promote community health.	240

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Public Health Pharmacy and Management (MPharm)	Core	*Exit-Level Outcome 4:* Implement the concepts and principles of public health to protect and promote general health and well-being. **[30 credits]**	*Assessment Criteria for Exit-Level Outcome 4:* 1. Outline and appraise the context of the public health environment. 2. Critically explore and analyse health systems. 3. Explain, appraise and apply the design, implementation, evaluation and review of public health policies and procedures. 4. Explain and evaluate the application of the pharmaceutical policy process at the relevant levels of pharmaceutical service delivery. 5. Demonstrate the ability to develop public health policies for the management and rational use of medicines to improve health services. 6. Analyse policy instruments for the delivery of pharmaceutical services. 7. Compile a policy and procedure manual for the healthcare organisation. 8. Demonstrate the ability to implement policy instruments and a policy and procedure manual. 9. Design and implement screening services for health promotion. 10. Apply social, psychological and behavioural aspects in health promotion, education and the design of interventions for the health and well-being of the community.	240

			11. Apply and appraise the principles of cold chain management and immunisation according to required standards. 12. Design and use surveillance tools to collect information on community health.	

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Public Health Pharmacy and Management (MPharm)	Core	*Exit-Level Outcome 5*: Provide strategic leadership for the management of pharmaceuticals in the health system. **[26 credits]**	*Assessment Criteria for Exit-Level Outcome 5*: 1. Evaluate and critically appraise access to medicines in South Africa. 2. Appraise and apply the essential medicines concept in the selection of medicines for the essential medicines lists. 3. Analyse and implement the framework and components of pharmaceutical supply systems. 4. Utilise a health management information system for decision-making and to improve access to pharmaceuticals. 5. Appraise and apply good financial management principles to ensure a continuous supply of medicines. 6. Demonstrate the ability to manage and develop human resources for the effective supply of pharmaceuticals. 7. Demonstrate the ability to implement a quality and risk management programme for effective pharmaceutical supply and use. 8. Design tools to monitor and evaluate the supply chain system and provide feedback to relevant stakeholders.	240

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Public Health Pharmacy and Management (MPharm)	Core	*Exit-Level Outcome 6:* Design and implement strategies for the rational use of pharmaceuticals to improve health services. **[28 credits]**	*Assessment Criteria for Exit-Level Outcome 6:* 1. Evaluate the use of pharmaceuticals within the medicines management cycle and health system. 2. Appraise and enhance rational drug use through the implementation of and participation in all the activities of the pharmacy and therapeutics committee by all stakeholders. 3. Distinguish and apply the different types of costs in pharmacoeconomic analysis. 4. Appraise and correctly apply the appropriate pharmacoeconomic tools to conduct analyses for the rational use of pharmaceuticals. 5. Critique pharmacoeconomic literature for application in pharmacoeconomic analyses and decision-making. 6. Construct a simple model for pharmacoeconomic evaluation and decision-making. 7. Identify and analyse priorities for rational drug use interventions and design strategies for interventions. 8. Demonstrate the ability to implement and monitor drug use interventions. 9. Design, apply and evaluate programmes for quality assurance of medicines use (e.g. adherence, medicine safety, medication errors). 10. Design pharmacovigilance and surveillance programmes for patient safety.	240

			11. Demonstrate the ability to implement pharmacovigilance, surveillance and quality assurance programmes.	

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Public Health Pharmacy and Management (MPharm)	Core	*Exit-Level Outcome 7:* Conduct research and prepare for publication in one of the specialisation fields of public health pharmacy and management. **[80 credits]**	*Assessment Criteria for Exit-Level Outcome 7:* 1. Critically evaluate information sources, literature and research on medicines and practices in terms of evidence for decision-making and implementation in practice. 2. Apply the principles of research methodology in the development of a research protocol and obtain ethical clearance. 3. Conduct research in accordance with established research methodology and ethics, as well as *Good Clinical Practice,* where necessary. 4. Analyse data, interpret findings and/or results and formulate conclusions and recommendations. 5. Write and submit a technical report, manuscript for publication or minor dissertation and obtain approval.	800

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Public Health Pharmacy and Management (MPharm)	Elective	*Exit Level Outcome 8:* Deepen knowledge of work in an appropriate interest area from the options in the range statement. Range statement: The range of topics for electives may include, but is not limited to, the following examples: • Pharmaceutical policy • Pharmacoeconomics • Logistics management in medicines supply • Pharmacovigilance • Health promotion • Preventative health, e.g. Expanded Programme on Immunisation (EPI) • Health systems strengthening for access to medicines • Application of research into health policy and health services • Palliative care in public health • Information systems **[16 credits]**	*Assessment Criteria for Exit Level Outcome 8:* 1. Perform a literature review of an area of interest. 2. Enhance skills in scientific analysis and debate utilising the assessment submissions for this exit-level outcome. 3. Improve the ability to engage in independent research and writing by assessment submissions for this exit-level outcome.	210

12. CRITICAL CROSS-FIELD OUTCOMES:

The following critical cross-field outcomes will form an integral part of the exit-level outcomes of this programme:

(a) Identify and solve problems in which responses display that responsible decisions using critical and creative thinking have been made;

(b) Work effectively with others as a member of a team, group, organisation and community;

(c) Organise and manage oneself and one's activities responsibly and effectively;

(d) Collect, analyse, organise and critically evaluate information;

(e) Communicate effectively using visual, mathematical and/or language skills in the modes of oral and/or written presentation;

(f) Use science and technology effectively and critically, showing responsibility towards the environment and the health of others;

(g) Demonstrate an understanding of the world as a set of related systems by recognising that problem-solving contexts do not exist in isolation;

(h) Promote the personal and professional development of each learner in the programme, and the social and economic development of the society at large, by creating an awareness of the importance of:

  (i) reflecting on and exploring a variety of strategies to learn more effectively;

  (ii) participating as responsible citizens in the lives of local, national and global communities;

  (iii) being culturally and aesthetically sensitive across a range of social contexts;

  (iv) exploring education and career opportunities; and

  (v) developing entrepreneurial opportunities.

13. INTERNATIONAL COMPARABILITY:

The professional Master's Degree in Public Health Pharmacy and Management has been designed and generated with the standards and guidelines as displayed in the qualifications being offered by institutions in South Africa, Tanzania, Australia, the United States of America and the United Kingdom.

Although these countries offer training in pharmacy administration, public health and management, the training is not identical to the qualification proposed in this document. Certain courses or modules offered by the programmes are comparable and were therefore used for benchmarking. The following examples are provided to illustrate the proposed curriculum's competitiveness and comparability among both developed and developing countries.

Africa: South Africa

The Master of Public Health (MPH) is offered by a number of institutions in South Africa, including the University of Pretoria, University of the Witwatersrand, Sefako Makgatho Health Sciences University, University of the Western Cape, University of Cape Town and the University of KwaZulu-Natal. The general focus of the MPH programme is to prepare professionals for leadership roles in the evaluation of health, health interventions, management and the healthcare system. Similar to the qualification proposed in this document, "public health" refers to the health of entire populations and is not limited to health services within the public sector. Another similarity is that the MPH is a practice-oriented degree and not a research degree.

The MPH exposes students to different disciplines. However, the field of health systems and public health is very wide, and students cannot become specialists in all its aspects, which is also the situation with the proposed qualification. The MPH programmes are structured in a way that students will acquire a good understanding of the entire field of health systems and public health, but they select one particular track or focus area in which they will develop detailed and sufficient competence.

The course content of the various MPH programmes examined is different, however, there are certain topics covered by most MPH programmes that are also covered, to a certain extent, by the qualification proposed in this document.

Comparable modules or courses include the following topics:

(a) Epidemiology and Biostatistics

(b) Health Policy and Management

(c) Environmental and Occupational Health

(d) Disease Control

(e) Health Research Ethics

(f) Health Promotion

(g) Financial Management in the Public Sector

(h) Project Management

Africa: Tanzania

The Muhimbili University of Health and Allied Sciences (MUHAS), Dar-es-Salaam, Tanzania, offers two degrees, of which some of the components are comparable with the proposed qualification.

The School of Pharmacy offers a Master of Science in Pharmaceutical Management, which is a four-semester degree programme, each semester consisting of 24 weeks.

The degree contains a dissertation comprising 45% of the total credits for the degree. This is similar to the coursework of the South African general Master's Degree, which contains a research project comprising a minimum of 60 credits at NQF Level 9, and culminates in a mini-dissertation, technical report, one or more creative performances or works, or a series of peer-reviewed articles or other research-equivalent outputs.

The degree programme contains the following courses:

(a) Bioethics

(b) Epidemiology & Research

(c) Healthcare Delivery and Pharmaceutical Regulatory Framework

(d) General Management

(e) Financial Management

(f) Educational Principles and Practices for the Health Sciences Professionals

(g) Pharmaceutical Supply Chain Management

(h) Managing Rational Use of Medicines

(i) Drug and Commodity Management in Health Facilities

(j) Pharmaceutical Marketing

(k) Fieldwork in Pharmaceutical Management

(l) Dissertation

The School of Public Health and Social Sciences offers a Master of Public Health (MPH) Executive Track, which is a modular programme. The aim of the programme is to train candidates to become public health specialists in government and non-governmental organisations (NGOs) as well as national and international organisations. The Research Methods module constitutes 8,5% and the Dissertation 20% of the total credits of the MPH, which is in line with the Higher Education Qualifications Sub-Framework recommendation for professional Master's Degrees in South Africa.

The MPH programme contains the following courses, which illustrate the similarity with the qualifications outlined in this document:

(a) Principles of Public Health

(b) Epidemiology and Biostatistics

(c) Implementing Change

(d) Special Public Issues

(e) Health Policy, Planning and Management

(f) Health Economics Financing and Evaluation

(g) Research Methods

(h) Dissertation

Australia: Queensland

The James Cook University School of Pharmacy offers a Master of Pharmaceutical Public Health over a period of two years. They define pharmaceutical public health as the development of pharmacy services and expertise to enhance the health and well-being of a whole population. The programme is designed to enable pharmacists to focus beyond the specific needs of individual patients and meet health goals for the whole

community. The course is structured for pharmacists who want to learn the principles of public health and develop services in their different fields of practice. These principles are in line with the scope of practice for this qualification.

The course consists of the following three core subjects:

(a) Epidemiology for public health

(b) Management of pharmaceutical services

(c) An option between public health management and public health leadership and crisis management.

For the degree to be awarded, students should complete a dissertation, the three core subjects (above) and additional elective subjects.

United States: Boston University

Boston University School of Public Health offers a Public Health Pharmaceuticals Programme for students to gain knowledge and expertise to address pharmaceutical issues from a public health perspective. The programme is offered at a master's level for students considering careers in the pharmaceutical industry, service delivery programmes, or pharmaceutical policy-making agencies. The pharmaceuticals programme prepares students for positions in both the public and private sectors, including positions in federal and state government agencies, the pharmaceutical industry, contracting research organisations and international agencies. Students are given a solid foundation in pharmaceuticals while providing flexibility to tailor their coursework towards a specific career path in policy, industry, or health programmes and non-governmental organisations.

The following three main tracks are offered, with a mandatory 'Pharmaceuticals in Public Health' course for all tracks:

Policy track

(a) Health policy

(b) Health services research methods

(c) Pharmacovigilance

(d) Clinical trials

(e) Patent law

(f) Insurance systems

(g) Qualitative research methods

Industry track

(a) Project management

(b) Good clinical practice

(c) Discovery and development

(d) Clinical trials

(e) Regulatory affairs

(f) Intellectual property

Service delivery track

(a) Project management

(b) Infectious diseases

(c) Rational drug management and medication adherence

(d) Vaccines

(e) Corruption

(f) Qualitative research

United States: Virginia

The School of Business, Virginia Commonwealth University, offers a combined Doctor of Pharmacy (PharmD) and Master of Business Administration (MBA). The programme is designed to take advantage of efficiencies and electives in both the PharmD and MBA programmes and seeks to prepare pharmacists for careers that encompass pharmacy and business theories and principles. Students in the combined programme can earn both degrees and save a year or more over the time required for enrolling in the programmes separately.

To obtain both degrees, students need to take all the pharmacy courses, the seven business foundation courses, the nine MBA core courses and three elective courses (see below). Many of the topics covered in the MBA programme compare well with the topics covered in the proposed qualification.

Business Foundation courses:

(a) Fundamentals of Accounting

(b) Concepts in Economics

(c) Financial Concepts of Management

(d) Statistical Elements of Quantitative Management

(e) Fundamentals of the Legal Environment of Business

(f) Management Theory and Practice

(g) Concepts and Issues in Marketing

MBA courses:

(a) Managerial Economics

(b) Organisation Leadership and Project Team Management

(c) Financial Management

(d) Remainder of the Advanced Programme

(e) Managerial Accounting

(f) Information Systems for Managers

(g) Information Systems for Business Intelligence

(h) Business Policy

(i) Operations Management

(j) Marketing Management

United Kingdom: Professional Standards for Public Health Practice for Pharmacy[9]

The Professional Standards for Public Health Practice for Pharmacy, published by the Royal Pharmaceutical Society in the UK, sets out a best practice framework for the delivery of public health services. The standards are intended to provide a framework to help pharmacy teams, commissioners and those contracting services to design, implement, deliver and monitor high-quality public health practice through pharmacy, regardless of the pharmacy settings from which services are delivered. The following nine key areas are covered by the standards:

(a) *Surveillance and assessment of the population's health and wellbeing:* Data are collected from a variety of sources to support a better understanding of the health and wellbeing needs of a population or community.

(b) *Public health intelligence:* Information and analysis of the health and well-being needs of the population or community are used to inform the development of pharmacy public health practice.

(c) *Assessing the evidence of effectiveness of health and healthcare interventions, programmes and services:* Population health is improved by the assessment and application of evidence-based public health interventions, programmes and public health services.

(d) *Health improvement:* Pharmacists and their teams improve the health and well-being of the population and help to reduce health inequalities by: proactively promoting health and well-being messages; supporting and enabling people to adopt healthier lifestyles and take responsibility for their own and their family's health; and supporting the concept of self-care.

(e) *Health protection:* The population's health and well-being are protected by supporting the prevention and transmission of communicable and other infectious diseases, screening for risk factors and disease, ensuring prudent use of antibiotics in helping to mitigate the risks of antimicrobial resistance, protecting against pharmaceutical hazards, and supporting the pharmacy response to an emergency.

(f) *Health and social service quality (also known as Healthcare Public Health):* Innovative, high-quality pharmacy public health services improve health outcomes and ensure fair and effective targeting of available resources.

[9] Royal Pharmaceutical Society. Professional Standards for Public Health Practice for Pharmacy. March 2014.

(g) *Policy and strategy development and implementation:* Local and national policies and strategies are developed and implemented in accordance with local and national needs to improve and protect the health of the community or population.

(h) *Strategic leadership and collaborative working for health:* Pharmacists and their teams take the lead in ensuring pharmacy's contribution to public health is recognised strategically and collaboratively in partnership with other practitioners and agencies to improve and protect the health and well-being of populations, helping to reduce health inequalities.

(i) *Academic public health:* Everyone working in pharmacy has a role in contributing to the evidence base for the contribution of pharmacy in improving and protecting the health of the population. This is strengthened by academic research and pharmacy practice research across the profession.

Conclusion

Although the Master of Pharmacy in Public Health Pharmacy and Management is a unique qualification and is geared towards meeting the specific needs of South Africa, it is evident that it compares favourably with modules or courses offered by postgraduate programmes internationally, as well as the Royal Pharmaceutical Society of the UK's recently published *Professional Standards for Public Health Practice for Pharmacy*.

14. INTEGRATED ASSESSMENT

A combination of integrated assessment strategies, which will combine both formative and summative assessment and evaluation, will be used to ensure that the purpose of the qualification is achieved. Assessments may include, but are not limited to, the following strategies:

(a) Portfolios of evidence;

(b) Simulations, role play and workplace assessments;

(c) Written and oral assessments and examinations;

(d) Written assignments;

(e) Case studies;

(f) Journal clubs; and

(g) Self-assessment strategies, peer-group assessment and preceptor evaluation.

15. CREDIT ACCUMULATION AND TRANSFER

Candidates may apply for recognition of credits obtained as part of an incomplete qualification at the same or a different institution, depending on individual institutional policies.

16. ARTICULATION (PROGRESSION)

Completion of a Professional Master's Degree meets the minimum entry requirement for admission to a Doctoral Degree, usually in the area of specialisation in the Master's Degree.

Articulation may also be horizontal to entries into other Master's Degrees in a similar or related field or area of specialisation. Horizontal articulation possibilities with this qualification include a Master of Public Health.

17. MODERATION OPTIONS

Suitable moderating options should be included in each application for accreditation to provide this qualification in accordance with the stipulations of the Council on Higher Education (CHE), as well as the relevant Education and Training Quality Assurance (ETQA) body (i.e. Council). Both internal and external moderation should form an integral part of the provision of this qualification.

18. CRITERIA FOR THE APPOINTMENT OF ASSESSORS

Assessors in the field of public health pharmacy and management must have a suitable background, with a proven track record and relevant experience, to enable them to make sound judgements through their expert application of the assessment criteria specified for this qualification.

Assessors should be in possession of suitably related postgraduate qualifications (i.e. Master's Degree and/or Doctoral Degree level) in public health pharmacy and Management, and/or other related fields of study, and have a good working knowledge of the higher education environment in South Africa.

19. NOTES

(a) All candidates must, in addition to their current registration as academic interns or pharmacists, be registered with Council for study towards the specialisation for the duration of the period of learning as specified in the current relevant legislation.

(b) The range of elective learning areas offered will be dependent on the approval of the provider and ETQA.

(c) Credit values reflected for each exit level outcome in Table 2 should be regarded only as a guideline.

(d) The respective assessment criteria aim to test the achievement of the specific learning outcomes. Some of these criteria are practice-based, thus, providers are required to include periods in their curricula for this purpose.

(e) After attaining the Master's Degree, the candidate may commence with the process for registration as a specialist pharmacist in public health and management with Council. Requirements for this registration process will be determined by Council.

See Appendix A

APPENDIX A

Requirements for registration as a specialist after obtaining the professional Master's degree in Public Health Pharmacy and Management

The prospective candidate should be a registered pharmacist with Council.

Training Site

A site recognised by or registered with Council as having the necessary scope to train specialist pharmacists in public health pharmacy and management at any of the levels of pharmaceutical services and public health (operational level, middle management or strategic management). Different rotation sites must be available for the candidate to gain experience in various fields of public health pharmacy and management.

Tutor or supervisor

An appropriately trained and qualified person, with extensive experience in the fields of public health pharmacy and management, jointly approved by the training institution and SAPC.

Practical training

As stipulated by Council.

Evaluation and panel

As stipulated by Council.