STAATSKOERANT, 4 JULIE 2025

No. 52945 3

# BOARD NOTICES • RAADSKENNISGEWINGS

#### BOARD NOTICE 807 OF 2025

#### SOUTH AFRICAN PHARMACY COUNCIL

#### BACHELOR OF PHARMACY – INTEGRATED CURRICULUM OUTLINE

The South African Pharmacy Council intends to publish the **Bachelor of Pharmacy – Integrated Curriculum Outline** in terms of Section 34 of the Pharmacy Act, 53 of 1974, read together with the *Regulations relating to pharmacy education and training* (as amended).

Interested parties are invited to submit, within **30 days** of publication of this notice, substantiated comments on or representations regarding the proposed **Bachelor of Pharmacy – Integrated Curriculum Outline**. Comments must be addressed to the Registrar, South African Pharmacy Council, by way of email at <u>BN@sapc.za.org</u> (for the attention of the Company Secretary and Legal Services).

#### SCHEDULE

#### 1. Bachelor of Pharmacy – Integrated Curriculum Outline

MR VM TLALA REGISTRAR

Address: 591 Belvedere Street, Arcadia, Pretoria, 0083.

Private Bag X40040, Arcadia, 0007. Telephone: 0861 7272 00

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



# **Bachelor of Pharmacy (BPharm)**

# **Integrated Curriculum Outline**

The underlying philosophy:

"Pharmacy as a dynamic, information-driven, patient-orientated profession, through its infrastructure, competence and skills, is committed to fulfilling the health care needs of South Africa" – Good Pharmacy Practice Manual and Associated SAPC rules

June 2025

## FOREWORD

The advancement of healthcare in South Africa is directly linked to the calibre of professionals educated to serve within it. As the regulatory authority entrusted with ensuring the highest standards of pharmacy education and practice, the South African Pharmacy Council (SAPC) is committed to shaping a pharmacy profession that is responsive, competent and equipped to meet the evolving health needs of our nation.

This Integrated Curriculum Outline for the Bachelor of Pharmacy (BPharm) qualification represents a critical step in ensuring that pharmacy graduates are prepared not only with foundational and advanced scientific knowledge but also with the applied skills necessary to deliver patient-centred pharmaceutical care in a complex and rapidly changing healthcare environment. It reflects a curriculum that is aligned with national education and training standards, the SAPC's competency framework and global trends in pharmaceutical sciences and practice.

The Outline integrates essential knowledge areas, including the cognate sciences, pharmaceutical and clinical disciplines, and indigenous knowledge systems, while ensuring alignment with the Exit-Level Outcomes (ELOs) and Associated Assessment Criteria defined for the qualification at National Qualifications Framework (NQF) Level 8. This structured approach reinforces Council's vision of producing graduates who are not only scientifically grounded but also ethically conscious, technologically adept and committed to lifelong learning.

Importantly, this document is the result of extensive consultation, collaboration and the dedication of expert educators, academics, practising pharmacists, as well as stakeholders who contributed their time and insight. Their commitment to the future of pharmacy education and practice is both acknowledged and deeply appreciated.

It is our strong conviction that this Outline will serve as a blueprint for higher education institutions in developing and delivering robust and relevant BPharm programmes, while ensuring consistency in graduate competencies across the country. It also reinforces the SAPC's commitment to upholding excellence in pharmacy education, and by extension, contributes meaningfully to achieving universal health coverage and improved health outcomes for all South Africans.

VM Tlala Registrar/CEO South African Pharmacy Council

## ACKNOWLEDGEMENTS

The integrated curriculum outline for the Bachelor of Pharmacy is evidence of the expertise, skills, dedication, and time afforded by the members of the *ad hoc* Task Team appointed by the South African Pharmacy Council. The constructive engagement and invaluable input of stakeholders are gratefully acknowledged. Thank you to each Task Team member and all who contributed to the consultative process. The efficient support of the Office of Council during the process is highly appreciated.

TASK TEAM	REVIEWERS AND CONTRIBUTORS
Prof. G Enslin (Project leader, Facilitator &	Ms S Cohen
Pharmaceutical Chemistry)	Dr A Gray
Ms Ingrid du Plessis (Facilitator: Curriculum	Ms C Hanson
Development – Health Sciences)	Dr E Kapp
	Mr L Hazelhurst
Prof. S van Dyk (Pharmaceutical Chemistry)	Dr M Madziva
	Prof. S Malan
Prof E Oosthuizen (Pharmacology)	Mr W Modiba
Mr T M Modeu (Pharmacology)	Dr S Moodley
Prof. K. Obikaza (Pharmacology)	Prof. N Shellack
Ma V Abroham (Pharmacology)	Ms K van Staden
MS V Abraham (Pharmacology)	Prof. S van Vuuren
	Prof. R Walker
Dr P Skosana (Clinical Pharmacy)	Prof. D Wolmarans
Prof. V Bangalee (Clinical Pharmacy)	
Dr C Oltmann (Pharmacy Practice)	
Prof. M Nlooto (Pharmacy Practice)	
Dr N Mayimele (Pharmacy Practice)	
Dr N Kubashe (Pharmacy Practice)	
Prof. S Burton (Pharmacy Practice)	
Prof. I Vermaak (Pharmaceutics)	
Mr T Manyama (Pharmaceutics)	
Ms S Harichander (Pharmaceutics)	
Dr M Govender (Pharmaceutics)	

# TABLE OF CONTENTS

FOREWORD	i
ACKNOWLEDGEMENTS	ii
TASK TEAM	ii
Reviewers and CONTRIBUTORS	ii
INTRODUCTION AND BACKGROUND	vi
EXIT-LEVEL OUTCOMES AND ASSOCIATED ASSESSMENT CRITERIA	۹ vi
THE CURRICULUM OUTLINE	vii
MINIMUM CURRICULUM REQUIREMENTS	viii
EDUCATIONAL TERMINOLOGY	х
Cognitive Theme	х
Procedural Knowledge	х
Knowledge Application	х
THE CURRICULUM OUTLINE FOR THE BACHELOR OF PHARMACY	1
FOUNDATIONAL KNOWLEDGE	1
CHEMISTRY	1
BIOCHEMISTRY	5
PHYSICS	6
MATHEMATICS AND STATISTICS	9
ANATOMY	10
PHYSIOLOGY	12
PATHOLOGY	13
PATHOPHYSIOLOGY	16
MICROBIOLOGY (including MEDICAL MICROBIOLOGY)	18
PHARMACEUTICAL MICROBIOLOGY	20
MEDICAL ETHICS, HEALTHCARE ETHICS AND BIOMEDICAL ETHICS	23
PHARMACOGNOSY AND INDIGENOUS KNOWLEDGE S' TRADITIONAL MEDICINE, COMPLEMENTARY MEDICINE	YSTEMS, 24
PHARMACOGNOSY	24
INDIGENOUS KNOWLEDGE SYSTEMS	25
COMPLEMENTARY AND ALTERNATIVE MEDICINE	26
TRADITIONAL MEDICINE	27
ADVANCED KNOWLEDGE	28
PHARMACOLOGY	28
CLINICAL PHARMACY	30

PHARMACEUTICS	37
PHARMACEUTICAL CHEMISTRY	40
PHARMACY PRACTICE	45
APPLICATION OF KNOWLEDGE AND SKILLS	54
PATIENT MEDICATION MANAGEMENT, RESOLUTION OF MEDICINE (I THERAPY PROBLEMS, MEDICATION REVIEWS	ORUG) 54
PHARMACOVIGILANCE PRINCIPLES AND REPORTING ADR	57
MEDICAL DEVICES	59
PATIENT-SPECIFIC EDUCATION AND COUNSELLING	62
PHARMACIST-INITIATED THERAPY (PIT)	63
MODERN TECHNOLOGIES IN PHARMACY	69
GOOD MANUFACTURING PRACTICES (GMP)	71
MEDICATION SAFETY PRACTICE (MSP)	73
COMPOUNDING TOOLS AND EQUIPMENT FOR MEDICINES	76
AUTOMATED MEDICATION DISPENSING UNITS (AMDU)	76
DRUG / Medicine INFORMATION DATABASES	77
ADVANCED DRUG / MEDICINE DISCOVERY	78
ADVANCED ANALYTICAL METHODOLOGIES	79
HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)	79
Nuclear Magnetic Resonance (NMR) SPECTROSCOPY	82
DNA SEQUENCING AND GENOTYPING	83
MEDICINE DEVELOPMENT: PRECLINICAL, CLINICAL, AND POST-CLI PHASES	NICAL 84
REGULATORY APPROVAL AND COMPLIANCE	85
LABORATORY TESTING AND GLP AND GCP	88
MEDICINE SAFETY ASSESSMENT PROCESSES	89
PHARMACOKINETICS IN DRUG DEVELOPMENT	90
MEDICINE FORMULATION, PHARMACOLOGICAL TESTING	91
DRUG/MEDICINAL PRODUCT STABILITY	92
TOXICITY STUDIES	93
WHOLESALING AND DISTRIBUTION OF MEDICINES	95
INVENTORY MANAGEMENT	95
STORAGE AND HANDLING	96
REGULATORY COMPLIANCE AND GSP AND GDP	97
SUPPLY CHAIN EFFICIENCY	97
PRODUCT AUTHENTICATION AND SERIALISATION	98
DISTRIBUTION OF SPECIALITY MEDICATIONS	98

USE OF FORMULARIES & SAFE, RATIONAL, AND COST-EFFECTIVE UMEDICINES	JSE OF 99
COMPOUNDING AND MANUFACTURING OF MEDICINES	101
DISPENSING OF MEDICINES AND PHASES AND THE DISPE PROCEDURE	NSING 102
DESTRUCTION AND/OR DISPOSAL OF PHARMACEUTICAL AND ME WASTE	EDICAL 104
PHARMACOVIGILANCE	105
PHARMACEUTICAL POLICIES	105
RESEARCH IN HEALTH SCIENCES	108
GOOD RESEARCH PRACTICES (GRP)	111
ETHICAL AND LEGAL ISSUES	111
RATIONAL USE OF MEDICINE	113
COST-EFFECTIVENESS AND FEASIBILITY OF MEDICATION	114
PATIENT CONSULTATION	115
EVIDENCE-BASED PRACTICE	117
MEDICINE SAFETY	119
HEALTH ECONOMICS COMMUNICATION	121
HEALTH DISASTERS COMMUNICATION	122
PRIMARY HEALTHCARE (PHC)	124
COMMUNICATE AND DISSEMINATE RESEARCH RESULTS	126
PATIENT-SPECIFIC INFORMATION & THERAPEUTIC PRINCIPLES	128
GLOBAL, ECONOMIC, ENVIRONMENTAL, INDUSTRIAL/TECHNOLO	GICAL
CHANGES	130
LEADERSHIP STRATEGIES	132
INTER-PROFESSIONAL COLLABORATION	133
BUSINESS ACUMEN	135
QUALITY MANAGEMENT SYSTEMS	137
HEALTHCARE EDUCATION PROGRAMMES	138
HEALTHCARE PRINCIPLES AND PATIENT EDUCATION TECHNIQUES	140
CONTINUING PROFESSIONAL DEVELOPMENT (CPD)	142
MEDICAL ETHICS_ THE SAFE AND RATIONAL USE OF MEDICINE	143
MEDICAL ETHICS_ ETHICAL AND LEGAL RESPONSIBILITIES PHARMACIST	OF A 144

# INTRODUCTION AND BACKGROUND

The South African Pharmacy Council (SAPC), in accordance with its statutory mandate as outlined in the Pharmacy Act, 53 of 1974, ensures the quality and integrity of pharmacy education and training in South Africa. Specifically:

- Section 3(e)(i) stipulates that one of the objectives of the SAPC is to establish, develop, maintain and control universally acceptable standards in pharmacy education and training; and
- (ii) Sections 33 and 34, read in conjunction with the *Regulations relating to Pharmacy Education and Training*, empower the SAPC to approve education and training providers and qualifications that lead to registration as a pharmacist.

The SAPC fulfils the above responsibilities by developing scopes of practice and qualifications, accrediting education providers and their programmes, quality assuring the delivery of the programmes, and ensuring consistency across learning programmes offered at the various higher education providers accredited with the SAPC and the South African Qualifications Authority (SAQA).

This **Integrated Curriculum Outline** sets out the minimum curriculum requirements for Bachelor of Pharmacy (BPharm) programmes in South Africa. It further serves as a guideline to assist higher education institutions in the design, development, and implementation of BPharm qualifications.

# EXIT-LEVEL OUTCOMES AND ASSOCIATED ASSESSMENT CRITERIA

The Exit-Level Outcomes (ELOs) for the Bachelor of Pharmacy (BPharm), a qualification awarded at NQF Level 8, have been framed against the current BPharm Qualification Standard<sup>1</sup>. They further align with the South African Pharmacy Council (SAPC) competency standards for pharmacists<sup>2</sup>, as well as the South African Qualification Authority (SAQA) level descriptors<sup>3</sup> to meet the competencies of the relevant NQF level. ELOs describe what the learner should be able to *know, do, and understand* upon completion of the BPharm learning programme.

The Associated Assessment Criteria (AAC) indicate what the learner must *do to show competence*, the knowledge involved, the context, the standard of assessment, and

<sup>&</sup>lt;sup>1</sup> CHE. Qualification Standard for Bachelor of Pharmacy, 2022.

<sup>&</sup>lt;sup>2</sup> SAPC. Competency Standards for Pharmacists in South Africa, 2018

<sup>&</sup>lt;sup>3</sup> SAQA. Level Descriptors for the South African National Qualifications Framework, November 2012.

the range, where applicable. It further indicates the nature and level of the assessment associated with the qualification and how the ELOs could be assessed<sup>4</sup>.

# THE CURRICULUM OUTLINE

The BPharm Curriculum Outline provides a set of minimum guidelines that define the essential knowledge fields at both foundational and advanced knowledge levels. It is a clear and systematic framework for the topics to be covered and competencies to be developed during the four-year BPharm academic endeavour. The knowledge fields are directly aligned with the Exit-Level Outcomes (ELOs) and Associated Assessment Criteria (AAC) of the BPharm qualification. Given the integrated nature of the ELOs and AAC, cross-referencing is provided to illustrate how specific knowledge areas contribute to multiple outcomes.

Curriculum and programme design remain the responsibility and prerogative of the accredited provider. This document does not prescribe the specific manner in which learning outcomes must be addressed within individual programme modules, nor does it dictate the sequence in which content should be delivered. It does, however, provide minimum guidelines for knowledge fields that must be covered to achieve the ELOs at NQF Level 8 and the AAC for competency assessment for student achievement of the learning outcomes.

The curriculum guideline document is organised according to the BPharm Qualification Standard and the ELOs and AAC of the BPharm qualification<sup>5</sup> as follows:

<sup>&</sup>lt;sup>4</sup> SAQA. Guidelines for the Development and Evaluation of Qualifications and part-qualifications for Registration on the National Qualifications Framework, 2023.

<sup>&</sup>lt;sup>5</sup> SAPC. Exit Level Outcomes and Associated Assessment Criteria for the Bachelor of Pharmacy, 2024.

(1) **Core knowledge requirements** relevant for the practice of pharmacy, which comprise of:

# Foundational knowledge of:

- The cognate sciences, chemistry, microbiology, biochemistry, mathematics and statistics, physics, anatomy, physiology, pathophysiology, anatomy and social and behavioural sciences, including biomedical ethics;
- Pharmacognosy and indigenous knowledge systems as relevant to the practice of pharmacy in the South African context; and Advanced knowledge of:
- The core pharmaceutical and clinical sciences, which include pharmacology, pharmaceutics, pharmaceutical chemistry, pharmacy practice and clinical pharmacy.

Core knowledge is addressed in ELO1 and the AAC.

# (2) Application of knowledge and skills

**Application of integrated knowledge** of the foundational, core pharmaceutical and clinical sciences to address complex and unfamiliar problems encountered in the practice of pharmacy.

The application of knowledge and skills is addressed in ELOs 2 – 9 and their AAC.

For a schematic representation of the curriculum, see the **Schematic diagram of the** curriculum outline.

# MINIMUM CURRICULUM REQUIREMENTS

**The minimum curriculum requirements** necessary to meet the Qualification Standard for the Bachelor of Pharmacy are detailed under the **Sub-Knowledge Fields** within each **Knowledge Field** section of this framework. These Sub-Knowledge Fields are compulsory and must be included to satisfy the minimum requirements for a compliant and comprehensive BPharm curriculum.

The accompanying **Detailed Knowledge Fields** provide additional guidance to support curriculum development and alignment with expected graduate competencies. Illustrative examples and cross-references have been included to assist providers in the design, application, and integration of content across the curriculum. These references are intended to guide, rather than prescribe, curriculum content.

Providers are required to ensure that all programmes remain compliant with the South African Pharmacy Council's Competency Standards for Pharmacists (2018), the Qualification Standard for the Bachelor of Pharmacy (2022), and the principles outlined in the Good Pharmacy Education (GPE) standards, to ensure graduates are equipped for contemporary pharmacy practice and patient-centred care.



Figure 1: Schematic diagram of the curriculum outline

**Application of knowledge and skills:** In accordance with the South African Pharmacy Council's (SAPC) competency standards and the Qualification Standard for the Bachelor of Pharmacy degree, it is imperative that accredited programmes integrate structured opportunities for interprofessional education to cultivate collaborative practice. For instance, incorporating case-based learning within small, multidisciplinary groups can effectively simulate real-world clinical scenarios, thereby enhancing interprofessional competencies. Additionally, programmes must ensure that learners demonstrate applied proficiency in medicines safety, with a particular focus on the statutory duties and professional accountability of the Responsible Pharmacist, as delineated in the Pharmacy Act, 53 of 1974, and SAPC practice standards. This approach aligns with the SAPC's commitment to fostering patient-centred care and upholding the highest standards of pharmacy practice.

# EDUCATIONAL TERMINOLOGY

# **COGNITIVE THEME**

Cognitive theme refers to a dominant pattern of thoughts, ideas, and mental processes related to cognitive functions. It shapes an individual's perception, understanding, and processing of information.

In cognitive science, it refers to a consistent mental pattern or framework that influences how individuals perceive, interpret, and remember information.

# PROCEDURAL KNOWLEDGE

Procedural knowledge refers to the understanding and ability to perform a <u>specific set</u> <u>of actions</u>, tasks, or procedures. It is a type of knowledge that is often associated with skills, routines, and <u>sequences of actions required to accomplish a particular goal</u>. Procedural knowledge is about knowing how to do something rather than simply knowing facts or information. It is Skill-based, Action-orientated, and Context-specific.

# **KNOWLEDGE APPLICATION**

Application of knowledge refers to the practical use or utilisation of acquired information, skills, and understanding in real-world situations. It involves taking theoretical or conceptual knowledge and employing it to solve problems, make decisions, or create tangible outcomes in various contexts.

# THE CURRICULUM OUTLINE FOR THE BACHELOR OF PHARMACY

## **EXIT-LEVEL OUTCOME 1**

## FOUNDATIONAL KNOWLEDGE

In terms of the scope of knowledge, knowledge literacy, and the ability to access, manage, and synthesise information related to the core pharmaceutical, clinical, and related sciences, a learner is able to:

**Exit-Level Outcome 1.1** Demonstrate the ability to integrate the basic principles of sciences cognate to pharmacy in the understanding and application of knowledge, theories, research methodologies and techniques at the forefront of the core disciplines of pharmacy in professional practice.

Cognate sciences: include but are not limited to: Chemistry, Microbiology, Biochemistry, Mathematics and Statistics, Physics, Anatomy, Physiology, Pathology, Pathophysiology, Pharmacognosy, and Social and Behavioural Sciences, including Biomedical Ethics.

## FOUNDATIONAL KNOWLEDGE

**Foundational knowledge:** Requirements are the basic principles of the cognate sciences and appropriate integration and application in the core disciplines of pharmacy.

# **CHEMISTRY**

Curriculum Outline for Cognate Sciences:

In order to provide a foundational understanding of the chemistry principles relevant to the core disciplines and the application of integrated knowledge and skills in the practice of pharmacy, the following content is suggested:

Curriculum outline:

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Matter (This area focuses on the fundamental properties and classification of matter, including the distinction between heterogeneous and homogeneous	Heterogeneous and homogeneous compounds Macroscale, microscale and nanoscale measuring and handling ( <b>also see sections on</b> <i>COMPOUNDING AND</i> <i>MANUFACTURING OF MEDICINES</i> under Application of Knowledge and Skills). States of matter

compounds and the measurement of matter at different scales.) Chemical compounds (This area focuses on the types, properties, and structures of chemical compounds, including molecular, inorganic, and organic compounds as they relate to medicines and biomolecules)

Chemical reactions

(This area focuses on the principles and types of chemical reactions, including reaction kinetics, thermodynamics, and stoichiometry, with application in pharmaceutical contexts) Molecular compounds Inorganic compounds Organic compounds (aliphatic compounds, aromatic compounds, carbonyl compounds, aromatic heterocyclic compounds) as they pertain to medicines and biomolecules lons and ionic compounds. Properties of compounds Chemical bonding. Intra and intermolecular forces, diploes and dipole moments, diploe - dipole bonding, hydrogen bonding, London dispersion forces (van der Waal's forces), charge transfer complexes, Conformation and configuration, absolute configuration, isomers, stereoisomers, racemic modifications, resolution of racemic modifications, geometric isomers, stereoisomerism and biological activity Moles and percentage composition, fundamental concepts of concentration Empirical and molecular formulas Elements essential to human health Biomolecules: carbohydrates, lipids, amino acids and proteins, DNA

Also see sections in: *PHARMACOLOGY* (Medicine classes)

Chemical equations Balancing chemical equations The Mole and chemical reactions Limiting reagents Percentage yield Chemical reactions: Types of reactions and selected examples: addition, substitution (exchange), elimination, free radical reactions, oxidation and reduction, rearrangement. Acid base reactions, buffers, chemical equilibria and the law of chemical equilibrium) (reaction kinetics, zero and first order (reaction rate and concentration, half-life, pseudo first order reactions, reaction rate and temperature, reaction rate and pressure, reaction rate and particle size, catalysts and inhibitors, applicable thermodynamics and applications, First and second Laws of Thermodynamics, entropy, enthalpy, exothermic and endothermic change, Gibbs Free Energy) Solution concentration Molarity and reactions in aqueous solution

2

Aqueous solution titrations – Principle of stoichiometry (as informed by uses in pharmacy – QC of medicines, for example) Energy and chemical reactions – nature of energy, conservation of energy, heat capacity, enthalpy and changes of state (incl. freezing and melting, vaporisation and condensation) (cross ref thermodynamics) Endothermic and exothermic reactions Reaction kinetics

# Electron configuration and the periodic table

(This area focuses on the arrangement of electrons in atoms, periodic trends, and their implications for chemical reactivity and pharmaceutical applications)

# States of Matter: Solids, Liquids and Gases

(This area focuses on the properties and behaviour of solids, liquids, and gases, including phase changes, gas laws, and solution chemistry as applied in pharmacy)

# Chemical Equilibrium

(This area focuses on the concept of chemical equilibrium, the equilibrium constant, and the factors affecting equilibrium in pharmaceutical systems)

## Solutes and Solutions

(This area focuses on the dissolution process, solubility, concentration measurements, and the properties of solutions relevant to pharmacy)

Acids and Bases (This area focuses on acid-base concepts, calculations, and their Electromagnetic radiation Periodic trends: atomic radii, ionic radii, ionisation energies, electron affinities Ion formation and ionic compounds Brief Introduction to Nuclear Magnetic Resonance

#### Properties

Ideal gases and Ideal Gas Law Gas mixtures and partial pressure Vapour pressure Phase changes Liquids, viscosity, pH, buffers, reactions in solutions Types of solids (crystalline, ionic, metallic, molecular, network, amorphous)

Characteristics of chemical equilibrium and the equilibrium constant (determining, using) Le Chatelier's principle Controlling chemical reactions

Solubility, intermolecular forces, enthalpy, entropy and dissolution, temperature and solubility Solution concentration and units of measurement of concentration Vapour pressures, boiling points, and freezing points of solutions Osmotic pressure of solutions Colloids Surfactants Water – properties

BronstedLowry concept Lewis acids and bases Autoionisation of water pH scale relevance to medicines, buffers, and pharmaceutical formulations)

Ionisation constants of acids and bases Problem solving using pKa and pKb calculations Molecular structure and acid strength Acid-base reactions of salts Medicines as acids and bases Buffers Acid base titrations principle Solubility equilibria and the solubility product constant (Ksp) Factors affecting solubility. Precipitation

#### Electrochemistry

(This area focuses on redox reactions, electrochemical cells, and their applications in pharmaceutical analysis and medicine)

#### **Nuclear Chemistry**

(This area focuses on radioactivity, nuclear reactions, and their application in radiopharmacy and medicine)

#### Laboratory Safety

(This area focuses on safe laboratory practices, equipment handling, chemical safety, and emergency procedures in the pharmacy setting)

#### Ethical and Environmental Impact of Chemistry on Society (*This area focuses on the ethical, legal,*

and environmental considerations of chemical use, including pharmaceutical waste management) Nature of radioactivity Nuclear reactions Stability of atomic nuclei Rates of disintegration reactions Applications of radioactivity in radiopharmacy.

Redox reactions

Electrochemical cells

Half reactions

Personal Protective Equipment (PPE) Laboratory equipment Laboratory safety, prevention of exposure to chemicals and infectious agents and policies and procedures to deal with this Handling of chemicals & equipment Material safety data sheets Evacuation procedures

Disposal of chemicals Pollution Also see the section on <u>DESTRUCTION AND/OR</u> DISPOSAL OF PHARMACEUTICAL WASTE

**APPLIED FIELDS IN PHARMACY:** Pharmaceutics; Pharmaceutical Chemistry; Pharmacology. Limited application in Pharmacy Practice and Clinical Pharmacy Practice.

# BIOCHEMISTRY

In order to provide a foundational understanding of the principles of biochemistry relevant to the core disciplines and the application of integrated knowledge and skills in the practice of pharmacy, the following content is suggested:

#### Curriculum Outline:

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Biological Chemistry (This area focuses on the molecular structure and function of biomolecules critical to pharmaceutical science)	Amino acids, protein structure (primary, secondary, tertiary and quaternary), properties of proteins, classes of proteins Cell membranes: structure and glycoprotein components Enzymes, properties and nature, enzyme-substrate complex, kinetics of simple enzyme-substrate interactions, regulation of enzymes, enzymes in medicine Nucleic acids Heredity and the cell, structure of nucleic acids
Biochemical Energetics (Explores energy production and utilisation in biological systems, relevant to drug metabolism)	Overview of energy in the body: ATP, ADP, AMP. Citric acid cycle, respiratory chain, oxidative phosphorylation
Metabolism & Metabolic Pathways (This area focuses on examining metabolic pathways of carbohydrates, lipids, and nitrogen compounds for drug design)	Glycogen metabolism, β-oxidation, cholesterol biosynthesis, urea cycle, drug-food interaction Carbohydrates, glycogen metabolism, glucose tolerance Catabolism of glucose Gluconeogenesis Glycated haemoglobin Lipids Absorption and distribution Storage and mobilisation
	β-oxidation of fatty acids Biosynthesis of fatty acids Biosynthesis of cholesterol Nitrogen compounds Synthesis of amino acids in the body Catabolism of amino acids Formation of urea other nitrogen compounds, e.g. uric acid

Nutrition (This area focuses on nutrient-drug interactions and dietary impacts on pharmacotherapy) Nutritional requirements Carbohydrates, lipids and proteins Drug-food interactions – **also see** <u>PHARMACOLOGY</u> (Medicine Interactions) Vitamins Minerals and trace elements

**APPLIED FIELDS IN PHARMACY:** Pharmacology; Pharmaceutical Chemistry; Clinical Pharmacy Practice; Pharmacy Practice; Pharmaceutics.

## PHYSICS

In order to provide a foundational understanding of the principles of physics that apply to the core disciplines of pharmacy, particularly in drug formulation and delivery systems, and the application of integrated knowledge and skills in the practice of pharmacy, the following content is suggested:

## **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

Basic Mathematical Concepts (This area covers foundational mathematics for measurement and units, pharmaceutical calculations and equipment calibration)

Mechanics: Forces & Newton's Laws of Motion as applied in Pharmacy (This area focuses on applying Newtonian physics to tablet compression, inhaler design, and packaging machinery)

#### DETAILED KNOWLEDGE FIELDS

Physical quantity and applicable SI units. Interconversion of units. Graphical representation and interpretation of relationships. Scalars and vectors (as applicable in mechanics) The concept of force and resultant force as a vector quantity. The different types of forces (gravitational, friction, normal, tension, drag) and the distinction between them. Newton's three laws of motion Applicable actions in pharmacy, weighing and sensitivity of balances, tablet compression (e.g. compression forces and tablet hardness measurement), tablet coating Syringe and inhaler design Translational equilibrium, Rotational equilibrium Tablet compression, single punch and rotary tablet press Sedimentation in suspensions

Pharmaceutical packaging machines, blister packing, capping machines

Momentum and impulse: The law of conservation of momentum Elastic and inelastic collisions Newton's second law Application to inhaler and aerosol devices, deposition of particles in the lungs, Pharmaceutical manufacturing, granulation and mixing equipment

Work, energy and power:

Work-energy theorem.

The law of conservation of mechanical energy. Application in tablet compression, compression force Packaging design for shock absorption

Stress, strain and Hooke's law: Define stress and explain the quantification of stress. Define strain and explain how it is quantified strain. The stress-strain graph. Young's modulus Elastic and plastic deformation as it affects tablet

strength, disintegration, dissolution. Tablet capping (lamination after compression)

Density and relative density. Surface tension The density of an object

Properties of fluids Density and relative density. Surface tension Viscosity The density of an object

Application in pharmacy, rheology, pharmaceutical dosage form design, manufacturing of liquids and semi-solid dosage forms, quality control, aerosol delivery in inhalers, blood flow and drug transport, IV infusion rates

Radiation: Energy emitted as particles or electromagnetic waves (e.g., alpha, beta, gamma, X-rays).

lonising and non-ionising radiation, particulate radiation

Static Fluids

Fluid Dynamics, Static Fluids, Fluid Flow and Hydrodynamics (This area focuses on rheology, IV infusions, and aerosol delivery systems. Density, surface tension, fluid flow, IV infusion rates)

# Radioactivity and Radiation

(This area focuses on radiopharmaceuticals, sterilisation, and heat transfer in manufacturing. Ionising radiation, gas laws, heat transfer modes)

#### Radioactive decay:

Radiopharmaceuticals (nuclear pharmacy), imaging, sterilisation, e.g. Technetium-99m, lodine-13, gamma radiation for sterilisation of heat-sensitive products and equipment

#### Thermodynamics and Heat Transfer

(This area focuses on providing a foundational understanding of numerous processes in physical chemistry, pharmaceutics and biopharmaceutics, particularly those involving energy changes, heat transfer, drug stability, solubility and chemical equilibrium)

## Gas Laws

(This area focuses on providing a foundational understanding of gas laws as applicable to aerosol products, spray technology, inhalation therapy, pressure vessels and sterilisation processes)

**Electromagnetic Radiation** 

#### Key terms and concepts:

Concept of a system and types of systems (open, closed, isolated)

State and state variables (temperature (T), pressure (P), volume (V), internal energy (U), entropy (S) and enthalpy (H))

Thermal equilibrium and Zeroth Law, (temperature as a measurable property)

Temperature, Thermal Expansion & Thermal Stress: Temperature and heat in terms of

Definition and SI unit, Kelvin (K). Common

conversions (Celsius to Kelvin)

Linear, area and volume thermal expansion.

Thermal stress

Specific heat capacity.

Latent heat of fusion and vaporisation.

Conservation of energy principle

Heat Transfer:

The modes of heat transfer, Conduction, Radiation. Application in pharmaceutical manufacturing

The kinetic theory of matter The properties of an ideal gas Boyle's Law and Charles's Law The pressure, volume and temperature of an enclosed gas The ideal gas law

Electromagnetic spectrum

Definition of a wave.

Differences between transverse and longitudinal waves.

Wavelength, period, frequency, amplitude Propagating speed of a wave in terms of frequency

and wavelength. Interaction of electromagnetic radiation with matter

(absorption, emission)

Basics of spectroscopy, UV-vis, IR, NMR

Pharmaceutical analyses – drug identification, quality control techniques, radiation therapy

**APPLIED FIELDS IN PHARMACY:** Pharmaceutics; Pharmacology; Pharmaceutical Chemistry; Pharmacy Practice; Clinical Pharmacy Practice.

# **MATHEMATICS AND STATISTICS**

In order to provide the essential mathematical skills required for pharmaceutical calculations and research, and the application of integrated knowledge and skills in the practice of pharmacy, the following content is suggested:

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Numerical Computations (Prior Knowledge) (This area focuses on foundational math skills essential for accurate dosage calculations, metric conversions, and basic pharmaceutical calculations)	The number system Estimating answers Use of significant digits Basic calculator operations Calculation of percentages Implementation of SI units
Mensuration and Geometry (Prior Knowledge) (This area focuses on applying geometric concepts to pharmaceutical formulations and dosage form design)	Perimeters and areas of two-dimensional figures Surface areas and volumes of three-dimensional figures
Algebra and Equations (This area focuses on developing algebraic manipulation and equation-solving skills necessary for pharmaceutical problem-solving and dosage computations)	Review of algebra Factorisation and finding roots of algebraic equations Concepts of ratio and proportion Linear equations and their graphical interpretation Systems of linear equations (including Cramer's Rule)
Functions and Graphing (This area focuses on understanding mathematical functions and their graphical representations to model drug behaviour and pharmacokinetic profiles)	Introduction to functions (domain, range, vertical line test, symmetry) Types of functions (power, polynomial, rational, trigonometric, exponential, logarithmic) Graph transformations (shifting, scaling, reflecting, composition) The exponential function (growth and decay, powers, number 'e', base conversion, log-log and semi-log methods) Inverse functions (definition, derivation of natural log, range) Analysis of functions (local extrema, intervals of

#### SUB-KNOWLEDGE FIELDS

#### DETAILED KNOWLEDGE FIELDS

increase/decrease, concavity, points of inflection, optimisation)

# Calculus: Limits, Derivatives, and Integration

(This area focuses on modelling and analysing rates of change in drug kinetics, optimising pharmaceutical processes, and understanding accumulation and decay phenomena)

#### **Probability and Statistics**

(This area focuses on supporting clinical trial design, drug safety analysis, interpretation of experimental data, and evidence-based pharmacy practice) Limits (definition, average rate of change, finite/infinite limits, continuity) Derivatives (first principles, rules, product/quotient/chain rules, implicit differentiation,

higher derivatives, applications) Integration (definite and indefinite integrals,

properties, substitution method, fundamental theorem of calculus)

Rules of probability (basic properties, addition/multiplication rules, conditional probability, contingency tables) Probability distributions (discrete: binomial, Poisson; continuous: normal,, chi-square, ) Sampling and estimation (distribution of sample mean, Central Limit Theorem, confidence intervals for means/proportions/variances) Hypothesis testing (null/alternative hypotheses, test statistics, p-value, power, decision making) Regression and correlation (least squares, significance testing, ANOVA for regression, prediction, multiple regression) Descriptive statistics (measures of central tendency and variability, graphical methods: histograms, box plots, bar graphs)

Pharmaceutical Calculations and Units (This area focuses on accurate measurement and preparation of pharmaceutical formulations and ensuring safe medication use) Concentration calculations Unit conversions and dimensional analysis

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

## **ANATOMY**

In order to provide a foundational understanding of the basic structure of the human body with a focus on the systems relevant to the core disciplines and practice of pharmacy, the following content is suggested:

# **Curriculum Outline:**

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Organisation of the Human Body (This area focuses on cellular to systemic anatomy for understanding drug delivery and toxicity)	Medical Terminology and surface anatomy Cellular level of organisation Tissue level of organisation Introduction to the integumentary system, as per organisation of the human body Embryological development of the integumentary system Tissue types, integumentary system, embryology. Support & Movement Relevant to musculoskeletal drug targets and drug delivery mechanisms. Skeletal/muscular systems, bone tissue, joint mechanics.
Principles of Support and Movement (This area focuses on aspects related to musculoskeletal drug targets and drug delivery mechanisms)	Bone tissue The skeletal system (axial) The skeletal system (appendicular) Articulations Muscle tissue Muscle tissue development
Control systems of the body (This area focuses on nervous and endocrine systems for neuropharmacology and hormone therapies)	Nervous tissue Brain and cranial nerves Special senses Somatic nervous system Autonomic nervous system Anatomy/neurotransmitters/receptors/effects Sympathetic Nervous System Parasympathetic Nervous System Endocrine system as per the control systems of the human body Spinal cord and spinal nerves Endocrine system as per the control systems of the human body
Maintenance of the human body (This area focuses on the continuity and addresses cardiovascular, respiratory, and reproductive systems for drug efficacy)	Cardiovascular system Lymphatic system and Immunity Respiratory system Digestive system Urinary system Male and female reproductive systems, as per the

continuity of the human body

Development and Inheritance as per the continuity of the human body

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology

## **PHYSIOLOGY**

In order to provide a foundational understanding of the basic function of the human body with a focus on the systems relevant to the core disciplines and practice of pharmacy, the following content is suggested:

#### **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

Organisation of The Human Body

The Essential Terminology of Physiology (This area focuses on the structural and functional organisation of the human body, from the chemical to the tissue level, with emphasis on homeostasis processes, and physiological terminology relevant to pharmacy)

#### Principles of Support and Movement

The Principles of Support and Movement (This area focuses on the principles underlying support and movement in the human body, including the structure and function of bone and muscle tissue, and related pathophysiological disorders)

#### Control Systems of the Human Body

Introduction to the major organ systems along with their role in the control and regulation of the major processes of the human body, including their physiological function in homeostasis, nutrition, movement and general senses and integration with each other, with a specific focus on the following organ systems: DETAILED KNOWLEDGE FIELDS

Cellular level of organisation Tissue level of organisation Integumentary system Chemical level of organisation Cellular level of organisation Integumentary system

Bone tissue Articulations The skeletal system Muscle tissue The muscular system

Nervous tissue Spinal Cord and Spinal nerves Brain and Cranial nerves Sensory, Motor, and Integrative Systems Special senses Autonomic Nervous System Endocrine System (This area focuses on the major organ systems responsible for control and regulation, including their physiological roles in homeostasis, integration, and response to internal and external stimuli)

## Maintenance of the Human Body

Introduction to the Major Organ Systems Responsible for the Maintenance & Metabolism Processes of the Human Body with Reference to the Following: (*This area focuses on the organ systems responsible for maintenance and metabolism, including cardiovascular, lymphatic, respiratory, digestive, and urinary systems, and their integration and pathophysiological disorders*)

## Continuity

(This area focuses on the physiological processes of continuity, including reproduction, development, inheritance, and related pathophysiological disorders) Fluid, electrolyte, and acid-base homeostasis

Cardiovascular System: Blood & heart Blood vessels and haemodynamics Lymphatic System Nonspecific resistance to disease and immunity Respiratory System Digestive System Urinary System

The male and female reproductive systems Development and inheritance Menstrual cycle and hormonal regulation The male and female reproductive systems Development and inheritance Menstrual cycle and hormonal regulation

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmacology

# PATHOLOGY

In order to provide foundational knowledge crucial for a comprehensive understanding of how diseases affect different organ systems and how pharmacological interventions can be tailored for effective management by applying integrated knowledge and skills, the following content is suggested:

## Curriculum Outline:

SUB-KNOWLEDGE FIELDS

DETAILED KNOWLEDGE FIELDS

General Pathology (This area focuses on the fundamental mechanisms of disease at the cellular level, including how cells respond to injury and adapt to stress)	Cellular Injury and Adaptation: Understanding how cells respond to stress or damage, including mechanisms like apoptosis and necrosis.
Systemic Pathology (This area focuses on disease processes as they affect specific organ systems, integrating principles of systemic pathology with clinical application)	
Cardiovascular System Pathology (This area focuses on diseases of the cardiovascular system and their pharmacological management.)	Hypertension: pathogenesis, complications, and pharmacological management. Atherosclerosis and ischemic heart disease. Heart failure and cardiomyopathies. Thromboembolic disorders and anticoagulant therapy.
Respiratory System Pathology (This area focuses on diseases of the respiratory system, including chronic and acute conditions and their management)	Chronic obstructive pulmonary disease (COPD) and asthma. Pneumonia and respiratory infections. Pulmonary embolism and lung cancer.
Gastrointestinal System Pathology (This area focuses on diseases of the gastrointestinal tract and associated organs, with emphasis on pathogenesis and treatment)	Peptic ulcer disease and gastroesophageal reflux disease (GERD). Inflammatory bowel diseases (Crohn's disease, ulcerative colitis). Hepatic disorders (cirrhosis, hepatitis, and liver failure). Pancreatitis and gallbladder diseases.
Renal and Urinary System Pathology (This area focuses on diseases of the kidney and urinary tract, and their pharmacological considerations)	Acute and chronic kidney disease Glomerulonephritis and nephrotic/nephritic syndromes Urinary tract infections and kidney stones Pharmacological considerations in renal dysfunction
Endocrine System Pathology (This area focuses on disorders of the endocrine glands and their systemic effects)	Diabetes mellitus (Type 1 and Type 2): pathophysiology and complications Thyroid disorders (hypothyroidism, hyperthyroidism). Adrenal gland disorders (Cushing's syndrome, Addison's disease).
Hematologic and Lymphatic System Pathology	Anaemia (iron deficiency, megaloblastic, hemolytic). Coagulation disorders (hemophilia, disseminated intravascular coagulation).

(This area focuses on disorders of blood and lymphatic systems, including anaemias and coagulation disorders)

#### Nervous System Pathology

(This area focuses on diseases of the nervous system, including neurodegenerative, seizure, and psychiatric disorders)

#### Musculoskeletal System Pathology

(This area focuses on diseases of the bones and joints, including metabolic and inflammatory conditions)

# Immune System and Infectious Diseases

(This area focuses on the body's response to infection, inflammation, immunopathology, and autoimmune diseases)

# Reproductive System Pathology

(This area focuses on diseases of the reproductive organs and sexually transmitted infections)

## **Oncology and Neoplasia**

(This area focuses on cancer biology, common cancers, tumour markers, and principles of chemotherapy)

**Dermatological Pathology** 

# Pharmacological Considerations in Systemic Pathology

(This area focuses on drug selection, drugdisease interactions, and the impact of disease on drug pharmacokinetics and pharmacodynamics) Neurodegenerative diseases (Alzheimer's, Parkinson's, multiple sclerosis). Epilepsy and seizure disorders. Stroke and cerebrovascular disorders. Psychiatric conditions (depression, schizophrenia).

Osteoporosis and metabolic bone diseases. Rheumatoid arthritis and osteoarthritis. Gout and crystal arthropathies.

Inflammation and Repair: The body's response to injury or infection, including acute and chronic inflammation and tissue healing. Immunopathology: The role of the immune system in health and disease, including hypersensitivity, autoimmunity, and immunodeficiency. Autoimmune diseases (systemic lupus erythematosus, rheumatoid arthritis). Hypersensitivity reactions and allergic conditions. Infectious diseases (bacterial, viral, fungal, and parasitic infections).

Male reproductive disorders (prostate hyperplasia, testicular cancer). Female reproductive disorders (polycystic ovary syndrome, endometriosis). Sexually transmitted infections and their management.

Basic principles of cancer pathogenesis. Common cancers (lung, breast, colorectal, prostate). Tumour markers and principles of chemotherapy.

Common skin disorders (psoriasis, eczema, acne). Skin infections and wound healing.

Drug selection based on disease pathophysiology. Impact of systemic diseases on drug absorption, metabolism, and excretion.

Drug-disease interactions and contraindications.

**Diagnostic Pathology** 

(This area focuses on laboratory and molecular diagnostic techniques, including genetic and epigenetic contributions to disease)

Molecular Pathology, Including Genetic and Epigenetic Contributions to Diseases

Application of pathology in personalised medicine and pharmacogenomics (This area focuses on the integration and application of pathology knowledge in pharmacy practice)

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmacology

# PATHOPHYSIOLOGY

In order to provide foundational knowledge crucial for understanding disease processes and their impact on the human body and disease management by applying integrated knowledge and skills, the following content is suggested:

## **Curriculum Outline:**

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Introduction and Basic Concepts of Disease Processes (This area focuses on the nature, causes, and cellular basis of disease, including disruption of homeostasis and adaptation mechanisms)	The nature of disease, its disruption of homeostasis in the human body. Aetiology and risk factors of diseases. Concepts of adaptation, compensation, and decompensation. Normal and abnormal cellular changes that take place in the body. The concepts of disease process that take place at a cellular level, e.g. cellular and molecular basis of disease, signal transduction pathways in disease, alterations in gene expression and epigenetics.

#### Pathophysiology of Body Systems

(This area focuses on the pathophysiological conditions affecting major body systems and their clinical implications)

The pathophysiological conditions in relation to the following systems of the body: Integumentary System Musculoskeletal System Blood and Circulatory System Lymphatic System Cardiovascular System Respiratory System Nervous System Sensory System Endocrine System Digestive System Renal System Reproductive System Immune System

#### Infectious Diseases Pathophysiology and Antimicrobial Stewardship (This area focuses on pathogen-host interactions, immune responses, systemic effects of infection, and antimicrobial stewardship.)

# Pathogen-Host Interactions

# Research and Evidence-Based

Practice Objectives

(This area focuses on the critical appraisal of literature and application of evidence-based guidelines in disease management and antimicrobial use)

## Chronic and Lifestyle Diseases

(This area focuses on the pathology of noncommunicable diseases such as diabetes, obesity, and cardiovascular diseases, which are critical for pharmacists)

**Emerging Areas in Pathology** 

Virulence factors of bacteria, viruses, fungi, and parasites. Mechanisms of invasion, colonisation, and tissue damage.

Skin pathology

Host immune responses: innate and adaptive Inflammatory processes and potential immunopathology. Systemic Effects of Infections. Fever, metabolic changes, and organ-specific damage. Sepsis and multi-organ dysfunction in severe cases.

Critically appraise literature on antimicrobial use and resistance.

Apply evidence-based prescribing guidelines.

Understanding the pathology of non-communicable diseases like diabetes, obesity, and cardiovascular diseases which are critical for pharmacists.

All topical areas of interest to personalised medicine and genomic strategies

(This area focuses on topical and emerging areas, including personalised medicine and genomic strategies)

Pathophysiology across the lifespan (This area focuses on how pathophysiology differs across age groups, including paediatric and geriatric populations, and the impact of environmental and occupational factors) Paediatric pathophysiology: organ maturation, body composition, neurodevelopment, immune responses, metabolic differences Geriatric pathophysiology: age-related changes across systems Environmental and occupational pathophysiology: effects of toxins, radiation, environmental factors

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmacology.

# MICROBIOLOGY (INCLUDING MEDICAL MICROBIOLOGY)

In order to provide a foundational understanding of the microbiological principles relevant to the core disciplines and the application of integrated knowledge and skills in the practice of pharmacy, the following content is suggested:

## **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

Prokaryotic Cell Structure and Function, Basic Principles (This area focuses on the differences between prokaryotic and eukaryotic cells, including Gram reactions and cell morphology)

#### **Microbial Nutrition**

This area focuses on the nutritional requirements and cultivation of microorganisms, including types of culture media and techniques for obtaining pure cultures.

#### DETAILED KNOWLEDGE FIELDS

Differences between prokaryotic and eukaryotic cells, basic principles Gram reactions, cell morphology

Cultivation media and plating techniques. Macronutrients

Micronutrients

The four main nutritional groups, basic principles The various processes by which cells obtain their nutrients from the environment, i.e. passive diffusion, facilitated diffusion and active transport, are basic principles.

The various types of culture media used for cultivating microorganisms, as well as the techniques used to obtain pure cultures.

#### **Microbial Growth**

(This area focuses on the phases and measurement of microbial growth, and the influence of environmental factors)

# The Control of Microorganisms by Physical & Chemical Agents

(This area focuses on methods for controlling microorganisms, including disinfection, sterilisation, and laboratory safety)

Viruses and other acellular agents (This area focuses on the structure, classification, and reproduction of viruses and other acellular agents)

## Fungi

(This area focuses on the characteristics, nutrition, metabolism, and reproduction of fungi)

## Protists

(This area focuses on the classification, nutrition, morphology, reproduction, and parasitic infections caused by protists)

# Medical Parasitology

(This area focuses on the general characteristics and pathogenesis of protozoa and complex human parasites)

From protozoa to complex human parasites

The different phases of growth in a closed culture system.

The measurement of microbial growth, i.e. cell numbers and cell mass.

The influence of different environmental factors on the growth of microorganisms.

The processes of disinfection, sanitation, antisepsis and sterilisation.

Differences in the destruction of vegetative cells, the pattern of microbial death and the influence of environmental factors on the efficacy of antimicrobial agents.

Safety aspects of the various physical and chemical agents to control microorganisms, as well as safety in the microbiology laboratory.

The general characteristics of viruses, as well as the structure of the four basic morphological groups of viruses

The cultivation of different viruses.

The reproduction of DNA, bacteriophages, emphasising the lytic cycle of these phages, as well as the lysogenic cycle of bacteriophages

The distribution and importance of fungi in general, as well as their morphological characteristics The nutrition and metabolism of fungi, basic principles The formation of both asexual and sexual reproduction, basic principles.

Different divisions of the organisms into groups Their nutritional patterns Their morphological structures, reproduction patterns and habitats Parasitic infections

General characteristics Pathogenesis

Medical Microbiology

(This area focuses on antibiotic resistance, resistance mechanisms, biofilms, and antimicrobial stewardship)

Antibiotic resistance and the main resistance mechanisms

Biofilms Limiting the uptake of the medicine Modification of a medicine target Inactivation of a medicine Active efflux of a medicine The role of antimicrobial stewardship

#### Infectious diseases

(This area focuses on infection and immunity, and the spectrum of infectious diseases relevant to pharmacy) Infection and immunity Infectious diseases, including bacterial, fungal, parasitic, protozoal and viral infections

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmacology.

# PHARMACEUTICAL MICROBIOLOGY

In order to integrate microbiological principles with the pharmaceutical sciences to equip pharmacists to address microbiological challenges in healthcare and the pharmaceutical industry, ensuring the safety, efficacy, and quality of pharmaceutical products, by applying integrated knowledge and skills, the following content is suggested:

#### SUB-KNOWLEDGE FIELDS

Microbial Nutrition (This area focuses on the nutritional requirements and cultivation of microorganisms, including types of culture media and techniques for obtaining pure cultures)	The various types of culture media used for cultivating microorganisms, as well as the techniques used to obtain pure cultures.
The Control of Microorganisms by Physical & Chemical Agents	The processes of disinfection, sanitation, antisepsis and sterilisation.
(This area focuses on methods for controlling microorganisms, including disinfection, sterilisation, and laboratory safety)	Differences in the destruction of vegetative cells, the pattern of microbial death and the influence of environmental factors on the efficacy of antimicrobial agents.

**DETAILED KNOWLEDGE FIELDS** 

Safety aspects of the various physical and chemical agents to control microorganisms, as well as safety in the microbiology laboratory.

#### Sterility Testing

(This area focuses on sterility testing of pharmaceutical products such as injectables, ophthalmic, and surgical devices)

#### Microbial Contamination Control

(This area focuses on preventing and monitoring contamination during pharmaceutical manufacturing)

#### Antiseptics, Disinfectants, and

Preservatives

(This area focuses on the use and efficacy testing of antimicrobial agents in pharmaceutical formulations)

#### Antimicrobial Effectiveness Testing

#### **Bioburden Testing**

(This area focuses on quantifying viable microorganisms in products before sterilisation)

#### **Endotoxin Testing**

(This area focuses on detecting and quantifying endotoxins in pharmaceutical products, especially injectables)

#### Antibiotic Potency Testing

(This area focuses on evaluating the effectiveness of antibiotics against specific microorganisms)

#### Pharmaceutical Water Testing

(This area focuses on testing water used in pharmaceutical manufacturing for microbial contamination) Injectables, ophthalmic, and surgical devices, etc.

Prevent contamination during the manufacturing process. Designing cleanrooms, controlling air quality, and monitoring microbial presence.

Efficacy of preservatives used in pharmaceutical formulations to inhibit the growth of microorganisms and ensure product safety.

Measuring the number of viable microorganisms on or in a product before sterilisation to ensure that microbial levels are within acceptable limits

Detecting and quantifying endotoxins produced by certain bacteria, which can cause harmful reactions in humans if present in pharmaceutical products, especially injectables.

Effectiveness of antibiotic medicines against specific microorganisms, often using methods like the disc diffusion test or broth dilution test.

Testing water used in pharmaceutical manufacturing for microbial contamination, as water is a common vehicle for microbial growth.

#### Validation of Aseptic Processing

(This area focuses on validating aseptic processes to ensure sterility in pharmaceutical manufacturing)

## Validation studies and protocols

## Applications of Pharmaceutical

Microbiology

(This area focuses on ensuring the quality and safety of medicines, developing antimicrobials, and regulatory compliance)

## Manufacturing of sterile medicines

(This area focuses on the processes, contamination prevention, and sterilisation methods for sterile pharmaceutical products)

## Manufacture of Antibiotics

(This area focuses on antibiotic production, alternatives, and the role of microorganisms in medicine manufacturing) Conducting studies to validate processes that ensure aseptic conditions during the manufacturing of sterile products.

Quality and safety of medicines. Developing and testing antimicrobial agents. Compliance with regulatory guidelines and standards.

Industrial pharmacy and cleanliness control. Product contamination prevention and sterilisation. Design of the sterilisation process Sterilisation methods

Antibiotic production methods: Natural fermentation, semi-synthetic (e.g., ampicillin, methicillin), and synthetic (e.g., quinolones). Antibiotic alternatives: Development of nonantibiotic antimicrobial agents and strategies to combat resistance.

Product contamination and sterilisation: Cleanroom design, sterilisation methods (steam autoclave, dry heat, ethylene oxide).

Design of the sterilisation process: Validation of sterilisation protocols for antibiotics and sterile products.

Sterilisation methods: Thermal (dry heat, moist heat), radiation, filtration, and chemical methods.

Use of microorganisms in medicine manufacturing: Microbial fermentation for antibiotics (e.g., penicillin, streptomycin) and vaccine production (e.g., viral antigen cultivation).

Vaccines: Role of microorganisms in vaccine development (e.g., viral vectors, bacterial antigens) and production processes (upstream/downstream)

**APPLIED FIELDS IN PHARMACY:** Pharmaceutics, Pharmacy Practice; Clinical Pharmacy.

# **MEDICAL ETHICS, HEALTHCARE ETHICS AND BIOMEDICAL ETHICS**

(AS PART OF SOCIAL AND BEHAVIOURAL SCIENCES)

SUB-KNOWLEDGE FIELDS

DETAILED KNOWLEDGE FIELDS

See ELO 4 Ethical and Legal Issues

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology



# EXIT-LEVEL OUTCOME 1.2

# FOUNDATIONAL KNOWLEDGE

In terms of the scope of knowledge, knowledge literacy, and the ability to access, manage, and synthesise information related to the core pharmaceutical, clinical, and related sciences, a learner is able to:

**Exit-Level Outcome 1.2:** Integrate principles of pharmacognosy and indigenous knowledge systems as they apply to traditional medicine and applicable complementary and alternative medicines in the provision of pharmaceutical care.

# PHARMACOGNOSY AND INDIGENOUS KNOWLEDGE SYSTEMS, TRADITIONAL MEDICINE, COMPLEMENTARY MEDICINE

## Associates Assessment Criteria

AAC 1.5. Engagement with and understanding of indigenous knowledge systems is supported by foundational knowledge of the theory and principles of pharmacognosy in the practice of pharmacy in the South African context.

Foundational knowledge: Basic principles and applications in pharmacy.

# PHARMACOGNOSY

In order to provide a foundational understanding of natural products, their sources, and their applications in drug discovery and development, the following content is suggested:

# **Curriculum Outline:**

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Natural Sources of Medicinal Compounds (This area focuses on biodiversity, ethnobotany, and the integration of indigenous knowledge systems in identifying medicinal resources)	Plant-derived medicinal compounds (alkaloids, terpenoids, flavonoids) Animal-derived bioactive substances (e.g., venoms, marine organisms) Microbial sources (antibiotics, fungal metabolites) Traditional African medicinal plants and their uses in IKS
Extraction, Isolation, and Chemical Analysis ( <i>This area focuses on modern and traditional</i>	Solvent extraction, distillation, and maceration Chromatography (TLC, HPLC, GC) Spectroscopic identification (UV-Vis, IR, NMR,

PHARMACOGNOSY AND INDIGENOUS KNOWLEDGE SYSTEMS, TRADITIONAL MEDICINE, COMPLEMENTARY MEDICINE 24
techniques for obtaining and characterising bioactive compounds from natural sources)	MS) Traditional preparation methods (decoctions, infusions) aligned with IKS practices
Pharmacological and Biological Activities (This area focuses on validating traditional medicinal uses through evidence-based research and mechanistic studies)	Bioassays for antimicrobial, anti-inflammatory, and antioxidant activity Mechanism of action studies (enzyme inhibition, receptor interactions) Synergistic effects of phytochemicals Preclinical evaluation (in vitro and in vivo models)
Quality Control and Standardisation (This area focuses on ensuring safety, efficacy, and consistency of natural medicinal products through scientific and traditional methods)	Phytochemical fingerprinting Quantification of markers (HPLC, spectrophotometry), Good Agricultural and Collection Practices (GACP), IKS-based quality indicators (e.g., plant morphology, seasonal harvesting)
Toxicology and Safety	Acute/chronic toxicity testing
(This area focuses on identifying risks,	Herb-drug interactions
contraindications, and safe use of traditional and	Allergenicity assessments
natural medicines)	Traditional safety practices (dosage protocols, detoxification methods in IKS)
Formulation Development and Regulatory	Conventional formulations (tablets, capsules, tinctures)
(This area focuses on translating natural compounds	Traditional dosage forms (powders, ointments,
into safe, effective dosage forms while respecting	teas)
legal and cultural frameworks)	Regulatory requirements (Medicines Act 101 of 1965, Indigenous Knowledge Systems Protection Act, 2004)
	Labelling and patient education for traditional remedies

APPLIED FIELDS IN PHARMACY: Pharmaceutics, Pharmaceutical Chemistry

# INDIGENOUS KNOWLEDGE SYSTEMS

In order to provide a foundational knowledge and understanding of the rich heritage of medicinal plant use, holistic health practices, and diversity in cultural healthcare practices the following content is suggested:

## **Curriculum Outline:**

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Indigenous Medicinal Plants (This area focuses on the identification, use, and significance of indigenous plants in South African healthcare traditions)	Selected typical examples of indigenous medicinal plants
Holistic Sensitivity for Diversity in Healthcare Practices (This area focuses on understanding and respecting the variety of cultural healthcare practices within South Africa)	Local knowledge Ethnobotany Respect for nature Collective decision-making (patient, pharmacist, and healthcare team)
Adapting to Modern Contexts (This area focuses on integrating indigenous knowledge and practices into contemporary pharmacy and healthcare settings)	Application and adaptation of traditional practices in modern healthcare

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **COMPLEMENTARY AND ALTERNATIVE MEDICINE**

In order to provide a foundational knowledge and understanding of the diversity in healthcare practices, the following content is suggested:

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Herbal and Botanical Products (This area focuses on the use, efficacy, and safety of herbal and botanical products in healthcare)	Examples of herbal supplements
Dietary Supplements (This area focuses on the role and regulation of dietary supplements in health maintenance and disease prevention)	Vitamins and minerals Dietary supplements
Awareness of Complementary Modalities (This area focuses on familiarising students with a range of complementary and alternative therapies used by patients)	Homeopathic remedies Other relevant complementary therapies

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology

# **TRADITIONAL MEDICINE**

In order to provide a foundational knowledge and understanding of the rich heritage of medicinal plant use, holistic health practices, and diversity in cultural healthcare practices, the following content is suggested:

### **Curriculum Outline:**

SUB-KNOWLEDGE FIELDS

Traditional Practices (This area focuses on the foundational principles and methods of traditional medicine in South Africa)

Collaboration with Traditional Healers (This area focuses on interdisciplinary collaboration and respectful engagement with traditional healers in patient care)

Relevant Laws, Regulations, and Ethical Guidelines (This area focuses on the legal and ethical framework governing traditional medicine in South Africa)

Collaboration with Traditional Healers

Relevant laws, regulations, and ethical guidelines

DETAILED KNOWLEDGE FIELDS

Overview of traditional healing practices

Strategies for effective collaboration

National and provincial laws Regulations Ethical guidelines

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# EXIT-LEVEL OUTCOME 1

# ADVANCED KNOWLEDGE

In terms of the scope of knowledge, knowledge literacy, and the ability to access, manage, and synthesise information related to the core pharmaceutical, clinical, and related sciences, a learner is able to:

**Exit-Level Outcome 1.3:** Demonstrate theoretical knowledge and understanding at the forefront of the core disciplines of pharmacy namely, pharmaceutics, pharmaceutical chemistry, pharmacology, pharmacy practice, and clinical pharmacy, by appropriately integrating and applying such knowledge in the practice of pharmacy in the diverse sectors of pharmacy to contribute effectively to patient well-being and positive healthcare outcomes.

**Exit-Level Outcome 1.4:** Demonstrate the ability to engage with knowledge critically, identify and evaluate information sources, synthesise information, assess knowledge production processes, and apply higher-order thinking skills within the context of the core disciplines of pharmacy.

# CURRICULUM OUTLINE FOR ADVANCED KNOWLEDGE IN THE CORE PHARMACEUTICAL AND CLINICAL SCIENCES

**Advanced knowledge**: theoretical knowledge and understanding as relevant to the integration and application of core pharmaceutical and clinical sciences in the practice of pharmacy in the diverse sectors of pharmacy.

# Associated Assessment Criteria (AAC)

AAC 1.1. Advanced comprehension, critical analysis, and creative thinking abilities are demonstrated in the disciplines of Pharmaceutics, Pharmaceutical Chemistry, Pharmacology, Clinical Pharmacy, and Pharmacy Practice.

AAC 1.2. Psycho-social and neuropsychopharmacology knowledge and principles, including ethical and legal considerations, are critically applied in the development of a comprehensive approach to drug therapy, pharmaceutical care and mental health.

AAC 1.3. Scholarly pharmaceutical literature is continuously reviewed to form new perspectives, compare and contrast various approaches, interrogate new technologies and apply new current good practice (cGXP) rules in decision-making processes in the practice of pharmacy.

# PHARMACOLOGY

# **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

#### Classification of Medicines

(This area focuses on foundational frameworks for organising drug classes and their therapeutic applications)

#### Pharmacokinetics

(This area focuses on the absorption, distribution, metabolism, and excretion of drugs to optimise dosing and minimise toxicity)

#### Also see sections:

#### PHARMACOKINETICS IN DRUG DEVELOPMENT

#### Pharmacodynamics

(This area focuses on drug-receptor interactions and their physiological effects)

# Therapeutic Use and Clinical Applications (*This area focuses on evidence-based drug therapy*

across physiological systems)

#### Also see sections:

PATIENT MEDICATION MANAGEMENT, <u>RESOLUTION OF MEDICINE (DRUG)</u> <u>THERAPY PROBLEMS, MEDICATION</u> <u>REVIEWS</u> <u>PHARMACOVIGILANCE PRINCIPLES AND</u> <u>REPORTING</u> TOXICITY STUDIES MEDICINE DEVELOPMENT: PRECLINICAL, CLINICAL, AND POST-CLINICAL PHASES REGULATORY APPROVAL AND COMPLIANCE LABORATORY TESTING AND GLP AND GCP

#### Medicine Interactions

(This area focuses on predicting and mitigating risks of polypharmacy)

#### DETAILED KNOWLEDGE FIELDS

International Non-proprietary Names (INN) Mechanism of Action (MOA) Structure Activity Relationships (SAR) Indications Routes of administration

ADMET (Absorption, Distribution, Metabolism, Elimination, Toxicity) Onset/duration of drug effects Qualitative/quantitative pharmacokinetics Membrane transporters

Agonists, antagonists, partial agonists Dose-response curves Signalling mechanisms (neurotransmitters, ANS)

Hypersensitivity, tolerance, patient-specific factors

Systems pharmacology (cardiovascular, CNS, antimicrobials, etc.) Therapy optimisation Adverse effects/toxicology (ADRs, antidotes, risk assessment) Medication management (dosage adjustment, monitoring)

Drug-drug, drug-food, drug-disease interactions Interactions with complementary medicines

30

Pharmacogenetics and Precision Medicine (This area focuses on genetic variability in drug response for personalised therapy)

#### Also see sections:

PATIENT MEDICATION MANAGEMENT. RESOLUTION OF MEDICINE (DRUG) THERAPY PROBLEMS. MEDICATION REVIEWS

Ethical and Legal Considerations (This area focuses on compliance with regulations and ethical frameworks in drug research/practice)

#### Also see sections:

<u>RESEARCH IN HEALTH SCIENCES</u> (Legal and Ethical Considerations) <u>GOOD RESEARCH PRACTICE</u> (GRP)

Emerging Research and Neuropharmacology (This area focuses on cutting-edge developments in neurological/psychiatric drug discovery) Genetic principles (DNA/RNA/protein synthesis) Variability in metabolising enzymes/targets Pharmacogenomic applications

Informed consent, confidentiality Animal welfare, responsible drug use South African Health Products Regulatory Authority (SAHPRA)/ICH guidelines

Pathophysiology of disorders (Alzheimer's, depression) Behavioural pharmacology (cognition, mood) Novel drug targets and delivery systems

APPLIED FIELDS IN PHARMACY: Pharmacology.

## **CLINICAL PHARMACY**

#### Curriculum Outline:

SUB-KNOWLEDGE FIELDS

Scope of Practice of a Clinical Pharmacist (This area focuses on the roles, responsibilities, and advanced clinical functions of the pharmacist within multidisciplinary healthcare teams)

Medication Reviews and Management (This area focuses on systematic evaluation of medication regimens to optimise therapy, ensure safety, and prevent adverse outcomes)

#### DETAILED KNOWLEDGE FIELDS

Scope of practice

Relation to pharmacotherapy Patient-centred care Patient pharmaceutical care plan Patient pharmaceutical care plan as informed by the scope of practice

Medication reviews Disease states Adverse medicine reactions/events Medicine interactions Medication Therapy Management (MTM) Medication Utilisation Review (MUR) Cost-effectiveness and feasibility of medication

#### Also see section <u>COST EFFECTIVENESS</u> AND FEASIBILITY OF MEDICATION

(Medication Utilisation Review (MUR))

Medication Management in Medical

Disasters/Emergencies

(This area focuses on the pharmacist's role in ensuring continuity and safety of medication use during health crises and disasters) Guidance on medication use in epidemics/disasters Patient education on adherence, side effects, and dosage Ward stock control (see GPP guidelines)

See GPP guidelines

# Specific Applied Fields in Pharmacy: Clinical Pharmacy, Pharmacy Practice, Pharmacology

Pharmacotherapy in Special Populations (*This area focuses on individualised drug therapy based on specific patient characteristics and needs*)

Pharmacotherapy and Patient Counselling (This area focuses on disease-specific pharmacotherapy, diagnostic support, and effective patient education and counselling)

Anatomical Therapeutic Chemical (ATC)

Classification and Disease Management

(This area focuses on the classification of medicines and their application in the management of various organ systems and disease states)

Pharmacotherapy general principles **Paediatrics** Geriatrics Palliative care Obesity Nutritional imbalance Pregnancy and lactation **Renal** impairment Hepatic impairment Porphyria Immunocompromised (incl. TB and HIV) and oncology patients Sports persons Medicines that may adversely affect the cardiovascular system Genetics

Ophthalmology Ear, Nose and Throat (ENT) Dermatology Diagnostic tests Pharmacoepidemiology (also see PP) Patient counselling and education Indications

Gastrointestinal System Oral health and related disorders Diarrhoea, IBS, IBDs, Constipation, Nausea and Vomiting Peptic ulcers, hyperacidity (GORD) Accessory organs (Liver, Gall bladder, Pancreas) Cardiovascular System

Hypertension Dyslipidaemia Heart Failure Ischaemic heart disease Peripheral Vascular disease Cardiac Arrhythmia Cerebral vascular diseases Coagulation disorders Renal diseases Miscellaneous **Respiratory System:** URTI Asthma COPD (Bronchitis, Emphysema) LRTI (Cystic fibrosis, Pneumonia, TB) Sinusitis, Rhinitis, Pneumonia, Colds and Flu, Cough) Miscellaneous Central Nervous System Epilepsy Mood Disorders Neurodegenerative Substance Abuse Anaesthetics (Local and General) Psychotropic medicines; antidepressants (SSRIs, SNRIs, TCAs, MAOIs, atypical antidepressants), antipsychotics first (typical) and second (atypical) generation, anxiolytics, mood stabilisers, stimulants, sedativehypnotics, cognitive enhancers Nociceptive system: Pain and inflammation: Musculoskeletal conditions (Gout, Arthritis, Osteoporosis, sports injuries) Headache and migraines NSAIDS, Opioids and Adjuncts Immune System and Immunotherapy Anti-Bacterial agents: **Beta-Lactam** inhibitors Protein Synthesis inhibitors Sulphonamides (UTIs) Anti-mycobacterial agents Antimicrobial stewardship General principles of anti-bacterial Miscellaneous Other chemotherapeutic agents: Antiretrovirals

32

# Special Topics: Special Topics in Clinical Pharmacy

(This area focuses on advanced clinical concepts and monitoring in pharmacotherapy)

#### Pharmacovigilance

(*This* area focuses on monitoring, detecting, and preventing adverse effects and ensuring medicine safety post-marketing)

## Medication Reconciliation and Clinical

#### Assessment

(This area focuses on accurate medication history, patient communication, and clinical evaluation to ensure safe and effective therapy)

#### Pharmacist Intervention and Clinical

#### Reasoning

(This area focuses on clinical decision-making, differential diagnosis, and the pharmacist's active role in patient care and interprofessional collaboration)

## Also see section on <u>PHARMACY</u> <u>PRACTICE</u> (Communication)

Anti-virals Vaccines and immunisation Anti-Fungal agents and conditions Anti-Protozoal and conditions Miscellaneous

Therapeutic Drug monitoring (TDM) Therapeutic Drug Monitoring (TDM) Pharmacokinetics Toxicology and pharmacovigilance Poisoning and treatment Endocrine and reproductive system pharmacotherapy Diabetes management **Also see section on PHARMACOKINETICS** Toxicology and Pharmacovigilance **Also see sections on TOXICOLOGY** and

## **PHARMACOVIGILANCE**

Poisoning and treatment (medicines in overdose, non-medicine chemicals, pesticides, medicines of abuse, venomous bites and stings)

Adverse drug reactions/events Medicine safety and effectiveness Pharmacoeconomics

Medication reconciliation Patient history taking Clinical presentation and assessment

## Pharmacist-Initiated-Therapy (PIT) **Also see the section on PIT** Clinical reasoning Differential diagnosis Pharmaceutical care Interpreting laboratory and diagnostic data. Interprofessional collaboration

# Other Specific Applied Fields in Pharmacy: Pharmacy Practice.

Medical Devices and Device Use (This area focuses on the selection, use, and interpretation of medical and diagnostic devices in patient care) Medical devices use Diagnostic devices and result interpretation

# Other Specific Applied Fields in Pharmacy: Pharmacy Practice, Pharmaceutics

#### Clinical Pharmacokinetics

(This area focuses on the application of pharmacokinetic principles to optimise drug dosing and monitoring in clinical practice)

## Pharmacogenetics

(This area focuses on the influence of genetic variation on drug response and the implementation of personalised medicine)

Therapeutic Drug Monitoring (TDM) Monitoring and evaluation Interpretation of results

Genes and medicine response Personalised medicine Common polymorphisms Genetic testing Ethical considerations Advances in pharmacogenetics

**Other Specific Applied Fields in Pharmacy:** Pharmacy Practice, Pharmaceutics, Pharmacology, Pharmaceutical Chemistry.

## Pharmacoepidemiology and

#### Pharmacoeconomics

(This area focuses on the study of medicine use, safety, and effectiveness in populations, and the economic evaluation of therapies) Applications of pharmacoepidemiology Pharmacovigilance Medicine safety and effectiveness Pharmacoeconomics (cost-effectiveness, affordability, utilisation research) Pharmacovigilance (PV)

#### Also see the section on <u>PV</u>

Medicine safety - Monitor the safety of medicines after they are released onto the market.

### See also the section on <u>MEDICINE SAFETY</u> <u>ASSESSMENT PROCESSES</u>

Medicine effectiveness - The effectiveness of medicines in real-world settings, outside of the controlled environment of clinical trials. Pharmacoeconomics - methods to evaluate the cost-effectiveness of medicines, quality use of medicines, medicines utilisation research, affordability to the health system and affordability to patients.

**Other Specific Applied Fields in Pharmacy:** Pharmacy Practice, Pharmaceutics, Pharmacology, Pharmaceutical Chemistry.

Admixtures and Compounding Admixtures, Compounding, and Specialised Dosage Forms (*This area focuses on the preparation, compatibility,* 

(This area focuses on the preparation, compatibility, and delivery of complex and specialised pharmaceutical formulations) Incompatibility and stability (chemical basis) **Also see the sections in:** <u>COMPOUNDING</u> <u>AND MANUFACTURING OF MEDICINES</u> Incompatibility and stability

Parenteral, pulmonary, nasal, oral, otic, optic, topical, rectal, vaginal medicine delivery

Biological medicines, cell and gene therapies Radiopharmaceuticals

**Other Specific Applied Fields in Pharmacy:** Pharmacy Practice, Pharmaceutics, Pharmacology, Pharmaceutical Chemistry.

Specialised dosage forms: Admixtures, Compounding, and Specialised Dosage Forms (This area focuses on the preparation, compatibility, and delivery of complex and specialised pharmaceutical formulations) Parenteral medicine delivery Pulmonary medicine delivery Nasal medicine delivery Oral medicine delivery Otic medicine delivery Optic medicine delivery Topical and transdermal medicine delivery Rectal and vaginal medicine delivery Radiopharmaceuticals Biological medicines, cell and gene therapies (e.g., CAR-T)

### Other Specific Applied Fields in Pharmacy: Pharmacy Practice, Pharmaceutics.

Sterile Pharmaceuticals

(This area focuses on the principles and practice of sterilisation, aseptic techniques, and the preparation of sterile products) Principles and practice of sterilisation and aseptic techniques Sources of contamination and its control/elimination Sterile products (parenteral, ocular medicine delivery) Principles of preservation

## Other Specific Applied Fields in Pharmacy: Pharmacy Practice, Pharmaceutics

Patient Education and Counselling (This area focuses on effective communication of medicine information and support for medication adherence and public health awareness)

## Also see section <u>PATIENT-SPECIFIC</u> <u>EDUCATION AND COUNSELLING</u>

Interpretation of professional product information Use of patient information leaflets Information related to medical conditions Public health awareness Medication adherence support

# **Other Specific Applied Fields in Pharmacy:** Pharmacy Practice, Pharmaceutics, Pharmacology, Pharmaceutical Chemistry.

Evidence-based practice and Quality Improvement (This area focuses on the identification, appraisal, and application of clinical evidence and the implementation of quality improvement initiatives) Identifying evidence, Identifying and assessing evidence Application to patient and population care Standard treatment guidelines Quality improvement processes

# Also see section <u>EVIDENCE-BASED</u> INFORMATION

# Other Specific Applied Fields in Pharmacy: Pharmacy Practice

Specialised Services and Chronic Disease Management

(This area focuses on advanced pharmacy services, collaborative practice, and the management of chronic conditions)

Individualised management plans Self-Management and monitoring, education and support Regular monitoring and follow-up Coordinated care Lifestyle modification support Risk identification and management related to complications and disease progression Access to care and community resources

# Other Specific Applied Fields in Pharmacy: Pharmacy Practice

Research in Clinical Pharmacy

(This area focuses on the design, conduct, and ethical considerations of clinical research in pharmacy practice)

## Medicines Governance

(This area focuses on the policies, procedures, and regulatory aspects of medicine management in healthcare settings)

**Research in Clinical Pharmacy Clinical trials** Research in clinical practice Ethical issues relating to research in the clinical context, including but not limited to: Informed Consent Confidentiality and privacy Conflict of interest Equity and fairness, post-trial access and vulnerable populations Patient safety and well-being Use of placebos **Resource allocation** Regulatory compliance: Adhering to all relevant laws, regulations, and guidelines governing clinical research Interdisciplinary collaboration Research integrity Pharmaceutics and therapeutic committees (PTCs) Restrictions and prior authorisation Medication reviews Education and communication Monitoring and evaluation Adverse Event Reporting (AER) Compliance with regulations Public and private sector differences Formulary access and equity Communication with stakeholders

Updating and revising the formulary

Section 21 items Application and procurement of new products (R&D, Patents, licensing agreements, generic) Audits of clinical research

Ethics and Professional Practice (This area focuses on ethical and legal responsibilities, professional standards, and ongoing professional development in pharmacy) Relevant legislation, e.g. Protection of Personal Information Act (POPI), Promotion of Access to Information Act (PAIA) Professional Practice and Ethics Also see section <u>ETHICAL AND LEGAL</u> <u>ISSUES</u> (confidentiality, Integrity, etc.)

## Other Specific Applied Fields in Pharmacy: Pharmacy Practice

Continuing Professional Development (CPD)

Also see the section: <u>CONTINUING</u> PROFESSIONAL DEVELOPMENT (CPD)

**APPLIED FIELDS IN PHARMACY:** Clinical Pharmacy and limited to the other disciplines as indicated under each knowledge field section.

# PHARMACEUTICS

#### Curriculum Outline:

SUB-KNOWLEDGE FIELDS

Medicine Formulation Design (This area focuses on the quantitative and theoretical principles guiding the integration of drug properties, excipients, and therapeutic needs in the design of safe and effective pharmaceutical products)

# Routes of Administration and Dosage Forms

(This area focuses on understanding the advantages, disadvantages, and applications of various administration routes and dosage forms in therapy)

#### DETAILED KNOWLEDGE FIELDS

Principles in the design of pharmaceutical products, including:

Physicochemical principles States of matter Dissolution, solubility Interfacial phenomena Solid state properties Rheology, colloids, dispersions Micromeritics

The various routes of administration, including the oral, parenteral, rectal, respiratory, sublingual, topical and vaginal routes, their advantages and disadvantages and applications in pharmaceutical therapy.

# Excipients (Inactive Pharmaceutical Ingredients)

(This area focuses on the selection and functional roles of excipients in formulation, manufacturing, stability, and patient acceptability)

### Pharmaceutical Calculations

(This area focuses on the application of mathematical principles to ensure accurate formulation, dosing, and therapeutic effectiveness of medicines)

# Pharmaceutical Pre-formulation and Formulation, Manufacturing

(This area focuses on the process of designing, developing, and manufacturing medicine products to ensure quality, efficacy, and regulatory compliance) Properties of different pharmaceutical dosage forms, including advantages, disadvantages, onset of action and pharmaceutical applications.

Overview of biopharmaceutical considerations, drug factors and therapeutic considerations influencing dosage form design.

The role and the critical attributes of excipients in pharmaceutical design, in line with the various dosage forms, allowing for: Formulation/Delivery Dosage Form Manufacture Stability, including API-IPI and IPI-IPI compatibility Patient acceptability (factors)

Pharmaceutical Calculations include:
Concentration calculations
Dilutions
Alligation
Freezing point depression
Milli-equivalent calculations
Compounding calculations
Dissolution Calculations
Stability calculations
Percentage/Ratio strengths
Bioequivalence
Pharmacokinetics calculations
Dosing calculations/Therapeutic medicine dosing

#### Pre-formulation testing

Dosage form and route selection

- Excipient selection
- Suitability of manufacturing techniques
- Quality control and regulatory parameters
- Evaluation of solid, semi-solid, liquid, and gaseous dosage forms

#### Also see section on <u>MEDICINE FORMULATION</u>, <u>PHARMACOLOGICAL TESTING</u>

Formulation design, selection of various excipients, manufacturing techniques and tests and parameters to assess for quality control and regulatory approval of common dosage forms such as: Solid dosage forms: (oral, rectal, vaginal) Semi-solids: (oral, topical, vaginal, optic) Liquids: (oral, topical, rectal, vaginal, otic, optic) Gases: (inhalations, aerosols) Above must include powders and granules, tablets, capsules, ointments, creams, solutions, suspensions, gels, emulsions, suppositories, pessaries, aerosols, etc.

Manufacturing methods and equipment Quality control

Regulatory parameters and compliance

Formulation changes to registered products that require stability studies

Packaging of Medicines

Selection and characteristics of various packaging containers for different dosage forms.

Tests and methods to evaluate the various dosage forms must be covered.

Storage conditions, including during transport and storage

## Also, see the section on DRUG /MEDICINAL PRODUCT STABILITY

Transportation, Distribution (Cold chain)

Stability testing Shelf-life estimation

## Also see sections on WHOLESALING AND DISTRIBUTION OF MEDICINES; STORAGE AND HANDLING

# Stability of Medicines

(This area focuses on the assessment, prediction, and assurance of medicine stability throughout manufacturing. storage, and distribution)

# Biopharmaceutics

(This area focuses on the relationship between drug formulation, pharmacokinetics, pharmacodynamics, and therapeutic outcomes in patients)

The biopharmaceutics principles may include the following:

Basic principles of pharmacokinetics (incl. patient's drug blood levels)

Application of noncompartmental and compartmental pharmacokinetics to estimate the MRT and MAT Drug absorption, distribution, metabolism, elimination Drug-dose responses, variability

Dosage calculations, therapeutic drug monitoring Compartmental/noncompartmental pharmacokinetics (incorporating the principles of pharmacokinetics and pharmacodynamics, including Drug Absorption, Drug Distribution, Drug Metabolism, Drug

Clearance/Elimination, Drug-dose Responses, Drug Variability, Drug Dosage Calculations and

Therapeutic Drug Monitoring)

Advanced Drug Delivery Systems, including Pharmaceutical Biotechnology (This area focuses on innovative and specialised delivery systems and the application of biotechnology in pharmaceutical development

Industrial Pharmaceutics and GMP

Modified release, nanotechnology, gene therapy Medical devices, personalised medicine Principles of biotechnology, biopharmaceuticals, biosimilars, vaccines

Pharmaceutical manufacturing processes Unit operations (granulation, drying, coating) Good Manufacturing Practice (GMP) Documentation and SOPs Quality Assurance principles Audits and inspection preparation and readiness Process validation Production equipment and cleanroom design

### Also see sections on: <u>GOOD MANUFACTURING</u> <u>PRACTICES (GMP)</u>;

Medicine Registration is covered under Regulatory Approval and Compliance,

Also see section <u>REGULATORY APPROVAL AND</u> <u>COMPLIANCE; COMPOUNDING AND</u> <u>MANUFACTURING OF MEDICINES; QUALITY</u> <u>MANAGEMENT SYSTEMS</u>

APPLIED FIELDS IN PHARMACY: Pharmaceutics

# PHARMACEUTICAL CHEMISTRY

## Curriculum outline:

#### SUB-KNOWLEDGE FIELDS

# Drug/Medicinal Compound Discovery and Design

(This area focuses on the scientific and strategic processes involved in identifying, designing, and optimising new drug candidates for therapeutic use)

Also see sections - <u>Advanced Drug</u> <u>Discovery</u>

#### DETAILED KNOWLEDGE FIELDS

The drug discovery process Target identification and validation Lead identification (e.g., sources of lead compounds; methods of lead identification; rational drug design strategies, etc.) Lead Optimisation and chemical synthesis of new compounds and congeners (e.g., drug-like properties, pharmacophore identification, SAR and QSAR, goals and strategies for lead

#### **Medicinal Chemistry**

(This area focuses on the structural features, functional groups, and pharmacodynamic interactions that determine the activity and safety of major medicine classes) optimisation bioisosterism, reaction mechanisms (homolytic, heterolytic and pericyclic, e.g. general: addition, substitution, elimination, free radical reactions, oxidation and reduction, rearrangement.

Isomers and stereoisomers

Selected examples of synthetic methods) Pre-clinical studies (use of *in vitro* and *in vivo* models to assess efficacy, safety, toxicity, bioavailability, ADME, etc., including link to ethical considerations in the use of animal models)

Also see the section on <u>LABORATORY</u> TESTING AND GLP AND GCP

Clinical Studies (introduction to clinical trials as part of the drug design process). **Also see sections on** <u>TOXICITY STUDIES</u>

Computer-aided drug design and modelling tools for drug discovery.

Major Medicine classes: structural features and reactions, functional groups, and pharmacodynamic interactions that determine their pharmacological activity - **See sections in** <u>PHARMACOLOGY</u> and <u>CLINICAL</u> <u>PHARMACY</u>, medicines identified per system, Inorganic medicines Natural products - **Also see** <u>INDIGENOUS</u> <u>KNOWLEDGE SYSTEMS</u>

## Other Applied Fields in Pharmacy: Pharmacology

#### Pharmaceutical Analysis

(This area focuses on the principles and application of analytical techniques for quality control, validation, and regulatory compliance of pharmaceutical products) Relevant compendial resources (pharmacopoeias e.g. B.P., E.P., U.S.P. Compendial resources (BP, EP, USP) Stability testing, documentation Analytical techniques (titrations, chromatography, spectroscopy, elemental analysis, crystallography, polarimetry) Quality Control (QC) and Quality Assurance (QA) documentation See also sections in: QUALITY MANAGEMENT SYSTEMS

## Analytical Techniques

Principles, application and data interpretation for applicable current analytical techniques and assays and QC procedures e.g. volumetric titrations, Karl Fisher analysis, Chromatographic techniques (HPLC, UPLC, GC, HPLC-MS, Spectroscopy (UV-VIS, IR, MASS, NMR), Elemental Analysis (AA), Crystallography (XRD), Polarimetry For selected examples, **see also sections on** <u>HIGH-PERFORMANCE LIQUID</u> <u>CHROMATOGRAPHY (HPLC); DNA SEQUENCING</u> <u>AND GENOTYPING; MASS SPECTROSCOPY</u>

# Other Applied Fields in Pharmacy: Pharmaceutics

Stability of Medicines and Common Degradation Reactions

Also see sections in <u>MEDICINE</u> <u>PRODUCT STABILITY</u>

Stability of Medicines and Chemical Instability Reactions (This area focuses on the identification, causes, and

mitigation of chemical degradation in medicines to ensure product safety and efficacy) Chemical instability reactions (incl. but not limited to)

Hydrolysis Oxidation Thermal degradation Photolysis

Factors that influence chemical instability reactions in medicines (incl., but not limited to)

Environmental conditions - Hydrolysis, oxidation, thermal degradation, photolysis Environmental, solvent, pH, contamination factors

Considerations to ensure stability of medicines (incl., but not limited to)

Storage, stabilising excipients, compounding, admixtures

# Other Applied Fields in Pharmacy: Pharmaceutics

Pharmaceutical Analysis

Calculations applicable The effect of physicochemical properties and molecular structure on pharmacodynamic properties of medicines (incl., but not limited to) Protein-ligand interaction profile of functional groups (incl., but not limited to, hydrogen bonding,  $\pi$ – $\pi$  interactions, pelority/lipaphilisity balance, electropic

polarity/lipophilicity balance, electronic effects, etc.)

pKa and degree of ionisation

Molecular size, stereochemical configuration and conformational flexibility The effect of functional groups on the physicochemical properties of molecules; solubility, predicting water solubility, acid-base properties

The effect of physicochemical properties and molecular structure on the pharmacokinetic properties of medicines Absorption

Molecular weight, size, stereochemical configuration (**see section** in <u>CHEMISTRY</u>) and conformational

p*K*a and degree of ionisation Medicine absorption (GI physiology, passive diffusion, active transport, influx and efflux transporters),

Membrane medicine transporters, transport mechanisms and classification of transporters, transporters relevant to medicine disposition, substrates of transporters, mechanisms for transport interactions and relevance, structural determinants for transporter-substrate interactions

See also PHARMACOLOGY

flexibility

Lipophilicity Protein binding

Medicine metabolism: pathways, Phase 1 and Phase 2 reactions, factors affecting metabolism, genetic polymorphism, physiologic factors, pharmacodynamic factors, environmental factors, major pathways of metabolism and relevant examples Human hepatic cytochrome P450 enzyme system (components and classification and CYP450 isoforms), metabolic oxidation reactions, substrate specificity, catalytic reactions, induction and inhibition of CYP450 isoforms, metabolic reduction reactions, medicine conjugation pathways, enterohepatic cycling, pre-systemic first pass metabolism, extrahepatic metabolism (intestinal, lung, nasal, brain, other tissues)

Distribution

Metabolism

Metabolic bioactivation and role in<br/>hepatotoxicity, idiosyncratic reactions, chemical<br/>carcinogenesis<br/>Stereochemistry and medicine metabolism<br/>Prodrugs<br/>The effect of functional groups on the ADME<br/>properties of medicinesThe effect of physicochemical properties<br/>and molecular structure on the safety andMetabolic bioactivation and role in

carcinogenesis

#### Other Applied Fields in Pharmacy: Pharmacology; Pharmaceutics.

Biotechnology and Biopharmaceuticals (This area focuses on the principles and applications of biotechnology in the development, analysis, and therapeutic use of biopharmaceuticals and advanced therapies

toxicity profile of medicines

Principles of biotechnology-derived medicines, e.g. MABs Principles of pharmacogenetics, genomics, transcriptomics,

hepatotoxicity, idiosyncratic reactions, chemical

Also see the section on:

PHARMACOGENETICS IN MEDICINE DEVELOPMENT

Advanced gene editing technologies, e.g. **Clustered Regularly Interspaced Short** Palindromic Repeats (CRISPR) technology Proteomics **Metabolomics DNA** sequencing Polymerase chain reaction Protein synthesis through recombinant DNA Stability of biotechnology-produced pharmaceuticals Pharmacokinetic considerations of biotechnology-produced proteins Monoclonal antibodies, antibody structure and hybridoma technology Monoclonal antibody-based diagnostic kits Antibody-medicine conjugates - design and linker technology and stability Vaccines – types Pharmacogenomics and personalised medicine Gene therapy

# See section in <u>BIOCHEMISTRY</u> and <u>PHARMACOLOGY</u>

G-protein coupled receptors Nuclear receptors Ion channel receptors

Receptor Targets – classes and general structure, properties and function.

Pharmacodynamics and pharmacodynamic agents, Receptor Targets and Pharmacodynamics (This area focuses on the structure, properties, and functions of drug receptor targets and their relevance to pharmacodynamics and clinical Enzyme / catalytic receptors

**See section** in <u>PHARMACOLOGY</u> and <u>CLINICAL PHARMACY</u>. As appropriate per class/medicine; clinical relevance, selected syntheses, ADME, pharmacodynamics, MoA, SAR, stability- G-protein coupled receptors, nuclear receptors, ion channels, enzyme receptors

- Pharmacodynamics, MoA, SAR, stability

APPLIED FIELDS IN PHARMACY: Pharmaceutical Chemistry

# PHARMACY PRACTICE

## **Curriculum Outline:**

efficacy)

#### SUB-KNOWLEDGE FIELDS

#### Pharmacy as a Profession

(This area focuses on the evolution, ethics, and professional identity of pharmacy, emphasising the pharmacist's role in society and healthcare)

#### DETAILED KNOWLEDGE FIELDS

Understanding <u>professionalism</u> Attributes of a profession Principles of ethics in professional life History and evolution of pharmacy Overview of pharmacy, including the various sectors

Professionalism attributes

Also see Pharmacy Practice – Pharmacy as a profession & Ethical and Legal considerations <u>CLINICAL PHARMACY – ETHICAL ISSUES</u> <u>ETHICAL & LEGAL ISSUES</u> <u>LEADERSHIP STRATEGIES</u> <u>INTERPROFESSIONAL COLLABORATION</u> <u>HEALTHCARE PRINCIPLES AND PATIENT</u> <u>EDUCATION TECHNIQUES</u>

#### Role of the Pharmacist in Healthcare

(This area focuses on the pharmacist's responsibilities, scope, and evolving roles within the healthcare system)

Characteristics of a pharmacist - "Nine-star pharmacist" Scope of practice of a pharmacist and other

pharmacy support personnel New and evolving roles in the profession Regulatory and professional bodies in pharmacy

# Introduction to Pharmacy Law and Regulations

(This area focuses on the legal framework, regulatory standards, and professional responsibilities guiding pharmacy practice) Scope of practice of a pharmacist and other pharmacy personnel

Also see sections on:

Pharmacist-Initiated Therapy (PIT) Principles of the CPD process <u>CONTINUING</u> <u>PROFESSIONAL DEVELOPMENT (CPD</u>)

# Other Applied Fields in Pharmacy: Clinical Pharmacy

## Healthcare Systems

(This area focuses on the structure and challenges of global and South African healthcare systems and their implications for pharmacy practice)

Socio-Behavioural Aspects of Health and Illness

(This area focuses on the social, cultural, and behavioural determinants of health and their impact on pharmacy practice) Global healthcare system Global health issues and the challenges they pose to Health Care Systems South African Health Care System Evolution of the healthcare system, Health issues and challenges, Models of healthcare systems including Universal Health Coverage (UHC)

Paying for healthcare

Access to healthcare

Organisation of health care services: primary, secondary and tertiary healthcare services Public vs private healthcare: Implications of healthcare systems for pharmacy practice Models of pharmacy practice within healthcare systems

Emerging trends and future directions of healthcare

Health and illness – definitions and dimensions Determinants and models of health, Process of illness, Health knowledge, beliefs, and attitudes Decision analysis and the process of behavioural change

The treatment process.

Prescribing for minor ailments Complementary and alternative medicines

Also see section on: <u>TRADITIONAL</u> <u>MEDICINES</u>

# Other Applied Fields in Pharmacy: Pharmacology – the treatment process; Clinical Pharmacy.

Understanding Medicines and Their Use (This area focuses on the principles of rational, safe, and evidence-based medicine use in patient-centred care) Functions of Medicines Rational Medicine Use Principles of appropriate, effective, and safe use of medicines.

# Patient Assessment and Clinical Reasoning

(This area focuses on the systematic approach to patient evaluation, diagnosis, and shared decisionmaking in pharmacy practice)

### Prescribing and Dispensing Process

(This area focuses on best practices, legal requirements, and patient safety in prescribing and dispensing medicines)

#### Also see the section on DISPENSING OF

MEDICINES AND PHASES AND THE DISPENSING PROCEDURE

#### Evidence-Based Medicine

Utilising research and clinical evidence in making medication-related decisions. Medication Management Cycle Fundamentals of person-centred care in the context of pharmaceutical care – principles Pharmacist patient care process Building therapeutic relationships **Also see the section on** *DRUG / Medicine INFORMATION* DATABASES

Approaches to differential diagnosis Obtaining a patient history Assessment of symptoms. Physical assessment

#### Also see sections on:

POINT-OF CARE TESTING - definition and different tests

Shared decision making

Understanding the considerations and steps in prescribing medications. Components and significance of a well-structured prescription.

Process and best practices in dispensing medications.

History taking and patient assessment Good Dispensing Practice as per cGPP Counselling for adherence Different phases as per cGPP

Phase 1: Interpretation and evaluation of prescription (incl. dosage forms selection) Phase 2: Preparation and labelling of the prescribed medicine (including extemporaneous compounding) Phase 3: Provision of information and instructions to the patient

Phase 4: Monitoring patient outcomes Automated dispensing units, **see the section on** *AUTOMATED MEDICATION DISPENSING UNITS (AMDU)* 

**Other Applied Fields in Pharmacy:** Pharmaceutical Chemistry; Pharmacology; Pharmacy Practice; Clinical Pharmacy.

## Individualised Care Planning and Person-Centred Medication Management

(This area focuses on person-centred medication management, adherence, and optimisation of therapy)

Pharmacogenomics and

Pharmacoeconomics

(This area focuses on the application of genetic and economic principles in optimising medication use and healthcare resource allocation)

Ethical and societal considerations

# Monitoring the Patient and Medication Review

(This area focuses on ongoing patient monitoring, medication review, and management of polypharmacy and medication safety) Also see section on: PHARMACIST-INITIATED THERAPY (PIT)

Basic economic concepts Types of pharmacoeconomic evaluations Cost minimisation analysis Cost-benefit analysis, Cost-effectiveness analysis Cost utility analysis Modelling in Pharmacoeconomics

Adherence and concordance

Substance use and non-medicinal use Pharmacoepidemiology

# Also see sections in:

#### PHARMACOVIGILANCE PRINCIPLES AND REPORTING ADR

Preventing Medication Errors Medication review Medication Therapy management (MTM) - *PATIENT MEDICATION* 

MANAGEMENT, RESOLUTION OF MEDICINE (DRUG) THERAPY PROBLEMS, MEDICATION REVIEWS

Medicine use review <u>-:</u> COST-EFFECTIVENESS AND FEASIBILITY OF MEDICATION Managing polypharmacy Deprescribing -HEALTHCARE EDUCATION PROGRAMMES

# **Other Applied Fields in Pharmacy:** Pharmaceutical Chemistry; Pharmacology; Pharmacy Practice; Clinical Pharmacy.

Communication and Patient Education (This area focuses on effective, empathetic, and culturally competent communication for improved patient outcomes) Patient education Conditions, treatment, overall health management Communication in relation to medicine use General and effective communication Communication skills Understanding the basics of verbal, non-verbal, and written communication Person-centred communication Techniques for effective medication counselling, including language simplification for understanding. Empathetic communication Cultural Competence and Sensitivity Communicating effectively with diverse patient populations. Health Literacy, including Pictograms and Health Information Assessing and addressing patients' health literacy levels. Motivational interviewing Interprofessional Communication Collaborative Communication with Healthcare Teams Professional Networking and Collaboration Influencing prescriber behaviour Communication in special populations Age-sensitive communication Communication with special needs Ethical considerations in communication Confidentiality Crisis and sensitive communication Digital and telecommunication Social media and online communication Communication skills (counselling on adherence and concordance, and influencing patient behaviour) Also see sections on: PHARMACIST-INITIATED THERAPY (PIT) Presentation skills Leaflets Document and record keeping

# **Other Applied Fields in Pharmacy:** Pharmaceutical Chemistry; Pharmacology; Pharmacy Practice; Clinical Pharmacy.

Quality Management and Business Management

(This area focuses on quality assurance, business operations, and leadership in pharmacy practice)

Pharmacy Business Management

### Good Pharmacy Practice (GPP) Manual and Associated SAPC Rules Quality Improvement Plan Role of the Responsible Pharmacist (RP)

#### Also see sections on: BUSINESS ACUMEN

Management functions Operations management Planning Optimising workflow Ensuring quality Risk management Managing people Organisational structure and behaviour

Human resources management functions and process Basic employment law Health and safety in the workplace Leadership **Financial management Financial reports** Budgeting Marketing Customer service Purchasing and inventory management (also see the section on **INVENTORY** MANAGEMENT) Supply chain management, see also SUPPLY CHAIN EFFICIENCY; REGULATORY COMPLIANCE AND GSP AND GDP; PRODUCT AUTHENTICATION AND SERIALISATION. DISTRIBUTION OF SPECIALITY MEDICATIONS Merchandising Managing value-added services Entrepreneurship and innovation

## Other Applied Fields in Pharmacy: Clinical Pharmacy

Clinical Services and Value-based Services	Point of care screening and monitoring
(This area focuses on the provision and	Immunisation and injections
management of clinical pharmacy services and	Baby-care services
value-based care models)	Reproductive health services, including
	emergency hormonal contraception
	PIMART
	Communicable and non-communicable
	conditions
	Chronic disease management services, e.g.
	diabetes, asthma, hypertension management
	Travel health services
	Pain management services, Incontinence care
	Stoma care
	Weight loss management
	Smoking cessation
	Wound care
	Screening

## Other Applied Fields in Pharmacy: Clinical Pharmacy

Optimising Medication Use and Health Promotion (This area focuses on the pharmacist's role in Medicine information and formularies Pharmaceutical and Therapeutics Committees optimising medication use, health promotion, and public health advocacy)

Health promotion strategies and programs Lifestyle and behavioural change Public health and advocacy Medicine information Formularies Pharmaceutical and Therapeutics Committee (PTC) **Also see the section on:** Cost-effectiveness and Feasibility of Medication – Pharmacoeconomics - <u>COST-EFFECTIVENESS</u> <u>AND FEASIBILITY OF MEDICATION</u> **Also see section on:** PHARMACOVIGILANCE

# Other Applied Fields in Pharmacy: Clinical Pharmacy; Pharmacology

Monitoring and Medication Review (This area focuses on ongoing patient monitoring, medication review, and management of polypharmacy and medication safety) Pharmacotherapy, Substance use and nonmedicinal use Pharmacoepidemiology Medication errors and reviews Medication Therapy Management (MTM) Deprescribing The process of medication review (including approaching) Medication safety

# Other Applied Fields in Pharmacy: Clinical Pharmacy; Pharmacology.

Optimising Medication Use and Health Promotion

(This area focuses on the pharmacist's role in optimising medication use, health promotion, and public health advocacy)

Fundamentals of Health Promotion Concepts and Principles Determinants of Health Models of health promotion delivery Role of Pharmacists in Health Promotion Pharmacists as Health Educators Community Engagement Health Promotion Strategies and Interventions Lifestyle and Behavioural Change Promoting healthy lifestyle choices, including nutrition, physical activity, and smoking cessation. **Chronic Disease Prevention and Management** Patient-centred Education and counselling Health Promotion Programs and Campaigns **Designing and Implementing Programs Evaluating Health Promotion Activities** Public Health Advocacy Policy and

Advocacy

Collaboration with Public Health Agencies

Working with local, national, and global health organisations.

Targeted Health Promotion Special Populations such as children, the elderly, or those with specific health conditions.

# Also see section: DISTRIBUTION OF SPECIALITY MEDICATIONS

Cultural Competence Innovative Approaches in Health Promotion Digital Health and Social Media Emerging Trends and Technologies – **Also see section:** <u>MODERN</u> <u>TECHNOLOGIES IN PHARMACY</u> Research in Health Promotion Participation in Health Promotion Research Ethical Considerations in Health Promotion

# Other Applied Fields in Pharmacy: Clinical Pharmacy; Pharmacology.

**Quality Assurance and Improvement** 

Integral part of pharmaceutical practice Models of quality improvement

# Other Applied Fields in Pharmacy: Clinical Pharmacy; Pharmaceutics.

Primary Healthcare and Research (This area focuses on the pharmacist's contribution to primary healthcare and research in pharmacy practice) Introduction to primary healthcare **Also see sections on:** <u>PRIMARY</u> <u>HEALTHCARE (PHC)</u> - Introduction to primary healthcare Pharmacy Practice Research

## Other Applied Fields in Pharmacy: Clinical Pharmacy.

Pharmacy Practice Research	Also see sections on: <u>RESEARCH IN HEALTH</u> <u>SCIENCES</u>
Ethical and Legal Considerations	Professionalism Code of conduct Morals, ethics and law Pharmacy-related legislation Registration with SAPC The Responsible Pharmacist (RP)
Continuing Professional Development (CPD)	Ethical and legal requirements CPD cycle

Also see section on: CONTINUING PROFESSIONAL DEVELOPMENT (CPD)



APPLIED FIELDS IN PHARMACY: Pharmacy Practice and limited to the other disciplines as indicated under each knowledge field sections

# APPLICATION OF KNOWLEDGE AND SKILLS

Exit-Level Outcomes 2 to 9 require the graduate to demonstrate an ability to apply integrated knowledge of the foundational, core pharmaceutical and clinical sciences to address complex and unfamiliar problems encountered in the practice of pharmacy.

# EXIT-LEVEL OUTCOME 2

*In respect of pharmaceutical methods and procedures, and the accessing, processing, and managing of information in the practice of pharmacy, the learner is able to:* 

2.1. Select and accurately apply appropriate knowledge and standard procedures to ensure the safe and rational use of medicines and medical devices within the scope of practice of a pharmacist.

2.2. Demonstrate advanced clinical practice knowledge and skills by providing appropriate counselling and patient-specific education as appropriate to the practice sector.

2.3. Demonstrate the application of advanced clinical practice knowledge and skills by undertaking Pharmacist-initiated therapy (PIT) and making interventions to improve medication adherence and optimise therapeutic outcomes.

2.4. Proficiently assess therapeutic outcomes, including applicable therapeutic medicine monitoring, and adeptly apply pharmacovigilance principles in the delivery of pharmaceutical care and pharmaceutical services.

2.5. Select and apply appropriate current and relevant technologies, standards, procedures, screening and diagnostic and pharmaceutical tools, and evidence-based knowledge in the evolving practice of pharmacy.

2.6. Integrate and apply cutting edge pharmaceutical knowledge of the core disciplines of pharmacy in all areas relating to the practice of pharmacy according to current good practice (cGXP) including, but not limited to, the discovery, development and supply of medicines and medical devices (including production, registration, wholesaling and distribution, supply chain management, formulary development, compounding, dispensing, disposal and destruction of pharmaceutical and medical waste).

# PATIENT MEDICATION MANAGEMENT, RESOLUTION OF MEDICINE (DRUG) THERAPY PROBLEMS, MEDICATION REVIEWS

# Associated Assessment Criteria (AAC):

AAC 2.1 Advanced integrated knowledge is applied, and appropriate standard procedures are followed, in the **management of patient medication**, the resolution of medicine-

*therapy related problems*, and in the conducting **of medication reviews** to ensure safe, rational and cost-effective use of medicines.

AAC 4.7 The principles and rules relating to Good Pharmacy Practice (GPP) are evaluated to determine the impact on patient safety, **medication management**, and the overall quality of patient care, and are appropriately implemented within the practice of pharmacy.

### Curriculum Outline:

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS	
Implementation of the SAPC Good Pharmacy Practice (GPP) rules and guidelines (This area focuses on applying GPP standards to ensure patient safety and quality care)	Interventions to ensure the safe, rational and cost-effective use of medicines Evidence appropriate to support and justify such interventions	
Pharmacotherapy Knowledge (This area focuses on integrating pharmacological and patient-specific factors for optimal therapeutic outcomes) Also see sections in: PHARMACOLOGY, CLINICAL PHARMACY)	Biological targets Pharmacodynamics; Efficacy, Potency, Therapeutic index, Mechanism of action, Structure activity relationships (SAR) Absorption, Distribution, Metabolism and Excretion (ADME), Patient-related parameters; pharmacogenomics, age, gender, comorbidities, lifestyle factors, medicine interactions, adverse effects	
<b>Specific Applied Fields in Pharmacy</b> : Pharmacology, Pharmaceutical Chemistry,		
Pharmacy Practice		
Therapy optimisation and medication review (This area focuses on structured medication review, therapy optimisation, and monitoring for safety and effectiveness)	Medication review techniques (structure of review, e.g. anamnesis, indications for current medication, adherence, self-medication. OTC and herbal or traditional products, follow-up and feedback, medicines that require monitoring for effectiveness of outcome, side-effects and significance, regimen and duration of therapy,	

# Safe and Rational and Cost-Effective Use of Medicine

(This area focuses on evaluating medication appropriateness and optimising dosing, especially in special populations) significance, regimen and duration of therapy access to clinical and laboratory records) Medication appropriateness Dose optimisation Avoiding therapeutic duplication Monitoring parameters (clinical, laboratory, outcomes, adherence) **Also see sections on:** 

### Medication-Related Problem Identification and Management (This area focuses on systematic identification, documentation, and resolution of medication-related problems)

**Therapeutic Duplication** 

## **Monitoring Parameters**

# **Documentation and Records**

Identification of Medication-related Problems

# COST-EFFECTIVENESS AND FEASIBILITY OF MEDICATION PHARMACOVIGILANCE PHARMACY PRACTICE

Patient assessment Classification of medication-related problems ADRs, interactions, non-adherence, unnecessary therapy, dosage/formulation issues, cost barriers ADME (Absorption, Distribution, Metabolism, Excretion) Special Populations

Mechanism of Action (MoA) Guidelines to prevent therapeutic duplication within organisations to ensure patient safety Medicine classes (therapeutic)

#### Examples include:

Clinical parameters: vital signs, blood glucose, pain scores, weight/BMI, symptom improvement

Laboratory values: renal function, liver function, CBC, electrolytes, medicine levels in plasma Therapeutic outcomes: BP control, HbA1c levels, INR, lipid profile, asthma control Adverse effects: GI symptoms, rash, allergic reactions, signs of toxicity – jaundice, etc., cognitive or mood changes

Medication adherence: patient self-report, pill counts, refill of repeat history, use of adherence tools

Drug interactions and polypharmacy, drug-drug interactions, drug-food interactions, duplicate or unnecessary therapy

Other special considerations: pregnancy, paediatric, geriatric groups, renal or hepatic dose adjustments, cultural

## As per GPP

Patient assessment Classification: improper medicine selection, untreated condition, dosage subtherapeutic or too high, ADR, medicine interaction, nonCollaborative Care and Documentation (This area focuses on interprofessional collaboration, communication, and documentation for optimal patient care) adherence, unnecessary therapy, medicine dosage form, route, regimen, cost-related barriers to adherence. (see Pharmacology and Clinical Pharmacy) Adverse Drug Reactions (ADR) Medicine interactions and medicine interaction mechanism Medication Therapy Management tools and Medication reconciliation ADME, SAR, medicine stereochemistry (e.g. enantiomers), stability, bioavailability, formulation and dosage form Medication administration monitoring Outcomes monitoring and monitoring parameters Clinical decision-making Patient education and counselling Pharmaceutical care plan development Stability and storage Toxicity - Also see section on: TOXICITY STUDIES

Interprofessional collaboration and communication Identifying and managing or triaging healthrelated problems – **GPP guidelines** & e.g. **FIP** Communication with prescribers

**APPLIED FIELDS IN PHARMACY**: Clinical Pharmacy; Pharmacy Practice, Pharmacology; Pharmaceutics, Pharmaceutical Chemistry

# PHARMACOVIGILANCE PRINCIPLES AND REPORTING ADR

# Associated Assessment Criteria (AAC)

AAC 2.2 Pharmacovigilance principles and practices, including the reporting of adverse drug reactions (ADR) and promotion of patient safety, are competently applied to ensure the safe and rational use of medicines.

AAC 2.17 Pharmaceutical, pharmacological, and clinical pharmacy strategies are developed and applied to enhance and integrate pharmacovigilance activities in the practice of pharmacy.

# Curriculum Outline:

#### SUB-KNOWLEDGE FIELDS

#### Implementation of GPP and SAHPRA Pharmacovigilance Standards

(This area focuses on regulatory compliance and the promotion of medicine safety through effective pharmacovigilance)

#### Medicine Safety Assessment and Management

(This area focuses on processes for monitoring, assessing, and managing medicine safety and adverse events)

Signal Management and Risk Assessment (This area focuses on detecting, evaluating, and managing safety signals and risks associated with medicines)

# Continuous Monitoring and Quality Assurance

(This area focuses on ongoing safety monitoring and the integration of pharmacovigilance into quality management systems)

#### SAHPRA Pharmacovigilance standards and guidelines

Medicine Safety Assessment Processes

Patient Medication Management

Data collection Reporting systems Documentation Regulatory compliance

Signal Management

Communication and information dissemination

#### DETAILED KNOWLEDGE FIELDS

SAPC GPP rules SAHPRA pharmacovigilance standards and guidelines

Medicine safety assessment Data collection and reporting systems Regulatory compliance (SAER, AEFI)

Signal detection and management Risk assessment and management **Also see sections in** PHARMACOLOGY **Also see the section on** DNA SEQUENCING AND GENOTYPING Communication and information dissemination

Continuous data collection and interpretation Medication reconciliation Quality assurance and post-marketing surveillance

#### See sections in <u>PHARMACY PRACTICE</u>

Medicine (drug) Therapy Problem – resolution Medicine review

Serious Adverse Event Reporting (SAER), Adverse Events After Immunisation (AEFI) reporting Regulatory Reporting Requirements

Signal detection: Identifying signals or potential safety concerns through the analysis of aggregated safety data

Interprofessional collaboration

Monitoring	Continuous collection, analysis, and interpretation of data related to the safety of medicines Also see: PATIENT MEDICATION MANAGEMENT, RESOLUTION OF MEDICINE (DRUG), THERAPY PROBLEMS, MEDICATION REVIEWS
Medication reconciliation	Also see the section in CLINICAL PHARMACY
Continuing Professional Development (CPD)	Also see <u>CONTINUING PROFESSIONAL</u> <u>DEVELOPMENT (CPD)</u>
Quality Assurance (QA)	Ensure that pharmacovigilance activities are conducted accurately and in compliance with regulatory requirements

Post-Marketing Surveillance

See section on: PHARMACOVIGILANCE

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology

# **MEDICAL DEVICES**

# Associated Assessment Criteria (AAC)

AAC 2.3 Specialised pharmaceutical, pharmacological and pharmaceutical care principles and procedures are applied in the selection and use of medical devices in the practice of pharmacy.

AAC 2.4 Specialised pharmaceutical and pharmacological principles and procedures are applied in the interpretation of point of care test results and in the appropriate counselling of the patient.

## Curriculum Outline:

#### SUB-KNOWLEDGE FIELDS

Medical Device Classification and Regulation (This area focuses on understanding regulatory categories and compliance for medical devices in pharmacy)

#### DETAILED KNOWLEDGE FIELDS

SAHPRA device classes (low to high risk) Combination Products (medical device) Current Good Pharmacy Practice Rules & Guidelines

Classes of medical devices (SAHPRA) – main classes:

Medicine Delivery and Diagnostic Devices (This area focuses on the selection, use, and interpretation of medicine delivery and diagnostic devices in pharmacy practice)

Diagnostic Devices: Point-of-Care (POC) Testing Devices

Low-risk medical devices, including in vitro diagnostics (require the least regulatory oversight, e.g. thermometers, surgical gloves), low-moderate risk (require compliance with specific regulatory controls and may need premarket clearance, e.g. hypodermic needles), moderate -high risk (e.g. infusion pumps, orthopaedic implants) and high risk (require the most rigorous regulatory controls, including pre-market approval (PMA) to ensure safety and effectiveness, e.g. HIV diagnostic tests, pacemakers) Special classes related to pharmacy: e.g. pill counters, surgical gloves, digital thermometers, blood glucose meters, nebulisers, pregnancy test kits, blood pressure monitors, syringes, insulin pens, infusion pumps for home care,

inhalers, HIV rapid tests, POC test kits Combination products - Devices that combine a medicine and a device: pre-filled syringes (heparin, insulin, certain vaccines, transdermal patches, drug-eluting stents, hormonal implants, IUDs

Inhalation devices Insulin pens and pumps Transdermal Patches Auto-Injectors Infusion Pumps Oral Medicine Delivery Devices Ocular Medicine Delivery Systems Implantable Medicine Delivery Devices Smart Medicine Delivery Systems (microelectronics and biosensors to optimise medicine release) Intranasal Medicine Delivery Devices

Enzyme-Linked Immunosorbent Assay (ELISA) kits for laboratory diagnostics Portable cholesterol meters Urine analysis dipsticks Glucose
Cholesterol screening (Cardio check device professional use only) Blood pressure (devices) HB Screening (devices) Blood type test (professional use only) Temperature (Saturations and Basic) **BMI** tests Baby weight & height **Baby** immunisations 24 hr blood pressure (information only) Pregnancy (rapid finger & home urine test) **Ketones** HIV (devices – home test & professional) Drug screening (devices - customer & professional) Alcohol **POCT** Services and Minimum Standards Testing to be performed on-site, training of personnel Conducting the test Clinical reasoning Decision-making Proper quality control procedures Specificity **Diagnostic Principles and Test** Sensitivity Interpretation **Reference ranges** Potential sources of error Screening and early detection, patient monitoring Monitor certain health parameters of patients Wearable Devices See cGPP (This area focuses on the use of wearable health Smartwatches with Health Monitoring Features technology and mobility aids to support patient care Continuous Glucose Monitors (CGMs) connected to a phone/laptop

MEDICAL DEVICES

Wearable Blood Pressure Monitors Wearable ECG Monitors Smart Patches and Bio-Sensors

Wearable Respiratory Monitors

**Pharmacy Practice** 

Wearable Pain Management Devices

Sleep

Activity Trackers for Monitoring Movement and

Smart Glasses for Augmented Reality (AR) in

Used for training pharmacists and in complex medication dispensing tasks.

	real-time information and medication instructions
Colorimetric Techniques (not devices, but techniques fundamental to various diagnostic devices):	Colorimetric analysers ELISA Microplate Readers Blood Glucose Monitors Urine Test Strips and analysers Haemoglobin meters
Mobility Aids	Canes and Walking Sticks Walkers and Rollators Crutches Wheelchairs and Transport Chairs Scooters Orthopaedic Aids and Braces
Pharmacist's Responsibilities in Devices (This area focuses on patient education, assessment, and collaboration regarding medical devices)	Patient education and training Assessment and recommendations Fitting and adjustment Counselling - preventative guidance Collaboration and communication with other health professionals Appropriate documentation Ethical and legal issues Regulatory compliance

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology

# PATIENT-SPECIFIC EDUCATION AND COUNSELLING

#### Associated Assessment Criteria (AAC):

AAC 2.5 Clinical and pharmaceutical knowledge, skills and appropriate educational approaches are integrated in the provision of patient-specific education and counselling to ensure optimal therapeutic outcomes.

#### Curriculum Outline:

#### SUB-KNOWLEDGE FIELDS

Current Good Pharmacy Practice Rules & Guidelines (GPP)

#### DETAILED KNOWLEDGE FIELDS

Potential for assisting pharmacists with

Good Pharmacy Practice (GPP) Psychodynamics of patient care

GPP Rules and Psychodynamics of Patient Care (This area focuses on integrating clinical and pharmaceutical knowledge with patient-centred education and counselling)	
Psychodynamics of Patient Care	See sections in <u>PHARMACY PRACTICE</u>
Medicine Therapy Management (MTM) and New Medicine Services (NMS) (This area focuses on comprehensive medication assessment and the use of new methodologies to optimise pharmaceutical care)	Behavioural changes (refer to discipline) <b>Also see the section</b> on <u>MEDICATION</u> <u>THERAPY MANAGEMENT</u> e.g. a full assessment on a patient with all their meds and write a comprehensive report (the methodology required to do this- MTM assessment and reporting New Medicine Services Methodologies for reducing inappropriate prescribing (e.g., STRIP)
Specific Current/New Methodologies	To enhance patient pharmaceutical care, e.g. STRIP systemic tool to reduce inappropriate prescribing
Educational Approaches and Patient Counselling (This area focuses on using educational strategies and technology to enhance patient understanding, adherence, and safety.)	Use of technology Clarifying doubts and concerns Medication information Disease/Condition management Medication adherence Patient safety

Patient/Person-centred Approach

Cultural competence Health literacy Continuous Professional Development (CPD)

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice

# PHARMACIST-INITIATED THERAPY (PIT)

# Associated Assessment Criteria (AAC):

ACC 2.6 Pharmacist-initiated therapy (PIT) and interventions, in collaborative consultation with other healthcare professionals, and in cognisance of local regulations, and the

pharmacist's scope of practice, is promoted and practiced, optimising the overall quality of pharmaceutical care and services.

#### **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS **DETAILED KNOWLEDGE FIELDS** Regulatory Framework and Scope of PIT GPP guidelines, SAPC regulations (This area focuses on the legal and professional Scope of practice, minimum standards, fee guidelines governing PIT and the pharmacist's structures scope of practice.) See Regulations 20 of the Pharmacy Act Services for which a pharmacist may levy a fee Minimum standards for services See Practice Regulations to the Pharmacy Act Scope of Practice of a Pharmacist and See regulation GNR1158 Pharmacist Support Personnel Minor ailments that pharmacists are able to Primary care interventions treat (Recognise these areas and provide clinical guidelines in an algorithm approach, together with the EML) **Clinical Assessment** Medical history assessed by the pharmacist; current medications, allergies, and relevant clinical parameters to identify potential medicine therapy problems Legal and Ethical Considerations Upholding patients' rights and considerations for confidentiality, patient safety and autonomy. Professional obligation to uphold professional standards of pharmacists and ensure continuity of care. Documentation and record-keeping Good Pharmacy Practice (GPP) Manual **Regulatory Framework for PIT** guidelines for PIT SAPC regulations on (This area focuses on understanding and applying the legal and professional guidelines that govern pharmacist-initiated services pharmacist-initiated therapy, ensuring compliance Scope of practice for pharmacists in PIT and optimal pharmaceutical care.) Integration of PIT within the broader healthcare system Compliance with the Medicines and Related

# Clinical Competencies for PIT

(This area focuses on developing and applying the clinical knowledge and skills necessary to effectively assess, diagnose, and treat patients within the scope of pharmacist-initiated therapy.)

#### PHARMACIST-INITIATED THERAPY (PIT)

Assessment and management of minor

Clinical decision-making in primary care

Substances Act

ailments

settings

Collaborative Healthcare Practice (This area focuses on fostering interprofessional relationships and communication to ensure seamless patient care and optimal outcomes in pharmacistinitiated therapy.)

#### Patient-centred Care in PIT

(This area focuses on delivering personalised, culturally sensitive care that respects patient autonomy and promotes shared decision-making in pharmacist-initiated therapy.)

#### Quality Assurance in PIT

(This area focuses on implementing systems and processes to monitor, evaluate, and improve the quality and safety of pharmacist-initiated therapy services.)

Ethical and Legal Aspects of PIT (This area focuses on navigating the ethical dilemmas and legal considerations inherent in pharmacist-initiated therapy, ensuring professional integrity and patient protection.) Pharmacological and non-pharmacological interventions Evaluation and management of drug therapy problems Application of evidence-based practice in PIT

Interprofessional communication and referral processes, Integration of PIT with other healthcare services Continuity of care in PIT Collaborative practice agreements with other healthcare providers Effective handover and follow-up procedures

Patient rights and informed consent in PIT Confidentiality and privacy considerations Cultural competence in PIT services Patient education and empowerment strategies Shared decision-making in treatment plans

Documentation and record-keeping for PIT services

Monitoring and evaluation of PIT outcomes Continuous professional development for PIT competencies

Implementation of quality improvement initiatives

Risk management and patient safety protocols

Professional standards and code of ethics in PIT

Legal boundaries and liability in PIT Ethical decision-making in complex PIT cases Management of conflicts of interest Adherence to the scope of practice limitations

APPLIED FIELDS IN PHARMACY: Pharmacy Practice, Clinical Pharmacy.

AAC 6.6 Patient-specific information is obtained, and therapeutic principles are applied to make informed recommendations. These recommendations are effectively communicated, documented, and applied in pharmacist-initiated therapy (PIT).

#### **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

Regulatory Framework and Scope of Practice of PIT (This area focuses on the legal and professional guidelines governing PIT and the pharmacist's scope of practice.)

Scope of Practice of a Pharmacist and Pharmacist Support Personnel

Primary Care Interventions: Also refer to the Scope of Practice

**Clinical Assessment** 

Legal and Ethical Considerations

#### **Regulatory Framework for PIT**

(This area focuses on understanding and applying the legal and professional guidelines that govern pharmacist-initiated therapy, ensuring compliance and optimal pharmaceutical care.)

#### **Clinical Competencies for PIT**

(This area focuses on developing and applying the clinical knowledge and skills necessary to effectively assess, diagnose, and treat patients within the scope of pharmacist-initiated therapy)

#### DETAILED KNOWLEDGE FIELDS

GPP guidelines, SAPC regulations Scope of practice, minimum standards, fee structures See Regulations 20 of the Pharmacy Act Services for which a pharmacist may levy a fee Minimum standards for services

See Practice Regulations to the Pharmacy Act See regulation GNR1158

Minor ailments that pharmacists are able to treat (Recognise these areas and provide clinical guidelines in an algorithm approach, together with the EML)

Medical history assessed by the pharmacist; current medications, allergies, and relevant clinical parameters to identify potential medicine therapy problems

Upholding patients' rights and considerations for confidentiality, patient safety and autonomy. Professional obligation to uphold professional standards of pharmacists and ensure continuity of care. Documentation and record keeping

Good Pharmacy Practice (GPP) Manual guidelines for PIT SAPC regulations on pharmacist-initiated services Scope of practice for pharmacists in PIT Integration of PIT within the broader healthcare system Compliance with the Medicines and Related

Compliance with the Medicines and Related Substances Act

Assessment and management of minor ailments Clinical decision-making in primary care settings Pharmacological and non-pharmacological interventions Evaluation and management of drug therapy problems Application of evidence-based practice in PIT

#### **Collaborative Healthcare Practice**

(This area focuses on fostering interprofessional relationships and communication to ensure seamless patient care and optimal outcomes in pharmacist-initiated therapy)

# Patient-centred Care in PIT

(This area focuses on delivering personalised, culturally sensitive care that respects patient autonomy and promotes shared decision-making in pharmacist-initiated therapy)

#### Quality Assurance in PIT

(This area focuses on implementing systems and processes to monitor, evaluate, and improve the quality and safety of pharmacist-initiated therapy services.)

# Ethical and Legal Aspects of PIT

(This area focuses on navigating the ethical dilemmas and legal considerations inherent in pharmacist-initiated therapy, ensuring professional integrity and patient protection.)

#### Clinical decision-making,

Clinical Competencies and Patient-Centred Care in PIT

(This area focuses on clinical skills, assessment, and personalised care in pharmacist-initiated therapy.)

#### Gathering Detailed Patient Medical History

(This area focuses on collecting comprehensive patient information to inform therapeutic decisions and care planning.)

#### Therapeutic Monitoring and Clinical Outcome Re-Evaluation

(This area focuses on ongoing assessment of therapy effectiveness and safety, with adjustments as needed.)

Interprofessional communication and referral processes, Integration of PIT with other healthcare services Continuity of care in PIT Collaborative practice agreements with other healthcare providers Effective handover and follow-up procedures

Patient rights and informed consent in PIT Confidentiality and privacy considerations Cultural competence in PIT services Patient education and empowerment strategies Shared decision-making in treatment plans

Documentation and record-keeping for PIT services

Monitoring and evaluation of PIT outcomes Continuous professional development for PIT competencies

Implementation of quality improvement initiatives

Risk management and patient safety protocols

Professional standards and code of ethics in PIT

Legal boundaries and liability in PIT Ethical decision-making in complex PIT cases Management of conflicts of interest Adherence to the scope of practice limitations

Assessment and management of minor ailments Clinical decision-making Patient rights, informed consent, cultural competence

Monitoring clinical outcomes Adjusting therapy based on response and adverse effects Re-evaluating patient progress

# Medication Initiation and Adjustment (*This area focuses on starting, modifying, or*

discontinuing medicines based on patient-specific factors and clinical judgment.)

Development of Pharmaceutical Care Plan See sections in PHARMACY PRACTICE (This area focuses on designing individualised care plans based on patient assessment and therapeutic goals.) Initiating therapy Dose titration and adjustment Discontinuation when appropriate

Identification of therapeutic needs Setting goals and selecting interventions Monitoring parameters and follow-up

Collaborative Practice Agreements (This area focuses on multi-disciplinary collaboration and referral to optimise patient care)

#### Patient Education

(This area focuses on providing counselling on disease management, medication use, and non-pharmacological self-care.)

# Monitoring for Adverse Effects

(This area focuses on identifying, managing, and preventing adverse drug reactions and interactions.)

Documentation and Record Keeping (This area focuses on accurate and comprehensive documentation of professional activities and patient medication records.)

#### Communication

(This area focuses on effective, empathetic communication with patients and healthcare providers to ensure optimal care.)

Follow-Up And Outcomes Assessment (This area focuses on ongoing evaluation of patient outcomes and therapy effectiveness, with adjustments as needed.) Multi-disciplinary collaboration with other healthcare professionals and patients in clinical decisions and referrals. Working with healthcare professionals Establishing referral pathways Shared decision-making

Providing patient counselling on disease, medication use and non-pharmacological selfcare. - Lifestyle and self-care advice Addressing patient questions and concerns

Monitoring for and managing adverse effects or medicine interactions. Recognising side effects and interactions Implementing mitigation strategies Reporting adverse events

Documentation for professional activities and record keeping patient medication records Maintaining patient records Documenting interventions and outcomes Ensuring legal and regulatory compliance

Effective communication with patients and other healthcare providers Patient communication Interprofessional communication Counselling and education

#### See sections in <u>PHARMACY PRACTICE</u> See sections in CLINICAL PHARMACY

Scheduling follow-up Assessing and documenting outcomes Adjusting care plans as necessary **APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmacology

# **MODERN TECHNOLOGIES IN PHARMACY**

#### Associated Assessment Criteria (AAC):

AAC 2.7 Modern technologies such as but not limited to electronic health records and automation systems, telepharmacy, mobile applications, and wearable devices are identified and applied where appropriate in the practice of pharmacy.

#### **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

# Pharmacy Information Systems and Automation

(This area focuses on the use of digital and automated systems to enhance pharmacy operations and patient care)

Mobile Health Applications (Apps), Telepharmacy, and Digital Tools (This area focuses on leveraging mobile and remote technologies for patient care, education, and workflow management.)

#### DETAILED KNOWLEDGE FIELDS

Pharmacy Information Systems (PIS), e.g. health force (there are others as well) Virtual consultations, telepharmacy Electronic Prescribing (e-prescribing) Automated Dispensing Systems:

ADS and inventory management systems

Medication use management Medication therapy management software Patient medication adherence systems

Via Connection to a personal device, phone or laptop, Telepharmacy services and secure data transmission

Medication Therapy Management (MTM) and comprehensive medication reviews are conducted remotely Patient education and counselling via digital

Patient education and counselling via digital platforms

Emergency protocols, including access to automated dispensing units during power failures

Mobile health applications for medication management and adherence Blockchain technology applications

Automated Medication Compounding Systems Pharmacy Information Systems (PIS)

Pharmacy Customised Systems

Inventory Management Systems (stock take and ordering)

**Regulatory Compliance Software** 

Pharmacy Robotics and Workflow Management

(This area focuses on automation in medication dispensing and pharmacy workflow to improve efficiency and safety.)

Mobile Health, Telepharmacy, and Digital Tools

(This area focuses on leveraging mobile and remote technologies for patient care, education, and workflow management.)

**Emergency Protocols** 

Quality Assurance, Education, and Regulatory Compliance

(This area focuses on ensuring quality, safety, and compliance in the use of modern technologies in pharmacy.)

Billing and reimbursement strategies

**Regulatory Compliance** 

Integration with Electronic Health Records (EHR)

Medication therapy management systems: Therapeutic drug monitoring data support system Drug-drug interactions monitoring systems

Barcode Medication Administration (BCMA) Automated order refill management systems

**Risk management** 

Pill counting, sorting, and packaging Medication dispensing robots Automated storage and retrieval Workflow management software

Medication dispensing technology Secure data transmission Medication Therapy Management (MTM) Comprehensive medication reviews, monitoring of treatment outcomes, and addressing medication-related problems remotely. Patient education and counselling Implementation of strategies to provide patient education and counselling remotely.

For example, access to automated dispensing units during power failures and cold chain protocols during power failures.

Implementation of quality assurance measures to monitor and assess the effectiveness of telepharmacy services.

Development of appropriate billing and reimbursement strategies to support the financial sustainability of telepharmacy services.

Considerations for the POPI Act, Electronic Communications Act and data privacy

Emerging Technologies: AI, VR/AR, IoT, Cloud Computing

(This area focuses on advanced technologies transforming pharmacy practice and patient care.)

Mobile applications Point-of-Care Testing (POCT) Devices and Mobile Applications (This area focuses on diagnostic tools and mobile apps to support medication management and patient engagement.) Virtual Reality (VR) and Augmented Reality (AR) Internet of Things (IoT) - Artificial Intelligence (AI) and Machine Learning (ML) Virtual Reality (VR) and Augmented Reality (AR)

Internet of Things (IoT) for patient data management

Cloud computing for quality control and telecommunication technology

POCT devices for rapid diagnostics Medication information and reference apps Clinical decision support apps Medication interaction and compatibility checkers Prescription scanning and refill apps Pharmacogenomics and personalised medicine apps Compounding apps

Compounding apps

Medication Information and Reference Apps Medication Management and Adherence Apps Pharmacy Operations and Workflow Management Apps Clinical Decision Support Apps Medicine Interaction and Compatibility Checkers Patient Education and Engagement Apps Prescription Scanning and Refill Apps Telepharmacy and Remote Consultation Apps Pharmacogenomics and Personalised Medicine Apps Compounding Apps

APPLIED FIELDS IN PHARMACY: Pharmacy Practice.

# **GOOD MANUFACTURING PRACTICES (GMP)**

# Associated Assessment Criteria (AAC):

ACC 2.8 Good manufacturing practice (GMP) principles are employed in the practice of pharmacy to provide quality, safe and effective medicines and medical devices.

# Curriculum Outline:

#### SUB-KNOWLEDGE FIELDS

#### GMP and GPP Rules and Guidelines (This area focuses on the principles and implementation of GMP and GPP to ensure safe, effective, and quality medicines.)

# Documentation, Traceability, and Quality Systems

(This area focuses on documentation, traceability, and quality management in pharmaceutical manufacturing.)

Pharmaceutical Quality Systems and Control

(This area focuses on validation, quality control, and regulatory compliance in pharmaceutical production.)

#### Documentation and Record-keeping

#### DETAILED KNOWLEDGE FIELDS

GMP/GPP rules and guidelines Premises, equipment, personnel, production planning Prevention of contamination, validation, inprocess controls

Documentation practices Batch records, product traceability, recall procedures QMS, SOPs, risk management, audits

Validation, qualification, QC principles Sampling, testing, stability programmes Regulatory compliance, training, import/export procedures

#### Principles

Required GMP Documentation (by type) Generation and Control of Documentation Good Documentation Practices Retention of Documents Specifications for starting and packaging materials. Specifications for intermediate and bulk products Specifications for finished products. Manufacturing Formula and Processing Instructions Packaging Instructions Labelling Batch/Ink Jet printing **Batch Processing Records Batch Packaging Records** Procedures and Records Receipt Sampling Testing Pharmacopoeia & guidelines to set up specifications & limits Product Release to Market

Product traceability and Recall procedures

Company overview & Departmental interactions

Complaints and product recall

Organograms (Roles of key personnel) QMS system in a manufacturing setting Management review

Risk management tools (CAPAs, Deviations, Change controls, Customer complaints, OOS) Site Master File Quality manual SOPs

#### Specific Applied Fields in Pharmacy: Pharmaceutics, Pharmacy Practice.

Pharmaceutical Quality Systems

Validation, qualification of instrumentation and methods

# Specific Applied Fields in Pharmacy: Pharmaceutics; Pharmaceutical Chemistry.

Quality Control (QC)

Principles Good Quality Control Laboratory Practice Documentation Sampling Testing Ongoing stability programme Technical transfer of testing methods Batch release testing (post-import)

Medicines Act, Compliance with SAHPRA

Requirements and preparation, internal and

requirements, ICH, ZA-CTD

Medicines Act

**Batch release** 

external

**Regulatory aspects** 

Ethical and Legal

Audits

Raw material selection and Procurement

**Risk Assessment** 

#### Specific Applied Fields in Pharmacy: Pharmaceutics

Releasing, Storage and Shipment

Importation, Exportation of medicine Batch release

# **APPLIED FIELDS IN PHARMACY:** Pharmaceutical Chemistry, Pharmaceutics

# **MEDICATION SAFETY PRACTICE (MSP)**

Associated Assessment Criteria (AAC):

AAC 2.11. Preclinical, clinical, and post-clinical phases of drug development are critically analysed in relation to regulatory approval and compliance, laboratory testing, drug safety assessment processes, efficacy, pharmacokinetics, including drug formulation, pharmacological testing, drug product stability and toxicity studies.

AAC 2.18. Existing pharmaceutical policies and procedures are assessed and critiqued in relation to the impact on safety, quality, and efficacy of medicines.

AAC 3.4. Current Good Practice (cGxP) principles and guidelines are critically evaluated, assessed and applied in the research project to safeguard research integrity and ensure quality, safety, and efficacy of products and processes.

AAC 4.4. The rational use of medicine is advocated, justified and applied for the protection of the health and safety of the public in the practice of pharmacy.

AAC 4.7. The principles and rules relating to Good Pharmacy Practice (GPP) are evaluated to determine the impact on patient safety, medication management, and the overall quality of patient care, and are appropriately implemented within the practice of pharmacy.

AAC 5.1. The cost-effectiveness and feasibility of available medication options are assessed, taking into consideration patient socio-economic factors, medicines' efficacy, safety and quality, patient preferences, and healthcare resources in the practice of pharmacy in South Africa.

AAC 6.1. The effectiveness of communication campaigns in raising awareness and promoting behaviour change related to drug safety and substance abuse is evaluated and applied in relation to the practice of pharmacy in South Africa.

AAC 6.3. Demonstrate competence in the production and dissemination of medicines-, drug safety- and substance abuse information, by offering creative insights, rigorous interpretation and solutions to problems and issues appropriate to the practice of pharmacy.

AAC 7.4. Effective quality management systems are observed through the examination of their components, and mitigation strategies are proposed/outlined to protect patient safety, prevent medication errors, and address adverse events as appropriate to the practice sector.

#### Curriculum Outline:

#### SUB-KNOWLEDGE FIELDS

#### **Medication Error Prevention**

(This area focuses on strategies to prevent, detect, and manage medication errors in all pharmacy settings.)

#### DETAILED KNOWLEDGE FIELDS

#### Also see section on: <u>PHARMACOVIGILANCE</u> <u>PRINCIPLES AND REPORTING ADR</u>

Error recognition, reporting, and management Monitoring for adverse drug reactions (ADRs), Recognising, reporting, and managing ADRs, and understanding how to monitor medications for potential side effects

#### Medication Reconciliation

(This area focuses on ensuring accurate and complete medication information transfer at all care transitions.)

# Patient Education and Counselling

(This area focuses on empowering patients through education and counselling for safe medication use.)

#### Innovations in Quality and Safety

(This area focuses on new methods and technologies for improving medication safety and quality assurance.)

# Risk Management and Quality Improvement

(This area focuses on systematic approaches to identify and mitigate risks in medication use.)

#### Safe Dispensing Practices

(This area focuses on ensuring accuracy and safety in medication dispensing processes.)

#### Clinical Decision Support Systems (CDSS)

(This area focuses on electronic tools to support safe and evidence-based clinical decisions.)

# Legal and Ethical Considerations in Medication Safety

(This area focuses on adherence to legal and ethical standards in all aspects of medication safety.)

#### Team Communication and Collaboration

(This area focuses on effective interprofessional communication to enhance medication safety.)

#### Medication Safety Culture

(This area focuses on fostering a culture that prioritises safety and encourages error reporting.)

#### Also see section on: PATIENT MEDICATION MANAGEMENT, RESOLUTION OF MEDICINE (DRUG) THERAPY PROBLEMS, MEDICATION REVIEWS - Medication management, therapy problem resolution, medication reviews

Also see section on: <u>PATIENT MEDICATION</u> <u>MANAGEMENT, RESOLUTION OF MEDICINE</u> (DRUG) THERAPY PROBLEMS, <u>MEDICATION REVIEWS</u>

For example, documentation of care, quality assurance tracking, and reporting methodology

Risk assessment Quality improvement initiatives

SAPC Good Pharmacy Practice rules & guidelines

Electronic systems to support safe prescribing, dosing adjustments, and medicine interaction checks

CDSS to help ensure evidence-based decisions

Adhering to regulations, professional guidelines, and ethical standards related to medication safety.

Confidentiality, informed consent, and regulatory reporting obligations.

Effective interprofessional communication with physicians, nurses, and other healthcare providers

Creating a workplace culture that prioritises safety & encourages reporting of errors

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice, Clinical Pharmacy, Pharmaceutics, Pharmacology.

# **COMPOUNDING TOOLS AND EQUIPMENT FOR MEDICINES**

#### Associated Assessment Criteria (AAC)

AAC 2.9 Screening, diagnostic and medicines compounding tools in pharmacy, such as, but not limited to, point-of-care testing (POCT) devices (see medical devices), compounding equipment, medical devices (see medical devices), drug information databases, automated medication dispensing cabinets are integrated into the practice of pharmacy.

#### Curriculum Outline:

SUB-KNOWLEDGE FIELDS

**DETAILED KNOWLEDGE FIELDS** 

SAPC Good Pharmacy Practice (GPP) rules & guidelines related to compounding

equipment

Good Manufacturing Practice (GMP)

APPLIED FIELDS IN PHARMACY: Pharmacy Practice, Pharmaceutics

# **AUTOMATED MEDICATION DISPENSING UNITS (AMDU)**

#### **Curriculum Outline:**

SUB-	KNOWL	FIELDS
000	1110111	

#### DETAILED KNOWLEDGE FIELDS

GPP Rules and Guidelines Regarding AMDUs (This area focuses on regulatory and operational standards for automated

dispensing units in pharmacy practice.)

#### Operational Procedures and Best Practices

(This area focuses on workflow, staff training, and inventory management in automated dispensing.)

# Regulatory Compliance and LegalRegulationsConsiderationsLegal implications(This area focuses on legal responsibilities and<br/>documentation in automated dispensing.)Patient/Provider in<br/>RoboticsAl in automationRegulations

Stocking Access control Handling Expired/recalled medicines Recordkeeping Audit trials

d Patient/Provider interaction Robotics AI in automation

# **DRUG / MEDICINE INFORMATION DATABASES**

#### **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

SAPC Good Pharmacy Practice (GPP) rules and guidelines relating to medicine information databases (This area focuses on the use and maintenance of accurate, comprehensive medicine information resources.)

#### DETAILED KNOWLEDGE FIELDS

Medicine Names and Identifiers Generic and brand names of the medicine. Dosage and Administration Recommended dosages for different patient populations Instructions on how to administer the medicine (e.g., oral, intravenous, etc.). Mechanism of Action How the medicine works in the body to achieve its therapeutic effects Pharmacokinetics Absorption, distribution, metabolism, and excretion of the medicine Half-life and time to reach peak concentration Contraindications Medical conditions or circumstances in which the medicine should not be used Interactions Medicine-medicine interactions Interactions with other medications Medicine-food interactions: Interactions with specific foods or dietary components Medicine-alcohol interactions: Effects of combining the medicine with alcohol Adverse Effects and Side Effects Common and serious adverse reactions associated with the medicine Information on monitoring and managing side effects Warnings and Precautions Special considerations or precautions when using the medicine

Potentially harmful effects or situations to be aware of **Pregnancy and Lactation Information** Safety and recommendations for using the medicine during pregnancy and breastfeeding Storage and Stability Storage conditions to maintain the medicine's effectiveness Patient Counselling Points Information for healthcare professionals to counsel patients on proper medicine use Tips on what patients should be aware of while taking the medication **Formulations** Different forms and strengths in which the medicine is available (e.g., tablets, capsules, injections) References Citations for the sources of information within the database. **Regulatory Information** Regulatory approvals, including approvals by foreign medicine national regulatory agencies (NRAs) and prequalifications by the WHO, if applicable. Updates and Revisions Information about when the database was last updated Clinical Trials and Studies Summaries of relevant clinical trials and research studies

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice, Clinical Pharmacy, Pharmacology, Pharmaceutics

# ADVANCED DRUG / MEDICINE DISCOVERY

# Associated Assessment Criteria (AAC):

AAC 2.10 Advanced medicine discovery approaches, analytical methodologies, and medicines manufacturing methods, such as, <u>but not limited to</u>, deoxyribonucleic acid (DNA) sequencing and genotyping, high-performance liquid chromatography (HPLC), and mass spectroscopy (MS) are appraised and appropriately applied in the practice of pharmacy.

#### SUB-KNOWLEDGE FIELDS

GPP Rules and Guidelines Relating to Medicine Discovery (This area focuses on regulatory and ethical considerations in drug discovery and development.)

Target Identification and Validation (*This area focuses on identifying and confirming biological targets for new medicines.*)

Combinatorial Chemistry, AI, and Omics (This area focuses on innovative approaches and technologies in drug discovery.)

# DETAILED KNOWLEDGE FIELDS

Key principles and application of advanced medicine discovery approaches

Hit identification, lead optimisation, highthroughput screening, computational drug design, fragment-based design, virtual screening, biological assays

Combinatorial chemistry, AI/ML, omics, biologics, gene therapies, pharmacokinetics, biomarkers, natural product discovery, gene editing, nanotechnology, data mining

**APPLIED FIELDS IN PHARMACY:** Pharmaceutical Chemistry, Pharmacy Practice, Clinical Pharmacy, Pharmacology, Pharmaceutics.

# ADVANCED ANALYTICAL METHODOLOGIES

AAC 2.10 Advanced medicine discovery approaches, analytical methodologies, and medicines manufacturing methods, such as, <u>but not limited to</u>, deoxyribonucleic acid (DNA) sequencing and genotyping, high-performance liquid chromatography (HPLC), and mass spectroscopy (MS), are appraised and appropriately applied in the practice of pharmacy.

#### **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

Good Laboratory Practice (GLP) rules and guidelines related to analytical methods (*This area focuses on laboratory standards and best practices for advanced analytical techniques in pharmacy.*)

See section on: <u>Error! Reference source</u> not found.

#### Advanced Analytical Techniques

#### DETAILED KNOWLEDGE FIELDS

Examples of detailed knowledge fields for selected analytical techniques

#### HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)

#### **Applications in Pharmacy**

(This area focuses on the diverse applications of HPLC in drug development, quality control and research)

(This area focuses on advanced analytical methods used in the pharmaceutical and clinical sciences in the discovery, development, manufacturing, quality and supply of medicines and medical devices.)

Advanced Instrumental Analytical Techniques, including, but not limited to: Spectroscopic techniques:

> UV-visible, infrared (IR), Nuclear Magnetic Resonance (NMR), Mass Spectroscopy (MS)

Chromatographic Techniques:

High Performance Liquid Chromatography (HPLC), Ultra High Performance Liquid Chromatography (UPLC), Gas Chromatography (GC), Thin Layer Chromatography (TLC)

Thermal Analysis Techniques: Differential Scanning Calorimetry (DSC), Thermogravimetric Analysis (TGA)

Electroanalytical Techniques: Potentiometry

Hyphenated Techniques:

LC-MS, GC-MS, LC-NMR

For each analytical technique:

Overview of the basic principles of the technique

Advantages and applications in the pharmaceutical field, quality control in the manufacturing of products and devices, regulatory compliance Key instrumentation and equipment Data processing and interpretation Overview of basic principles of chromatography (separation of compounds in a chemical mixture) and specialised HPLC techniques (including UPLC): reverse-phase, ion exchange, size exclusion

Advantages and applications in the industry Compliance with regulatory and pharmacopoeial standards

Application to pharmaceutical products, small drug molecules, protein, peptide and biopharmaceuticals: biological drugs and biosimilars

Instrumentation and equipment, key components: pump to deliver mobile phase, solvent (mobile phase) reservoir, injection system (autosampler and injector), chromatographic column (stationary phase), detector, data collection system

#### Applications in Pharmacy:

Quality control: qualitative (identification) and quantitative analysis of raw materials (active pharmaceutical ingredients, excipients) and finished products,

potency determination (assay), including chiral (enantiomers) separations, detection and analysis of impurities and degradation products, residual solvents and contaminants, potential cross-contamination detection in production lines, cleaning validation

Dissolution testing (in vitro dissolution studies, correlation with in vivo drug release,

biopharmaceutics classification system) Pharmacokinetic and bioavailability studies, Formulation and product development Stability testing

Method Development and Optimisation Method Validation: Accuracy, precision, specificity, reproducibility and robustness Regulatory Compliance with regulatory guidelines and standards Processing and interpretation of HPLC chromatograms and data.

Related techniques: HPTLC (High-Performance Thin Layer Chromatography), LC-MS, LC-MS/MS (Liquid Chromatography–Mass

Spectrometry), GC (Gas Chromatography), GC-MS, SFC (Supercritical Fluid Chromatography)

#### MASS SPECTROSCOPY

Principles and Applications in Pharmacy (This area focuses on the diverse applications of mass spectrometry in drug development, qualitative and quantitative analysis, quality control, and clinical practice.)

Overview of the basic principles; analytical technique used to measure the mass-to-charge ratio (m/z) of ions

GLP rules and guidelines for analytical methods Advantages and applications in the pharmaceutical field and the industry Basic principles of mass spectrometry Analytical technique for measuring mass-tocharge ratio (m/z) of ions Instrumentation: ion source, mass analyser, detector, data collection system Ionisation techniques: ESI, MALDI, APCI Mass analysers: Quadrupole, TOF, Ion Trap, FT-ICR Instrumentation, ion source, a mass analyser, and a detector and data collection system.

**Ionisation Techniques** 

Electrospray Ionisation (ESI), Matrix-Assisted Laser Desorption/Ionisation (MALDI), Atmospheric Pressure Chemical Ionisation (APCI).

Mass Analysers (FT-ICR)

Different types of mass analysers. Quadrupole, Time-of-Flight (TOF), Ion Trap, and Fourier Transform Ion Cyclotron Resonance

Identification and characterisation of molecules Molecular structure and weight confirmation Screening metabolites and degradation products Detection and analysis based on m/z values

Pharmacokinetic studies

Qualitative and quantitative analysis

Fragmentation patterns

Metabolite identification in ADME studies

High sensitivity for trace detection

Medicine development stages

Proteomics and biomarker discovery

Quality control: identity, purity, detection of

impurities and contaminants

Data analysis and interpretation software Molecular structure and molecular weight confirmation, screening of metabolites and degradation products

Pharmacokinetics studies

Metabolite Identification in ADME studies Medicine concentrations in biological samples.

High sensitivity for trace-level detection Medicine Development

Proteomics and Biomarker Discovery

Proteomics research, identifying and quantifying proteins in biological samples.

Discovering biomarkers.

**Quality Control** 

Identity and purity of APIs (Detection of impurities, residual solvents, and degradation products)

Data Analysis Software

Processing and interpretation mass spectrometry data.

#### NUCLEAR MAGNETIC RESONANCE (NMR) SPECTROSCOPY

Principles and applications in pharmacy (*This area focuses on the use of NMR for qualitative and quantitative analysis in pharmaceutical sciences.*)

Overview of the basic principles. GLP rules and guidelines for analytical methods Advantages and applications in the pharmaceutical field and the industry Basic principles of NMR spectroscopy (Magnetic properties of certain atomic nuclei, nuclear spin states, transition between spin states and the chemical environment of the nuclei) Basic overview of the usefulness of NMR in structure elucidation, quality control, formulation development.

Identification and characterisation of molecules Molecular structure and weight confirmation Screening metabolites and degradation products Detection and analysis based on m/z values Pharmacokinetic studies Qualitative and quantitative analysis Fragmentation patterns Metabolite identification in ADME studies High sensitivity for trace detection Medicine development stages Proteomics and biomarker discovery Quality control: identity, purity, detection of impurities and contaminants Data analysis and interpretation software Molecular structure and molecular weight confirmation, screening of metabolites and degradation products Pharmacokinetics studies Metabolite Identification in ADME studies Medicine concentrations in biological samples. High sensitivity for trace-level detection **Medicine Development** Proteomics and Biomarker Discovery Proteomics research, identifying and quantifying proteins in biological samples. Discovering biomarkers. **Quality Control** Identity and purity of APIs (Detection of impurities, residual solvents, and degradation products) Data Analysis Software Processing and interpretation of mass spectrometry data.

**APPLIED FIELDS IN PHARMACY:** Pharmaceutical Chemistry, Pharmaceutics, Pharmacology.

# DNA SEQUENCING AND GENOTYPING

# **Curriculum Outline:**

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Cood Laboratory Practice (CLD) Bulas and	CLP rules and guidelines for analytical methods
Guidelines	GLF fulles and guidelines for analytical methods
(This area focuses on laboratory standards and best	Basic principles and techniques
practices for analytical genetic methods in	DNA sequencing techniques
pharmacy.)	Genotyping (Polymerase Chain Reaction
	(PCR)), Real-time PCR (q-PCR) are examples

Principles and Applications in Pharmacy

(This area focuses on the foundational concepts and clinical application of genetic and genomic technologies in pharmacy practice.)

Applications: Pharmacogenomics Genetic variations (CYP450 genotyping) Medicine response and metabolism prediction Personalised medicine tailored treatment plans Disease risk prediction Genetic markers Medicine selection and dosing optimisation Individualised dosing Medicine Metabolism Genotyping for cytochrome P450 (CYP) enzymes involved in medicine metabolism **Disease Risk Assessment** Susceptibility to Adverse Reactions **Treatment Optimisation** Patient's genetic makeup, pharmacists' contribution to optimising treatment plans. Ethical and privacy considerations Informed consent Education and Counselling Education and counselling to patients about the genetic factors influencing their medicine response and the implications for their treatment **Research and Advancements** Implications of genetic information. Patients about genetic test results Ongoing research in pharmacogenetics Medicine discovery to discover new medicine targets Regulatory aspects and Quality Assurance Ethical aspects

**APPLIED FIELDS IN PHARMACY:** Pharmacology, Clinical Pharmacy, Pharmacy Practice, Pharmaceutics.

# MEDICINE DEVELOPMENT: PRECLINICAL, CLINICAL, AND POST-CLINICAL PHASES

Associated Assessment Criteria (AAC):

AAC 2.11 Preclinical, clinical, and post-clinical phases of medicine development are critically analysed in relation to regulatory approval and compliance, laboratory testing, medicine safety assessment processes, efficacy, pharmacokinetics, including medicine formulation, pharmacological testing, medicine product stability and toxicity studies.

#### **Curriculum Outline:**

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
GxP Guidelines and Rules	Preclinical drug discovery and development; (development/identification of a drug candidate
SA Good Clinical Practice: Clinical Trial Guidelines – SAHPRA	that demonstrates acceptable efficacy, safety and pharmacokinetic parameters to allow entry into clinical trials) Target identification, hit identification, hit to lead optimisation, lead optimisation, in vitro (cell- based assays) and in vivo testing (animal- based studies), PK and PD studies, toxicology studies. Formulation development Regulatory compliance Documentation
	Clinical development Phases 1, II, III and IV clinical trials Marketing approval (submission of
	application for registration of a medicine with the regulatory authority); Submission to SAHPRA
	Clinical study design and terminology, e.g. crossover design, washout period, randomisation and blinding, sample size determination
	Approval and post-marketing surveillance Lifecycle management Pharmacovigilance

**APPLIED FIELDS IN PHARMACY:** Pharmaceutical Chemistry, Pharmaceutics, Clinical Pharmacy, Pharmacy Practice, Pharmacology.

# **REGULATORY APPROVAL AND COMPLIANCE**

Associated Assessment Criteria (AAC)

AAC 2.11 Preclinical, clinical, and post-clinical phases of medicine development are critically analysed in relation to <u>regulatory approval and compliance</u>, laboratory testing, medicine safety assessment processes, efficacy, pharmacokinetics, including medicine formulation, pharmacological testing, medicine product stability and toxicity studies.

#### **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

SAHPRA Regulatory Systems

(This area focuses on the regulatory frameworks and processes for medicines and medical devices in South Africa and the region)

#### DETAILED KNOWLEDGE FIELDS

Role of SAHPRA (control and regulation of health products intended for human and animal use, the licensing of manufacturers, wholesalers and distributors of medicines, medical devices, radiation emitting devices and radioactive nuclides, and the conduct of clinical trials) Licensing of manufacturers, wholesalers, distributors Regulation of health products, clinical trials Post-importation testing Manufacturer licensing requirements and process The site master file SAHPRA's role in monitoring clinical trials Recalls and withdrawals Labelling and advertising Professional and patient information leaflets Cost-effective medicines – measures to ensure Offences and implications of non-compliance, penalties Preservation of secrecy and Disclosure of information **Delegation of powers** Regulations under the Act Batch release Section 22A authorisations

Medicines Act and general regulations Regulatory approval and review Product registration processes and CTD (eCTD) modules, Chemistry, manufacturing, and controls (CMC) Regulatory approval and review

Product registration process and the CTD (eCTD) clinical data, safety, efficacy, manufacturing, and labelling Chemistry related

The Medicines and Related Substances Act, 101 of 1965, as amended, General Regulations.

(This area focuses on the legal requirements for product registration and compliance.)

Product Registration and Classification (This area focuses on the procedures and requirements for registering medicines and devices.)

#### Compliance and Oversight

(This area focuses on regulatory inspections, postimportation testing, and compliance monitoring.)

aspects - QC methods, formulation, API source and changing source, synthesis of APIs: APIs, limits of contaminants and solvents, byproducts of synthetic reactions (purification) The eCTD comprises 5 modules Module 1: region-specific, product information (labels, professional information package inserts, patient information leaflet) Module 2: Summaries Quality overall summary, non-clinical overview, clinical overview and clinical summary Module 3: Quality (Chemistry, manufacturing and controls): drug substance API (specifications, synthesis, stability, and quality control) Drug product (finished product) (formulation, manufacturing, packaging, quality tests, and stability data), GMP compliance and manufacturing site details Module 4: Non-clinical studies reports (pharmacology, pharmacokinetics - ADME, toxicology (acute, sub-chronic, chronic, genotoxicity, carcinogenicity, reproductive), animal study reports Module 5: Clinical pharmacology (PK/PD) studies), clinical efficacy and safety trials (Phases 1 to III), biostatistics, post-marketing data, investigator brochures and case report forms Scheduling of medicines Registers of medicines and medical devices, amendments to the register Submitting an application for new medicine or generic (INN) medicine, medical device or in vitro diagnostic device to the regulatory authority (SAHPRA) Categories and classification of medicines: Category A medicines registered for use in humans Category A medicines: unregistered medicines, section 21 applications Category B medicines (Medicines intended for use in humans and animals which cannot normally be administered without further manipulation)

Category C medicines (veterinary medicines)

Category D medicines: Complementary medicines Medical Devices and in vitro diagnostics (IVDs) Biologicals Radiation Control SAHPRA guidelines and circulars, PIC/S (Pharmaceutical Inspection Cooperation Scheme) SAHPRA inspections; GxP (GMP, GWP, GCP, GVP) and product-related inspections

**APPLIED FIELDS IN PHARMACY:** Pharmaceutical Chemistry, Pharmaceutics, Pharmacology, Clinical Pharmacy, Pharmacy Practice

# LABORATORY TESTING AND GLP AND GCP

**Curriculum Outline:** 

SUB-KNOWLEDGE FIELDS

DETAILED KNOWLEDGE FIELDS

LABORATORY TESTING AND GLP AND GCP

Good Laboratory Practice (GLP) rules and guidelines related to analytical methods, contamination control processes and sterility

Principles and Application in Pharmacy

Good Clinical Practice (GCP) Rules and Guidelines related to analytical methods, contamination control processes and sterility

Principles and Application in Pharmacy

Quality control Method validation (accuracy, precision, specificity, linearity, range, and robustness) Standard Operating Procedures for each analytical method Data integrity: recording, calculations, traceability Calibration and maintenance of instrumentation Contamination control and environmental monitoring Aseptic techniques for microbiological testing Validation of sterilisation methods Sterility testing Personnel training Investigational Product (IP) handling Role of the pharmacist in IP chain of custody (receipt of product, dispensing, handling, including labelling and reconstitution, maintenance of blinding, storage, and transportation, managing expiry dates, destruction of unused IPs) Advise investigators and staff on medication use and potential interactions Documentation and audit trails (accurate records of receipt, storage, dispensing, and return/destruction of IPs) Confidentiality of participants' records Quality assurance, audits or monitoring visit participation, ensure compliance with SOPs and relevant regulations. Ethical conduct Regulatory compliance

**APPLIED FIELDS IN PHARMACY:** Pharmaceutical Chemistry, Pharmaceutics, Pharmacology, Clinical Pharmacy, Pharmacy Practice

# **MEDICINE SAFETY ASSESSMENT PROCESSES**

# Associated Assessment Criteria (AAC):

AAC 2.11. Preclinical, clinical, and post-clinical phases of drug development are critically analysed in relation to regulatory approval and compliance, laboratory testing, <u>drug safety</u>

assessment processes, efficacy, pharmacokinetics, including drug formulation, pharmacological testing, drug product stability and toxicity studies.

#### **Curriculum Outline:**

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Good Clinical Practice (GCP) for Safety Assessment (This area focuses on regulatory and procedural standards for medicine safety assessment in all development phases.)	Preclinical Studies Animal Pharmacology and Toxicology Dose-extrapolation studies across species Clinical Trial Phases Post-marketing surveillance Syndromic surveillance Adverse Event Monitoring: evaluation and appropriate action Risk identification, Assessment, Intervention and Management Regulatory Oversight, interdisciplinary regulatory oversight, including regulatory toxicology Labelling and Packaging, product safety characteristics summary in the labelling Environmental toxicology Molecular and chemical toxicology Pharmacogenomics Pharmacoepidemiology Ethical aspects <b>Also see the section on:</b> Pharmacovigilance
APPLIED FIELDS IN PHARMACY: P Pharmacology, Clinical Pharmacy, Ph	harmaceutical Chemistry, Pharmaceutics, armacy Practice.

# PHARMACOKINETICS IN DRUG DEVELOPMENT

#### Associated Assessment Criteria (AAC):

AAC 2.11. The preclinical, clinical, and post-clinical phases of drug development are critically analysed in relation to regulatory approval and compliance, laboratory testing, drug safety assessment processes, efficacy, pharmacokinetics, including drug formulation, pharmacological testing, drug product stability and toxicity studies.

#### Curriculum Outline:

SUB-KNOWLEDGE FIELDS

DETAILED KNOWLEDGE FIELDS

See section in **PHARMACEUTICS** 

Pharmacokinetic Parameters (This area focuses on the study of drug absorption, distribution, metabolism, excretion, and related modelling in drug development.) Absorption, Distribution, Metabolism, Excretion Clearance, Half-Life Pharmacokinetic studies Dose Individualisation Medicine-Medicine interactions Pharmacokinetic modelling and simulation

•

**APPLIED FIELDS IN PHARMACY:** Pharmaceutical Chemistry, Pharmaceutics, Pharmacology, Clinical Pharmacy, Pharmacy Practice

# **MEDICINE FORMULATION, PHARMACOLOGICAL TESTING**

#### Associated Assessment Criteria (AAC):

AAC 2.11. The preclinical, clinical, and post-clinical phases of drug development are critically analysed in relation to regulatory approval and compliance, laboratory testing, drug safety assessment processes, efficacy, pharmacokinetics, including <u>drug formulation</u>, <u>pharmacological testing</u>, drug product stability and toxicity studies.

#### **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

Preformulation studies and Formulation Development (This area focuses on the design, testing, and optimisation of pharmaceutical dosage forms.)

Quality Control and Analysis of Formulated Product

DETAILED KNOWLEDGE FIELDS

See section in PHARMACEUTICS

#### See section in PHARMACEUTICS

Typical finished product control includes (as applicable to the relevant dosage form): identification tests for API, assay, content uniformity, mass variation between dosage units, dissolution testing (in vitro release profile), disintegration rate for solid dosage forms, physical appearance and description, moisture content, microbial limit tests, sterility, preservative efficacy, viscosity, impurities and degradation products, specific tests as required per dosage form, e.g. hardness for tablets, particulate matter for large volume parenteral products etc.

Stability Studies (This area focuses on the assessment and See section in <a href="PHARMACEUTICS">PHARMACEUTICS</a>

assurance of medicine stability under various conditions.)

Pharmacokinetics and Pharmacodynamics studies, Pharmacokinetic profiling

Biopharmaceutical Considerations, Bioavailability

Pharmacological Testing and Bioequivalence Studies (This area focuses on in vitro and in vivo testing for efficacy, safety, and equivalence.)

**Toxicology Studies** 

Bioavailability studies Also see sections in: PHARMACEUTICS PHARMACOLOGY CLINICAL PHARMACY

Also see the section in PHARMACEUTICS ADME studies Biopharmaceutics Classification System (BCS) (as relevant to API in formulated product)

#### Also see section in PHARMACEUTICS

(Biopharmaceutics) Definition of bioequivalence Pharmacokinetic parameters and Bioequivalence criteria Pharmaceutical equivalence, therapeutic equivalence Applicable regulatory guidelines (SAHPRA) Highly variable drugs – considerations Biologics and biosimilars (not standard BE, comparability study) BCS classification and biowaivers Ethical and legal aspects

Evaluation of the potential toxicity and adverse effects of the medicine through preclinical studies

Also see sections in: <u>PHARMACOLOGY</u> <u>CLINICAL PHARMACY</u> <u>MEDICINE SAFETY ASSESSMENT</u> <u>PROCESSES</u> TOXICITY STUDIES

**APPLIED FIELDS IN PHARMACY:** Pharmaceutical Chemistry, Pharmaceutics, Pharmacology, Clinical Pharmacy, Pharmacy Practice.

# DRUG/MEDICINAL PRODUCT STABILITY

# Associated Assessment Criteria (AAC):

AAC 2.11. The preclinical, clinical, and post-clinical phases of drug development are critically analysed in relation to regulatory approval and compliance, laboratory testing, drug safety assessment processes, efficacy, pharmacokinetics, including drug formulation, pharmacological testing, <u>drug product stability</u> and toxicity studies.

#### Curriculum Outline:

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Good Manufacturing Practice (GMP) Rules and Guidelines Good Laboratory Practice (GLP) Rules and Guidelines Related to Medicine Product Stability ( <i>This area focuses on regulatory standards and</i> <i>analytical methods for ensuring pharmaceutical</i> <i>product stability.</i> )	Stability testing (physical, chemical, microbiological) Dissolution rate Container-closure integrity Compatibility (excipients, container closure) Light, temperature, humidity sensitivity Shelf-life determination (accelerated, real-time, intermediate studies) Regulatory requirements, stability reports, ongoing monitoring Stability-indicating analytical methods Statistical analysis Storage, labelling, documentation
Shelf-life determination	Accelerated stability studies Real-Time stability studies Intermediate stability studies Applicable calculations Regulatory requirements Stability reports and documentation Ongoing stability monitoring
Stability-indicating analytical methods	Stability-indicating analytical methods Statistical analysis Statistical analysis
Regulatory Compliance	Also see section on: <u>REGULATORY</u> <u>APPROVAL AND COMPLIANCE</u>

**APPLIED FIELDS IN PHARMACY:** Pharmaceutical Chemistry, Pharmaceutics.

# **TOXICITY STUDIES**

# Associated Assessment Criteria (AAC):

AAC 2.11. The preclinical, clinical, and post-clinical phases of drug development are critically analysed in relation to regulatory approval and compliance, laboratory testing, drug safety

assessment processes, efficacy, pharmacokinetics, including drug formulation, pharmacological testing, drug product stability and toxicity studies.

#### **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

#### **DETAILED KNOWLEDGE FIELDS**

Preclinical and Clinical Toxicity Assessment (This area focuses on systematic evaluation of potential toxicity and safety of medicines in preclinical and clinical settings.)

Good Clinical Practice (GCP) Rules and Guidelines related to potential Toxicity

**Ethical Considerations** 

Study design and objectives Animal models and species selection Dose selection Route of administration selection Mechanism of toxicity – chemical interaction with targets in the body Poisoning, including management, impact and public health prevention strategies Duration of study Control groups Clinical observations Clinical pathology Histopathology Pharmacogenomics Pharmacoepidemiology Dose-response relationship (individual, graded or quantal dose-response relationships) Adverse effects assessment and management **Recovery Studies** Dose-response extrapolation across species Environmental toxicology (air quality studies, stability studies, airborne toxins Molecular and chemical toxicology Data analysis and interpretation, including prediction science Regulatory guidelines, interdisciplinary integration Report writing and documentation

The ethics of pre-clinical research - a systematic and ethical approach to animal experimentation, acknowledging the importance of scientific progress while emphasising the responsibility to treat animals with care and respect

94

# WHOLESALING AND DISTRIBUTION OF MEDICINES

#### Associated Assessment Criteria (AAC):

AAC 2.12 Good Storage Practice (GSP) and Good Distribution Practice (GSDP) guidelines and standards involved in the wholesaling and distribution of medicines are analysed and evaluated for efficiency and compliance including, but not limited to, the inventory management, storage and handling, regulatory compliance, supply chain efficiency, product authentication and serialisation, and the distribution of medicines.

#### Curriculum Outline:

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
SAPC_Good Pharmacy Practice (GPP) Rules, Guidelines, and Standards	Supply chain management Procurement and sourcing Warehousing and inventory management
SAPC_Good Storage Practice (GSP) Rules, Guidelines, and Standards	Quality Control (QC) and Quality Assurance (QA) aspects Regulatory compliance
SAPC_Good Distribution Practice (GDP) Rules, Guidelines, and Standards	Order filling Distribution networks Cold chain management
(This area focuses on efficient, compliant, and safe distribution and storage of medicines.)	Customer service and support Returns and expiry management Technology integration Risk management Documentation and record keeping Continuous improvement Emergency preparedness



**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice, Clinical Pharmacy, Pharmaceutics, Pharmacology.

# **INVENTORY MANAGEMENT**

**Curriculum Outline:** 

#### SUB-KNOWLEDGE FIELDS

SAPC\_Good Storage Practice (GSP) Rules, Guidelines, and Standards

SAPC\_Good Distribution Practice (GDP) Rules, Guidelines, and Standards

SAPC\_Good Wholesale Practice (GWP) Rules, Guidelines, and Standards

(This area focuses on effective inventory management to ensure medicine availability and compliance.)

#### DETAILED KNOWLEDGE FIELDS

Continuous improvement Compliance and regulations Training and staff education Environmental considerations Quarantine of products, including in clinical trials, for example, expired, recalls and unused products

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice, Clinical Pharmacy, Pharmaceutics, Pharmacology.



# **STORAGE AND HANDLING**

#### Curriculum Outline:

#### SUB-KNOWLEDGE FIELDS

SAPC\_Good Storage Practice (GSP) Rules, Guidelines, and Standards

SAPC\_Good Distribution Practice (GDP) Rules, Guidelines, and Standards

SAPC\_Good Wholesale Practice (GWP) Rules, Guidelines, and Standards

(This area focuses on maintaining medicine quality through proper storage and handling practices.)

#### DETAILED KNOWLEDGE FIELDS

Temperature control Light and UV Protection Humidity control Packaging Integrity Segregation and Organisation First-In-First-Out (FIFO) System Medication labelling **Restricted Access Controlled Substances Handling Emergency Preparedness** Personal Protective Equipment (PPE) Training and Education of pharmacy staff (ongoing) **Regular Audits and Inspections Proper Disposal** Documentation Pharmacist Oversight Adverse Event Reporting (AER) Regulatory Compliance
# **REGULATORY COMPLIANCE AND GSP AND GDP**

# Associated Assessment Criteria (AAC):

AAC 2.12. Good Storage Practice (GSP) and Good Distribution Practice (GDP) guidelines and standards involved in the wholesaling and distribution of medicines are analysed and evaluated for efficiency and compliance including, <u>but not limited to</u>, the inventory management, storage and handling, <u>regulatory compliance</u>, supply chain efficiency, product authentication and serialisation, and the distribution of medicines.

## Curriculum Outline:

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
SAPC_Good Storage Practice (GSP) Rules, Guidelines, and Standards	Licensing and authorisation Storage and handling conditions Product traceability
SAPC_Good Distribution Practice (GDP) Rules, Guidelines, and Standards	Documentation and record keeping Product Authentication and Verification Quality Management System
SAPC_Good Wholesale Practice (GWP) Rules, Guidelines, and Standards ( <i>This area focuses on regulatory compliance</i>	Adverse Event Reporting (AER) Wholesale distribution practices Recall procedures Counterfeit prevention Training and competence
in storage, distribution, and wholesale of medicines.)	Regulatory inspections and audits Labelling and packaging compliance Data Integrity

APPLIED FIELDS IN PHARMACY: Pharmacy Practice.

# **SUPPLY CHAIN EFFICIENCY**

## **Curriculum Outline:**

SUB-KNOWLEDGE FIELDS

#### DETAILED KNOWLEDGE FIELDS

SAPC\_Good Storage Practice (GSP) Rules, Guidelines, and Standards

SAPC\_Good Distribution Practice (GDP) Rules, Guidelines, and Standards

SAPC\_Good Wholesale Practice (GWP) Rules, Guidelines, and Standards

(This area focuses on optimising supply chain processes for medicine distribution.)

Inventory Management Demand Forecasting Order Processing Distribution Network Design Transportation and Logistics Cold Chain Management Quality Assurance and Regulatory Compliance Serialisation and Track-and-Trace Technology Integration Collaboration and Communication

APPLIED FIELDS IN PHARMACY: Pharmacy Practice.

# **PRODUCT AUTHENTICATION AND SERIALISATION**

# **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

SAPC\_Good Storage Practice (GSP) Rules, Guidelines, and Standards

SAPC\_Good Distribution Practice (GDP) Rules, Guidelines, and Standards

SAPC\_Good Wholesale Practice (GWP) Rules, Guidelines, and Standards

(This area focuses on ensuring the authenticity and traceability of medicines through serialisation and authentication technologies.)

#### DETAILED KNOWLEDGE FIELDS

Serialisation Authentication Technologies Data Integration Regulatory Compliance Tamper Evidence Verification at Point of Dispensing Aggregation Supply Chain Visibility Serialisation Data Exchange Recall Management Training and Education

APPLIED FIELDS IN PHARMACY: Pharmacy Practice.

# DISTRIBUTION OF SPECIALITY MEDICATIONS

#### SUB-KNOWLEDGE FIELDS

SAPC\_Good Storage Practice (GSP) Rules, Guidelines, and Standards

SAPC\_Good Distribution Practice (GDP) Rules, Guidelines, and Standards

SAPC\_Good Wholesale Practice (GWP) Rules, Guidelines, and Standards

(This area focuses on the specialised distribution handling, and support for specialty medications

#### DETAILED KNOWLEDGE FIELDS

Quick and reliable delivery due to the nature of the product and its use Specialised handling and storage Cold chain management Regulatory compliance and reporting Quality control and assurance Traceability and serialisation Inventory management

Order filling and timely delivery Patient privacy and confidentiality Support and education for pharmacies

Collaboration with manufacturers Distributors may offer training and educational resources to pharmacies

Handling returns and expired products Data management and technology Packaging and labelling requirements

Special requirements according to physicochemical properties, radiopharmaceuticals

Contingency plans.

Emergency preparedness, e.g., natural disasters or supply chain interruptions Unexpected events that may disrupt the distribution process

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice, Pharmaceutical Chemistry, Clinical Pharmacy.

# USE OF FORMULARIES & SAFE, RATIONAL, AND COST-EFFECTIVE USE OF MEDICINES

#### Associated Assessment Criteria (AAC):

ACC 2.13 In-depth understanding and application of techniques used in the compilation, use of and amendments to formularies in the safe, rational, and cost-effective use of medicines in both the private and public sectors is exhibited.

# **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

# Medicine Selection and Formulary Development

(This area focuses on evidence-based selection and ongoing management of formulary medications to ensure safety, efficacy, and cost-effectiveness.)

# Therapeutic Guidelines and Evidence-Based Care

(This area focuses on aligning formulary decisions with population health needs and current clinical evidence.)

#### Medicine Substitution Strategies

(This area focuses on cost-saving substitution strategies that maintain therapeutic equivalence and patient safety.)

### Patient education and communication: Patient and Provider Education (This area focuses on educating stakeholders about

formulary content and rational medicine use.)

Pharmacovigilance and Safety Monitoring (this area focuses on post-marketing surveillance and adverse event reporting)

# Pharmacy and Therapeutic Committee Governance

(This area focuses on governance, compliance, and ethical oversight of formulary systems.)

Therapeutic Guidelines, Indications, Patient Population

Medicine Class Reviews and Pharmacodynamic Considerations (This area focuses on the scientific evaluation of medicine classes to inform formulary decisions)

#### DETAILED KNOWLEDGE FIELDS

Classification of medicines Indications Safety, efficacy and cost-effectiveness Updating and revising the formulary Indications, safety, efficacy Cost-effectiveness analysis Updating and revising formularies

Epidemiology of patient population Evidence-based care guidelines

Generic substitution Therapeutic interchange helps reduce costs while maintaining therapeutic efficacy

Substitute a different medication within the same therapeutic class based on formulary guidelines and clinical judgment

Public and private sector differences Awareness of formulary inclusions and exclusions

Monitoring and evaluation Adverse Event Reporting (AER) Formulary committees must carefully select medications

Monitoring/updating of formularies and guidelines Authorisation and restrictions Medicine reviews Compliance with regulations Formulary access and equity Communication with stakeholders

Chemical form (salts, esters, hydrates, polymorphs, stereoisomers) Prodrugs Therapeutic class and therapeutic interchange Cost Analysis and Resource Allocation (This area focuses on pharmacoeconomic evaluations to optimise resource allocation)

**Conflict of Interest Management** 

Pharmacokinetic and pharmacodynamic aspects

Cost-effectiveness, cost-minimisation, cost-utility analyses

Committee members must manage conflicts of interest transparently to maintain the integrity of decision-making



**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice, Pharmaceutical Chemistry, Pharmaceutics, Clinical Pharmacy.

# COMPOUNDING AND MANUFACTURING OF MEDICINES

## Associated Assessment Criteria (AAC):

AAC 2.14 Pharmaceutical (including pharmaceutical chemistry & pharmaceutics), pharmacological and clinical knowledge and skills are integrated and applied in the compounding and manufacturing of medicines.

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Prescription and Ingredient Standards (This area focuses on compliance with prescription standards and selection of high-quality ingredients.)	Prescription requirements Quality ingredients (official monographs)
Aseptic Technique and Facility Management (This area focuses on maintaining sterility and safety in compounding environments.)	Aseptic technique Compounding facilities (cleanroom standards)
Compounding Equipment and Techniques (This area focuses on tools, methods, and customization for patient-specific dosage forms.)	Compounding equipment/tools Techniques for liquids, solids, semi-solids Individualised dosage forms
Formulation Development and Presentation (This area focuses on designing stable, palatable, and allergen-free formulations.)	

Documentation and labelling, Quality Assurance and Regulatory Compliance (This area focuses on ensuring product quality and regulatory adherence.)

Patient-centred Compounding Practices (This area focuses on ethical communication and legal accountability in compounding.)

Record keeping, Pharmacovigilance and Adverse Event Reporting

(This area focuses on monitoring, reporting, and mitigating risks associated with compounded medicines.)

Ethical and Legal Responsibilities

(This area focuses on upholding ethical standards, patient confidentiality, and legal accountability in compounding.)

Education and Continuous Improvement (This area focuses on staff training and precision in pharmaceutical calculations.)

Pharmaceutical Calculations, Safety and Hazard Management (This area focuses on safe handling and disposal of

hazardous materials.)

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice, Pharmaceutics, Pharmaceutical Chemistry; Clinical Pharmacy, Pharmacology.

# DISPENSING OF MEDICINES AND PHASES AND THE DISPENSING PROCEDURE

## Associated Assessment Criteria (AAC):

AAC 2.15 Pharmaceutical (pharmaceutical chemistry & pharmaceutics), pharmacological and clinical knowledge and skills are integrated and applied in all phases of the <u>dispensing of</u> <u>medicines</u>.

# **Curriculum Outline:**

## SUB-KNOWLEDGE FIELDS

DETAILED KNOWLEDGE FIELDS

Ensure safe and effective compounding practices

Patient-specific considerations

SAPC Good Pharmacy Practice (GPP) Rules, Guidelines, and Standards

See sections in Pharmacy Practice and **Regulatory Compliance** (This area focuses on adherence to legal, ethical, and professional standards governing dispensing practices.)

#### Prescription Management

(This area focuses on accurate interpretation, validation, and preparation of prescriptions to ensure patient safety and therapeutic efficacy.)

Verification

Patient Identification

**Medication Review** 

**Medication Preparation** 

Labelling

# Patient-centred Dispensing

(This area focuses on ethical, patient-specific communication and confidentiality during dispensing and patient counselling.)

#### Quality Assurance and Safety

(This area focuses on systems to minimise errors and ensure dispensing accuracy.)

Documentation and Record Keeping (This area focuses on traceability, accountability, and compliance in dispensing records.)

Adverse Event Reporting (AER)

APPLIED FIELDS IN PHARMACY: Pharmacy Practice, Pharmaceutics, Pharmaceutical Chemistry, Pharmacology, Clinical Pharmacy.

# DESTRUCTION AND/OR DISPOSAL OF PHARMACEUTICAL AND MEDICAL WASTE

# Associated Assessment Criteria (AAC):

AAC 2.16 Protocols, methods and ethical decision-making skills are applied in the destruction and/or disposal of pharmaceutical and medical waste for the mitigation of human health risks and impact on the environment.

### Curriculum Outline:

#### SUB-KNOWLEDGE FIELDS

#### DETAILED KNOWLEDGE FIELDS

Regulatory Compliance and Good Pharmacy Practice (GPP) (This area focuses on adherence to SAPC rules, GPP, and all relevant waste disposal regulations.)

# Waste segregation, Identification and labelling

(This area focuses on systematic classification, clear labelling, and separation of different types of waste to ensure safe handling and disposal)

#### Secure storage, Waste transportation

(This area focuses on safe, secure, and compliant storage and movement of waste to prevent exposure and contamination.)

## Training and Staff Competency

(This area focuses on ongoing education and competency of staff in safe waste management practices.)

## Pharmaceutical Return Programmes

Hazardous Waste Handling and Disposal and Cost of API and Waste (This area focuses on protocols for handling, treating, and disposing of hazardous pharmaceutical and medical waste.)

## **Disposal Methods**

Train staff on the proper handling, segregation, and disposal procedures/compliance with waste disposal regulations

Including solvents, sharps disposal Including chemotherapeutic agents

Methods include incineration, autoclaving, and landfill disposal. See procedures (GxP on waste disposal)

### Documentation and Record Keeping

(This area focuses on maintaining accurate records for traceability, compliance, and accountability in waste management.)

Environmental responsibility and Sustainability (This area focuses on minimising environmental impact and promoting responsible waste management.)

Emergency Preparedness Audits and Inspections (This area focuses on readiness for waste-related incidents and continuous quality improvement through regular audits and inspections.)

#### Regular audits and inspections

Include waste manifests, disposal certificates, and records of staff training

Recycling when feasible, to minimise the environmental impact of waste disposal

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice, Pharmaceutics, Pharmacology.

# PHARMACOVIGILANCE

Associated Assessment Criteria (AAC)

AAC 2.17. Pharmaceutical, pharmacological, and clinical pharmacy strategies are developed and applied to enhance and integrate pharmacovigilance activities in the practice of pharmacy

Curriculum Outline:

#### SUB-KNOWLEDGE FIELDS

DETAILED KNOWLEDGE FIELDS

See section Pharmacovigilance Principles and Reporting ADR

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice, Clinical Pharmacy, Pharmaceutics, Pharmacology.

# PHARMACEUTICAL POLICIES

## Associated Assessment Criteria (AAC):

AAC 2.18 Existing pharmaceutical <u>policies and procedures are assessed and critiqued</u> in relation to the impact on safety, quality, and efficacy of medicines.

# **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

#### Policy Goals and Effectiveness

(This area focuses on evaluating whether policies achieve objectives like access, affordability, and rational medicine use.)

#### Economic Impact and Sustainability

(This area focuses on the economic consequences of policies on healthcare systems and industry innovation.)

#### Equity and Access

(This area focuses on ensuring equitable access to medicines for vulnerable and underserved populations.)

## Quality and Safety and Regulatory Compliance

(This area focuses on policies ensuring medicine quality and patient safety through robust regulation.)

#### Innovation and Research and Ethics

(This area focuses on balancing innovation incentives with ethical access and public health needs.)

#### DETAILED KNOWLEDGE FIELDS

The most important policies and procedures related to the safety, quality and efficacy of medicines in South Africa.

Essential medicines, their affordability and financing, supply systems, monitoring and evaluation.

Relevant regional and international polices focussing on essential medicines, making essential medicines affordable, assuring the quality and safety of medicines, promoting quality use of medicines, and developing missing essential medicines can be debated.

The economic consequences of the policies, including:

Effects on drug prices and overall healthcare costs

Impact on pharmaceutical industry innovation and investment

Consequences for healthcare budgets and sustainability

Examine how the policies affect different population groups:

Impact on vulnerable populations (e.g., lowincome, elderly, chronically ill) Geographic disparities in access to medicines Effects on out-of-pocket expenses for patients

Assess the policies' influence on: Quality control measures for pharmaceuticals Pharmacovigilance and adverse event reporting Regulation of drug manufacturing and distribution

Analyse how the policies impact: Incentives for pharmaceutical research and development Support for neglected diseases and orphan drugs Balance between innovation and affordability

Implementation and Governance (This area focuses on practical execution,	Evaluate the practical aspects of policy implementation:
transparency, and stakeholder engagement in policy frameworks.)	Transparency and accountability in decision- making processes
	Stakeholder engagement and participation
	Regulatory capacity and enforcement
Unintended Consequences (This area focuses on identifying and mitigating	Identify any unforeseen effects of the policies, such as:
unforeseen policy impacts.)	Changes in prescribing patterns or healthcare utilisation
	Impact on the generic drug market
	Potential for drug shortages or supply chain disruptions

**Please note**: Some of this content may also be covered in sections dealing with legislation, i.e. the Pharmacy Act and Medicines Act.

**APPLIED FIELDS IN PHARMACY:** Pharmaceutical Chemistry, Pharmaceutics, Pharmacology, Clinical Pharmacy, Pharmacy Practice.



# EXIT-LEVEL OUTCOME 3

Demonstrate the ability to undertake research to analyse and address complex and abstract problems arising in the practice of pharmacy to contribute to the improvement of healthcare.

# **RESEARCH METHODOLOGIES**

### Associated Assessment Criteria (AAC):

AAC 1.4. Current original research studies, systematic reviews, and meta-analyses and emerging evidence in the field are critically appraised to assess possible implications for the promotion of pharmaceutical knowledge production.

AAC 3.1 A research need is identified, justified, and a strategy for conducting the research is outlined and a mini research project is conducted to address the challenge.

AAC 3.2: Appropriate research methodologies are employed to investigate and address challenges in the pharmaceutical (including pharmaceutical chemistry & pharmaceutics), pharmacological, practice, clinical and other areas of pharmacy.

AAC 3.3: Current Good Practice (cGxP) principles and guidelines are critically evaluated, assessed and applied in the research project to safeguard research integrity and ensure quality, safety, and efficacy of products and processes.

**cGxPs** include but are not limited to: Good Pharmacy Practice (GPP); Good Manufacturing Practice (GMP); Good Laboratory Practice (GLP); Good Clinical Practice (GCP); Good Distribution Practice (GDP); Good Pharmacovigilance Practice (GVP); Good Documentation Practice (GDocP); Good Data Management Practice (GDMP); Good Automated Manufacturing Practices (GAMP); Good Radiopharmacy Practice (GRPP); Good Clinical Laboratory Practice (GCLP); Good Wholesaling Practice (GWP).

AAC 4.6. Ethical principles, legal standards, and regulatory guidelines are applied to make informed decisions and solve complex problems in pharmacy practice and research.

# **RESEARCH IN HEALTH SCIENCES**

#### Curriculum Outline:

SUB-KNOWLEDGE FIELDS

DETAILED KNOWLEDGE FIELDS

Introduction to Health Sciences Research

(This area focuses on foundational principles and the role of research in advancing pharmaceutical knowledge and healthcare.) Concept of research Importance of ongoing research in health sciences

#### **Research Processes**

Research proposal development (including ethical approval) Scientific literature review and information retrieval Evidence-based medical research Integrative review approaches in the synthesis of new knowledge Critical appraisal of research articles Reference management techniques (including reference software) Study design and sampling techniques Sample size determination Randomisation, blinding and allocation procedures Data collection methods Collaboration and teamwork Research project coordination and oversight Research budgets

Research Designs and Methodologies (This area focuses on identifying research needs, designing studies, and ensuring ethical compliance.)

Data Analysis and Interpretation

(This area focuses on applying statistical and qualitative methods to derive meaningful insights.)

# Ethical, Legal, and Regulatory Compliance

(This area focuses on safeguarding research integrity and participant rights.)

Data Management and Quality Assurance

Interpretation of Research Findings

Research Funding

Qualitative and Quantitative, including appropriate statistical analysis Software for data analysis

Qualitative vs Quantitative research

Mixed-methods research

Informed consent and participant protection, including overcoming applicable communication barriers Research Ethics Committees (RECs) approval process National HReC (NHReC) Research disclosure Research misconduct and responsible conduct Conflict of interest and authorship guidelines Legal agreements with data sources (MoAs, MoUs, NDAs, etc.)

Data coding and entry Data cleaning and validation Quality control procedures Data storage and re-use of data

Presenting results effectively Discussion and conclusion

Budgeting and resource allocation

109

Grant writing basics (basic processes)

Scientific writing and publishing

Research Communication and Dissemination (This area focuses on effectively sharing findings and translating knowledge into practice.)

Medicine Reconciliation

Clinical Trial Pharmacy Practice

(This area focuses on the pharmacist's role in clinical research and patient-centred care.)

Conference presentations Knowledge translation and public engagement

Investigational product accountability and adherence Role of the pharmacist through interaction with participants

Discussing strategies to enhance patient adherence, tracking of participant usage of the investigational product

#### ETHICAL ISSUES IN HEALTH RESEARCH:

Medical Research - The Rights of Participants

Applicable reports and guidelines, such as and not limited to: Nuremberg Code (1949) Declaration of Geneva (1948) Declaration of Helsinki (1964, 2024) The National Research Act (1974) – Tuskegee Syphilis Study ICH GCP 2016 SA GCP 2021 The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979) The Public Health Services Act (1985) – Stanford Prison Experiment (1971) Vulnerable Populations

ł

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **GOOD RESEARCH PRACTICES (GRP)**

AAC 3.2 Good research practice guidelines are appropriately applied and adhered to in conducting a research project in a field of pharmacy.

# Curriculum Outline:

#### SUB-KNOWLEDGE FIELDS

See Good Clinical Practice (GCP) guidelines involving research in health, as per the Department of Health (SA GCP – most updated version).

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

## EXIT LEVEL OUTCOME 4

In respect of the ethical and professional practice of pharmacy, and the application of evidence-based solutions, a learner is able to apply critical thinking informed by the acquired knowledge of professional ethics, health- and pharmacy related law, and relevant cultural values in assessing and addressing societal, health, safety, and ethico-legal issues in the provision of patient-centred care.

# **ETHICAL AND LEGAL ISSUES**

# Associated Assessment Criteria (AAC):

AAC 4.1: The selection and implementation of specific patient-centred care interventions are justified and applied based on evidence and ethical decision-making abilities in the practice of pharmacy.

AAC 4.2: Ethical and legal issues are addressed through critical reflection and responsible decision-making in the practice of pharmacy.

AAC 4.3: The ethical, legal, and social implications of health and pharmacy-related laws are assessed, critically evaluated and acted upon in the context of patient rights and access to medication.

## Curriculum Outline:

## SUB-KNOWLEDGE FIELDS

DETAILED KNOWLEDGE FIELDS

# SAPC Rules as Pertaining to the Ethical and Professional Practice of Pharmacy

(Focus is on moral principles and obligations in terms of decision-making within complex and dilemma-filled situations, such as when a pharmacist is faced with moral conflicts and dilemmas in advancing optimal patient outcomes.)

# Ethical Decision-Making Frameworks (This area focuses on applying moral reasoning and legal principles to resolve ethical conflicts in patient care.)

Code of conduct for pharmacists and other persons registered in terms of the Pharmacy Act

Professionalism – see Good Pharmacy Practice rules

History and definition of professionalism Key aspects of professionalism as related to ethics and code of conduct

Biomedical ethics principles – autonomy,

beneficence, non-maleficence, justice Obligation to educate the patient pertaining to the meaning of

Death – (criteria, brain death, cardiopulmonary death)

Informed consent

Confidentiality Also see the section on: Continuing Professional Development (CPD) Also refer to Competency standards for Pharmacists in SA Conflict resolution

Decision-making capacity

Pharmacist competence (Professional integrity, <u>medical errors</u>, legal competence in terms of shared decision-making, surrogate decisionmaking, <u>next of kin</u>) Patient competence (mental, general and health literacy), <u>oral and written advance</u>

## <u>directive</u>

Moral reasoning (Patient Harm; Risk; Vulnerability; Cultural diversity; Pluralism; nondiscrimination; non-stigmatisation; patientpharmacist relationship) Veracity - Honest and transparent communication in terms of death (criteria, brain death, cardiopulmonary death) Withdrawal of care Futile treatment Access to medications Palliative care Organ and tissue donation Abortion Euthanasia

Physician-assisted suicide

Do not resuscitate orders (DNR orders)

Patient-Centred Care and Rights

(This area focuses on upholding patient rights, socio-cultural equity, and legal standards in pharmaceutical care.)

Observe and uphold patients' rights and responsibilities in the following aspects during the provision of pharmaceutical patient care – (cross-reference to the Batho Pele principles in the PHC section) Patient's access to medications/medicines and education Patient's socio-cultural and economic factors Informed consent Confidentiality Organ and tissue donation Abortion Euthanasia and physician-assisted suicide Do not resuscitate orders (DNR orders)

Human dignity

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology

# **RATIONAL USE OF MEDICINE**

(Also referred to as the QUALITY USE OF MEDICINE (QUM))

# Associated Assessment Criteria (AAC):

ACC 4.4 The rational use of medicine is advocated, justified and applied for the protection of the health and safety of the public in the practice of pharmacy.

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Principles of Rational Medicine Use	Critical decision making
(This area focuses on evidence-based decision-	Safety and quality considerations
making to ensure safe, effective, and appropriate	Health and safety of the public
medicine utilisation.)	Drug information
Regulatory Aspects and Ethical Frameworks (This area focuses on compliance with legal standards and ethical guidelines governing medicine use.)	Regulatory and ethical considerations Continuous Professional Development
Pharmacoepidemiology and Economic	Medication review
Evaluation	Economic considerations

(This area focuses on monitoring medicine use patterns and assessing economic impacts to optimise resource allocation)

Patient-centred Pharmaceutical Care (*This area focuses on individualised care aligned with patient needs, preferences, and socio-cultural contexts.*) Pharmacovigilance - Adverse Drug Event Monitoring (ADEM)

Patient preferences Patient factors Patient counselling Collaborative care

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **EXIT-LEVEL OUTCOME 5**

Access, collect and critically evaluate evidence to support the safe, rational and cost-effective use of medicines, and provide such evidence-based medicine information to healthcare professionals and patients.

# **COST-EFFECTIVENESS AND FEASIBILITY OF MEDICATION**

## Associated Assessment Criteria (AAC): 1

AAC 5.1: The cost-effectiveness and feasibility of available medication options are assessed, taking into consideration patient socio-economic factors, medicines' efficacy, safety and quality, patient preferences, and healthcare resources in the practice of pharmacy in South Africa.

## **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

SAPC\_Good Pharmacy Practice (GPP) Guidelines and Associated Rules (This area focuses on promoting rational, costeffective prescribing and equitable access within healthcare resource constraints.)

Medication Variables and Equivalency (This area focuses on evaluating medication-specific factors to ensure therapeutic efficacy and costefficiency.)

Patient-centred Variables

## DETAILED KNOWLEDGE FIELDS

Promotion of rational and economic prescribing and optimal use of medicines Optimal use of healthcare resources Responsible use of limited healthcare resources Access to healthcare services

Generic medications Therapeutic equivalents Monitoring and compliance

Patient education Patient preferences

(This area focuses on addressing socio-economic, geographic, and cultural factors influencing medication feasibility.)	Medication synchronisation for patient convenience Patient socio-economic factors Employment status Geographic location Education level and health literacy Family and social support Chronic health conditions Pharmacy selection
Medicine Management Strategies (This area focuses on systematic approaches to optimise medication use and reduce costs.)	Medicine Utilisation Review (MUR) Medication Therapy Management (MTM) Formulary management Prior authorisation assistance Medication co-payments and deductibles Waste reduction Pharmacoeconomics
Collaborative Prescribing Practices (This area focuses on enhancing prescribing efficiency through technology and interprofessional collaboration.)	Prescribing practices (Adoption of e-prescribing and clinical decision support systems) Adoption of technology Collaboration with prescribers Income and Health Insurance/Medical Scheme coverage and review

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **PATIENT CONSULTATION**

## Associated Assessment Criteria (AAC):

AAC 5.2 <u>Patient consultation</u> is undertaken in a professional manner to gather relevant patient information and determine holistic healthcare needs, including drug therapy.

#### **Curriculum Outline:**

#### SUB-KNOWLEDGE FIELDS

### DETAILED KNOWLEDGE FIELDS

See also sections in PHARMACY PRACTICE - Introduction and Establishing Rapport

Patient Identification/ Patient Consultation Initiation

Introduction and rapport-building techniques Patient identification (e.g., ID documents,

(This area focuses on establishing trust, verifying identity, and creating a conducive environment for effective communication.)

#### Assessment of Patient Information

(This area focuses on gathering holistic health information to inform safe and effective therapy.)

#### Medication Reconciliation

(This area focuses on comparing and resolving discrepancies between home and prescribed medications to prevent errors.)

#### Allergy Assessment

(This area focuses on identifying, documenting, and evaluating patient allergies and previous adverse reactions to prevent harm.)

#### **Review of Medical Devices**

(This area focuses on assessing the use, appropriateness, and patient competence with medical devices relevant to therapy.)

# Patient Education and Culturally Sensitive Communication

# Explanation of Medications and Patient Education

(This area focuses on clear, empathetic communication tailored to patient needs and cultural context.)

# Documentation and Follow-up

(This area focuses on accurate record-keeping and continuity of care.)

#### Ethical and Legal Compliance

Privacy and Confidentiality

(This area focuses on adhering to confidentiality laws and patient rights.)

Continuous Professional Development (CPD) (This area focuses on enhancing consultation skills through ongoing learning.) medical records) Ensuring privacy and minimising interruptions

Medical history, including allergies, chronic conditions, and current medications (prescription and over-the-counter)

Patient's current medication list with the prescribed medications to identify any discrepancies

Clear and concise information about the prescribed medication(s), including the medicine's name, purpose, dosage, route of administration, duration, take with food, avoid alcohol, and potential side effects; discuss storage requirements; proper disposal of medications

Adhere to relevant privacy laws and regulations

Latest pharmaceutical knowledge and best practices through ongoing education and training

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmacology.

# **EVIDENCE-BASED PRACTICE**

### Associated Assessment Criteria (AAC):

AAC 5.3 Evidence-based information is critically assessed to determine the relevance and applicability to specific patient cases or clinical scenarios.

#### **Curriculum Outline:**

### SUB-KNOWLEDGE FIELDS

#### DETAILED KNOWLEDGE FIELDS

Assessment, Relevance and Applicability of Information and Application

Systematic Review and Meta-Analysis **Clinical Trials** 

Evidence Types and Critical Appraisal (This area focuses on evaluating the quality, validity, and Adverse effects and safety profiles relevance of different types of evidence in pharmacy practice.)

Patient-specific factors and Education (This area focuses on tailoring evidence-based decisions to individual patient needs and improving health literacy.)

Drug Properties and Safety Considerations (This area focuses on integrating pharmacokinetic, pharmacodynamic, and safety data into evidence-based decisions.)

Guidelines, Formularies, and Cost-Effectiveness (This area focuses on applying clinical guidelines and economic evaluations to optimise resource use.)

Monitoring, Collaboration, and Clinical Application (This area focuses on ongoing evaluation of therapy

# outcomes and interprofessional teamwork in complex cases.)

Pharmacokinetics and Pharmacodynamics

APPLIED FIELDS IN PHARMACY: Pharmacy Practice; Clinical Pharmacy
Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **EXIT-LEVEL OUTCOME 6**

In respect of producing and communicating information in academic and occupational discourse, as well as offering analytical insights and informed recommendations to a range of audiences, a learner is able to:

6.1. Demonstrate competence in the promotion of health and wellness, and the provision of primary healthcare by offering creative insights, rigorous interpretation and solutions to problems and issues appropriate to the practice of pharmacy.

6.2. Demonstrate competency in the critical analysis and professional communication of epidemic and health disaster management principles and solutions within the scope of practice as a pharmacist.

6.3. Demonstrate competence in the production and dissemination of medicines-, drug safetyand substance abuse information, by offering creative insights, rigorous interpretation and solutions to problems and issues appropriate to the practice of pharmacy.

6.4. Communicate concepts, arguments, information and propose solutions to problems in a manner appropriate to the scope of practice of a pharmacist and the recipients of the communication, considering professional, social and cultural factors.

# **MEDICINE SAFETY**

## Associated Assessment Criteria (AAC):

AAC 6.1 The effectiveness of <u>communication</u> campaigns in raising awareness and promoting behaviour change related to drug safety and substance use disorder is evaluated and applied in relation to the practice of pharmacy in South Africa.

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Drugs Safety Principles and Substance Misuse Prevention and Management Strategies (This area focuses on foundational concepts and strategies to ensure medication safety and prevent substance misuse in pharmacy practice.)	Clear and accessible information about the prescribed medications, including dosage, frequency, and potential side effects
Medication review and Follow-Up (This area focuses on systematic assessment and ongoing monitoring to optimise therapy and identify safety concerns.)	Identify safety concerns during medication review
Clear and Accessible Communication (This area focuses on delivering medication and	Use plain language to enhance patient understanding; Encourage patients to ask

health information in a manner that is understandable and actionable for diverse audiences.)

Patient Counselling and Education (This area focuses on empowering patients through tailored education and ongoing support for medicine use and safety.)

Counselling on Over-the-Counter Medications

Medication Review and Follow-Up (This area focuses on systematic assessment and ongoing monitoring to optimise therapy and identify safety concerns.)

Pregnancy and Lactation Considerations

Side Effect Awareness

Adverse Event Reporting (AER)

**Medicine Information** 

Test Kits for Substances Commonly Prone to Non-Medicinal Use

Controlled Substances Management and Opioid Stewardship

(This area focuses on safe management, monitoring, and patient education regarding controlled substances and opioids.)

Patient Assessment

# Pharmacy Protocols Policies and Quality Assurance

(This area focuses on adherence to regulations, continuous improvement, and ethical practice in medicine safety.)

Collaboration Community Outreach, and Public Health Promotion (This area focuses on interdisciplinary teamwork and questions and address any concerns they may have about their medications

Potential interactions with prescribed medicines.

Also see sections on: Pharmacovigilance

Home test kits

Inventory control and monitoring for controlled substances to prevent diversion and abuse; Legitimacy of prescriptions for controlled substances and adhering to legal requirements

Patient-specific factors Screening patients at risk of substance abuse or addiction, also referral and counselling substance abuse treatment programs

Adherence to Regulations Quality Assurance Continuous improvement processes

Interdisciplinary collaboration and effective communication

public engagement to promote medicine safety and wellness.)

Promotion of Non-Pharmacological Approaches

Discuss non-pharmacological approaches for managing pain Communicate the importance of lifestyle modifications for overall health and well-being.

Patient Privacy and Confidentiality and Cultural Sensitivity (This area focuses on respecting patient rights and delivering culturally competent care.)

Continuing professional development (CPD)

Staff Training & Prevention Programmes

Assuring Effectiveness of Medicines

For example, GPP guidelines and associated publications

Adherence to Professional Codes of Ethics and Staff Training (This area focuses on ongoing education and skills development for pharmacy professionals.)

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **HEALTH ECONOMICS COMMUNICATION**

## Associated Assessment Criteria (AAC):

AAC 6.2 The impact and outcomes of advocacy efforts or initiatives addressing health economic issues are synthesised and communicated to a range of audiences.

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Health Economic Evaluation Methods	Cost-Effectiveness Analysis (CEA)
(This area focuses on understanding and applying	Cost-Benefit Analysis (CBA)
economic analyses to inform healthcare decisions	Cost-Utility Analysis (CUA)
and policy.)	Cost-minimisation analysis (CMA)

# **Communication of Cost-Effective Practices**

(This area focuses on educating patients and providers about cost-effective medication use and adherence strategies.)

Pharmacoeconomics Research and Collaboration

(This area focuses on conducting and applying research to optimise resource allocation and interprofessional practice.)

Medicine Pricing, Reimbursement and Access

(This area focuses on navigating pricing, insurance, and policy frameworks to enhance medication affordability.)

# Healthcare Resource Utilisation and Value-**Based** Care

(This area focuses on optimising resource use to improve patient outcomes and system sustainability.)

Patient education and counselling on costeffective practices Adherence counselling

Applied analyses Interprofessional collaboration

Healthcare policy and legislation Formulary management Pharmacy Benefit Management (PBM) Medical scheme options Health insurance and coverage

Generic substitution and biosimilars Medication adherence and health outcomes Pharmacy services and value-based care

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# HEALTH DISASTERS COMMUNICATION

# Associated Assessment Criteria (AAC):

AAC 6.3 Effective communication strategies in managing epidemics, health disasters, or promoting primary healthcare initiatives are applied in the context of pharmacy practice.

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Crisis Communication and Communication Channels (This area focuses on utilising diverse and effective communication platforms to ensure timely, accurate, and broad dissemination of information during health disasters.)	Information on the latest developments and guidelines related to epidemics and/or health disasters
Medicine Management during Health Crises (This area focuses on ensuring medication access,	Appropriate medicine and its availability during epidemics and health disasters



safety, and regulatory compliance during emergencies.)

Supply Chain Management and Information (*This area focuses on managing medication availability during crises through proactive communication and strategic collaboration.*)

# Community Engagement and Cultural Sensitivity

(This area focuses on fostering trust and solidarity through culturally appropriate outreach and education.)

Vaccination and Preventive Measures (This area focuses on promoting immunisation and infection control to mitigate disaster impacts.)

## **Regulatory Changes**

Emergency Preparedness and Response (This area focuses on proactive planning and crisis

communication to manage disasters effectively.)

# Collaboration with Healthcare Providers and Health Authorities

(This area focuses on coordinated responses and adherence to ethical/legal standards.)

## Patient Wellness

(This area focuses on educating patients about the impact of health-related factors on overall wellbeing, empowering them to make informed choices for better health outcomes.)

Mental Health Support (Pharmacists) (This area focuses on recognising, addressing, and supporting the mental health and well-being of pharmacists and pharmacy staff, including access to professional counselling, peer support, and training Monitoring its use

Communicate disruptions or changes in the supply chain that may affect the availability of medications or healthcare products

Participating in public health initiatives, outreach programs, and collaborative efforts with other healthcare providers. Foster a sense of community and solidarity Patient education regarding epidemics and health disasters

Promotion of vaccine benefits Addressing concerns and questions Promotion of immunisation services

Temporary changes in regulations related to medication distribution and prescription rules

Implement and communicate crisis preparedness plans within the pharmacy Ensure that staff are trained to handle increased demand, potential shortages, and other challenges that may arise during an epidemic or health disaster

Sharing patient information, addressing medication concerns, and managing patient care

Collaborate with local health authorities and other healthcare providers to align communication strategies and ensure a coordinated response to the epidemic or health disaster

Increased focus on educating patients about the impact on health-related aspects

Seek counselling for mental health issues that may arise, affecting the mental health of pharmacists to manage work-related stress and mental health challenges.)

#### Data Management and Reporting

(This area focuses on accurate data collection and reporting to inform public health responses.)

#### Legal and Ethical Considerations

(This area focuses on upholding ethical standards and legal requirements when communicating and making decisions during health crises.)

# Continuity of Care - Patients with Chronic Conditions

(This area focuses on maintaining ongoing care and support for patients with chronic illnesses during disruptions caused by epidemics or disasters.)

#### Infection Control Measures

(This area focuses on educating staff and the public about disease transmission and prevention strategies during health disasters.)

#### Prevention and Preparedness Training / Education and Awareness

(This area focuses on proactive education and training to prepare staff and the public for health emergencies and promote preventive behaviours.)

Accurate data recording and reporting to local authorities or other stakeholders

Navigate ethical dilemmas, such as medication allocation in times of scarcity, ensuring fair and equitable access to treatments Adhere to legal and ethical standards in

communication.

Protect patient confidentiality and privacy while ensuring transparency and honesty.

Ensure follow-up monitoring systems are in place for patients with chronic conditions

Educate both staff and the public about the epidemic, including its causes, symptoms, prevention measures, and available treatments.

Emphasise the importance of preventive measures, such as vaccination, hand hygiene, wearing masks, and social distancing.

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **PRIMARY HEALTHCARE (PHC)**

## Associated Assessment Criteria (AAC):

AAC 6.4 Healthy lifestyles are promoted, and preventive measures are proactively advocated to manage risk factors for illness or disease. An initial assessment of patient's health needs is conducted, interpreted, and appropriate solutions are communicated within the context of the provision of <u>primary healthcare</u>.

#### SUB-KNOWLEDGE FIELDS

Overview And Goals of Primary Health Care (PHC) and Health Services (This area focuses on the foundational principles, objectives, and scope of PHC to ensure accessible, comprehensive, and sustainable quality care.)

#### PHC Services Delivery

(This area focuses on the organisation, implementation, and quality assurance of PHC services in line with national and international guidelines.)

# Factors that Influence Implementation of PHC

(This area focuses on the resource, policy, and operational factors that affect effective PHC delivery.)

#### Pharmaceutical Care in PHC

(This area focuses on the pharmacist's role in delivering patient-centred care, medicine management, and information provision within PHC settings.)

#### Medicine Management in PHC

(This area focuses on ensuring rational, safe, and effective use of medicines and the integration of technology and data for better health outcomes.)

#### DETAILED KNOWLEDGE FIELDS

PHC principles and concepts Definition of comprehensive PHC Core principles of PHC Accessibility Comprehensive, sustainable quality care Community participation Intersectoral collaboration Preventive, promotive, curative, rehabilitative and palliative care Organisation of PHC services Interprofessional collaboration Health promotion & Disease prevention Pharmacist-initiated therapy Quality assurance in PHC practices Management of PHC conditions as per national guidelines Community-based services Health communication techniques Monitor and evaluation of PHC services The ideal health facility realisation and maintenance

Service delivery factors & allocation Resources (Financial-, Human-, and infrastructure, equipment, information and technology factors) Policies and procedures

Human resources Patient-centred care Provision of medicine information Integration of the Batho Pele principles emphasising patient-centred service delivery Improving patient experience of care Medicine control References (Essential medicine list and the application, STGs, etc.) Rational prescribing and use of medicine (traditional medicines, vaccines, diagnostics; accessibility, safe use and protection of personal data, information systems use to collect high-quality data, improve information continuity, disease surveillance, transparency,

### Collaborative practice in PHC

(This area focuses on interprofessional and intersectoral collaboration, referral systems, and community engagement for integrated PHC delivery.)

Legal and ethical aspects in PHC (This area focuses on the legal, regulatory, and ethical frameworks guiding PHC practice and upholding professional standards.)

Global and Local Context and Initiatives (This area focuses on the international and national frameworks shaping PHC, including key declarations and sustainable development goals.) accountability and monitoring of health system performance; use technology to enrich health service delivery, improve quality of service and patient safety and increase efficiency and coordination of care) Medication review and reconciliation Use of high-quality, safe, effective and affordable medicines

Interprofessional & intersectoral collaboration Referral systems & continuity of care Community engagement in PHC Integration of pharmacy services in PHC

Scope of Practice for Pharmacy Ethical considerations in PHC Regulatory framework for PHC services Professional standards and conduct Ethical & legal implications of the Batho-pele principles

Global and local context and initiatives; Alma-Ata Declaration (1978), World Health Report: primary health care now more than ever (2008), Astana Declaration (2018), Sustainable Development Goals (SDGs), especially Goal 3: Good Health and well-being.

**Reference:** WHO, Declaration of Astana, 2018, post Declaration of Alma-Ata, 1978, UHC and Sustainable Development Goals for 2030.

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# COMMUNICATE AND DISSEMINATE RESEARCH RESULTS

# Associated Assessment Criteria (AAC):

AAC 6.5 Present and **communicate** academic ideas and disseminate research results in a manner that makes research and other related information accessible and user-friendly for all intended audiences by offering creative insights and rigorous interpretations.

# SUB-KNOWLEDGE FIELDS

Principles of Scientific and Professional Communication (This area focuses on the foundational skills and standards required for clear, accurate, and ethical research communication.)	Scientific writing techniques for research papers and reports Oral presentation skills for research findings Communication of data and results Timeliness Health literacy in research communication
Research Dissemination Methods and Communication Platforms (This area focuses on selecting and utilising appropriate channels and formats to maximise the impact and accessibility of research findings.)	Appropriate research communication platforms and formats (e.g. written reports, presentations, electronic platforms, etc.) Social media for research communication and data collection Responsible use of technology in the dissemination of research findings
Audience-specific Communication (This area focuses on tailoring research messages to meet the needs and understanding of diverse audiences.)	Translate research for lay audiences - different groups require different levels of detail and technicality Communicating with healthcare professionals Presenting to policymakers and stakeholders
Regulatory and Ethical Considerations in Research Communication (This area focuses on maintaining ethical standards, data security, and legal compliance when sharing research information.)	Data collection, confidentiality, management and security Informed consent Knowledge and application of the POPI Act Responsible reporting of results Addressing conflict of interest Authorship and acknowledgement practices
Patient-Centred Communication (This area focuses on empowering patients by providing accessible, relevant, and actionable research information.)	Patient-friendly language and patient involvement in decision-making. Empowering patients with information about their health and treatment options

**DETAILED KNOWLEDGE FIELDS** 

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **PATIENT-SPECIFIC INFORMATION & THERAPEUTIC PRINCIPLES**

# Associated Assessment Criteria (AAC):

AAC 6.6 **Patient-specific information** is obtained, and **therapeutic principles** are applied to make informed recommendations. These recommendations are effectively **communicated** and <u>applied in pharmacist-initiated therapy (PIT)</u>.

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Pharmaceutical Care (Patient-Centred Practice) (This area focuses on the philosophy and application of patient-centred care, emphasising the pharmacist's role in ensuring positive healthcare outcomes.)	Philosophy and principles of pharmaceutical care, e.g. Patient-centred approach Pharmaceutical care process and documentation Identifying and resolving drug therapy problems Patient advocacy Medication Therapy Management Evidence-based practice Interprofessional collaboration Ethical practice Continuous Professional Development (CPD) Quality Assurance
Patient Assessment	Comprehensive patient history taking and
(Comprehensive Evaluation)	medication use (including patient's name, date
(This area emphasises the ability to gather	of birth, medical conditions, medicines, allergies
thorough patient information to inform	and sensitivities)
pharmaceutical care decisions, considering medical	Physical examination techniques.
history, physical findings, medicines, and cultural	Interpretation of laboratory and diagnostic data
factors.)	Cultural competence and sensitivity
Medication History and Reconciliation	Medication review techniques
(Ensuring Accuracy)	Identification of medication-related problems
(This area focuses on obtaining a complete	Drug-drug and drug-disease interactions
medication history and reconciling discrepancies to	Reconciliation across care transitions
prevent medication errors and adverse events,	Documentation of current medications (including
including prescription and non-prescription	OTC and supplements)
products.)	Expiry dates of medications
Dispensing	Interpretation and evaluation of prescriptions
(Safe Medication Supply)	Preparation and labelling of prescribed
(This area emphasises the accurate interpretation,	medicines.
preparation, and provision of medications, adhering	Extemporaneous compounding

to legal and ethical standards to ensure patient safety and medication efficacy.)

# Patient Education and Counselling (Empowering Patients)

(This area focuses on effectively communicating medication information to patients, promoting adherence, and addressing their questions and concerns to improve health literacy and selfmanagement skills.)

# Monitoring and Follow-up (Optimising Outcomes)

(This area focuses on assessing the effectiveness and safety of medication therapy, identifying adverse effects, and making necessary adjustments to achieve desired therapeutic outcomes.)

# Documentation and Privacy (Maintaining Records)

(This area focuses on maintaining accurate and confidential patient records, ensuring compliance with legal and ethical requirements for data protection and information sharing.) Legal and ethical considerations in dispensing. Prescription information (medication name, strength, dosage form, quantity, directions for use) Prescriber information (name, contact information) Verification and Authorisation **Refill information** Medication safety Technology integration Medication adherence strategies Health literacy considerations Use of patient information leaflets Motivational interviewing techniques Patient's guestions and concerns Medicine information and education Health promotion and disease prevention (GPP guidelines FIP publication)

Therapeutic drug monitoring Adverse drug reaction identification and management Treatment outcome evaluation Continuous care planning and adjustment Medication reviews

Privacy and Confidentiality Contact information Signature, Date and Time Documentation practices

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **EXIT-LEVEL OUTCOME 7**

In the context of systems and their effective operation and management, together with an understanding of the roles and relationships among their elements, a learner is able to:

## Associated Assessment Criteria (AAC):

AAC 7.1. Demonstrate in-depth understanding of the impact of global, economic, environmental, industrial/technological changes and societal factors on the local context and governance system(s) for the practice of pharmacy.

AAC 7.2. Demonstrate an understanding of how to lead work productively in a productive and supportive manner, whether independently or within an inter-professional team, based on an understanding of the roles and relationships between the members of the professional team in diverse environments.

AAC 7.3. Demonstrate a high level of knowledge with respect to entrepreneurship, leadership and management, enabling the development of business acumen, organisational and quality management skills, and to apply these skills in the development of pharmaceutical policy and management systems in the various sectors of pharmacy.

# GLOBAL, ECONOMIC, ENVIRONMENTAL, INDUSTRIAL/TECHNOLOGICAL CHANGES

Associated Assessment Criteria (AAC):

AAC 7.1 The impact of global, economic, environmental, industrial/technological changes, and societal factors are interpreted and synthesised in the context of relevant aspects of the pharmacy profession, such as regulatory frameworks, ethical considerations, and/or patient outcomes.

# Curriculum Outline:

#### SUB-KNOWLEDGE FIELDS

Globalisation of the Pharmaceutical Industry, Emerging Markets (*This area focuses on the impact of multinational pharmaceutical companies on South Africa's healthcare system, the opportunities and challenges of global production and distribution, and strategies for promoting local manufacturing while adhering to international guality standards.*)

## Supply Chain Disruptions

(This area focuses on identifying and mitigating risks in international medicine supply chains, including political instability and global health crises, while exploring strategies for local sourcing, supplier diversification, and improving disruption readiness.)

## DETAILED KNOWLEDGE FIELDS

Globalised, with the production and distribution of medicines occurring across borders Increased demand for pharmaceuticals. Adapt to the changing dynamics of medicine distribution and access, importing and exporting

Political instability and global health crises Manage shortages and alternative medicine options.

International medicine supply chains

# Environmental Sustainability and Changes

(This area focuses on minimising the environmental impact of pharmaceutical production and waste disposal, promoting eco-friendly manufacturing practices, and addressing climate change concerns in the pharmaceutical industry.)

# Regulation and Access to Advanced New Generation Medicines

(This area focuses on the evolving landscape of advanced therapies, their accessibility, and regulatory implications.)

Economic Pressures and Impact on Health Care Within the Pharmacy Profession (This area focuses on the financial aspects of healthcare and their effects on pharmacy practice.)

# Global, Economic, Technology and Environmental Patient Healthcare

## **Public Health Emergencies**

(This area focuses on the pharmacist's role in crisis management, emergency preparedness, and ensuring continuity of care.)

# Industrial and Technological Changes, Artificial Intelligence (AI)

(This area focuses on the integration of advanced technologies in pharmacy practice, research, and patient care.)

Awareness of the environmental impact of pharmaceutical production and waste disposal and how this affects the industry. Promotion of eco-friendly medicine manufacturing. Climate change

Global emerging drug therapies, challenges and opportunities, e.g. biotechnology and speciality medicines, biosimilars, nano medicines, gene therapy Ethical and legal implications

Rising healthcare costs Medical aid and Medical Insurance roles and regulations Cost-effective treatment options (e.g., Universal Health Coverage, formulary development, STG and EML, Health Technology Assessment)

Globalisation and cultural competence Use of technology in patient healthcare Electronic health record (EHR) integration, Interprofessional collaboration among healthcare providers Strategies for improving patient health outcomes through teamwork

Pandemics and Epidemics Natural Disasters Infection control, Strategies for managing medication shortages Pandemic Preparedness Plans Allocation of scarce resources, ethical considerations

#### AI

Machine learning Telepharmacy and e-Health, Pharmacy automation Digital health systems (Provide consultations and monitor patients remotely, ensuring the safe and effective use of medications) Pharmaceutical research and development. Electronic Health Records (EHRs) E-Prescribing

Automation, e.g. warehouse picking, ADUs and RADUs

Applied Fields in Pharmacy: Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# LEADERSHIP STRATEGIES

## Associated Assessment Criteria (AAC):

AAC 7.2 Leadership strategies are assessed to gain a deeper understanding of interprofessional collaboration or independent work, with the aim of enhancing productivity and efficiency within the context of a pharmacy-related system.

# **Curriculum Outline:**

## SUB-KNOWLEDGE FIELDS

Strategic Vision for Effective Operation of the Pharmacy

(This area focuses on establishing a clear vision for pharmacy operations that enhances productivity, safety, and quality within the system.)

# Adaptive Leadership and Management in a Changing Environment

(This area focuses on demonstrating adaptive leadership through proactive change management, fostering team resilience, and strategic stakeholder engagement to navigate the dynamic pharmacy system.)

#### DETAILED KNOWLEDGE FIELDS

Key performance indicators (KPIs) for the team include goals and objectives, risk management, resource management, fostering a culture of innovation and continuous improvement, business organisation and structure, ethical governance, as well as long-term strategic planning for the pharmacy.

Self- and staff development, mentorship, resilience within the team, leadership and teamwork, leading and motivating teams, leadership styles, effective communication and interpersonal skills.

Building a culture of collaboration and accountability, responsible decision making, leading change management, stakeholder engagement in navigating change Effective communication, team collaboration and collaboration with other healthcare professionals to ensure coordinated care for patients.

Conflict resolution
Community health and environment and outreach Engagement in public health initiatives, provision of health screening services, and promote medication adherence in the community Financial management Pharmacy leaders may also be responsible for financial management

financial management, such as budgeting, cost control, and inventory management.

# Championing Medication Safety and Compliance

(This area focuses on promoting pharmaceutical care and the culture of medication safety by ensuring adherence to regulatory requirements to protect patients and maintain the integrity of the pharmacy system.)

# Professionalism

(This area emphasises the importance of integrity, responsibility, and continuous learning for effective and ethical pharmacy leadership.)

Promote pharmaceutical care and the culture of medication safety and ensure regulatory compliance Clinical competence, Patient-centred Care, Effective communication Continuing professional development (CPD and lifelong learning)

Background and history, attributes, conduct, behaviour, dress code, work ethic and attitude, online imprint, ethical and accountable decision-making, advocacy and sense of agency, representation of the profession

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **INTER-PROFESSIONAL COLLABORATION**

AAC 7.2 Leadership strategies are assessed to gain a deeper understanding of **interprofessional collaboration** or independent work, with the aim of enhancing productivity and efficiency within the context of a pharmacy-related system.

## **Curriculum Outline:**

# SUB-KNOWLEDGE FIELDS DETAILED KNOWLEDGE FIELDS examples

Professionalism and Effective Professional Communication, Ethical Considerations Multidisciplinary expertise leveraging, Interprofessional participation, Information sharing (This area focuses on respectful communication in a multidisciplinary team informed by pharmacy professional values and ethical considerations.)

## Interprofessional Collaboration

Effective teamwork, Effective communication, Respect and recognition

#### Also see:

**Clinical Pharmacy - Pharmacist intervention Pharmacy Practice – communication** Patient Medication – Collaborative care Pharmacist-Initiated Therapy - Collaborative Healthcare practice Medication Safety Practice - Team communication and collaboration Evidence-based practice Health Economics Communication -Pharmacoeconomics Research Primary Healthcare (PHC) – Services Delivery & Collaborative Practice in PHC Patient-specific information and therapeutic principles - Pharmaceutical Care Business Acumen – Ethical and adaptive practice Healthcare Education programmes Healthcare Principles and Patient education techniques - Professionalism Ethics and Collaboration

# Patient-centred Collaborative Care

(This area focuses on prioritising the patient-specific needs when collaborating with other professionals.)

## **Collaborative Medication Review**

(This area focuses on collaborative medication management to reduce errors and enhance patient outcomes and safety).

Roles and Responsibilities within the Interprofessional Team, including taking into account the scope of practice Patient-centred care and medication safety, Patient education

Medication safety and management within a professional team, Detailed medicine review and safety Quality Management System (skills to collaborate)

Pharmacist interventions and recommendations, Pharmacists review of prescriptions for accurate dosing and drug interactions, correct administration, Public health: Pharmacist role in vaccination programmes, disease trends and stock management, awareness campaigns on chronic diseases,

Advanced drug therapy and clinical trials:

Pharmacokinetics and pharmacodynamics expertise, new drug formulations, Compliance with safety regulations

Collaborative problem-solving and shared decision making

Medication access Care planning Continuity of care Patient education Reduce bottlenecks and ensure efficient workflow

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **BUSINESS ACUMEN**

AAC 7.3 Existing business acumen in the practice of pharmacy is evaluated, outlined, and applied, considering the key elements such as their impact on customer satisfaction, market share, and overall success.

## **Curriculum Outline:**

SUB-KNOWLEDGE FIELDS	DETAILED KNOWLEDGE FIELDS
Foundational Business Skills and Financial Literacy (This area focuses on understanding core business and financial principles and applying them effectively in pharmacy settings.)	Also see <u>Pharmacy Practice</u> (Pharmacy Business Management)
Strategic and Analytical Skills (This area focuses on developing strategic thinking, analytical problem- solving, and decision-making abilities for effective pharmacy management.)	Develop a business plan: SWOT analysis (strengths, weaknesses, opportunities, threats) Goal setting and objective development, Strategic planning frameworks Market analysis and opportunity identification, Competitive positioning strategies Risk assessment and management Quantitative analysis tools, Market segmentation and targeting Effective Risk Management Strategies Leveraging data and technology for informed decision- making,

Embracing digital tools Cybersecurity awareness

### Operational Excellence

(This area focuses on improving efficiency, productivity, and quality in pharmacy operations to enhance customer satisfaction and reduce costs. Integrates Technology.)

## Customer and Relationship Management

(This area focuses on prioritising customer satisfaction and building strong relationships with stakeholders, partners, and customers to foster collaboration and create business opportunities.) Operations Optimisation Workflow analysis and optimisation Inventory management systems Quality control and assurance programs Lean management principles Supply chain management E-commerce and online ordering platforms Data Analysis and Technology Utilisation (Data analytics tools and techniques Point-of-sale (POS) systems Inventory management software Customer relationship management (CRM) systems)

Sales and Marketing Acumen (Customer segmentation and targeting, Marketing principles and techniques Sales strategies Advertising and promotion Online marketing and social media) Customer-Centric Approach (Customer relationship management (CRM) systems) Customer feedback mechanisms, Service excellence training Complaint resolution processes Customer loyalty programs Networking strategies Communication and interpersonal skills Public speaking and presentation skills Community engagement Market trend analysis

# Ethical and Adaptive Practice

(This area emphasises the importance of ethical conduct and adaptability in a changing environment. Leadership and Teamwork skills, interprofessional collaboration emphasised.) Adaptability and Innovation

(Change management principles, Innovation strategies
Legal and Ethical Business Practices (Pharmacy laws and regulations)
Ethical principles in business
Corporate social responsibility
Data privacy and security
Intellectual property protection
Conflict of interest management
Communication and interpersonal skills
Conflict resolution and negotiation

- Performance management and feedback
- Interprofessional Collaboration:

(How business acumen informs and enhances the pharmacist's role in interprofessional teams, promoting optimised patient care within ethical and sustainable frameworks)

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **QUALITY MANAGEMENT SYSTEMS**

AAC 7.4 Effective quality management systems are observed through the examination of their components and mitigation strategies are proposed/outlined to protect patient safety, prevent medication errors, and address adverse events as appropriate to the practice sector.

# **Curriculum Outline:**

### SUB-KNOWLEDGE FIELDS

Foundations of Quality and Compliance

(This area focuses on understanding regulatory frameworks, documentation standards, ethical conduct, and risk management principles essential for effective QMS.)

### **Operational Quality Assurance**

(This area focuses on implementing standardised procedures, ensuring staff competency, and maintaining facilities/equipment to support medication safety and quality.)

# Patient/Customer-Centred Quality and Risk Mitigation

# DETAILED KNOWLEDGE FIELDS

SAPC Rules pertaining to the ethical and professional practice of pharmacy Compliance with regulations - Ethical and professional conduct - Good Documentation Practices (GDP) Internal Audits Data Integrity Key Performance Indicators (KPIs) – Root Cause Analysis (RCA) Quality Assurance

Standard Operating Procedures (SOPs) -Personnel training, competence, and assessment-Competency assessment of the workforce Document Control and record keeping Facility and equipment maintenance Medication storage and handling Medication traceability (Batch number) Supplier Quality Management Self-inspection assessment process

Patient counselling and education Patient privacy and data security - Medication error prevention

137

(This area focuses on emphasising the significance of ethical and professional conduct, patient privacy and data security, patient counselling and education, and feedback mechanisms in delivering patientcentred care, as well as reduce risk and mitigate it.)

Emergency preparedness Customer feedback and complaint handling Risk management Incident Management Medication Safety Culture, Safety and Vigilance Reporting Adverse Drug Reaction (ADR) Medical Device Reporting Systems Ethical and professional conduct, Medication storage and handling, Medication traceability, Customer feedback and complaint handling, Patient privacy and data security, ADE reporting.

Continuous Improvement and Monitoring (This focuses on the ongoing process of improving and optimising pharmacy practices. Internal and external audits, Quality Improvement Plan, Process Validation, Quality risk management, Data analysis and performance measurement. This group highlights the significance of QMS in Pharmacy practice with ongoing monitoring and auditing.) Quality and safety of medicines, Staff training and competency, Continuous improvement, Customer feedback and complaint handling, Emergency preparedness: Pharmacovigilance

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# **EXIT-LEVEL OUTCOME 8**

In managing learning and incorporating critical reflection into the application of effective learning strategies, as well as addressing ongoing professional learning needs for themselves and others, a learner is able to:

8.1. Demonstrate the capacity to develop and provide appropriate health care education to health care professionals and to patients as and when necessary.

8.2. Demonstrate an ability to critically reflect on learning needs and apply learning strategies to address continuing professional development of self and others effectively.

# **HEALTHCARE EDUCATION PROGRAMMES**

Associated Assessment Criteria (AAC):

AAC 8.1 The effectiveness of a health care education programme implemented in a pharmacy setting is analysed and evaluated for its impact on the knowledge, skills, and attitudes of health care professionals and patients.

### Curriculum Outline:

#### SUB-KNOWLEDGE FIELDS

Interprofessional collaboration (transdisciplinary, intra-professional collaboration) (This area focuses on integrating teamwork, communication, and collaboration among healthcare professionals to enhance shared decision-making.)

Interprofessional Education and Collaborative Practice

# Comprehensive Medication Management and Optimisation

(This area focuses on equipping healthcare professionals with advanced knowledge and skills in medication therapy management and the safe, rational use of medicines.)

# Targeted Education for Special Populations

(This area focuses on addressing the unique therapeutic challenges and considerations in special populations, with a focus on evidence-based approaches.)

### DETAILED KNOWLEDGE FIELDS

Teamwork, communication, and collaboration among healthcare professionals from different disciplines, such as pharmacists, physicians, nurses, and allied health professionals Understanding the different definitions of (transdisciplinary, intra-professional collaboration) Development of shared decision-making frameworks to improve patient outcomes Clinical skills: Practical training in skills relevant to medication administration, medicine calculations, and sterile compounding

Simulation-based education to develop proficiency in managing real-world scenarios Detailed instructions on medication therapy management, including pharmacokinetics, pharmacodynamics, medicine interactions, an

pharmacodynamics, medicine interactions, and medication safety.

Integration of technology (e.g., medication management systems) to optimise therapeutic outcomes.

Medication review

Addressing the unique therapeutic challenges and considerations in special populations, with a focus on evidence-based approaches. Training on reporting and documentation systems for adverse medicine reactions, medication errors, and pharmacovigilance. Integration of regulatory and ethical principles. Medication review.

Focus on deprescribing and reducing polypharmacy in chronic disease management.

# Proactive Risk Management and

Medication Safety (This area focuses on enabling healthcare professionals to proactively mitigate risks associated with medication use and adverse events.)

# Culture and Health Promotion

(This area focuses on building strong relationships through culturally sensitive communication and strategies designed to promote health behaviour change.) Training on reporting and documentation systems for adverse medicine reactions, medication errors, and pharmacovigilance. Focus on deprescribing and reducing polypharmacy in chronic disease management. Integration of regulatory and ethical principles. Medication review.

Strategies to adapt educational materials and delivery methods for varied cultural and socioeconomic contexts.

Strategies to adapt educational materials and delivery methods for varied cultural and socioeconomic contexts.

Leveraging digital tools, virtual simulations, and online platforms to enhance the accessibility and scalability of education programmes Training in telehealth and remote patient education techniques

**APPLIED FIELDS IN PHARMACY:** Pharmacy Practice; Clinical Pharmacy Practice; Pharmaceutics; Pharmaceutical Chemistry; Pharmacology.

# HEALTHCARE PRINCIPLES AND PATIENT EDUCATION TECHNIQUES

AAC 8.2 The contextual understanding and knowledge of healthcare principles and patient education techniques are demonstrated through practical and real-life scenarios.

# **Curriculum Outline:**

# SUB-KNOWLEDGE FIELDS

# DETAILED KNOWLEDGE FIELDS

# HEALTHCARE PRINCIPLES

Patient-Centred Care Communication (This area focuses on emphasising patient needs and effective communication strategies to provide personalised and respectful pharmaceutical care.)

Patient-centred care Effective Communication: Verbal & Non-verbal Health literacy: Assessing understanding, tailoring information

### Professionalism, Ethics, and Collaboration (This area focuses on promoting ethical conduct and effective teamwork among healthcare professionals to ensure responsible patient care.)

# Evidence-Based Practice and Health Promotion

(This area focuses on integrating evidence-based research and health promotion techniques to improve patient health outcomes and prevent disease.)

# Patient Education Techniques and Teaching Material Development

(This area focuses on providing education and training to the patients to help them understand more about how to manage and treat their conditions) Cultural Competence: Sensitivity to diverse backgrounds Medication counselling Behavioural change techniques

Ethics and professionalism (Confidentiality, privacy, POPIA, informed consent). Interprofessional collaboration Feedback and evaluation: Improving techniques and materials Behavioural change techniques: Using patientcentred counselling to motivate change

Evidence-Based Practice: Critically appraising literature, interpreting findings, applying guidelines Health Promotion and Disease Prevention: Identifying risk factors, lifestyle modifications, immunisations, screening

Evaluating patients' understanding of health information.

Tailoring communication to the patient's health literacy level, using visual aids, and reinforcing key messages

Using patient-centred counselling techniques to motivate behaviour change

Patient-friendly educational materials

Ensuring that materials are culturally sensitive, easy to understand, and available in multiple formats.

Identifying risk factors and opportunities for prevention.

Educating patients on lifestyle modifications, immunisations, and screening.

Using feedback to improve educational materials and techniques

Teaching materials development

Feedback and evaluation

# **CONTINUING PROFESSIONAL DEVELOPMENT (CPD)**

AAC 8.3 Personal and professional growth areas are identified through self-reflection and well-rounded continuing professional development (CPD) plans for themselves, and team members are guided in the development of individual improvement plans, taking into consideration personal styles, goals, and professional responsibilities.

# **Curriculum Outline:**

### SUB-KNOWLEDGE FIELDS

### DETAILED KNOWLEDGE FIELDS

SAPC\_GPP Guidelines and Rules regarding CPD CPD Guidance Document

CPD Principles and Requirements (This area focuses on understanding and adhering to the foundational guidelines and regulations governing CPD for pharmacists in South Africa.)

Critical Self-assessment Skills (This area focuses on developing critical selfassessment skills to identify individual learning needs and professional growth areas.)

Mentorship and Guidance for CPD (This area focuses on guiding pharmacists and other pharmaceutical support personnel to enhance their competencies.) The CPD cycle Submitting CPDs Compliance with CPD requirements Planning for CPD

Self-reflection and critical self-assessment skills maintaining competence, metacognition, professional audit of self and group (professional audit, which is the study of the structure, process or outcome of pharmacy practice carried out by individual pharmacists, groups of pharmacists or groups of health care practitioners, to plan and prepare and to measure the degree of attainment of agreed objective)

Training pharmacists to become effective mentors and guides for CPD Developing skills to create personalised CPD plans that consider individual learning styles and professional responsibilities. Incorporating professional audits as a tool for group reflection and improvement.

# **EXIT-LEVEL OUTCOME 9**

Take responsibility for his/her own work, demonstrate judicious decision-making and the efficient use of resources in various pharmacy contexts and accept accountability for both individual and team decisions and actions. – suggest hyperlinking of this ELO together with its AACs.

# MEDICAL ETHICS\_ THE SAFE AND RATIONAL USE OF MEDICINE

Associated Assessment Criteria (AAC):

AAC 9.1 Full accountability and ethical decision-making is applied to the safe and rational use of medicine in the practice of pharmacy.

### Curriculum Outline:

### SUB-KNOWLEDGE FIELDS

Professional Conduct in Rational Medicine Use

(This area focuses on applying ethical principles to ensure patient safety and effective medicine management.)

# Pharmaceutical Waste Management & Environmental Responsibility

(This area focuses on understanding the environmental impact of pharmacy practices in all sectors and ensuring responsible waste disposal.)

### DETAILED KNOWLEDGE FIELDS

# Also see ETHICAL AND LEGAL ISSUES

Control and prevention of counterfeit medicine sale and resale of medicines to patients, medicines misuse,

Understanding the principles of CCMDD Preventing harm from medicines - GPP guidelines and other resources, e.g. FIP Professional conduct regarding the sale of cigarettes, alcohol etc in pharmacies Storage and handling of hazardous substances Control of substances, medical devices and medicines sold in a pharmacy

### Disposal of medicines

API and FPP manufacturing; management and proper disposal of waste, solvents and byproducts in terms of hygiene and prevention of contamination and pollution of the environment

Appearance of the area (manufacturing, wholesale and pharmacy/dispensary)

•

# MEDICAL ETHICS\_ ETHICAL AND LEGAL RESPONSIBILITIES OF A PHARMACIST

AAC 9.2 The ethical and legal responsibilities of a pharmacist in pharmacy practice are acknowledged and applied in accordance with professional and ethical standards, regulations, and the professional code of conduct.

### **Curriculum Outline:**

### SUB-KNOWLEDGE FIELDS

Professional, Ethical and Legal Accountability in Pharmacy Practice (This area focuses on adhering to ethical and legal standards governing the pharmacist's conduct and patient care.)

Self-Care Model in Pharmacy Practice (Focus on pharmacist-guided empowerment of patients to manage their own health within the ethical and legal framework of pharmacy practice)

## DETAILED KNOWLEDGE FIELDS

**See** ETHICAL AND LEGAL ISSUES Exercising professional autonomy without infringement of the patient's right

Educate and prepare patients to be knowledgeable and well-informed and have the skills to manage their own health

