

### Framework for the Qualifying Professional Examinations for Pharmacists Applying for Registration with the Pharmacists Council of Zimbabwe

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This framework was developed by the International Pharmacotherapy Education and Research Initiative (IPERI). The framework development consisted of the following activities:

- 1. A desk study on how pharmacy practice entry level qualifying examinations are implemented globally
- 2. Drafting the framework with suggestions on the structure of the examination for Zimbabwe
- 3. Compiling the theory skills expected of undergraduate training programs and the Zimbabwe specific pharmacy practice entry-level competencies
- 4. Submitting the draft documents to the Pharmacists Council for review and feedback
- 5. Submitting the final framework with competency statements and examination questions.

It was with the vision of the first Council Chairperson Ms Gugu Mahlangu that the idea of introducing entry level qualifying examinations for pharmacists was initiated in 2007. Its completion was seen through by the second Council Chairperson, Mr Eric Chiro who showed great enthusiasm towards improving standards in pharmacy education and professional practice.

All the activities were coordinated by Mr A. Karonga, Registrar of the Pharmacists Council of Zimbabwe. The framework was prepared by IPERI's Director and Principal Investigator, Dr Charles Chiedza Maponga.

Initial review of the draft framework was carried out on behalf of the Pharmacists Council by a special committee on Zimbabwe Entry Level Pharmacy Qualifying Examinations which comprised of Mr C Gurajena, Mrs B Gwata, Mrs R Mukonoweshuro, Mrs L Mvere, Mr E Mujuru, Mr B Ndemera, and Dr D Tagwireyi.

Our most sincere appreciation to colleagues, staff of IPERI, and members of the PCZ's Education and Liaison Committee who were all responsible for the success of the project.

CC Maponga

### ABBREVIATIONS

- AIDS Acquired Immunodeficiency Syndrome
- APEC Australian Pharmacy Examination Council
- GCP Good Clinical Practice
- GMP Good Manufacturing Practice
- GDP Good Dispensing Practice
- HIV Immunodeficiency Virus
- MCAZ Medicines Control Authority of Zimbabwe
- MCQ Multiple Choice Question
- MoHCW Ministry of Health and Child Welfare
- NAPLEX North American Pharmacist Licensure Examination
- NAPRA National Association of Pharmacy Regulatory Authorities
- PCZ Pharmacists Council of Zimbabwe
- PC-ELC Pharmacists Council Education and Liaison Committee
- PEBC Pharmacy Examination Board of Canada
- PSZ Pharmaceutical Society of Zimbabwe
- UZ-SOP University of Zimbabwe School of Pharmacy
- UZ-CHS University of Zimbabwe College of Health Sciences

### PART A:

### Framework for the Implementation of Qualifying Professional Examinations for Pharmacists Applying for Registration with the Pharmacists Council of Zimbabwe

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### Framework for the Implementation of Qualifying Professional Examinations for Pharmacists Applying for Registration with the Pharmacists Council of Zimbabwe

### **1. INTRODUCTION**

The Pharmacists Council of Zimbabwe (PCZ) previously required applicants wishing to register as pharmacists in Zimbabwe to submit only degree certificates and academic transcripts from any recognizable local or foreign based school of pharmacy. A recognizable school of pharmacy was defined generally as any pharmacy degree program known to produce pharmacists qualified to practice the profession of pharmacy within its own country of origin. No pre-registration examinations have been prescribed by the Council except the forensic pharmacy examination set by the Medicines Control Authority of Zimbabwe (MCAZ). As pharmacy develops academically and professionally, regulators of professional practice need not only assure the quality of pharmacy education but also ensure that specific knowledge, skills and attitudes imparted by academic institutions remain adequate as well as appropriate within the targeted practice settings.

# 2. BACKGROUND ON THE ROLE OF PHARMACISTS IN DEVELOPING COUNTRIES

The role of pharmacists in health care systems of developing countries was outlined in a World Health Organization (WHO) report prepared by a consultative group following a meeting held in New Delhi, India sponsored by the WHO Action Programme on Essential Drugs in December of 1988. The New Delhi report delineated the knowledge, expertise, and contributions of pharmacists in the acquisition, control, distribution as well as the rational use of drugs and other health-related functions. The meeting also proposed some necessary developments in the undergraduate, postgraduate and continuing education of pharmacists. It further proposed the actions necessary to optimize the use of pharmacists in health care systems, and offered arrangements for monitoring these developments and actions. A follow-up workshop was later held in

Nyanga, Zimbabwe in April 1997 which then defined some expected skills for pharmacists practicing in the Southern African Development Community (SADC) region.

# 3. CHALLENGES OF THE OPERATING ENVIRONMENT FOR PHARMACY IN ZIMBABWE

Zimbabwe experienced severe economic difficulties since 1999, characterized by serious macroeconomic distortions such as severe foreign currency shortages, galloping hyperinflation, a build up of public debt and reduced industrial capacity. These factors, among others, have seen the governments' budgetary allocation to the health sector progressively decline in real terms. This has had serious repercussions on all government supported programs including higher education, specifically at the University of Zimbabwe where resource allocation to the school of pharmacy fell to unprecedented levels with potentially negative effects on the quality of pharmacy training in the country. The PCZ's inspection report of 2008 subsequently revealed some serious shortcomings in the school of pharmacy's training program. This led the Council to call for proactive measures aimed at maintaining the professional competence of all the pharmacists that it registered.

#### 4. GLOBAL CONTRAST IN PHARMACY COMPETENCIES

Globally, the pharmacy profession has diversified significantly, creating some important differences in the pharmacy competencies required for practice in different countries and regional settings. It has, therefore become increasingly difficult to guarantee automatic approval of pharmacists from any school of pharmacy. The contrast in competency requirements of different practice settings dictates that automatic acceptance of foreign trained pharmacy graduates should no longer be granted simply on the basis of the pharmacy curriculum's recognition in its own country of origin.

Some important examples of contrasting competencies include such issues as; "the essential medicines concept", the policies concerning affordable, accessible, equitable, and sustainable provision of generic medicinal products, as well as the importance of pharmaco-vigilance with respect to substandard and counterfeit medicines. All these

concepts and issues are more highly valued in developing countries such as Zimbabwe than in the developed world. Other topics of importance to the Zimbabwean pharmacy practitioner involve the emphasis on HIV and AIDS, tuberculosis, malaria and other tropical diseases which are not necessarily critical in some parts of the world. Furthermore, Zimbabwe and other regional settings greatly focus on such subjects as primary health care, nutritional disorders, and paediatric pharmaceutical dosage formulations. These are in sharp contrast to the increased demand for "high-tech" medicine with greater emphasis on geriatric pharmaceutical needs of the many aging populations of the developed world. All these examples illustrate that pharmacists need to possess competencies that are relevant to their local situation and respond appropriately towards the Zimbabwe national medicines policy.

#### 5. VALIDATION OF APPLICANTS' QUALIFICATION

On a more negative note, there have been a few but significant cases where applicants tried to take advantage of the modern advances in technology by downloading some degree transcript formats from the websites of certain lesser known foreign institutions, and modifying them for the purpose of attempting to register using forged documents. This justified a swift response by the PCZ in its capacity as the responsible professional practice regulatory agency. In the interest of public safety, it has become necessary for the PCZ to design a "safety net" or validation system to ensure that only those pharmacists with genuine qualifications and with the necessary skills for practicing pharmacy in Zimbabwe would indeed be registered.

With respect to the local pharmacy degree program, the findings of the 2008 PCZ assessment indicate that the under resourced situation prevailing in the school of pharmacy has raised enough doubt to force the Council to seek extra reassurance regarding the quality of its outputs. The Council has therefore resolved that applicants from the local institution should also take the qualifying entry level examination in addition to completing the twelve months preregistration internship.

#### 6. SEEKING REGISTRATION AS A PHARMACIST GLOBALLY

A review of registration requirements globally has revealed that many countries in the developed world such as Canada, Australia, the United Kingdom and the United States of America have for a long time been requiring qualifying examinations for both their local and foreign applicants. The main reason is that in those countries, multiple schools of pharmacy exist, often located in different provinces or states where practicing standards differ. The professional regulatory agencies therefore have sought to standardize the entry level requirements in order to allow free transfer of professionals from one part of the same country to another. Also, because those developed countries enjoy free immigration of large numbers of qualified foreign professionals, they have developed methods of screening for the best qualified professionals.

In contrast the developing countries have had to settle for any, often minimally qualified pharmacists due to the fact that many of them either did not have their own schools of pharmacy to produce graduates or they have shortage of professionals. This has denied them the opportunity to scrutinize the quality of applicants. The literature review also has revealed that in the past few decades, the pharmacy profession has developed significantly in many developing countries in Africa. Some of those countries such as Ghana, Kenya, and South Africa have already introduced qualifying examinations albeit mostly for foreign trained applicants.

While different countries have used different systems for screening for the appropriate competencies, there are some general areas of commonality in their requirements. For example, seeking initial registration to practice as a pharmacist (i.e. in an "entry level" position) generally involves the following;

 pharmaceutical education, in which an academic institution awards a degree as evidence that the student has successfully completed an approved course of study in pharmacy

- a certificate of competency granted by the professional regulatory body as evidence that an individual has successfully met an evaluation standard for entry into safe and effective pharmacy practice
- the granting of a license by a regulatory authority, as evidence of the individual's overall qualification, practice training, and readiness to begin practice as a pharmacist
- evidence of practical experience, language proficiency, and pharmacy law examinations on pharmacy legislation and practice standards

### 7. PURPOSE OF THE QUALIFYING EXAMINATION

Qualifying examinations are designed for the evaluation of applicants' competency (knowledge, skills and abilities) to practice pharmacy safely and effectively in "entry level" positions. These evaluations are generally based on the practice competencies defined by the official regulatory body. The PCZ has through its Education and Liaison Committee produced a document defining those competencies that reflect the current standard of practice in Zimbabwe. This Framework document has drafted those competencies. The qualifying examination ensures that successful candidates have met the required standard of competence. Through a process of producing regular updates of the required competencies, the PCZ will position itself to directly influence the direction of pharmacy practice in the country as required by the Health Professions Act [Cap 27:19].

Assessment of competence requires the understanding and application of knowledge, attitudes, and skills as well as the performance of key professional tasks. Some important professional skills and abilities cannot be measured well with a traditional, multiple-choice question format. The Council therefore reserves the right to introduce other methods such as performance-based assessment, or interviews.

### 8. MINIMUM REQUIREMENTS FOR PHARMACY PRACTICE AND THE STRUCTURE OF QUALIFYING EXAMINATIONS IN ZIMBABWE

The minimum requirements for registering to practice pharmacy in Zimbabwe are clearly defined and accessible to all applicants locally as well as internationally. There is accessibility of those requirements even for early career seekers in high school in order to promote early professional attitude development. Those requirements are also available on the PCZ website for effective achievement of this goal.

With reference to other pharmacy professional regulators globally, the PCZ has implemented the following minimum requirements for pharmacy practice:

## A. Evidence of successful completion of a degree in pharmacy from a recognized or accredited school of pharmacy

The local minimum academic requirement is the Bachelor of Pharmacy Honors {B. Pharm (Hons)} degree available from the University of Zimbabwe's School of Pharmacy, or an equivalent four-year pharmacy degree from another accredited local or recognized foreign university (as defined in paragraph # 9 below). It is already known that in some foreign countries the minimum entry level requirements have gone up to Masters or Doctor of Pharmacy levels. Those qualifications would also become the acceptable entry level requirements for applicants originating from those countries but without any additional advantage over the local bachelor of pharmacy honors degree.

#### B. Evidence of successful completion of pre-registration internship

Applications should provide evidence of successful completion of the required 12 months pre-registration internship training according to the PCZ pre-registration guidelines. Those applicants with proof of registration as qualified pharmacists in foreign countries where they obtained their degrees might be exempted from the local pre-registration internship requirement provided they submit a certificate of good standing from their foreign registering regulatory authority.

#### C. Successful completion of qualifying examinations

Every applicant who submits evidence of minimum academic qualifications (unless exempted or denied eligibility by the Council) would be eligible to write a qualifying examination. The examination would be taken in two major levels; one covering technical theory and the other covering Zimbabwe specific practice in professional, ethical, social, legal and administrative subjects as described below.

# 9. <u>QUALIFYING EXAMINATION - LEVEL I:</u> This level is designed to confirm the technical and theoretical understanding of pharmacy obtained by the applicant from didactic academic university training

This level of examination would be offered to all applicants who receive pharmacy degrees from recognized foreign or accredited local institutions. A recognizable foreign school of pharmacy shall be defined as any pharmacy degree program known to produce pharmacists qualified to practice the profession of pharmacy within its own country of origin. Accreditation of local academic pharmacy programs would normally be awarded following a thorough evaluation and assessment of the training program including facility inspection, curriculum review and a review of examinations systems with special attention being given to external examiners' reports.

Since the initiation of the local pharmacy degree program, the PCZ (formerly under the Health Professions Council) has exercised its legal mandate to regularly review the University of Zimbabwe's pharmacy curriculum and used this as the basis for the unconditional approval for registration of local pharmacy graduates once they completed the twelve months of pre-registration training and submitted a First Aid certificate obtained from a local Ambulance Agency. The forensic examination has been taken as part of the degree curriculum although by statutory demands the examination had to be set, supervised, and marked by the Medicines Control Authority of Zimbabwe. The regular periodic review of the University of Zimbabwe's pharmacy curriculum would continue and the results of the review used to accredit the local program. The accreditation of the local pharmacy program would be renewable every 3 to 5 years based on a review or inspection instituted by the PCZ.

Level I examination will be divided into two parts as follows;

Level I (A)

This examination shall cover the Forensic Pharmacy examination which is administered by the Medicines Control Authority of Zimbabwe (MCAZ). It is worth noting that in other countries all the examination responsibilities have been mandated to the professional regulatory body. In those cases, the regulatory bodies have formed professional examination boards or councils that administer all professional and regulatory examinations. The PCZ would continue to liaise with the MCAZ for the purpose of coordinating how this assessment process should be implemented in Zimbabwe.

#### Level I (B)

This level of the qualifying examination would consist of multiple-choice questions (MCQ) aimed at assessing the applicant's understanding of some general concepts of the core basic scientific subjects in pharmacy including, biostatistics, biochemistry, biopharmaceutical sciences, analytical chemistry, pathophysiology, microbiology, clinical pharmacology, over-the-counter preparations, and natural products. This assessment would essentially avoid duplicating university type of theory examinations but emphasize the application of knowledge of these subjects to pharmacy practice problems, as well as the ability to make judgments and problem-solve in situations relevant to pharmacy practice.

10. <u>QUALIFYING EXAMINATION - LEVEL II</u>: This level covers the professional, ethical, legal, social, policy, and regulatory issues unique to Zimbabwe which an entry pharmacist needs to demonstrate before receiving authorization to enter into practice in the country

This examination would cover professional competencies expected of a pharmacist practicing in Zimbabwe including ethics, social pharmacy, communication skills, as well as health related national policies and guidelines. An appreciation of key competencies specifically required in different practice areas such as industry, retail, wholesale, education and research, would be tested at this level. Input has been obtained from experienced practitioners in these various areas to define the competencies that would be tested. Candidates would be prescribed the current documents covering these

materials prior to writing the examination. Summary of the structure of the Zimbabwe Pharmacy Qualifying Examinations is shown in table 1.

The assessment would ideally be task or practical case oriented. The PCZ may in addition to a written examination introduce an oral examination where appropriate and when its resources permit.

### 11. LANGUAGE PROFICIENCY

Although there might be no need for language examination requirements, candidates are advised that the qualifying examinations will be in English language hence language proficiency may affect their performance. Language support and enhancement is therefore recommended for completion before the applicant attempts the qualifying examination.

Level	Content
Level I (A):	As currently administered by the Medicines Control
Forensic Pharmacy	Authority of Zimbabwe
Examination	
Level I (B):	Analytical chemistry, Biochemistry
General concepts in	Biopharmaceutical sciences, Pharmaceutics
core basic scientific	Biostatistics, Epidemiology, Community health
subjects	Pathophysiology, Microbiology
	Clinical pharmacology, Pharmacotherapeutics
	Over-the-counter preparations, Natural products
	Pharmacoeconomics
	Toxicology and Drug Information
	Pharmaceutical biotechnology
Level II:	Policy and management
Professional Core	Public sector pharmacy practice
Competencies,	Clinical (hospital) pharmacy
Ethics, Regulatory,	Community (retail) pharmacy
Policy and	Industrial pharmacy
Management	$\succ$ Ethical, legal and regulatory enforcement and
	promotion
	Pharmacy education and research practice

<u>Table</u>	1:	Summary	of	the	Structure	of	the	Zimbabwe	Pharmacy	Qualifying
Exami	nati	ions							-	

### 12. COMPETENCY EXAMINATION FOR REGISTERED MEMBERS FOUND GUILTY OF GROSS PROFESSIONAL INCOMPETENCY

In situations where registered pharmacists have been found guilty of gross professional misconduct that might be attributed to the individual's incompetence, the PCZ may require that such members retake the qualifying examination before being re-instated onto the register. The appropriate legal instrument to implement this measure has been put in place.

### **13. ADMINISTRATION OF THE EXAMINATIONS**

Administration of the Zimbabwean pharmacy qualifying examinations is the direct responsibility of the PCZ. The PCZ has set up a special qualifying professional examinations board. The board is responsible for reviewing the competence statements to ensure that they are reflective of pharmacy practice requirements in the various sectors and also that the required competencies effectively provide direction for pharmacy professional practice in the country.

The PCZ has initially allocated four sittings for the examination per year to allow applicants to sit for Level I examination during the first three months of pre-registration. Level II examination would then become available for those candidates to write after at least nine months of the 12-months internship period. The PCZ has designed an appropriate fee structure charged to applicants before taking the examinations.

Applicants who fail the qualifying examination would be allowed <u>to retake the</u> <u>examination only once using their initially submitted degree transcripts</u>. Any <u>further attempt would only be authorized if the applicant submits a fresh</u> <u>application indicating additional degree studies</u>. Summary of the requirements for qualifying to write the two levels of the examination are shown in table 2.

<u>Table 2:</u> Summary of Requirements for Applicants to Take the Qualifying Examination

LEVEL		REQUIREMENTS
Level I (May be written within	$\triangleright$	Degree certificate and transcript
the first three months of pre-	$\triangleright$	First AID certificate
registration internship)	$\geqslant$	Examination fees as determined by the PCZ
Level II (May be written after at	$\triangleright$	Level I certificate
least nine months of pre- registration internship)	<b>A</b>	Pre-registration certificate (or evidence of least 9 months of pre-registration) or Certificate for Good standing (for foreign trained applicants)
	$\succ$	Examination tees as determined by the PCZ

#### PART B:

### PROFESSIONAL COMPETENCY STATEMENTS FOR ENTRY LEVEL PHARMACY LICENSE APPLICANTS

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4. Level I (A): Forensic Pharmacy: Required competencies in regulatory affairs pharmacy (Level 1 (A) paper 100%

- 5. Required competencies in basic scientific subjects (Level 1 (B) paper 100 %)
- 6. Level II: Zimbabwean Sector Specific core competencies for pharmacy practice
- 7. Practice Sector Specific competency examination
- 8. Area of professional responsibility # I: Policy and management
- 9. Area of professional responsibility # II: Public Sector Pharmacy Practice
- 10. Area of professional responsibility # III: Clinical (hospital) pharmacy
- 11. Area of professional responsibility # IV: Community (retail) pharmacy
- 12. Area of professional responsibility # V: Industrial pharmacy

13. Area of professional responsibility # VI: Ethical, legal, and regulatory enforcement and promotion

14. Area of professional responsibility # VII: Pharmacy Education and research

### PROFESSIONAL COMPETENCY STATEMENTS FOR ENTRY LEVEL PHARMACY LICENSE APPLICANTS

The Pharmacists Council of Zimbabwe's competency statements presented in this document form part of the framework for the implementation of a qualifying professional examination process for pharmacists applying to register with the Pharmacist Council of Zimbabwe (PCZ). The competency statements provide an outline of the topics covered in the examination and offer important information about the knowledge, skills and judgment that the applicant is expected to demonstrate as an entry-level pharmacist. An excellent understanding of the competency statements is highly recommended for the applicant preparing to write the examination.

### **1. Broad responsibilities of a pharmacist**

A pharmacist is a registered and licensed professional who:

- practices in accordance with professional registration and license, and professional standards within a given practice setting
- possesses both broad-based and pharmacy specific knowledge
- uses critical-thinking, problem-solving and decision-making skills appropriate to the pharmacist's role
- mentors fellow pharmacists, pharmacy students or interns, pharmacy technicians and others
- takes responsibility for personal continuing professional development and commits to life-long learning

According to the World Health Organization (WHO) a pharmacist is uniquely qualified because he/she:

- provides an interface between the duties of prescribing and dispensing medicines and, in so doing, disposes of any perceived or potential conflict of interest between prescribing and dispensing
- engages and appreciates the intricacies of the medicines distribution chain and the principles of efficient stock-keeping and stock turnover
- familiarizes with the pricing structures applied to medicinal products found within the markets in which pharmacists operate
- > keeps technical information on medicines that are available on the market
- provides informed advice to patients with minor illnesses and those with chronic conditions who are on established maintenance therapy
- > understands the principles of quality assurance with respect to medicines

**This WHO inventory of activities** implies that dispensing of medicines is the core responsibility of the pharmacy practitioner. This is, without question, destined to remain the case in virtually every national setting particularly in the developing countries such as Zimbabwe. However, the distinctive expertise of the pharmacist provides members of the profession with a suitable background to assume diverse responsibilities in; public and private pharmacy administration, pharmacy education and research, medicines manufacture and supply, ethical and legal affairs relating to pharmacy, as well as patient medication therapy management.

**Competencies of the pharmacist are already proven and evident** in the following areas:

- medication therapy management, including advising on the selection of the best choice of medication and compounding where necessary to ensure availability of suitable dosage forms for individual patients
- assurance of product quality throughout the distribution chain
- national and institutional formulary committees
- drug procurement agencies
- direction and administration of pharmaceutical services
- medicines regulation and control
- formulation and quality assurance of pharmaceutical products
- inspection and assessment of medicines manufacturing facilities
- practice in clinical research settings

### 2. Structure of the PCZ qualifying examination

Combining the broad responsibilities of the pharmacist, the WHO defined inventory of activities, and proven areas of effective practice by pharmacists described above, the PCZ requires that applicants sit for its qualifying examination in two levels; one designed to validate the applicant's theoretical competency and the other testing the applicant in the core competencies unique to the practice of pharmacy in Zimbabwe. These competencies, described below, shall be reviewed regularly in order to ensure that they remain relevant to the direction of pharmacy practice in the country.

### LEVEL I: THEORETICAL COMPETENCY EXAMINATION

### 3. EXPECTED THEORETICAL KNOWLEDGE AND EXPERTISE OF A PHARMACIST

The contribution of a pharmacist to health care in Zimbabwe is based upon a body of knowledge and expertise acquired from university degree (or equivalent) education, combined with formally designed supervised practical and undergraduate experience. Starting at undergraduate level, basic professional education should be reinforced by a professional obligation to observe ethical, statutory, and professional measures related to the control of safety and quality of medicines and procedures.

**From basic undergraduate education,** a pharmacy student should acquire a broad understanding of the scientific principles and techniques of the pharmaceutical sciences and the ability to keep pace with the developments in medicine and pharmacy. Knowledge and expertise should extend to all aspects of the preparation, distribution, action and uses of drugs and medicines. A pharmacist should have acquired sufficient scientific discipline to become an efficient self-learner who engages in continuing education, as well as undertake postgraduate training or research should the individual pharmacist so choose.

**Regulatory affairs pharmacy** is practiced mostly through the Medicines Control Authority of Zimbabwe (MCAZ) and the PCZ. Assessment of applicant's competence in this area shall consist of the forensic pharmacy examination administered by the Medicines Control Authority of Zimbabwe (MCAZ). The PCZ shall liaise with the MCAZ so that the two regulatory bodies collaborate on this assessment process, particularly since there is an apparent need to combine the legal affairs with ethics.

### LEVEL I (A): FORENSIC PHARMACY

### 4. Required competencies in regulatory affairs pharmacy (paper 100%)

- The applicant should, without reference to statutes, books or other documents, be able to;
- state, in general, the important provisions of the relevant acts and regulations relating to medicines in Zimbabwe
- describe the functions, duties, powers, meetings and compositions of the Pharmacists Council of Zimbabwe (PCZ) and its various committees
- describe the duties of the PCZ Register and issues pertaining to registration, offences in connection with the register and erasure form register
- > explain the code of ethics and principles governing pharmacy practitioners
- summarize the contents of the Pharmaceutical Chemists (Professional Conduct) Regulations and describe their significance to pharmacists
- > explain the regulations pertaining to pharmacists' pre-registration training
- define the various medicinal and prohibited dangerous drugs
- describe the powers of inspectors in connection with dangerous drugs
- state the personnel authorized to possess, use, monitor and account for some dangerous drugs and describe in detail their manner of keeping dangerous drugs register including the onus upon them when they cease to practice
- state the requirements for prescriptions for dangerous drugs and the precautions a pharmacist takes before and while dispending them according to the Dangerous Drugs Regulations
- describe the functions, compositions and powers of the Medicines Control Authority of Zimbabwe (MCAZ) and its committees
- describe the functions of the MCAZ register of medicines, registration, and labeling requirements of medicines
- state the minimum requirements of premises, the licensing of persons and describe wholesale dealers and sales representatives permits
- describe the various categories for distributing drugs and give examples of drugs in each category
- describe the information required on package inserts and information recorded in the drugs register pertaining to every registered drug
- describe the requirements for labels of prescription preparations and pharmaceutical premises
- describe the requirements for application for approval of clinical research trials involving human subjects

- briefly describe some of the application forms
- define hazardous substances and articles, their regulations and the functions of MCAZ inspectors and laboratory analysts

### LEVEL I (B): BASIC SCIENTIFIC SUBJECTS

### 5. Required competencies in basic scientific subjects (paper 100%)

Level I (B) of the PCZ's qualifying examination shall comprise of a one hour test consisting of 60 multiple-choice questions (MCQ) designed around the applicant's undergraduate training. For this level of the examination, the applicant should demonstrate an understanding of general concepts in core basic scientific subjects including; analytical chemistry, biochemistry, biopharmaceutical sciences, biostatistics, pharmaceutics, pathophysiology, microbiology, clinical pharmacology, pharmacotherapy, community health, over-the-counter preparations, natural products, pharmacoeconomics, and pharmaceutical biotechnology.

This assessment should essentially avoid duplicating university type of theory examinations and emphasize the application of knowledge of these subjects to pharmacy practice problems as well as the ability to make judgments and solve problems in situations relevant to pharmacy practice. The following are the competencies upon which the applicant's theoretical understanding should be assessed.

- Perform calculations required to compound, dispense, and administer medication
- Calculate the quantity of medication to be compounded or dispensed; reduce and enlarge formulation quantities and calculate the quantity of ingredients needed to compound the product
- Calculate the rate of drug administration
- > Calculate or convert drug concentrations, ratio strengths, and/or extent of ionization
- Calculate nutritional needs and the caloric content of nutrient sources
- Demonstrate the ability to select and dispense medications in a manner that promotes safe and effective use
- Identify medicinal products by their generic and/or common names and where necessary by their brand names
- Assess pharmacokinetic parameters and quality assurance data to determine equivalence among manufactured drug products, and identify products for which inequivalence exists
- Provide information regarding appropriate packaging, storage, handling, administration, and disposal of medications
- Provide information regarding the appropriate use of equipment and apparatus required to administer medications

- Demonstrate the knowledge to compound extemporaneous preparations and sterile products
- Identify techniques, procedures, and equipment related to drug preparation, compounding, and quality assurance
- Identify the important physicochemical properties of a preparation's active and inactive ingredients
- Identify the mechanism of and evidence for the incompatibility or degradation of a product or preparation and methods for achieving its stability.
- Demonstrate thorough knowledge of classes, mechanisms of action, pharmacodynamic effects, and uses of a wide variety of pharmacologic agents
- > Explain mechanisms of action of various important drug classes
- Identify old and new classes of drugs
- > Select drugs of first choice for various pathological conditions
- > Differentiate pharmacodynamic versus pharmacokinetic effects of drugs
- Demonstrate the ability to analyze medicinal products and ascertain their quality and conformity to established regulatory standards
- Identify the equipment required to carry out various quality tests in drug quality control laboratory
- Identify the sources of quality standards for medicinal products
- List the steps followed in quality testing of pharmaceutical products
- Demonstrate thorough knowledge of medicinal products generally stocked in a pharmacy including, over-the-counter preparations and traditional African medicines, and the ability to give appropriate recommendations to patients
- Identify the appropriate over-the-counter (OTCs) preparation given a patient presentation scenario
- Identify by name and known active ingredients of frequently used traditional African medicines (ATMs), other alternative medicines
- Identify potential interactions between prescription and non-prescription medications including OTCs, ATMs, and other alternative medicines
- Identify, interpret, and evaluate patient information to determine the presence of a disease or medical condition, assess the need for treatment and/or referral, and identify patient-specific factors that affect health, pharmacotherapy, and/or disease management
- Identify and assess patient information including medication, laboratory, and disease state histories
- Identify patient specific assessment and diagnostic methods, instruments, and techniques and interpret their results
- Identify and define the etiology, terminology, signs, and symptoms associated with diseases and medical conditions and their causes and determine if medical referral is necessary

- Identify and evaluate patient genetic, and biosocial factors, and concurrent drug therapy, relevant to the maintenance of wellness and the prevention or treatment of a disease or medical condition.
- Evaluate information about pharmacoeconomic factors, dosage regimen, dosage forms, delivery systems and routes of administration in order to select optimal pharmacotherapeutic agents, for patients
- Identify appropriate routes of administration, dosage forms, and pharmaceutical characteristics of drug dosage forms and delivery systems, to assure bioavailability and enhance therapeutic efficacy
- Evaluate drug therapy for the presence of pharmacotherapeutic duplications and interactions with other drugs, food, and diagnostic tests
- Identify and evaluate potential contraindications and provide information about warnings and precautions associated with a drug product's active and inactive ingredients
- Evaluate and manage drug regimens by monitoring and assessing the patient and/or patient information, collaborating with other health care professionals, and providing patient education to enhance safe, effective, and economic patient outcomes
- Evaluate patient signs and symptoms, and the findings of monitoring tests and procedures to determine the safety and effectiveness of pharmacotherapy
- Identify pharmacotherapeutic outcomes and endpoints
- Recommend needed follow up evaluations or tests when appropriate
- Identify, describe, and provide information regarding the mechanism of adverse reactions, allergies, side effects, iatrogenic, and drug-induced illness, including their management and prevention
- Identify, prevent, and address methods to remedy medication non-adherence, misuse, or abuse
- Evaluate current drug regimens and recommend pharmacotherapeutic alternatives or modifications.
- Identify, evaluate, and apply information to promote optimal health care
- Identify the typical content of specific sources of drug and health information for both health care providers and consumers, and recommend appropriate resources to address questions or needs
- Evaluate the suitability, accuracy, and reliability of clinical and pharmacoeconomic data by analyzing experimental design, statistical tests, interpreting results, and formulating conclusions.
- Recommend and provide information to educate the public and healthcare professionals regarding medical conditions, wellness, dietary supplements, and medical devices
- Recommend and provide health care information regarding the prevention and treatment of diseases and medical conditions, including emergency patient care and vaccinations

- Recommend and provide health care information regarding nutrition, lifestyle, and other non-drug measures that promote health or prevent the progression of a disease or medical condition
- Recommend and provide information regarding the documented uses, adverse effects, and toxicities of dietary supplements
- Recommend and provide information regarding the selection, use, and care of medical/surgical appliances and devices, self-care products, and durable medical equipment, as well as products and techniques for self-monitoring of health status and medical conditions.
- Demonstrate an ability to provide drug and toxicology information to patients and health professionals
- > Take down and classify a request
- > Carry out library searches on specific drug information topics
- > Use literature to respond to a query or solve a clinical problem
- Evaluate the different literature classifications
- Provide information on management of common poisons including the appropriate use of antidotes for poisonous snakes and agricultural products
- Demonstrate an ability to provide a clinical pharmacokinetic dosing service including measurement of serum drug concentrations and their interpretation for the benefit of individual dosage requirements
- > Advice other health professionals on correct drug level sampling times
- Analyze samples for drug levels
- Interpret drug assay results
- Report results and follow-up patients whose drug levels require monitoring
- Counsel patients who are under the service on drug issues
- Maintain readily retrievable records of drug assays

### LEVEL II:

### 6. ZIMBABWEAN SECTOR SPECIFIC CORE COMPETENCIES FOR PHARMACY PRACTICE

The pharmacy profession has diversified significantly thereby creating some significant differences in competency requirements in the various areas of pharmacy practice. **With regard to other professional aspects of pharmacy practice,** there are some key areas distinguishing pharmacy practice in Zimbabwe from other regions, particularly those outside the African region. Such issues include; "the essential medicines concept", the policies concerning affordable, accessible, equitable, and sustainable provision of generic medicinal products, as well as the importance of pharmacovigilance with respect to substandard and counterfeit medicines. Other topics of importance to the Zimbabwean pharmacy practitioner include the emphasis on HIV and AIDS, tuberculosis, malaria and other tropical diseases. Further, Zimbabwe and other regional settings greatly focus on such subjects as primary health care, nutritional disorders, and paediatric pharmaceutical dosage formulations. All these issues demand the

pharmacist to possess competencies that are relevant to the local situation in order to fulfill the pharmacist's role in the implementation of the Zimbabwe national medicines policy.

### 7. PRACTICE SECTOR SPECIFIC COMPETENCY EXAMINATION

Pharmacy practice globally and specifically in Zimbabwe has historically been defined reflective of the various sectors of practice including; hospital, community (retail), wholesale, industry, academic, research, and regulatory affairs.

# This level of the PCZ qualifying examination shall comprise of an hour long test consisting of 60 multiple choice questions based on seven areas of responsibility and sector specific competencies which include;

- I. Policy and management (10% of examination)
- II. Public sector pharmacy practice (10% of examination)
- III. Clinical (hospital) pharmacy (20% of examination)
- IV. Community (retail) pharmacy (20% of examination)
- V. Industrial pharmacy (15% of examination)
- VI. Ethical, legal and regulatory enforcement and promotion (10% of examination)
- VII. Pharmacy education and research practice (15% of examination)

The pharmacist's responsibilities and required competencies in each of these areas are outlined below.

### 8. AREA OF PROFESSIONAL RESPONSIBILITY # I: POLICY AND MANAGEMENT

#### Pharmacist's sector specific responsibilities in policy and management

When practicing in position of authority either in the public or private sectors, the pharmacist is expected to possess a thorough understanding of national policy documents upon which pharmacy services are derived. The pharmacist in such a position, whether in the public or private sector, would be expected to interpret such policies and guidelines in order to provide the most appropriate advice and ensure smooth implementation in the interest of public health.

### Required competencies in policy and management (10% of the examination)

- Demonstrate thorough knowledge and understanding of the latest versions of key policy and guideline documents upon which pharmacy services are derived
- Define and identify the key elements of in the Zimbabwe National Health Policy, the Zimbabwe National Medicines Policy, the National Traditional Medicines Policy, and the National HIV and AIDS Policy
- Identify the key elements and describe the effectiveness of policy documents for malaria, tuberculosis, alcohol & drug abuse

- Describe the key elements of such essential guidelines as the Essential Drug List for Zimbabwe (EDLIZ), EDLIZ for HIV and AIDS, and Guidelines for Drug donations
- Describe the processes involved in the development of key national policy documents and guidelines
- Demonstrate an understanding of the Zimbabwean health care system and the role of the pharmacist and other health care professionals within it
- Describe the policies that drive Zimbabwe's health care system from the rural or urban health centre to central hospital including the referral system
- Identify the role of the pharmacist in national policy formulation for the selection, procurement, importation, manufacturing, and distribution of medicines
- Identify the challenges the pharmacy profession faces in influencing medicines policy in Zimbabwe

### 9. AREA OF PROFESSIONAL RESPONSIBILITY # II: PUBLIC SECTOR PHARMACY PRACTICE

### Pharmacist's sector specific responsibilities in public sector pharmacy practice

It is estimated that about 70% of Zimbabwe's population lives in rural areas and well over 90% of the population depends on the public sector for their health care services in a country that places strong emphasis on primary health care. The pharmacy profession is therefore called upon to ensure that its members participate visibly in health care teams and their role within the team should be recognized particularly at district level. Within the district primary health care system, the pharmacist is expected to act as an essential member of the district health management team.

In response to this call, in 2007 the PCZ introduced a requirement that all newly registered pharmacists be given restricted licenses to practice only in designated health institutions. Through that initiative, apart from providing an obligatory service, the pharmacist is expected to gain valuable experience serving in the public sector. This section of the examination is therefore partially designed to prepare the pharmacist for practice in the public sector.

### <u>Required competencies in public sector pharmacy practice (10% of the examination)</u>

- Demonstrate an understanding of primary health care principles and how they apply to Zimbabwe's health delivery system
- Identify the issues surrounding community health and epidemiology
- Describe the organisation and delivery of health care as well as financing health care in Zimbabwe
- Describe the epidemiology of communicable and non-communicable diseases

- Describe the elements of Zimbabwe's vvaccination program including preventable diseases involved and cold chain management
- Describe the various therapeutic prophylaxis programs including malaria and HIV post-exposure prophylaxis
- Describe the therapeutic prevention programs and the effectiveness of the HIV prevention of parent-to-child-transmission and those for prevention of opportunistic infections
- Demonstrate an understanding of Zimbabwe's health referral system
- > Explain the general arrangements for health-care in Zimbabwe
- Explain the roles of the following: the District Health Executive, the District Pharmacist, the Village Health Worker, the District Nursing Officer, the Community Nurse and Environment Health Technicians, community leaders, and traditional healers
- > Describe the diseases most prevalent and mortality and morbidity statistics
- Identify the pharmacy services referral system including the (A, B, C, and S) categorization of medicines in the Essential Drugs List for use in primary health care, district, provincial and central institutions
- Demonstrate an understanding of the role of the pharmacist in both rural and urban settings
- Describe generally the role of the pharmacist in the rural district and provincial settings
- Explain challenges encountered by health personnel in drug supply, communication, morbidity and mortality within the rural settings
- Identify possible health related community projects in which pharmacists can be involved to promote primary health care
- Describe briefly the legal framework that controls the profession of pharmacy and the distribution of medicines
- Demonstrate an understanding of Zimbabwe's principles designed to ensure sustainable and equitable distribution of accessible, available, safe, and good quality medicines
- Describe the Essential Drugs Concept and its application
- Describe the principles of rational drug use
- Describe the role of treatment guidelines and formularies
- > Appraise critically the generic medicines policy in Zimbabwe
- > Describe the processes involving medicines procurement, quantification, quality assurance and medicines donations
- Describe the safe storage and distribution: system design; inventory control; storage; distribution; monitoring and evaluation

### 10. AREA OF PROFESSIONAL RESPONSIBILITY # III: CLINICAL (HOSPITAL) PHARMACY PRACTICE

### Pharmacist's sector specific responsibilities in clinical (hospital) pharmacy practice

A fully functional hospital pharmacy service normally consists of the distributive services as well as clinical services. The distributive services involve pharmacists working within the pharmacy; ordering, stocking on-site manufacturing, distributing and dispensing medicines. The clinical services would involve the pharmacist in ward pharmacy providing drug information to patients and health professional. In Zimbabwe, particularly led by the national Drug and Toxicology Information Service hosted at the Parirenyatwa Central Hospital in the University of Zimbabwe's College of Health Sciences, pharmacists have for the past three decades provided a valuable consultancy service for the management of poisoning cases as well as pharmacokinetic dosing of medicines on a nationwide basis. Owing to the persistent staff shortage in hospitals, clinical pharmacy services have largely been left out in most hospitals. It is hoped that with the improvement of pharmacist staff positions, clinical work will immerge. Areas of hospital pharmacy involvement should at least include the following;

- Distributive
  - Supply chain management
  - Emergency drug supply
  - Management of DDA medicines
- Ward
  - Therapeutic reviews
  - P&T committee
  - Disinfectant policy implementation
  - Poisoning case management
  - Pharmacokinetic dosing consultancy

### <u>Required competencies in Clinical (Hospital) Pharmacy Practice (20% of the examination)</u>

- Apply relevant knowledge in the performance of tasks related to:
- Fill in and attend to ward baskets
- > Compound and manufacture products on a small scale on-site
- Make up nutritional supplements (enteral and parenteral feeds)
- > Dispense (including labeling) and prepare sterile pharmaceutical products
- Identify storage and handling conditions to ensure stability
- Order and dispose of medicines
- Dispense and account for dangerous drugs
- Prepare, inspect and update emergency drug trays, antidotes for poisons, first aid kits and post-exposure prophylaxis medications

- Demonstrate ability to supervise distribution of medicines and medical supplies including specialist areas within the clinical setting and to play a role in serving on key institutional committees
- > Maintain safe and effective systems of drug supply and distribution
- Supervise pharmacy support staff
- Identify and respond to actual or potential problems within the drug distribution system
- Ensure adequate stock management in special areas such as Oncology Units (cytotoxics), Opportunistic Infections clinics (antiretrovirals, antifungals, antituberculosis drugs), theatre (anaesthetics)
- Ensure adequate stocks of medical supplies including sutures, disinfectants, and intravenous fluids
- Organize and direct the functions of a pharmacy and therapeutics committee
- Promote rational drug use within a hospital setting
- Develop, implement, and review a hospital disinfectant policy
- > Review patient charts systematically to assess medicines utilization patterns

### • Identify and prioritize actual and potential drug therapy problems

- Ensure that a patient receives the required good quality medicines at the right dose at the correct time in an appropriate dosage form
- Monitor adverse drug reactions, drug interactions (including drug-drug, drug-food, drug-laboratory test, drug-disease, or drug-blood product)
- Implement an effective pharmacovigilance program in which adverse drug reactions are reported to the Medicines Control Authority of Zimbabwe
- Document identified drug therapy problems, prioritizing the interventions, patient's outcome, recommendations, and follow-up communication with patient and health care professionals
- Identify patient specific assessment and diagnostic methods, instruments, and techniques and interpret their results.

### 11. AREA OF PROFESSIONAL RESPONSIBILITY # IV: COMMUNITY (RETAIL) PHARMACY PRACTICE

### Pharmacist's sector specific responsibilities in community (retail) pharmacy practice

The community pharmacist is the health professional most accessible to the public. The pharmacist supplies medicines in response to prescription or, when legally permitted, may sell them without a prescription. To meet individual needs, extemporaneous preparation of medicines should be maintained and developed according to guidelines for good manufacturing and distribution practices.

In addition to ensuring an accurate supply of appropriate products, the professional activities of a community pharmacist also cover counseling of patients at the time of dispensing of prescription and non-prescription drugs, drug information to health

professionals, patients and the general public, and participation in health-promotion programs.

### <u>Required competencies in Community (retail) pharmacy practice (20% of the examination)</u>

- Demonstrate knowledge of the basic the retail pharmacy layout and awareness of the business aspects
- Identify members of staff and their roles, sections of the pharmacy, computers and position of the intern in administrative structure, conditions of service
- Estimate requirements, order, receive, price, storage, stock cards, stock taking
- Invoice, receipt, discounts, records of creditors and debtors, the accounts computer program, annual accounts
- Stock O.T.C. medicine, cosmetics, veterinary medicine, baby care, food supplements, sunglasses, photography, displays, advertising, first aid kits, alternative medications (traditional African medicines)
- Filing systems price lists, package inserts, minutes of professional meetings, newsletters, formal letters
- Prescription reading, recording, patient profiles, controls, containers, labeling, pricing, patient compliance and counseling
- Extemporaneous manufacturing, costing, packaging, labeling, expiry dates and batch numbers storage and distribution
- Identify laws and regulations in the context of retail practice
- Demonstrate the ability to select and dispense medications in a manner that promotes safe and effective use
- Identify drug products by their generic, brand, and/or common names
- Identify whether a particular drug dosage strength or dosage form is commercially available and whether it is available on a nonprescription basis
- Identify commercially available drug products by their characteristic physical attributes
- Identify and provide information regarding appropriate packaging, storage, handling, administration, and disposal of medications
- Identify and provide information regarding the appropriate use of equipment and apparatus required to administer medications
- Assess the health status, patient's concerns, desired therapeutic outcomes, support the implementation of the therapeutic plan, and monitor the patient's progress
- > Use appropriate data, techniques and procedures to assess the patient's health
- Identify factors (e.g., risk factors, financial, lifestyle, nutrition) that impact on the therapeutic outcome
- Integrate knowledge of the patient's health status with knowledge of drug and nondrug treatment options
- Outline the benefits and/or consequences of treatment options and enable the patient to make choices

- Provide patient education (e.g., counseling information and education on adherence issues, either verbal or written)
- Assess patient's understanding of the therapeutic plan and recognizing the important clinical indicators (e.g., signs and symptoms, laboratory tests, adverse effects)
- > Assess tolerance, safety of therapy, and the patient's adherence to therapy
- Develop a trusting professional relationship with the patient where both parties are interacting in a way where the obligations, expected benefits, and consequences are clearly defined
- > Establish and maintain rapport by using effective communication skills
- > Demonstrate a caring, empathetic, and professional attitude
- Elicit the patient's needs, values and desired care and outcomes regarding drug therapy

### 12. AREAS OF PROFESSIONAL RESPONSIBILITY # V: INDUSTRIAL PHARMACY PRACTICE

### Pharmacist's sector specific responsibilities in industrial pharmacy practice

The pharmacist is employed in pharmaceutical industry to perform tasks in departments for which pharmaceutical responsibility is crucial such as quality assurance services, marketing, clinical trials, post-marketing surveillance, and in management positions. The industry employs properly trained pharmacists in the area of marketing and promotion of medicines and medical devices in order to maintain high professional standards, in accordance with ethical criteria.

### Required competencies in Industrial Pharmacy Practice (15% of the examination)

- Demonstrate knowledge of standards and procedures that apply in the manufacturer of medicines
- > Define and describe the application of Good Manufacturing Practice (GMP)
- Explain the importance of Standard Operational Procedures (SOPs) in manufacturing
- Define and explain the importance of quality assurance and quality control (QA/QC) in the context of medicines manufacturing
- Explain the role of marketing, sales, and importance of following ethical marketing principles with regard to medicines
- Explain the process of drug development including the stages of pre-clinical and clinical trials
- Recognize the important steps in manufacturing such as costing, packaging, labeling, expiry dates and batch numbers storage and distribution
- Explain the importance of formulation tools such as use of standard formulae and recognized reference books
- > Recognize ingredient compatibility, labeling and warnings on medicinal products

- Recognize the role of the pharmacist in regulatory affairs relating manufacturing premises, procedures, as well as submission of the final product to the regulatory agency
- Demonstrate the knowledge to compound extemporaneous preparations and sterile products
  - Identify techniques, procedures, and equipment related to drug preparation, compounding, and quality assurance
  - Identify the important physicochemical properties of a preparation's active and inactive ingredients
  - Identify the mechanism of and evidence for the incompatibility or degradation of a product or preparation and methods for achieving its stability.

### 13. AREAS OF PROFESSIONAL RESPONSIBILITY # VI: ETHICAL, LEGAL, AND REGULATORY ENFORCEMENT AND PROMOTION

### <u>Pharmacist's sector specific responsibilities in ethical, legal and regulatory</u> <u>enforcement and promotion</u>

With appropriate education, the pharmacist should be involved in the formulation of new drug legislation and in the revision and updating of existing legislation, as well as in all aspects of the enforcement of regulations. In addition the pharmacist should be able apply legal and ethical requirements including national legislation, policies, by-laws and standards.

### <u>Required competencies in ethical, legal, and regulatory pharmacy practice (10% of the examination)</u>

- Demonstrate the ability to uphold and act on the ethical principle that a pharmacist's primary accountability is to the patient
- ensure patient confidentiality
- advocate on behalf of the patient
- involve the patient in decision-making
- respect the rights of patients to make their own choices
- consider patient-specific circumstances
- > identify the components of the Zimbabwean patient's charter
- Demonstrate the importance of personal and professional integrity in pharmacy practice
- Acceptance of responsibility for actions and decisions
- > Show respect for the dignity of the patient
- Maintain appropriate professional boundaries practicing within personal limits of knowledge, skills and abilities

- Demonstrate an understanding of the pharmacist's involvement in legal and regulatory processes
- State in general, the important provisions of the relevant acts and regulations relating to medicines in Zimbabwe
- > Explain the code of ethics and principles governing pharmacy practitioners
- > Pharmacist's role in regulating clinical trials research
- Connect the forensic examination offered by the Medicines Control Authority of Zimbabwe (MCAZ) to the other areas of pharmacy practice

### 14. AREAS OF PROFESSIONAL RESPONSIBILITY # VII: PHARMACY EDUCATION AND RESEARCH PRACTICE

#### <u>Pharmacist's sector specific responsibilities in pharmacy education and research</u> <u>practice</u>

Membership of academic faculty in pharmacy education institutions should be proportionally balanced with respect to professional pharmacists versus pharmaceutical scientists. In view of the professional and vocational nature of pharmacy education, the majority of the academic staff should consist of pharmacists with appropriate postgraduate education and qualifications. Schools of pharmacy should ensure that all academic staff members are committed to research, while being competent teachers who also participate in professional practice. Preferably, the pharmacy educator should be trained in education concepts such as curriculum planning and design in relation to health service and community needs. The pharmacy educator should also have capabilities in management and evaluation of curricula, and the assessment of student performance and competence. Pharmacists should participate in training of medical and other health personnel, including community health workers.

The pharmacist contributes towards the growth and development of professional practice through scientific and practice-based research. The research pharmacist should be involved as research protocol pharmacists in clinical research and also endeavor to become principal investigators. This effort requires special training in the conduct of research in general as well as in Good Clinical Practice (GCP)

### Required competencies in pharmacy education and research pharmacy practice (15% of the examination)

- Demonstrate an ability to assume responsibility for accessing, retrieving, evaluating and disseminating relevant information to ensure safe and effective patient care
- Clarify requests for information and identifying key target audiences
- Evaluate the suitability, accuracy, and reliability of clinical data by analyzing experimental design, statistical tests, interpreting results, and formulating conclusions

- Demonstrate an ability to provide a consultancy service in medication related services
- > Identify the pharmacist's role in a drug and toxicology information service
- > Identify the role of a pharmacist in poisoning management
- > Identify the role of a pharmacist in a pharmacokinetic consultancy service
- Demonstrate and ability to design, implement and evaluate an education plan for individuals and groups
- Identify the learning needs of participants, assessing personal abilities to carry out a particular educational plan
- Select educational methods that are appropriate for the learner(s)
- Implement an educational plan for individual or groups and assessing outcomes of an educational program

### • Demonstrate effective communication skills

- > Comprehension and proficiency in written and verbal English
- Select appropriate verbal, non-verbal and listening skills, effective interview techniques
- Select clear, concise and effective writing skills, appropriate communication techniques for use with patients and other health care professionals
- Demonstrate the ability to evaluate scientific information and identify issues in pharmacy practice and drug utilization
- > Assess the adequacy of research design (e.g., ethics, methodology, etc.)
- Assessing the relevance, applicability, accuracy, reliability, validity and generalizability of information
- > Interpret information in order to address issues in individual pharmacy practice
- Interpret research findings for use to improve practice
- Communicate results to appropriate audiences
- Demonstrate an ability to conduct independent research in a pharmacy related area
- > Identify the role of protocol pharmacists in clinical research studies
- Outline the key elements of Good Clinical Practice (GCP)
- Recognize the role of pharmacists as research investigators

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17. Global Pharmacy Workforce and Migration Report. Appendix 6: Registration requirements for foreign pharmacists. Pages 47 – 49.

18. EICS The Educational Commission for foreign medical graduates international credentials services. Health Professions Council of South Africa

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### LIST OF STUDY MATERIALS FOR QUALIFYING EXAMINATIONS

### Level 1 (A): Forensic Pharmacy

- 1. Health Professions Act Chapter 27:19
- 2. Medicinal, Dental & Allied Professions (information) Regulations, 1993.
- 3. Dangerous Drugs Act: Chapter 15:02
- 4. Dangerous Drugs Regulations, 1975.
- 5. Hazardous Substances & Articles Regulations.
- 6. Hazardous Substances & Articles Act: Chapter 15:05.
- 7. Medicines & Allied Substances Control Act: Chapter 15:03
- 8. Medicines & Allied Substances Control (General) Regulations, 1997
- 9. Pharmaceutical Chemists (Professional Conduct) Regulations, 1989.
- 10. Pharmaceutical Chemists (Pre registration Training) Regulations, 1976.

### Level I (B): General concepts in core basic scientific subjects

- 1. Shargel Leon, Hutnick Alan H., Souney Paul F., Swanson Larry N. Comprehensive Pharmacy Review. 6<sup>th</sup> Edition 2007 (or later). Publisher; Wolters Kluwer, Loppincott, Williams and Wilkins
- 2. Dispensing for Pharmaceutical Students, 12<sup>th</sup> edition, Carter, S.J., Pitman Publishing, Inc., (latest edition)
- 3. Cooper and Gunn's Dispensing for Pharmaceutical Students; edited by SJ Carter.
- 4. Pharmaceutical Practice; edited by DM Collett and ME Aulton.
- 5. Pharmaceutics the science of dosage form design; edited by ME Aulton.
- 6. Science and the Beauty Business The Science of Cosmetics; edited by JV Simmons.
- 7. Pharmaceutical Production Facilities: Design and Application; edited by G Cole.
- 8. The Rules Governing Medicinal Products in the European Community, Volume IV Guide to good manufacturing practice for medicinal products.
- 9. Pharmaceutical Biotechnology; edited by DJA Crommelin and RD Sindelar.
- 10. Pharmaceutics the science of dosage form design; edited by M. E. Aulton\*.
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