



**REPUBLIC OF KENYA**

**MINISTRY OF HEALTH**

**PHARMACY AND POISONS BOARD**

# **Guidelines on Recognition of Pharmacy Specialties**

**June 2017**

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**Table 1: The list of contributors and reviewers**

| <b>Name</b>                     | <b>Position</b>                       | <b>Institution</b>             |
|---------------------------------|---------------------------------------|--------------------------------|
| Dr. Kipkerich C. Koskei, OGW    | Chief Pharmacist/Registrar            | MOH/Pharmacy and Poisons Board |
| Dr. F. M. Siyoi                 | Deputy Registrar                      | Pharmacy and Poisons Board     |
| Prof. Anastasia Guantai         | Dean, School of Pharmacy              | University of Nairobi          |
| Prof. Gichuru Muriuki, EBS, OGW | Professor of Pharmacology/Consultant  | University of Nairobi          |
| Dr. Philip Mwangi               | Dean, School of Pharmacy              | Kenyatta University            |
| Dr. S. Chandrasekhar            | Dean, School of Pharmacy              | Mt. Kenya University           |
| Dr. Jocelyn Kamau               | Dean, School of Pharmacy              | JKUAT                          |
| Prof. James Ombega              | Dean, School of Pharmacy              | KEMU                           |
| Dr. Apollo Maima                | Member TATC /Dean, School of Pharmacy | PPB/USIU                       |
| Dr. E. F. Odhiambo              | Chairman TATC/ Lecturer               | PPB/ KeMU                      |
| Dr. Beatrice Amugune            | Member TATC/ Lecturer                 | PPB/ University of Nairobi     |
| Dr. Peter Karimi                | Member TATC                           | PPB/ University of Nairobi     |
| Dr. Rogers Atebe                | Board Member / Industry               | PPB/ Regal Pharmaceuticals Ltd |
| Dr. Titus Suge                  | Dean, School of Pharmacy              | Kabarak University             |

|                            |   |   |
|----------------------------|---|---|
| Dr. T. B. Menge            | Chairman  | Hospital pharmacy practice –HOPAK       |
| Dr. Boniface Muiru         | Director/ Pharmacist Practitioner                                 | Lemuma Pharmacy Ltd/ Community pharmacy |
| Dr. Paul Mwaniki           | President   | Pharmaceutical Society of Kenya (PSK)   |
| Dr. Charles Ndungu         | FKPM  | Pharmaceutical Industry                 |
| Dr. Heather Njuguna        | Representing CEO  | Supply chain –KEMSA                     |
| Dr. Dorothy Aywak          | HOPAK   | KNH                                     |
| Dr. Josephat Mbuva         | SDCP  | Ministry of Health                      |
| Dr. Claver Kimathi         | Chairman, County Pharmacists Forum                                | County Government                       |
| Dr. Nancy Gakii            | HOPAK   | Nakuru                                  |
| Dr. Faith Okalebo          | Senior Lecturer /Resource Person                                  | University of Nairobi                   |
| Dr. Titus M. Kahiga        | Lecturer  | Kenyatta University                     |
| Dr. Gabriel Kigen          | Senior Lecturer and HOD, Department of Pharmacology & Toxicology, | Moi University School of Medicine       |
| Dr. Wilberforce Wanyanga   | Consultant  | UNIDO                                   |
| Dr. Wilfred Ochieng’ Oguta | Director, Pharmacy Practice & Regulation of Training              | PPB                                     |
| Dr. Stephen Kimathi        | Director, MIPV  | PPB                                     |
| Dr. Kariuki Gachoki        | Head, Pharmacy Practice   | PPB                                     |
| Dr. Peter Mbwiiri Ikamati  | Product Registration  | PPB                                     |
| Dr. Felistas Yano          | NMRO EAC, Nairobi   | PPB                                     |
| Dr. Ronald Inyangala       | Director, QMS   | PPB                                     |
| Dr. Alice Inyangala        | Deputy Chief Pharmacist   | MOH                                     |
| Dr. Humphrey Mwavale       | Head, Training  | PPB                                     |
| Prof. Cornelius D. Pitts   | Adjunct Professor/Consultant                                      | Philadelphia College of Pharmacy, USA   |

|                      |   |                    |
|----------------------|---|--------------------|
| Dr. E. M. Mwangangi  | Deputy CEC Health<br>Kitui/Board Member   | Kitui County/ PPB  |
| Mr. Abdi O. Jama     | Board Member                              | PPB                |
| Dr. S. Kimatu        | Secretariat                               | PPB                |
| Mr. Godwin M. Kitala | Member TATC                               | PPB                |
| Dr. Eunice Gathitu   | Ass. Chief Pharmacist/<br>Resource Person | Ministry of Health |
| Dr. Mikal Ayiro      | Head, CPD and Accreditation               | PPB                |
| Mr. Joshua Plekwa    | Secretariat                               | PPB                |
| Mrs. Dorcas Too      | Secretariat                               | PPB                |
| Mr. Moses Mutungi    | Secretariat                               | PPB                |
| Mr. Henry Chweya     | Secretariat                               | PPB                |
| Ms. Esther Kamau     | Secretariat                               | PPB                |
| Ms. Monica Mbiti     | Secretariat                               | PPB                |
| Ms. Rita Gikandi     | Secretariat                               | PPB                |

## ACRONYMS AND ABBREVIATIONS

|          |   |  |
|----------|---|--|
| P.S.K    | - | Pharmaceutical Society of Kenya                    |
| KNPP     | - | Kenya National Pharmaceutical Policy               |
| P.P.B    | - | Pharmacy and Poisons Board                         |
| M.O.H    | - | Ministry of Health                                 |
| W.H.O    | - | World Health Organization                          |
| T.A.C    | - | Technical and Assessment Committee                 |
| T.A.T.C  | - | Training and Assessment Technical Committee        |
| H.N.D    | - | Higher National Diploma                            |
| T.D.M    | - | Therapeutic Drug Monitoring                        |
| G.M.P    | - | Good Manufacturing Practices                       |
| B. Pharm | - | Bachelor of Pharmacy                               |
| NMRO     | - | National Medicine Regulatory Officer               |
| EAC      | - | East Africa Community                              |
| SDCP     | - | Senior Deputy Chief Pharmacist                     |
| HOPAK    | - | Hospital Pharmacists Association of Kenya          |
| USIU     | - | United States International University             |
| KEMU     | - | Kenya Methodist University                         |
| MIPV     | - | Medicines Information and Pharmacovigilance        |
| QMS      | - | Quality Management Systems                         |
| FKPM     | - | Federation of Kenya Pharmaceutical Manufacturers   |
| CEO      | - | Chief Executive Officer                            |
| KEMSA    | - | Kenya Medical Supplies Authority                   |
| UNIDO    | - | United Nations Industrial Development Organization |
| CPD      | - | Continuing Professional Development                |

## 1.

## BACKGROUND

The Pharmacy and Poisons Act, Cap 244 Laws of Kenya, mandates the Pharmacy and Poisons Board to control the profession of pharmacy and the trade in drugs and poisons in Kenya.

One of the objectives of the Kenya National Pharmaceutical Policy (KNPP) is to enlist services of various specialists which begin with recognition, licensure and registration. The specialties may include Regulatory Affairs and Health Policy, Pharmacotherapy (Clinical Pharmacy and Community Pharmacy), Natural Therapy, Pharmaceutical Medicine (Industrial Pharmacy and Pharmaceutical Analysis), Public Health Pharmacy, among many others. Clear procedures are required to better utilize this pharmaceutical expertise, and thereby spur demand for rational development of pharmaceutical personnel, and their involvement and specialization in areas that are relevant to pharmaceutical and health policy.

The Kenya National Pharmaceutical Policy gave the mandate through Sessional Paper No. 4 of 2012 to review the schemes of service for the pharmaceutical personnel in order to recognize specialization in handling the complexities of the pharmaceutical sector through appropriate deployment and career progression. This highly skilled and specialized human Resource will provide adequate pharmaceutical services and compete effectively in the global market.

In view of the foregoing, the Pharmacy and Poisons Board has developed the policy guidelines for the recognition of specialization of pharmacists in Kenya.

## **2. PHARMACY SPECIALIZATIONS**

### **2.1 INTRODUCTION**

According to Thesaurus, specialization is a skill, field of study, service, or activity in which somebody has special interest and involves possession of notable or distinctive characteristic or quality. The term also prescribes the standards of skills, education and training that prepare members of the specialty with the particular knowledge and skills necessary to perform their specialist roles. In addition, they are subject to the strict codes of conduct enshrining rigorous ethical and moral obligations of their mother profession. Professional standards of practice and ethics for a particular specialty are typically agreed upon and maintained through recognized specialty associations.

Specialization in healthcare disciplines dates back to over 1000 years. It came about as a response to practitioners working in patient-focused areas and the need to be recognized as experts in those areas. It is expected that the Specialist Pharmacist will be skilled, efficient and knowledgeable in his/her specialization area. Specialization is a unique level of knowledge that is specifically applicable and that which improves product quality and /or service and care outcomes.

Pharmacists practice in a variety of areas including, but not limited to, healthcare management, public health, clinical settings, industry, academia, veterinary, research and regulatory affairs which do form the bases of specialization.

Globally, pharmacy specializations are emerging as the profession evolves. This is backed by the existence of many opportunities for pharmacists who desire to expand their specialized roles in providing comprehensive pharmaceutical products, care and services.

The drive towards specialization is also being supported by the heightened role of the pharmacist as a collaborator in the patient care team. As pharmacists become more involved in evaluating patients' therapeutic options, they will need to possess expertise in a broad array of different areas leading to even further sub-specializations. The Specialists can monitor patients and make changes to drug therapies based on patients' responses and cost-effectiveness.



In Pharmaceutical manufacturing, new technologies keep coming and the desire to have high quality and efficacious drugs increases by the day. Highly specialized pharmacists in research and product development, quality assurance, production and quality control need to be both trained and recognized. Novel formulations and patient specific and creative drug delivery devices are all geared towards better patient outcomes.

In Public Health, which focuses on disease prevention, health promotion and prolonging life in the population, we would require specialists who can play a leading role in promoting healthy practices and behaviours.

There is a rich culture and availability of natural therapies. Our patients would require pharmacy specialists who have knowledge, skills and attitudes to offer alternative care.

Despite the above, there exists a gap or a model to address the specialists' needs and to provide a framework and environment for their practice. The concept of specialization inherently brings up issues of qualifications, recognition, certification, registration, licensure and operationalization.

As specialization grows, both in numbers and varieties, the Board will need to regulate the profession to avoid proliferation of unjustified specialties. There is a need to ensure that available pharmacy specializations serve a critical role in improvement of product quality and patient's care outcomes.

This document enumerates the proposed areas of specializations in the pharmacy profession. The requirements, objectives and functions of each category of specialists are well exemplified in the different subsections. The areas of specialization in pharmacy have been divided into five key areas/tracks on the basis of areas of practice, the expected knowledge and skills that a specialist should possess, as follows:

## **2.2 PHARMACOTHERAPY**

Pharmacotherapy is the treatment of disease through the administration of drugs. Pharmacotherapists are responsible for ensuring the safe, appropriate, and economical use of

medicines. The skills required to function as a pharmacotherapist require specialized knowledge, training and experience in biomedical, pharmaceutical and clinical sciences. Pharmacotherapy is applicable in the two broad practice areas of clinical pharmacy and community pharmacy.

## **2.3 CLINICAL PHARMACY**

### **Introduction**

Pharmacy services in recent years have expanded significantly beyond drug manufacture, dispensing and distribution. The evolutionary changes in pharmacy are reflected in the greater involvement by pharmacists in drug related decision making in patient care. The World Health Organization through the concept of pharmaceutical care recognizes a pharmacist as an integral member of the health care team. The discipline of Clinical Pharmacy is responsible for ensuring the safe, appropriate, and cost-effective use of drugs, through the application of specialized skills and knowledge. Clinical pharmacists require in-depth of knowledge and competence in patient centred care. They are required to have a unique set of knowledge, skills and attitude that enhance the provision of pharmaceutical care at patient level.

### **Objectives**

The main objective of the clinical pharmacy specialization is to improve knowledge, skills and attitudes to enhance patient outcomes. This discipline requires integration of knowledge of the biological, biomedical, and pharmaceutical sciences with clinical information to make decisions regarding rational drug therapy.

### **Functions**

Functions of a Community Pharmacist include:

1. Preparation of patient medication history chart
2. Monitoring of patient response to medication
3. Providing medication counselling
4. Participating in medical emergencies.

5. Providing services in total parenteral nutrition, intravenous therapy, and clinical pharmacokinetics, selection of drug therapy and determination of therapeutic end point.
6. Management of chronic diseases.
7. Participating in clinical trials
8. Drug administration and drug distribution in the patient care area.
9. Educating medical, pharmacy and nursing personnel in the patient care areas.
10. Detecting and reporting adverse drug reactions and drug interactions.
11. Prescribing medications
12. Conducting clinical research
13. Training and mentoring other clinical pharmacists
14. Provision of immunization services

### **Areas of practice**

Clinical pharmacy professionals offer their services primarily in clinical areas.

### **Qualifications**

To qualify as a clinical pharmacist, one should meet the following minimum qualifications:

- Be a holder of a Bachelor of Pharmacy degree or its equivalent
- Be registered to practice by the Pharmacy and Poisons Board
- Be a holder of a Master of Pharmacy degree in Clinical Pharmacy
- The Master of Pharmacy in Clinical Pharmacy program should have a minimum duration of two years (or 1600hrs or as per CUE requirements)
- Have completed one year post masters residency in a clinical setting.
- Pass a Board Certified qualifying examination.

## 2.4 FORENSIC PHARMACY AND TOXICOLOGY

### Introduction

Forensic pharmacy is the application of the science of drugs to resolve legal issues. Forensic pharmacists engage in work relating to litigation, regulatory processes and criminal justice. The changing environment and social structures have brought new challenges to the society. The incidence of poisoning is increasing due to suicide, homicide or accidents leading to litigations.

### Objectives

The main objective of this specialization is to improve knowledge, skills and attitudes in order to identify toxicants, describe their effects on the body and also assist in the criminal justice system. This discipline requires integration of knowledge of the biological, biomedical, and pharmaceutical sciences with clinical information to make decisions regarding poisoning.

### Functions

- Providing information on poisoning and management.
- Management of poison centres.
- Serving as expert witnesses in a court of law.
- Carrying out tests using scientific techniques, such as infrared spectroscopy, mass spectrometry, and scanning electron microscopy.
- Preparing written reports based on evidence analysis.
- Coordinating the activities related to crime scene collection, preservation, and transportation.
- Serving as a liaison between the forensic laboratory and crime scene investigators.
- Developing, maintaining and updating work quality standards, standard operating procedures, and similar methods and procedures.

- Performing human-performance forensic toxicology, determining the absence or presence of drugs and chemicals in the blood, hair, tissue, breath, etc.

### **Areas of practice**

- Medical examiners offices.
- Forensic laboratories.
- Police departments.
- Hospital and chemical laboratories.
- Prosecution attorneys and criminal defense.
- Pharmaceutical industries.
- Research centres.
- Academic institution

### **Qualifications**

To qualify as a Forensic pharmacy and toxicology specialist one should meet the following minimum qualifications:

- Be a holder of a Bachelor of Pharmacy degree or its equivalent.
- Be registered to practice by the Pharmacy and Poisons Board.
- Be a holder of a Master of Pharmacy degree in forensic pharmacy and toxicology or its equivalent.
- The Master of Pharmacy in Clinical Pharmacy program should have a minimum duration of two years (or 1600hrs or as per CUE requirements).
- Have completed two year post masters residency in an appropriate setting.
- Pass a Board Certified qualifying examination.

## 2.5 COMMUNITY PHARMACY

### Introduction

The proliferation of community pharmacy practice and change in consumer behaviour in Kenya has created the need to focus on the quality and quantity of services offered at this level. Community pharmacies are increasingly providing services outside the traditional scope of community pharmacy. These emerging services include patient counselling and disease management. The setting of the practice of pharmacy will soon expand to include pharmacotherapy clinics; patients' home care and follow up. To achieve these competencies, Community Pharmacists need additional skills such as management, psychology and pharmacotherapy. The Pharmacy and Poisons Board has provided a roadmap to ensure that the aspirations of consumers and the nation are catered for. To achieve this desire this document has been developed to facilitate appropriate and focused approach in provision of community pharmacy services.

### Objectives

The objective of community pharmacy practice is to provide advanced pharmaceutical services to the public and enhance their health status. Specifically the community pharmacists will provide medications and promote rational use of drugs for both human and animals. This specialist will also be involved in health promotion.

### Functions

Functions of Community Pharmacists include:

- Processing prescriptions
- Patient counselling
- Provision of drug information
- Documentation and reporting of Adverse Drug Reactions (ADR)
- Dispensing and training on use of medical devices to patients
- Compounding of medicines

- Management of Controlled Substances
- Management of Over-the-counter products
- Diagnosis of disease and monitoring of treatment outcomes
- Patient referrals
- Human Resource Management
- Public health education
- Management of veterinary and agricultural products
- Disease prevention and vaccination
- Provision of reproductive health services
- Training and Mentoring junior Pharmaceutical personnel
- Drug administration
- Medication therapy management.
- Management of drug addiction
- Provision of cosmetics.
- Provision of nutraceuticals.

### **Areas of practice**

Community Pharmacy professionals offer their services primarily in community pharmacy settings, hospital pharmacies, research in community settings and academia.

### **Qualifications**

To qualify as a community pharmacy specialist one should meet the following minimum qualifications:

- Be a holder of Bachelor of Pharmacy degree or its equivalent
- Be registered to practice by the Pharmacy and Poisons Board

- Be a holder of a Master of Pharmacy degree in Community Pharmacy or Clinical Pharmacy with a bias to Community Pharmacy and Pharmacy Management, Sport medicine, Veterinary pharmacy or their equivalents.
- The Master of Pharmacy degree in Community Pharmacy program should have a minimum duration of two years (or 1600hrs)
- Have two years post masters qualification experience in a Community Pharmacy setting.
- Pass a Board Certified qualifying examination.

## **2.6 NATURAL THERAPY**

### **Introduction**

Natural therapy is any practice that is put forward as having curative effects of medicine but may not strictly be based on scientific evidence but through ethno use. Natural therapy covers a range of disciplines within complementary health with a holistic approach, including nutritional medicine, herbal medicine and naturopathy.

The use of natural therapy is an old practice and is still widely used. There have been lots of discussion and evidence of their usefulness in clinical practice. However, there are currently many commercial preparations of herbal medicines and others that are subject to research.

This discipline requires integration of knowledge of the biological, biomedical, and pharmaceutical sciences and anecdotal information to make decisions.

The increasing interest in evidence based practices and the unpublished observations on safety and efficacy of natural therapies create a reasonable basis for regulation and accreditation of practitioners.



## Objectives

The main objective of Natural Therapy is to promote knowledge, skills and attitudes to improve patient outcomes with natural therapies.

## Functions

Functions of Natural Therapists include:

- Research into natural therapies
- Preparation of various natural therapy preparations in accordance with good practices.
- Management of diseases using natural therapy
- Gathering and communicating information about natural therapies
- Carrying out quality control of natural products

## Areas of practice & Specialties

- Research into natural therapies e.g. Masters in Pharmacognosy/Complimentary & alternative medicines
- Preparation of natural therapies
- Quality control of natural therapies
- Biopharming
- Biodiversity conservation and Exploitation- Masters in Biodiversity conservation and exploitation

- Outlets of natural therapy practice- Acupuncture/ Aromatherapy/ Moxibustion/ Hydrotherapy/ Ayuverda/ Homeopathy/ Herbal therapy/ African traditional therapy/ traditional Chinese medicine/Probiotics and use of whole organisms

## **Qualifications**

To qualify as a Natural therapy professional one should meet the following minimal qualifications:

- Be a holder of Bachelor of Pharmacy or its equivalent
- Be a holder of a Master of Pharmacy degree in Pharmacognosy, Complimentary & alternative medicines and Biodiversity conservation & exploitation
- The duration of a Master of Pharmacy in Pharmacognosy should be minimum duration of two years (or 1600hrs)
- Have 2 year residency/apprenticeship/work experience or completion of a Fellowship program in natural therapy
- Pass a Board Certified qualifying examination

## **2.7 PUBLIC HEALTH PHARMACY**

### **Introduction**

Public Health is the study of health and other disease related states at population level. It involves the active and passive collection of data so as to inform policy formulation and implementation.

Pharmacists with specialization in Public Health focus on drug related issues such as guideline development, pharmaceutical expenditure and promotion of rational drug use. In addition, they are also involved in health promotion and research.

Public Health pharmacists work in collaboration with county government, public health agencies, and other health workers and are well positioned to serve the mission of public health.

### **General Objective**

To promote and protect health and wellbeing, prevent ill health and prolong life through the organized efforts of society.

### **Functions**

Major functions of Public Health Pharmacists are:

- Health Promotion activities which includes Vaccination, mass education, and other preventive activities
- Advocacy
- Promotion of the quality of Health and Pharmaceutical services
- Provision of strategic leadership in health programs
- Medicines risk communication
- Formulation of health and pharmaceutical policies, such as treatment guidelines and formularies
- Evaluation of cost-effectiveness of health and pharmaceutical interventions
- Monitoring and evaluation of the implementation of health policies and interventions
- Collection of epidemiological data on disease states, drug consumption and other health related complications
- Tertiary prevention of complications of chronic diseases,
- Screening for cancer, HIV, diabetes, hypertension and other chronic diseases
- Disease management in special populations

### **Areas of Practice:**

- County and national government
- Regional and International public health agencies
- Drug regulatory agencies
- Public health agencies
- Private consultancy and Research

**Qualifications:**

- Bachelor of Pharmacy degree or its equivalent as recognized by the PPB
- Registration as a pharmacist in Kenya
- Masters in Public Health, Health systems management, Pharmacoepidemiology, pharmacovigilance or pharmacoconomics
- One year residency
- Pass in speciality qualifying exams
- Applicants with 3 years work experience in public health agency/government department (working under the guidance and supervision of a specialist in Public Health) may be exempted from residency

**Qualifications of the Consultant:**

- A specialist will qualify to be a consultant after a successful two – year practice under the guidance and supervision of a consultant in his/her field of specialization **OR**;
- Applicants with at least a twelve month sub-specialization or a PhD degree in the field of specialization

## **2.8 PHARMACEUTICAL INNOVATION AND DRUG DEVELOPMENT**

### **Introduction**

Pharmaceutical Innovation and Drug Development is the scientific discipline concerned with the research, discovery, design, innovation, development, evaluation of medicines for the benefit of patients and public health.

### **Objectives**

The main objectives of Pharmaceutical Innovation and Drug Development include the preclinical and clinical testing of medicines and translation of pharmaceutical drug research into new medicines.

### **Functions**

Major functions of Pharmaceutical Innovation and Drug Development specialists are:

- Drug Discovery
- Technology development
- Novel Drug delivery systems
- Drug Design- Including Computer Aided drug design
- Clinical trials and post marketing surveillance
- Intellectual Property rights

Suggested areas of Practice/ Qualifications

- Drug Design and development e.g. Masters medicinal chemistry, molecular pharmacology/Pharmaceutical Biotechnology/pharmaceutical microbiology
- Novel drug delivery systems- Masters Pharmaceutical Technology
- Clinical trials e.g. masters in Clinical Trials
- Bioequivalence e.g. Masters in Biostatistics/Masters in Clinical Trials

## Qualifications

### Specialist

- Bachelor of Pharmacy degree or its equivalent as recognized by the PPB
- Registration as a pharmacist in Kenya
- Master of pharmacy degree in medicinal chemistry, molecular pharmacology, Pharmaceutical Biotechnology, pharmaceutical microbiology, Pharmaceutical Technology, Biostatistics and Clinical Trials
- Have 2 year residency/apprenticeship/work experience in a recognized R&D Centre, Clinical Trials centre or Bioequivalence Centre or completion of a Fellowship program
- Sat and passed speciality qualifying exams set by the Board

## 2.9 INDUSTRIAL PHARMACY

### Introduction

Industrial pharmacy is mainly concerned with sourcing of raw materials, manufacturing, marketing and post marketing surveillance/pharmacovigilance. In addition, industrial pharmacy entails Quality assurance (GMP), Pharmaceutical development and Scale-up. There is need to increase productivity of quality pharmaceuticals, biologicals, nutraceuticals cosmetics, medical devices & Diagnostics, veterinary and agrochemicals within our local industry.

### Objectives

To promote the development of specialist pharmacists with skills in the various areas of industrial pharmacy (formulation, manufacture, quality management, storage, Distribution and pharmacovigilance)

#### Functions/areas of practice

- Formulation development
- Validation of manufacturing process
- Manufacturing
- Quality Assurance (GXP e.g. GMP/GLP)
- Regulatory Affairs
- Pharmacovigilance
- Plant design
- Pharmaceutical Engineering
- Chemical and Microbiological Analysis

#### Suggested Specialties

- Production e.g. Masters Pharmaceutical technology/Industrial pharmacy
- Quality Assurance e.g. Masters GMP/Pharmaceutical Quality Management
- Pharmaceutical Analysis- e.g. Masters Pharmaceutical analysis
- Pharmaceutical microbiology e.g. Masters in pharmaceutical Microbiology.
- Facility design- Masters in Pharmaceutical engineering

#### **Qualifications**

Specialist

- Bachelor of Pharmacy degree or its equivalent as recognized by the PPB
- Registration as a pharmacist in Kenya
- Master of pharmacy degree in industrial pharmacy, pharmaceutical chemistry, pharmaceutical Analysis, Pharmaceutical technology , GMP, Pharmaceutical Quality Management, pharmaceutical Microbiology, Pharmaceutical engineering
- Have 2 year residency/apprenticeship/work experience in a recognized pharmaceutical industry, Drug Regulatory Authority or completion of a Fellowship program
- Sat and passed speciality qualifying exams set by the Board

## **2.10 REGULATORY AFFAIRS & HEALTH POLICY**

### **2.10.1 PHARMACEUTICAL MANAGEMENT AND POLICY**

#### **Introduction**

The health sector is critical to the development of any country. A vibrant sector founded on strong policies and legal framework is necessary to ensure health and safety of the population as well as promotion of national economic growth. Pharmacists specializing in pharmaceutical management and policy have an important role in formulating regulatory and policy issues concerning human resource, pharmaceuticals, medical devices or healthcare facilities.

In the dynamic environment where patient needs and expectations are ever changing, new knowledge is being generated and emerging issues have to be accommodated and solved, there is need to continually scan and formulate or adjust policy and regulatory framework.

#### **Objectives**

The objective is to manage effectively finances, human resource, commodity supply for the pharmaceutical sector.



## **Functions**

The major functions of this specialty are:-

- Developing and regularly reviewing relevant health policies and legislation to govern the pharmaceutical sector
- Formulating the norms and standards of Pharmacy Practice
- Conducting economic evaluations and performance reviews
- Managing the pharmaceutical human resource effectively
- Ensuring an efficient pharmaceutical supply chain management for health commodities and technologies.
- Ensuring efficient and effective utilization of funds in the pharmaceutical sector
- Providing Leadership.
- Spearheading intersectoral and international collaboration.

## **Areas of Practice**

- Leadership at programme, National and county levels
- Head of Institutions e.g. hospitals, NGOs, Central Medical stores, Manufacturing Industry, colleges, university,
- Leadership at Regulatory Institutions
- Academia
- Administration
- Research
- Occupational Health and safety

## **Qualifications**

To qualify as a management & health policy specialist, one should meet the following minimum qualifications:

- Be a holder of Bachelor of Pharmacy degree
- Have an active practice license
- Be of good professional standing
- Be a holder of a Masters degree in any of the fields of Pharmaceutical management and policy, Management and leadership, Health supply chain and logistics, Health systems management, Strategic management, Health program management, Pharmaceutical marketing, Healthcare management, Health informatics, Pharmaceutical information management, International pharmaceutical trade and diplomacy, Health economics/ Pharmacoeconomics and Health Policy/ Pharmaceutical Policy or their equivalents.

Be registered as pharmacist in Kenya by the PPB

- Have a minimum of 2 years experience in the area of specialization
- Show evidence of continuous professional development

### **2.10.2 PHARMACEUTICAL REGULATORY AFFAIRS**

#### **Introduction**

The pharmaceutical industry is a regulated industry. Over the years, emphasis has been placed on ensuring compliance with the regulations and laws pertaining to quality, safety, efficacy and economic value of medicines as well as maintaining high standards of pharmacy practice. Pharmacy regulatory affairs specialists have the knowledge, skills and attitudes to provide

regulatory guidance and technical support to the members of the healthcare sector and /or regulatory agencies.

## **Objectives**

To ensure quality, safe and effective and economic value of pharmaceutical products in the market, and to regulate the health products and pharmaceutical practice.

## **Functions**

The functions of this specialty are:

- Developing regulatory standards and guidelines to govern pharmacy practice, training, pharmaceutical manufacturing, product evaluation and registration and clinical trials
- Working with regulatory and enforcement agencies concerned with approval, registration, and quality control of drugs, foods, cosmetics , medical devices and health technologies.
- Coordinating professional registration of pharmaceutical personnel and licensing requirements
- Working with international agencies and professional bodies concerned with technical and administrative functions in drug and health related issues
- Enforcing compliance with the legal requirements and ethics within the pharmaceutical industry and ensuring professionalism
- Advise on matters related to pharmaceutical and health related laws

## **Areas of Practice**

- Manufacturing Industry
- Regulatory Authority

- Other health institutions requiring regulatory specialists e.g. NGOs, hospitals, pharmaceutical distributors, faith based organizations and related areas.
- Academia
- Clinical research organizations

### **Qualifications**

To qualify as a pharmaceutical regulatory affairs specialist, one should meet the following minimal qualifications:

- Be a holder of Bachelor of Pharmacy or its equivalent
- Be a holder of a Masters in pharmaceutical regulatory affairs/science, Medicines Control, Law, forensic Science, pharmacovigilance or their equivalents.
- Be a registered pharmacist, hold an active practice licence
- Have a minimum of 2 years experience in the area of specialization
- Show evidence of continuing professional development

### **2.10.3 PUBLIC HEALTH PHARMACY**

#### **Introduction**

Public Health is the study of health and other disease related states at population level. It involves the active and passive collection of data so as to inform policy formulation and implementation.

Pharmacists with specialization in Public Health focus on drug related issues such as guideline development, pharmaceutical expenditure and promotion of rational drug use. In addition, they are also involved in health promotion and research.

Public Health pharmacists work in collaboration with county government, public health agencies, and other health workers and are well positioned to serve the mission of public health.

#### **General Objective**

To promote and protect health and wellbeing, prevent ill health and prolong life through the organized efforts of society.

## **Functions**

Major functions of Public Health Pharmacists are:

- Health Promotion activities which includes Vaccination, mass education, and other preventive activities
- Advocacy
- Promotion of the quality of Health and Pharmaceutical services
- Provision of strategic leadership in health programs
- Medicines risk communication
- Formulation of health and pharmaceutical policies, such as treatment guidelines and formularies
- Evaluation of cost-effectiveness of health and pharmaceutical interventions
- Monitoring and evaluation of the implementation of health policies and interventions
- Collection of epidemiological data on disease states, drug consumption and other health related complications
- Tertiary prevention of complications of chronic diseases,
- Screening for cancer, HIV, diabetes, hypertension and other chronic diseases
- Disease management in special populations

## **Areas of Practice:**

- County and national government
- Regional and International public health agencies
- Drug regulatory agencies

- Public health agencies
- Private consultancy and Research

**Qualifications:**

- Bachelor of Pharmacy degree or its equivalent as recognized by the PPB
- Registration as a pharmacist in Kenya; Possess an active Practice License;
- Masters in Public Health Pharmacy, Health systems management, Pharmacoepidemiology and Pharmacovigilance, Global/ International health, Community Health, Public Health Education and Environmental Health/ **Bio safety, bio-security and( hazardous/ medical and pharmaceutical/ bio hazardous)** waste management.
- The equivalents of these masters programs will be considered.
- Two year residency/ apprenticeship/work experience or Completion of a Fellowship program (under the guidance and supervision of a specialist pharmacist in Public Health).

**Qualifications of the Public Health Specialist Pharmacist:**

- A specialist will qualify to be a specialist after a successful two – year practice under the guidance and supervision of a specialist in his/her field of specialization **OR;**
- Applicants with at least a twelve month sub-specialization or a PhD degree in the field of specialization

**2.11 DRUGS AND POISONS INFORMATION**

**Introduction**

Provision of accurate and evidence based information on drugs and poisons is one of the fundamental functions of a pharmacist. The information may be patient specific, at population level or from educational or academic purposes. Patient specific information is provided in a clinical setting with the objective of improving disease management and improves treatment

outcomes. Poisons information may be used in management of poisoning episodes and in public education for prevention of such incidences. Population level information is used for formulary and guideline development. A drug information specialist should have skills and knowledge in evidence synthesis, information retrieval and dissemination.

## **Objectives**

The main objective of a drug and poisons information specialist is to provide timely and accurate information on substances to institutional and individual users as a means of enhancing safe, effective and rational use of medicines

## **Functions**

The functions of this specialty are:

- To collect evidence-based medicine information on indications, contraindications and dosage for specific drugs; drug interactions and adverse effects; drug use in pregnancy, breastfeeding, liver and renal impairment; identification of medicines and information on sourcing of medicines
- To disseminate medicine information through call-in centres, publications and electronic media
- To moderate content of medicine marketing materials and advertisements
- Create education resources for patients and health care professionals such as pamphlets
- Periodically educate health care workers on drug related issues
- Create and administer continuous education programs
- Establish and maintain resources on drug information
- Coordinate investigational drug services
- Develop clinical decision support tools
- Document all information requests

## **Areas of Practice**

- Medicine information centres
- Information Technology in Pharmacy practice
- Poisons Information
- Regulatory Affairs
- Other health institutions requiring medicine information specialists e.g. NGOs, hospitals, pharmaceutical distributors, faith based organizations
- Academia
- Clinical research organizations

## **Qualifications**

To qualify as a medicine Information specialist, one should meet the following minimal qualifications:

- Be a holder of Bachelor of Pharmacy
- Be a registered pharmacist
- Be a holder of a Masters in Medicine Information or Masters in Medical Informatics or its equivalent
- Have completed one year residency in a Drug Information Centre that is recognized by the Board.
- Show evidence of continuous professional development



### **3. IMPLEMENTATION OF THE GUIDELINES**

#### **3.1 EVALUATION AND ASSESSMENT**

#### **3.2 ELIGIBILITY CRITERIA FOR EVALUATION AND ASSESSMENT**

The Evaluation and Assessment is to ensure that all candidates who are assessed meet the basic requirements for purposes of registration as a specialist.

**A candidate shall:**

- Be a holder of Bachelor of Pharmacy or its equivalent, and in addition
- Be a holder of a Master of Pharmacy, or equivalent, or higher qualification in the intended area of specialization
- Be registered to practice by the Pharmacy and Poisons Board
- The Master of Pharmacy in the specialization program should have a minimum duration of two years ( or 1600 hours or in accordance with CUE requirements)
- Have 2 years post masters qualification experience in a practice setting.

#### **3.2.1 APPLICATION PROCEDURE**

A candidate who meets the eligibility criteria above should obtain an Application form for Evaluation and Assessment for Registration as a Specialist from the Registrar, Pharmacy and Poisons Board and shall be required to:

- i. Pay a prescribed non-refundable application fee
- ii. Submit a duly filled and completed Evaluation and Assessment application form at least three (3) months before the examinations date.

### 3.2.2 DOCUMENTATION REQUIRED FOR ASSESSMENT

1. Duly filled and signed application form for evaluation and assessment for Registration as a Specialist
2. Certified copy of the National Identity card or Passport.
3. Certified copy of the B. Pharm. certificate or its equivalent.
4. Certified copy of M. Pharm. (or higher degree/qualification) certificate or its equivalent.
5. Certified academic transcripts for each academic year of training completed for the M. Pharm. or higher degree/qualification (or its equivalent), showing numbers of years, subjects, contact hours and examination results (marks, grades) obtained.
6. Certified copy of certificate of registration as a pharmacist in Kenya
7. Assessment report from supervisor
8. A letter of recommendation from a supervisor/mentor specialised in the same field
9. Two current coloured passport size photographs (indicating name & ID. /passport No. at the back).

#### NOTE:

- If documents are in a language other than English or Kiswahili, they must be translated and certified by an official translator or relevant authority.
- All certificates obtained from foreign institutions must be equated by the Commission for University Education.
- The original documents must be presented to the Pharmacy and Poisons Board upon request.
- **Presentation of any fraudulent document is a criminal offence. This shall attract prosecution and barring from sitting the Pharmacy and Poisons Board's professional examinations for life.**

### **3.2.3 QUALIFYING EXAMINATIONS**

#### **Certification Examination**

1. To qualify as a specialist or a sub-specialist the candidate shall be required to pass an examination administered by the Pharmacy and Poisons Board.
2. The examination will be both written and oral.
3. The examination will be designed to assess knowledge, skills and attitudes required for practice as a specialist
4. The conduct of the examination shall be approved by a committee of experts
5. The pass mark shall be 60 per cent
6. A candidate who passes the examination shall be awarded a certificate of recognition as a specialist which shall be valid for 5 years

#### **Re- certification**

1. Re- certification shall be done after every 5 years.
2. To qualify for recertification, a candidate shall be expected to show evidence of continuous professional development and practice in the area of specialization.
3. In the absence of evidence of 2 above.....

### **3.2.4 TRANSITION**

Prior to the implementation of this policy guideline, holders of Masters of Pharmacy degree, or other higher qualifications that are recognized by the Board, and a practice experience of at least 5 years may apply for waivers or exemptions. The applications should reach the Board not more than one year of the commencement of these policy guidelines.

### **3.2.5 COMMITTEE ON PHARMACY SPECIALITIES**

The Board shall establish a standing committee of pharmacy specialists that will have the following functions:

- Identify, define and recommend the areas of specializations
- Receive recommendations for, assess and approve new specialties
- Evaluate the candidates through the qualifying examination
- Identify and accredit institutions and preceptors for residency programs
- Specify the knowledge, competencies and skills expected of specialists
- Develop standard operating procedures for evaluation and administration of specialists examinations
- Any other relevant responsibility that the committee may decide from time to time

#### ***Membership of the committee***

- The committee shall be composed of nine members who shall be representatives from all broad areas of Pharmacist specialization, and 1 human resource specialist
- The committee shall be appointed by the Pharmacy and Poisons Board.