BOARD NOTICES • RAADSKENNISGEWINGS

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THE SOUTH AFRICAN PHARMACY COUNCIL

BACHELOR OF PHARMACY - INTEGRATED CURRICULUM OUTLINE

The South African Pharmacy Council hereby published for **implementation** 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).

SCHEDULE: Bachelor of Pharmacy - Integrated Curriculum Outline

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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

FOREWORD

The advancement of health care 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. This curriculum comprises of a solid theoretical basis as well as a work-integrated learning (WIL) component, including work-based learning (WBL). 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

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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:

- (i) 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 Standard¹. They further align with the South African Pharmacy Council (SAPC) competency standards for pharmacists², as well as the South African Qualification Authority (SAQA) level descriptors³ 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

¹ CHE. Qualification Standard for Bachelor of Pharmacy, 2022.

² SAPC. Competency Standards for Pharmacists in South Africa, 2018

³ 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 assessed⁴.

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 qualification⁵ as follows:

⁴ SAQA. Guidelines for the Development and Evaluation of Qualifications and part-qualifications for Registration on the National Qualifications Framework, 2023.

⁵ 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 (including medical and pharmaceutical microbiology), biochemistry, mathematics and statistics, physics, physiology, pathology, 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.

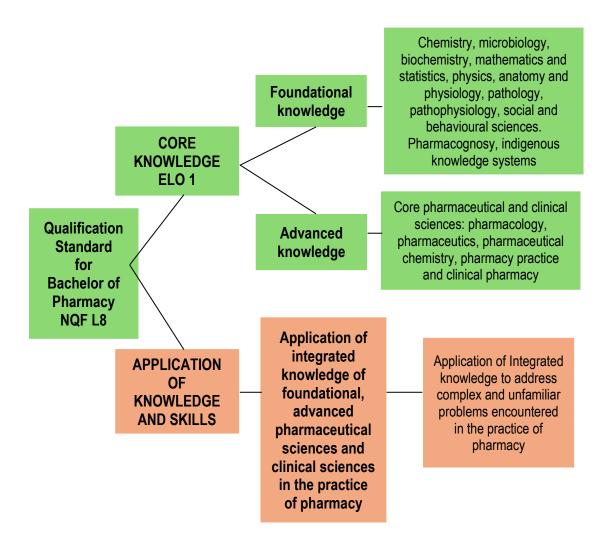


Figure 1: Schematic diagram of the curriculum outline

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 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.

CREDIT ALLOCATION

The statutory credit and level structure is prescribed by the Higher Education Qualifications Sub-Framework (HEQSF). A 480-credit professional bachelor's degree (NQF Level 8) – e.g. BPharm – represents a higher cognitive level with greater learning volume and prepares graduates for master-level study.

For the BPharm degree, 120 credits are required at NQF Level 8. The credit guideline provides framework-level allocations – not prescriptive module-level breakdowns. Each university retains autonomy in designing its teaching modules, provided the total credit structure and programme design meets national requirements, i.e. HEQSF, SAPC Qualification Standard for the BPharm and the Competency Standards for Pharmacists. The HEQSF defines a standard full-time academic year as 30 weeks; thus, the credit load (i.e., workload) should reflect the notional study time expected at the national level.

The allocation of credits across the Bachelor of Pharmacy (BPharm) curriculum is designed to promote a balanced representation of all knowledge fields in line with national expectations for professional training and the requirements of the Higher Education Qualifications Sub-Framework (HEQSF) Credit distribution reflects the integrated nature of pharmacy education, combining foundational, core, applied, and research components that together support the development of comprehensive professional competence.

The credit allocation supports comprehensive coverage of all knowledge fields across the curriculum (breadth) while providing adequate focus and rigour within specialised areas of study (depth), and at the same time allows Higher Education Institutions the flexibility to design and structure their learning programmes in a manner that best aligns with their teaching context and resources.

Foundational knowledge of Cognate Sciences

An allocation of 120 credits to foundational knowledge of the cognate sciences is suggested as a guideline. A specific requirement is that a minimum of four (4) credits is allocated to each foundational knowledge field, chemistry, microbiology (including medical microbiology), pharmaceutical microbiology, biochemistry, mathematics and statistics, physics, anatomy, physiology, pathology, pathophysiology, pharmacognosy (including indigenous knowledge systems) and behavioural sciences, ensuring students are firmly grounded in the cognate sciences.

This credit allocation includes fundamental academic competencies supporting success in higher education, such as literacy, numeracy, computer literacy and life skills.

Advanced knowledge of core disciplines

With respect to advanced knowledge of the core pharmaceutical and clinical sciences, 290 credits are allocated, with no less than forty (40) credits to be assigned to each of the following disciplines: pharmacology, pharmaceutics, pharmaceutical chemistry, pharmacy practice, and clinical pharmacy, promoting professional depth and competency.

Research

Research is a compulsory component of the 480-credit BPharm (NQF Level 8) degree. Students must complete a discrete, supervised research project of at least worth at least thirty (30) credits. This is intended to prepare graduates for progression to master's-level study by providing them with research capacity in the methodology and research techniques of pharmacy and the related pharmaceutical and clinical sciences.

Work-Integrated Learning

Work-Based Learning (WBL) credits are assigned according to current WBL guidelines, which require forty (40) credits, ensuring experiential training reflects contemporary pharmacy practice and maintains national consistency.

If the total number of credits of a programme exceeds the minimum total of 480 credits prescribed in the HEQSF for a professional bachelor's degree, the excess may not exceed ten percent (10%), and institutions must justify the extra credit as proportional to actual study time within a standard thirty (30)-week full-time academic year. Implementation of this guideline applies to knowledge fields or fields of learning and not to specific modules or subjects. Each higher education institution remains responsible for designing its own learning programme and associated modules, ensuring progressive alignment from NQF Levels 5 to 8 under the appropriate Classification of Educational Subject Matter (CESM) codes.

The following table provides a summary of the general guidelines for credit distribution across the Bachelor of Pharmacy qualification:

Table 1 Summary of general guidelines for credit distribution across the Bachelor of Pharmacy qualification

| Knowledge Field | Minimum Credits |
|---|-----------------|
| Foundational Knowledge of Cognate Sciences | 120 |
| Core Pharmaceutical and Clinical Science (Integrated Applied Knowledge and Skills) | 290 |
| Research | 30 |
| Work-Based Learning (WBL) | 40 |
| Total | 480 |

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 (including medical and pharmaceutical 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 (also see sections on COMPOUNDING AND MANUFACTURING OF MEDICINES under Application of Knowledge and Skills). |

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)

States of matter

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

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

(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 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)

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

Acids and Bases

(This area focuses on acid-base concepts, calculations, and their

Bronsted-Lowry concept Lewis acids and bases Autoionisation of water relevance to medicines, buffers, and pharmaceutical formulations)

pH scale

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)

Redox reactions Half reactions

Electrochemical cells

Nuclear Chemistry

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

radiopharmacy and medicine)

Nature of radioactivity Nuclear reactions

Stability of atomic nuclei

Rates of disintegration reactions

Applications of radioactivity in radiopharmacy.

Laboratory Safety

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

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

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)

Disposal of chemicals

Pollution

Also see the section on DESTRUCTION AND/OR 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 Amino acids, protein structure (primary, secondary, (This area focuses on the molecular structure tertiary and quaternary), properties of proteins, and function of biomolecules critical to classes of proteins pharmaceutical science) 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 Overview of energy in the body: **Biochemical Energetics** (Explores energy production and utilisation in ATP, ADP, AMP. biological systems, relevant to drug Citric acid cycle, respiratory chain, oxidative metabolism) phosphorylation Glycogen metabolism, β-oxidation, cholesterol Metabolism & Metabolic Pathways biosynthesis, urea cycle, drug-food interaction (This area focuses on examining metabolic pathways of carbohydrates, lipids, and Carbohydrates, glycogen metabolism, glucose nitrogen compounds for drug design) 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**PHARMACOLOGY (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)

Static Fluids

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

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)

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

Radioactivity and Radiation

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

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

lonising and non-ionising radiation, particulate radiation

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)

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

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)

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 Radiation

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 |

SUB-KNOWLEDGE FIELDS

DETAILED KNOWLEDGE FIELDS

methods)

Inverse functions (definition, derivation of natural log, range)

Analysis of functions (local extrema, intervals of 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, pharmaceutical processes, and understanding accumulation and decay phenomena)

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)

Probability and Statistics

(This area focuses on basic principles to support clinical trial design, drug safety analysis, interpretation of experimental data, and evidence-based pharmacy practice) 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 | Cardiovascular system Lymphatic system and Immunity Respiratory system |

(This area focuses on the continuity and addresses cardiovascular, respiratory, and reproductive systems for drug efficacy) 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

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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

DETAILED 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)

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

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)

Bone tissue Articulations The skeletal system Muscle tissue The muscular system

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

Nervous tissue Spinal Cord and Spinal nerves Brain and Cranial nerves Sensory, Motor, and Integrative Systems function in homeostasis, nutrition, movement and general senses and integration with each other, with a specific focus on the following organ systems: (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)

Special senses Autonomic Nervous System Endocrine System

Maintenance of the Human Body

Fluid, electrolyte, and acid-base homeostasis

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)

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

Continuity

(This area focuses on the physiological processes of continuity, including reproduction, development, inheritance, and related pathophysiological disorders)

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

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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)

> Hypertension: pathogenesis, complications, and pharmacological management.

Atherosclerosis and ischemic heart disease.

Heart failure and cardiomyopathies.

Thromboembolic disorders and anticoagulant therapy.

Cardiovascular System Pathology

(This area focuses on diseases of the cardiovascular system and their pharmacological management.)

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

(This area focuses on disorders of the blood and lymphatic systems, including anaemias and coagulation disorders) Anaemia (iron deficiency, megaloblastic, hemolytic). Coagulation disorders (hemophilia, disseminated intravascular coagulation).

Nervous System Pathology

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

Neurodegenerative diseases (Alzheimer's, Parkinson's, multiple sclerosis). Epilepsy and seizure disorders. Stroke and cerebrovascular disorders. Psychiatric conditions (depression, schizophrenia).

Musculoskeletal System Pathology

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

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

Immune System and Infectious Diseases

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

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).

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

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

Oncology and Neoplasia

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

Basic principles of cancer pathogenesis.

Common cancers (lung, breast, colorectal, prostate).

Tumour markers and principles of chemotherapy.

Dermatological Pathology

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

Pharmacological Considerations in Systemic Pathology

(This area focuses on drug selection, drugdisease interactions, and the impact of disease Drug selection based on disease pathophysiology. Impact of systemic diseases on drug absorption, metabolism, and excretion.

Drug-disease interactions and contraindications.

on drug pharmacokinetics and pharmacodynamics)

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** The nature of disease, its disruption of homeostasis Introduction and Basic Concepts of in the human body. **Disease Processes** Aetiology and risk factors of diseases. (This area focuses on the nature, causes, and Concepts of adaptation, compensation, and cellular basis of disease, including disruption of decompensation. homeostasis and adaptation mechanisms) 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

Skin pathology

Infectious Diseases Pathophysiology and Antimicrobial Stewardship

(This area focuses on pathogen-host interactions, immune responses, systemic effects of infection, and antimicrobial stewardship.)

Virulence factors of bacteria, viruses, fungi, and parasites.

Mechanisms of invasion, colonisation, and tissue damage.

Pathogen-Host Interactions

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.

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)

Critically appraise literature on antimicrobial use and resistance.

Apply evidence-based prescribing guidelines.

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

Emerging Areas in Pathology

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 | DETAILED KNOWLEDGE FIELDS |
|---|---|
| Prokaryotic Cell Structure and Function, Basic Principles (This area focuses on the differences between prokaryotic and eukaryotic cells, including | Differences between prokaryotic and eukaryotic cells, basic principles Gram reactions, 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. | 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 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 Control of Microorganisms by Physical & Chemical Agents

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

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.

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

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

Fungi

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

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.

Protists

(This area focuses on the classification, nutrition, morphology, reproduction, and parasitic infections caused by protists) Different divisions of the organisms into groups Their nutritional patterns

Their morphological structures, reproduction patterns and habitats

Parasitic infections

Medical Parasitology

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

From protozoa to complex human parasites

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 | DETAILED 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. |

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) Injectables, ophthalmic, and surgical devices, etc.

Microbial Contamination Control

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

Prevent contamination during the manufacturing process.

Designing cleanrooms, controlling air quality, and monitoring microbial presence.

Antiseptics, Disinfectants, and Preservatives

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

Antimicrobial Effectiveness Testing

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

Bioburden Testing

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

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

Endotoxin Testing

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

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

Antibiotic Potency Testing

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

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

Pharmaceutical Water Testing

(This area focuses on testing water used in pharmaceutical manufacturing for microbial contamination) 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)

Conducting studies to validate processes that ensure aseptic conditions during the manufacturing of sterile products.

Validation studies and protocols

Applications of Pharmaceutical Microbiology

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

Quality and safety of medicines.

Developing and testing antimicrobial agents.

Compliance with regulatory guidelines and standards.

Manufacturing of sterile medicines

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

Industrial pharmacy and cleanliness control. Product contamination prevention and sterilisation.

Design of the sterilisation process Sterilisation methods

Manufacture of Antibiotics

(This area focuses on antibiotic production, alternatives, and the role of microorganisms in medicine manufacturing)

Antibiotic production methods: Natural fermentation, semi-synthetic (e.g., ampicillin, methicillin), and synthetic (e.g., quinolones). Antibiotic alternatives: Development of non-antibiotic 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 (This area focuses on modern and traditional | Solvent extraction, distillation, and maceration Chromatography (TLC, HPLC, GC) Spectroscopic identification (UV-Vis, IR, NMR, |

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 medicin:

(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

(This area focuses on identifying risks, contraindications, and safe use of traditional and natural medicines)

Acute/chronic toxicity testing
Herb-drug interactions
Allergenicity assessments
Traditional safety practices (dosage protocols, detoxification methods in IKS)

Formulation Development and Regulatory Compliance

(This area focuses on translating natural compounds into safe, effective dosage forms while respecting legal and cultural frameworks)

Conventional formulations (tablets, capsules, tinctures)

Traditional dosage forms (powders, ointments, teas)

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 | DETAILED KNOWLEDGE FIELDS |
|--|---|
| Traditional Practices (This area focuses on the foundational principles and methods of traditional medicine in South Africa) | Overview of traditional healing practices |
| Collaboration with Traditional Healers (This area focuses on interdisciplinary collaboration and respectful engagement with traditional healers in patient care) | Strategies for effective collaboration |
| Relevant Laws, Regulations, and Ethical | National and provincial laws |
| Guidelines | Regulations Ethical guidelines |
| (This area focuses on the legal and ethical framework governing traditional medicine in South Africa) | Ethical guidelines |
| Collaboration with Traditional Healers | |
| Relevant laws, regulations, and 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

DETAILED KNOWLEDGE FIELDS

Classification of Medicines

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

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

Pharmacokinetics

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

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

Also see sections:

PHARMACOKINETICS IN DRUG DEVELOPMENT

Pharmacodynamics

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

Agonists, antagonists, partial agonists
Dose-response curves
Signalling mechanisms (neurotransmitters,
ANS)
Hypersensitivity, tolerance, patient-specific
factors

Therapeutic Use and Clinical Applications (This area focuses on evidence-based drug therapy across physiological systems)

Also see sections:

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

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

Medicine Interactions

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

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

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

Genetic principles (DNA/RNA/protein synthesis)

Variability in metabolising enzymes/targets Pharmacogenomic applications

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)

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

Also see sections:

RESEARCH IN HEALTH SCIENCES (Legal and Ethical Considerations)
GOOD RESEARCH PRACTICE (GRP)

Emerging Research

(This area focuses on cutting-edge developments in neurological/psychiatric drug discovery)

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)

Scope of practice

Relation to pharmacotherapy

Patient-centred care

DETAILED KNOWLEDGE FIELDS

Patient pharmaceutical care plan

Patient pharmaceutical care plan as

informed by the scope of practice

Medication Reviews and Management

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

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 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

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

Ophthalmology

Ear, Nose and Throat (ENT)

Dermatology

Diagnostic tests

Pharmacoepidemiology (also see PP)

Patient counselling and education

Indications

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)

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, sedative-

hypnotics, 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

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

Special Topics: Special Topics in Clinical Pharmacy

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

Therapeutic Drug monitoring (TDM) Therapeutic Drug Monitoring (TDM) Pharmacokinetics Toxicology and pharmacovigilance

Poisoning and treatment Endocrine and reproductive system pharmacotherapy

Diabetes management

Also see the 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)

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 PHARMACY PRACTICE (Communication)

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

Medical devices use Diagnostic devices and result interpretation interpretation of medical and diagnostic devices in patient care)

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)

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

Pharmacogenetics

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

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 PV

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

See also the section on MEDICINE SAFETYASSESSMENT PROCESSES

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,

Incompatibility and stability (chemical basis)

Also see the sections in: COMPOUNDING

AND MANUFACTURING OF MEDICINES

and delivery of complex and specialised pharmaceutical formulations)

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 their 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

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

Identifying evidence, Identifying and assessing evidence

(This area focuses on the identification, appraisal, and application of clinical evidence and the implementation of quality improvement initiatives)

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)

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

Worldoning and Evaluation

Adverse Event Reporting (AER) Compliance with regulations

Medicines Governance

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

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>

Other Specific Applied Fields in Pharmacy: Pharmacy Practice

Continuing Professional Development (CPD)

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

ISSUES (confidentiality, Integrity, etc.)



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 | DETAILED 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) | Principles in the design of pharmaceutical products, including: Physicochemical principles States of matter Dissolution, solubility Interfacial phenomena Solid state properties Rheology, colloids, dispersions Micromeritics |
| Routes of Administration and Dosage Forms | The various routes of administration, including the oral, parenteral, rectal, respiratory, sublingual, topical |

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

and vaginal routes, their advantages and disadvantages and applications in pharmaceutical therapy.

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.

Excipients (Inactive Pharmaceutical Ingredients)

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

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

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

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

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)

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 the 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 <u>DRUG /MEDICINAL PRODUCT STABILITY</u>

Transportation, Distribution (Cold chain)

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

Stability testing
Shelf-life estimation

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

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

Industrial Pharmaceutics and GMP

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

Also see sections on: GOOD MANUFACTURING PRACTICES (GMP);

Medicine Registration is covered under Regulatory Approval and Compliance.

Also see section REGULATORY APPROVAL AND COMPLIANCE; COMPOUNDING AND MANUFACTURING OF MEDICINES; QUALITY MANAGEMENT SYSTEMS



APPLIED FIELDS IN PHARMACY: Pharmaceutics

PHARMACEUTICAL CHEMISTRY

Curriculum outline:

| SUB-KNOWLEDGE FIELDS | DETAILED 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) | 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.) |

Also see sections - Advanced Drug Discovery

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 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 LABORATORY TESTING AND GLP AND GCP

Clinical Studies (introduction to clinical trials as part of the drug design process). **Also see sections on TOXICITY STUDIES**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 PHARMACOLOGY and CLINICAL PHARMACY, medicines identified per system, Inorganic medicines
Natural products - Also see INDIGENOUS KNOWLEDGE SYSTEMS

Medicinal Chemistry (This area focuses on the structural features,

functional groups, and pharmacodynamic interactions that determine the activity and safety of major medicine classes)

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 HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC); DNA SEQUENCING AND GENOTYPING; MASS SPECTROSCOPY

Other Applied Fields in Pharmacy: Pharmaceutics

Stability of Medicines and Common Degradation Reactions

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

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, π – π interactions, 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 and acidbase properties

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

Molecular weight, size, stereochemical configuration (**see section** in CHEMISTRY) and conformational flexibility pKa 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

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

hepatotoxicity, idiosyncratic reactions, chemical

carcinogenesis

Stereochemistry and medicine metabolism

Prodrugs

The effect of functional groups on the ADME

properties of medicines

The effect of physicochemical properties and molecular structure on the safety and toxicity profile of medicines

Medicine-Medicine interactions Metabolic bioactivation and role in hepatotoxicity, idiosyncratic reactions, chemical 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

Principles of biotechnology-derived medicines, e.g. MABs

Principles of pharmacogenetics, genomics, transcriptomics,

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

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

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

G-protein coupled receptors Nuclear receptors Ion channel receptors

Enzyme / catalytic receptors

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 efficacy)

See section in PHARMACOLOGY and CLINICAL PHARMACY. 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:

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

CLINICAL PHARMACY - ETHICAL ISSUES

ETHICAL & LEGAL ISSUES

LEADERSHIP STRATEGIES

INTERPROFESSIONAL COLLABORATION

HEALTHCARE PRINCIPLES AND PATIENT

EDUCATION TECHNIQUES

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 CONTINUING
PROFESSIONAL DEVELOPMENT (CPD)

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) 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

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) 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> MEDICINES

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

use of medicines.

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

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

Patient Assessment and Clinical Reasoning (This area focuses on the systematic approach to patient evaluation, diagnosis, and shared decision-making in pharmacy practice)

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

Also see sections on:

<u>POINT-OF-CARE TESTING</u> - definition and different tests
Shared decision making

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

Understanding the considerations and steps in prescribing medications.

Components and significance of a well-structured prescription.

Also see the section on DISPENSING OF MEDICINES AND PHASES AND THE DISPENSING PROCEDURE

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)

Also see section on: PHARMACIST-INITIATED THERAPY (PIT)

Pharmacogenomics and Pharmacoeconomics

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

Basic economic concepts
Types of pharmacoeconomic evaluations
Cost minimisation analysis
Cost-benefit analysis, Cost-effectiveness
analysis

Cost-utility analysis

Modelling in Pharmacoeconomics

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)

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 : 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)

Good Pharmacy Practice (GPP) Manual and

Associated SAPC Rules
Quality Improvement Plan

Role of the Responsible Pharmacist (RP)

Pharmacy Business Management

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 (This area focuses on the provision and management of clinical pharmacy services and value-based care models)

Point of care screening and monitoring Immunisation and injections

Baby-care services

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 - COST-EFFECTIVENESS

AND FEASIBILITY OF MEDICATION

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 non-

medicinal 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: MODERN

TECHNOLOGIES IN PHARMACY

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 contribu-

(This area focuses on the pharmacist's contribution to primary healthcare and research in pharmacy practice)

Introduction to primary healthcare
Also see sections on: PRIMARY

HEALTHCARE (PHC) - Introduction to primary

healthcare

Pharmacy Practice Research

Other Applied Fields in Pharmacy: Clinical Pharmacy.

Pharmacy Practice Research Also see sections on: RESEARCH IN HEALTH

SCIENCES

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: <u>CONTINUING</u>
PROFESSIONAL DEVELOPMENT (CPD)

4

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



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) | Biological targets Pharmacodynamics: Efficacy, Potency, Therapeutic index, Mechanism of action, Structure activity relationships (SAR) |
| Also see sections in: PHARMACOLOGY, CLINICAL PHARMACY) | Absorption, Distribution, Metabolism and Excretion (ADME), Patient-related parameters: pharmacogenomics, age, gender, comorbidities, lifestyle factors, medicine interactions, adverse effects |



Specific Applied Fields in Pharmacy: 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, access to clinical and laboratory records)

Safe and Rational, and Cost-Effective Use of Medicine

(This area focuses on evaluating medication appropriateness and optimising dosing, especially in special populations)

Medication appropriateness
Dose optimisation
Avoiding therapeutic duplication
Monitoring parameters (clinical, laboratory, outcomes, adherence)
Also see sections on:

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

Medication-Related Problem Identification and Management

(This area focuses on systematic identification, documentation, and resolution of medication-related problems)

Therapeutic Duplication

Mechanism of Action (MoA)

Guidelines to prevent therapeutic duplication within organisations to ensure patient safety

Medicine classes (therapeutic)

Monitoring Parameters

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

Documentation and Records

As per GPP

Identification of Medication-related Problems

Patient assessment

Classification: improper medicine selection, untreated condition, dosage subtherapeutic or too high, ADR, medicine interaction, non-

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 the 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

Collaborative Care and Documentation (This area focuses on interprofessional collaboration, communication, and documentation for optimal patient care)

Interprofessional collaboration and communication Identifying and managing or triaging health-related 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 | DETAILED KNOWLEDGE FIELDS |
|--|--|
| Implementation of GPP and SAHPRA Pharmacovigilance Standards (This area focuses on regulatory compliance and the promotion of medicine safety through effective pharmacovigilance) | SAPC GPP rules SAHPRA pharmacovigilance standards and guidelines |
| Medicine Safety Assessment and Management (This area focuses on processes for monitoring, assessing, and managing medicine safety and adverse events) | Medicine safety assessment Data collection and reporting systems Regulatory compliance (SAER, AEFI) |
| Signal Management and Risk Assessment (This area focuses on detecting, evaluating, and managing safety signals and risks associated with medicines) | 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 Monitoring and Quality Assurance (This area focuses on ongoing safety monitoring and the integration of pharmacovigilance into quality management systems) | Continuous data collection and interpretation Medication reconciliation Quality assurance and post-marketing surveillance |
| SAHPRA Pharmacovigilance standards and guidelines | |
| Medicine Safety Assessment Processes | See sections in PHARMACY PRACTICE |
| Patient Medication Management | Medicine (drug) Therapy Problem – resolution Medicine review |
| Data collection Reporting systems Documentation Regulatory compliance | Serious Adverse Event Reporting (SAER), Adverse Events After Immunisation (AEFI) reporting Regulatory Reporting Requirements |
| Signal Management | Signal detection: Identifying signals or potential safety concerns through the analysis of aggregated safety data |
| Communication and information dissemination | 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

Also see CONTINUING PROFESSIONAL

(CPD) <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.

| SUB-KNOWLEDGE FIELDS | DETAILED KNOWLEDGE FIELDS |
|--|--|
| Medical Device Classification and Regulation (This area focuses on understanding regulatory categories and compliance for medical devices in pharmacy) | SAHPRA device classes (low to high risk) Combination Products (medical device) |

Current Good Pharmacy Practice Rules & Guidelines

Classes of medical devices (SAHPRA) – main classes:

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

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

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

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

Diagnostic Principles and Test Interpretation

Specificity Sensitivity

Reference ranges

Potential sources of error

Screening and early detection, patient

monitoring

Monitor certain health parameters of patients

Wearable Devices

(This area focuses on the use of wearable health technology and mobility aids to support patient care

See cGPP

Smartwatches with Health Monitoring Features

Continuous Glucose Monitors (CGMs)

connected to a phone/laptop

Wearable Blood Pressure Monitors

Wearable ECG Monitors

Smart Patches and Bio-Sensors

Activity Trackers for Monitoring Movement and

Sleep

Wearable Respiratory Monitors

Wearable Pain Management Devices

Smart Glasses for Augmented Reality (AR) in

Pharmacy Practice

Used for training pharmacists and in complex medication dispensing tasks.

Potential for assisting pharmacists with 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.

| SUB-KNOWLEDGE FIELDS | DETAILED KNOWLEDGE FIELDS |
|---|---|
| Current Good Pharmacy Practice Rules & Guidelines (GPP) | 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 PHARMACY PRACTICE

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) **Also see the section** on MEDICATION

THERAPY MANAGEMENT

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.

| SUB-KNOWLEDGE FIELDS | DETAILED KNOWLEDGE FIELDS |
|--|--|
| Regulatory Framework and Scope of PIT (This area focuses on the legal and professional guidelines governing PIT and the pharmacist's scope of practice.) | 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 |
| Scope of Practice of a Pharmacist and Pharmacist Support Personnel | See Practice Regulations to the Pharmacy Act See regulation GNR1158 |
| Primary care interventions | Minor ailments that pharmacists are able to 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 |
| 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.) | 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 Substances Act |
| 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.) | 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.)

Interprofessional communication and referral processes, Integration of PIT with other healthcare services

Continuity of care in PIT

Continuity of care in Fit

Collaborative practice agreements with other healthcare providers

Effective handover and follow-up procedures

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.)

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

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.)

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

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.)

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).

SUB-KNOWLEDGE FIELDS

DETAILED 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.)

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 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)

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-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)

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

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.)

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

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.)

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

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.)

Assessment and management of minor ailments

Clinical decision-making Patient rights, informed consent, cultural competence

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.) 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.)

Initiating therapy Dose titration and adjustment Discontinuation when appropriate

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.)

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)

Multi-disciplinary collaboration with other healthcare professionals and patients in clinical decisions and referrals. Working with healthcare professionals Establishing referral pathways Shared decision-making

Patient Education

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

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

Monitoring for Adverse Effects

(This area focuses on identifying, managing, and preventing adverse drug reactions and interactions.) Monitoring for and managing adverse effects or medicine interactions. Recognising side effects and interactions Implementing mitigation strategies Reporting adverse events

Documentation and Record Keeping

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

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

Communication

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

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

Follow-Up And Outcomes Assessment

(This area focuses on ongoing evaluation of patient outcomes and therapy effectiveness, with adjustments as needed.)

See sections in **PHARMACY PRACTICE** 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.

| SUB-KNOWLEDGE FIELDS | DETAILED 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) | 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 |
| Mobile Health Applications (Apps), Telepharmacy, and Digital Tools (This area focuses on leveraging mobile and remote technologies for patient care, education, and workflow management.) | 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 platforms Emergency protocols, including access to automated dispensing units during power failures Mobile health applications for medication management and adherence Blockchain technology applications |
| Pharmacy Customised Systems | Automated Medication Compounding Systems Pharmacy Information Systems (PIS) |

Integration with Electronic Health Records (EHR)

Electronic Medication Administration Records (eMAR)

Medication therapy management systems: Therapeutic drug monitoring data support system

Drug-drug interactions monitoring systems

Inventory Management Systems (stock take and ordering)

Barcode Medication Administration (BCMA) Automated order refill management systems

Regulatory Compliance Software

Risk management

Pharmacy Robotics and Workflow Management

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

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

Mobile Health, Telepharmacy, and Digital Tools

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

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.

Emergency Protocols

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

Quality Assurance, Education, and Regulatory Compliance

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

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

Billing and reimbursement strategies

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

Regulatory Compliance

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.)

Virtual Reality (VR) and Augmented Reality (AR) Internet of Things (IoT) - Artificial Intelligence (AI) and Machine Learning (ML) Virtual Reality (VR) and Augmented Reality

Internet of Things (IoT) for patient data management

Cloud computing for quality control and telecommunication technology

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.)

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

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.

SUB-KNOWLEDGE FIELDS DETAILED KNOWLEDGE FIELDS GMP and GPP Rules and Guidelines GMP/GPP rules and guidelines (This area focuses on the principles and Premises, equipment, personnel, production implementation of GMP and GPP to ensure safe, planning effective, and quality medicines.) Prevention of contamination, validation, inprocess controls Documentation practices Documentation, Traceability, and Quality Batch records, product traceability, recall Systems (This area focuses on documentation, traceability, procedures and quality management in pharmaceutical QMS, SOPs, risk management, audits manufacturing.) Validation, qualification, QC principles Pharmaceutical Quality Systems and Sampling, testing, stability programmes Control (This area focuses on validation, quality control, and Regulatory compliance, training, regulatory compliance in pharmaceutical production.) import/export procedures Principles Documentation and Record-keeping 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 Complaints and product recall Company overview & Departmental Organograms (Roles of key personnel) QMS system in a manufacturing setting interactions 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)

Regulatory aspects Medicines Act, Compliance with SAHPRA

requirements, ICH, ZA-CTD

Ethical and Legal Medicines Act

Audits Requirements and preparation, internal and

external

Raw material selection and Procurement

Risk Assessment

Specific Applied Fields in Pharmacy: Pharmaceutics

Releasing, Storage and Shipment Batch release

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: PHARMACOVIGILANCE PRINCIPLES AND REPORTING ADR

Error recognition, reporting, and management. Trending and root cause analysis.

Monitoring for adverse drug reactions (ADRs). Recognising, reporting, and managing ADRs. 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.)

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

Patient Education and Counselling

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

Also see section on: PATIENT MEDICATION MANAGEMENT, RESOLUTION OF MEDICINE (DRUG) THERAPY PROBLEMS, **MEDICATION REVIEWS**

Innovations in Quality and Safety

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

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

Risk Management and Quality Improvement

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

Risk assessment Quality improvement initiatives

Safe Dispensing Practices

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

SAPC Good Pharmacy Practice rules & quidelines

Clinical Decision Support Systems (CDSS) (This area focuses on electronic tools to support

safe and evidence-based clinical decisions.)

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

CDSS to help ensure evidence-based decisions

Legal and Ethical Considerations in **Medication Safety**

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

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

Confidentiality, informed consent, and regulatory reporting obligations.

Team Communication and Collaboration

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

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

Medication Safety Culture

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

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.)

Stocking

Access control

Handling

Expired/recalled medicines

Recordkeeping

Audit trials

Regulatory Compliance and Legal

Considerations

(This area focuses on legal responsibilities and documentation in automated dispensing.)

Regulations

Legal implications

Patient/Provider interaction

Robotics

Al 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 **DETAILED KNOWLEDGE FIELDS** Key principles and application of advanced GPP Rules and Guidelines Relating to medicine discovery approaches Medicine Discovery (This area focuses on regulatory and ethical considerations in drug discovery and development.) Target Identification and Validation Hit identification, lead optimisation, highthroughput screening, computational drug (This area focuses on identifying and design, fragment-based design, virtual confirming biological targets for new screening, biological assays medicines.) Combinatorial chemistry, AI/ML, omics, Combinatorial Chemistry, AI, and Omics biologics, gene therapies, pharmacokinetics, (This area focuses on innovative biomarkers, natural product discovery, gene approaches and technologies in drug editing, nanotechnology, data mining discovery.)



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.

| SUB-KNOWLEDGE FIELDS | DETAILED KNOWLEDGE FIELDS |
|--|--|
| Good Laboratory Practice (GLP) rules and guidelines related to analytical methods | Examples of detailed knowledge fields for selected analytical techniques |
| (This area focuses on laboratory standards and best practices for advanced analytical techniques in pharmacy.) | HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) |
| See section on: <u>Error! Reference source</u> not found. | Applications in Pharmacy (This area focuses on the diverse applications of HPLC in drug development, quality control and |
| Advanced Analytical Techniques | 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 of 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

| SUB-KNOWLEDGE FIELDS | DETAILED KNOWLEDGE FIELDS |
|---|---|
| Good Laboratory Practice (GLP) Rules and | GLP rules and guidelines for analytical methods |
| Guidelines | OLF fules 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 **DETAILED KNOWLEDGE FIELDS** SAHPRA Regulatory Systems Role of SAHPRA (control and regulation of (This area focuses on the regulatory frameworks health products intended for human and animal and processes for medicines and medical devices in use, the licensing of manufacturers, South Africa and the region) 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 The Medicines and Related Substances Medicines Act and general regulations Regulatory approval and review Act, 101 of 1965, as amended, General Product registration processes and CTD Regulations. (eCTD) modules, Chemistry, manufacturing, (This area focuses on the legal requirements for and controls (CMC) product registration and compliance.) Regulatory approval and review **Product Registration and Classification** Product registration process and the CTD (This area focuses on the procedures and (eCTD) clinical data, safety, efficacy, requirements for registering medicines and devices.) manufacturing, and labelling Chemistry related

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

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 the 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>

<u>assessment processes</u>, 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 Also see the section on: Pharmacovigilance |



APPLIED FIELDS IN PHARMACY: Pharmaceutical Chemistry, Pharmaceutics, Pharmacology, Clinical Pharmacy, Pharmacy 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, <u>pharmacokinetics</u>, 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):

(This area focuses on the assessment and

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 | DETAILED KNOWLEDGE FIELDS |
|--|--|
| Preformulation studies and Formulation Development (This area focuses on the design, testing, and optimisation of pharmaceutical dosage forms.) | See section in PHARMACEUTICS |
| Quality Control and Analysis of Formulated Product | 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 | See section in PHARMACEUTICS |

MEDICINE FORMULATION, PHARMACOLOGICAL TESTING

assurance of medicine stability under various conditions.)

Pharmacokinetics and Pharmacodynamics

studies, Pharmacokinetic profiling

Bioavailability studies Also see sections in:

PHARMACEUTICS PHARMACOLOGY CLINICAL PHARMACY

Biopharmaceutical Considerations,

Bioavailability

Also see the section in PHARMACEUTICS

ADME studies

Biopharmaceutics Classification System (BCS) (as relevant to API in formulated product)

Pharmacological Testing and Bioequivalence Studies

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

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

Toxicology Studies

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

Also see sections in:

PHARMACOLOGY CLINICAL PHARMACY

MEDICINE SAFETY ASSESSMENT

PROCESSES

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 (This area focuses on regulatory standards and analytical methods for ensuring pharmaceutical product stability.) | 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: REGULATORY APPROVAL AND COMPLIANCE |



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

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

Ethical Considerations

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



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

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 | Packaging and labelling 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

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 effective inventory management to ensure medicine availability and compliance.)

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) Licensing and authorisation Rules, Guidelines, and Standards Storage and handling conditions Product traceability Documentation and record keeping SAPC Good Distribution Practice (GDP) Product Authentication and Verification Rules, Guidelines, and Standards Quality Management System Adverse Event Reporting (AER) SAPC Good Wholesale Practice (GWP) Wholesale distribution practices Rules, Guidelines, and Standards Recall procedures Counterfeit prevention (This area focuses on regulatory compliance Training and competence in the storage, distribution, and wholesale of Regulatory inspections and audits medicines.) Labelling and packaging compliance **Data Integrity**



APPLIED FIELDS IN PHARMACY: Pharmacy Practice.

SUPPLY CHAIN EFFICIENCY

Curriculum Outline:

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|------|-----|--------------|----------|------------|----------------|
| | ΙF | I FD ! | I ED KNC | I ED KNOWI | I FD KNOWI FDO |

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 **DETAILED KNOWLEDGE FIELDS** SAPC Good Storage Practice (GSP) Serialisation Rules, Guidelines, and Standards Authentication Technologies **Data Integration** SAPC Good Distribution Practice (GDP) Regulatory Compliance Rules, Guidelines, and Standards Tamper Evidence Verification at Point of Dispensing Aggregation SAPC Good Wholesale Practice (GWP) Supply Chain Visibility Rules, Guidelines, and Standards Serialisation Data Exchange Recall Management (This area focuses on ensuring the authenticity and Training and Education traceability of medicines through serialisation and authentication technologies.)



APPLIED FIELDS IN PHARMACY: Pharmacy Practice.

DISTRIBUTION OF SPECIALITY MEDICATIONS

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 the specialised distribution handling, and support for specialty medications

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 DETAILED KNOWLEDGE FIELDS Medicine Selection and Formulary Classification of medicines Indications Development Safety, efficacy and cost-effectiveness (This area focuses on evidence-based selection and Updating and revising the formulary ongoing management of formulary medications to ensure safety, efficacy, and cost-effectiveness.) Indications, safety, efficacy Cost-effectiveness analysis Updating and revising formularies Epidemiology of the patient population Therapeutic Guidelines and Evidence-Evidence-based care guidelines **Based Care** (This area focuses on aligning formulary decisions with population health needs and current clinical evidence.) Generic substitution Medicine Substitution Strategies Therapeutic interchange helps reduce costs (This area focuses on cost-saving substitution strategies that maintain therapeutic equivalence and while maintaining therapeutic efficacy patient safety.) Substitute a different medication within the same therapeutic class based on formulary guidelines and clinical judgment Patient education and communication: Public and private sector differences Awareness of formulary inclusions and Patient and Provider Education exclusions (This area focuses on educating stakeholders about formulary content and rational medicine use.) Monitoring and evaluation Pharmacovigilance and Safety Monitoring Adverse Event Reporting (AER) (This area focuses on post-marketing surveillance and adverse event reporting.) Formulary committees must carefully select medications Monitoring/updating of formularies and Pharmacy and Therapeutic Committee quidelines Governance Authorisation and restrictions (This area focuses on governance, compliance, and ethical oversight of formulary systems.) Medicine reviews Compliance with regulations Therapeutic Guidelines, Indications, Patient Formulary access and equity Communication with stakeholders **Population** Chemical form (salts, esters, hydrates, Medicine Class Reviews and polymorphs, stereoisomers) Pharmacodynamic Considerations **Prodrugs** (This area focuses on the scientific evaluation of Therapeutic class and therapeutic interchange medicine classes to inform formulary decisions)

Pharmacokinetic and pharmacodynamic aspects

Cost Analysis and Resource Allocation

(This area focuses on pharmacoeconomic evaluations to optimise resource allocation)

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

Conflict of Interest Management

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 customisation 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.)

Patient-specific considerations

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.)

Ensure safe and effective compounding practices

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 medicines</u>.

Curriculum Outline:

SUB-KNOWLEDGE FIELDS

DETAILED KNOWLEDGE FIELDS

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.)

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

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.)

Including solvents, sharps disposal Including chemotherapeutic agents

Disposal Methods

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.)

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

Environmental responsibility and Sustainability

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

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

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



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

DETAILED KNOWLEDGE FIELDS

Policy Goals and Effectiveness

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

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.

Economic Impact and Sustainability

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

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

Equity and Access

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

Examine how the policies affect different population groups:

Impact on vulnerable populations (e.g., low-income, elderly, chronically ill)

Geographic disparities in access to medicines Effects on out-of-pocket expenses for patients

Quality and Safety and Regulatory Compliance

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

Assess the policies' influence on:

Quality control measures for pharmaceuticals Pharmacovigilance and adverse event reporting Regulation of drug manufacturing and distribution

Innovation and Research and Ethics

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

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, transparency, and stakeholder engagement in policy frameworks.)

Evaluate the practical aspects of policy implementation:

Transparency and accountability in decisionmaking processes

Stakeholder engagement and participation Regulatory capacity and enforcement

Unintended Consequences

(This area focuses on identifying and mitigating unforeseen policy impacts.)

Identify any unforeseen effects of the policies, such as:

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

| 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.)

Qualitative vs Quantitative research Mixed-methods research

Data Analysis and Interpretation (This area focuses on applying statistical and

qualitative methods to derive meaningful insights.)

Qualitative and Quantitative, including appropriate statistical analysis

Software for data analysis

Ethical, Legal, and Regulatory Compliance

(This area focuses on safeguarding research integrity and participant rights.)

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 Management and Quality

Assurance

Data coding and entry

Data cleaning and validation

Quality control procedures

Data storage and re-use of data

Interpretation of Research Findings

Presenting results effectively Discussion and conclusion

Research Funding

Budgeting and resource allocation

Grant writing basics (basic processes)

Research Communication and

Dissemination

(This area focuses on effectively sharing findings and translating knowledge into practice.)

Scientific writing and publishing

Conference presentations

Knowledge translation and public engagement

Medicine Reconciliation

Investigational product accountability and adherence Role of the pharmacist through interaction with participants

Clinical Trial Pharmacy Practice (This area focuses on the pharmacist's role in clinical research and patient-centred care.)

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



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 the 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.)

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

Ethical Decision-Making Frameworks

(This area focuses on applying moral reasoning and legal principles to resolve ethical conflicts in patient care.)

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> directive

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 (This area focuses on evidence-based decision-making to ensure safe, effective, and appropriate medicine utilisation.) | Critical decision making Safety and quality considerations Health and safety of the public 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 Evaluation | Medication review Economic considerations |

(This area focuses on monitoring medicine use patterns and assessing economic impacts to optimise resource allocation.)

Pharmacovigilance - Adverse Drug Event Monitoring (ADEM)

Patient-centred Pharmaceutical Care (This area focuses on individualised care aligned with patient needs, preferences, and socio-cultural contexts.)

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):

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.

| SUB-KNOWLEDGE FIELDS | DETAILED KNOWLEDGE FIELDS |
|---|---|
| SAPC_Good Pharmacy Practice (GPP) Guidelines and Associated Rules (This area focuses on promoting rational, cost- effective prescribing and equitable access within healthcare resource constraints.) | 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 |
| Medication Variables and Equivalency (This area focuses on evaluating medication-specific factors to ensure therapeutic efficacy and costefficiency.) | Generic medications Therapeutic equivalents Monitoring and compliance |
| Patient-centred Variables | 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

See also sections in PHARMACY PRACTICE - Introduction and Establishing Rapport Patient Identification/ Patient Consultation Introduction and rapport-building techniques Patient identification (e.g., ID documents,

DETAILED KNOWLEDGE FIELDS

(This area focuses on establishing trust, verifying identity, and creating a conducive environment for effective communication.)

medical records)
Ensuring privacy and minimising interruptions

Assessment of Patient Information

(This area focuses on gathering holistic health information to inform safe and effective therapy.)

Medical history, including allergies, chronic conditions, and current medications (prescription and over-the-counter)

Medication Reconciliation

(This area focuses on comparing and resolving discrepancies between home and prescribed medications to prevent errors.)

Patient's current medication list with the prescribed medications to identify any discrepancies

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.)

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

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.)

Adhere to relevant privacy laws and regulations

Continuous Professional Development (CPD)

(This area focuses on enhancing consultation skills through ongoing learning.)

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.)

Pharmacokinetics and Pharmacodynamics

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.)



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 safety and 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.) questions and address any concerns they may have about their medications

Patient Counselling and Education

(This area focuses on empowering patients through tailored education and ongoing support for medicine use and safety.)

Potential interactions with prescribed medicines.

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

Home test kits

Controlled Substances Management and Opioid Stewardship

(This area focuses on safe management, monitoring, and patient education regarding controlled substances and opioids.)

Inventory control and monitoring for controlled substances to prevent diversion and abuse; Legitimacy of prescriptions for controlled substances and adherence to legal requirements

Also see sections on: Pharmacovigilance

Patient Assessment

Patient-specific factors
Screening patients at risk of substance abuse or addiction, also referral and counselling to

substance abuse treatment programs

Pharmacy Protocols, Policies and Quality Assurance

(This area focuses on adherence to regulations, continuous improvement, and ethical practice in medicine safety.)

Adherence to Regulations
Quality Assurance
Continuous improvement processes

Collaboration, Community Outreach, and Public Health Promotion

(This area focuses on interdisciplinary teamwork and

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 (This area focuses on understanding and applying economic analyses to inform healthcare decisions and policy.) | Cost-Effectiveness Analysis (CEA) Cost-Benefit Analysis (CBA) Cost-Utility Analysis (CUA) 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.)

Patient education and counselling on costeffective practices Adherence counselling

Pharmacoeconomics Research and Collaboration

(This area focuses on conducting and applying research to optimise resource allocation and interprofessional practice.)

Applied analyses Interprofessional collaboration

Medicine Pricing, Reimbursement and Access

(This area focuses on navigating pricing, insurance, and policy frameworks to enhance medication affordability.)

Healthcare policy and legislation Formulary management Pharmacy Benefit Management (PBM) Medical scheme options Health insurance and coverage

Healthcare Resource Utilisation and Value-Based Care

(This area focuses on optimising resource use to improve patient outcomes and system sustainability.)

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.)

Monitoring its use

Supply Chain Management and Information (This area focuses on managing medication availability during crises through proactive communication and strategic collaboration.)

Communicate disruptions or changes in the supply chain that may affect the availability of medications or healthcare products

Community Engagement and Cultural Sensitivity

(This area focuses on fostering trust and solidarity through culturally appropriate outreach and education.)

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

Vaccination and Preventive Measures (This area focuses on promoting immunisation and infection control to mitigate disaster impacts.)

Promotion of vaccine benefits

Addressing concerns and questions

Promotion of immunisation services

Regulatory Changes

Emergency Preparedness and Response (This area focuses on proactive planning and crisis communication to manage disasters effectively.)

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

Collaboration with Healthcare Providers and Health Authorities

(This area focuses on coordinated responses and adherence to ethical/legal standards.)

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

Patient Wellness

(This area focuses on educating patients about the impact of health-related factors on overall well-being, empowering them to make informed choices for better health outcomes.)

Increased focus on educating patients about the impact on health-related aspects

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 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.)

Accurate data recording and reporting to local authorities or other stakeholders

Legal and Ethical Considerations

(This area focuses on upholding ethical standards and legal requirements when communicating and making decisions during health crises.) 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

Adhere to legal and ethical standards in communication.

Protect patient confidentiality and privacy while ensuring transparency and honesty.

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.) Ensure follow-up monitoring systems are in place for patients with chronic conditions

Infection Control Measures

(This area focuses on educating staff and the public about disease transmission and prevention strategies during health disasters.)

Educate both staff and the public about the epidemic, including its causes, symptoms, prevention measures, and available treatments.

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.)

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 HEALTH CARE (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 the patient's health needs is conducted, interpreted, and appropriate solutions are communicated within the context of the provision of primary health care.

SUB-KNOWLEDGE FIELDS

DETAILED 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 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

PHC Services Delivery

(This area focuses on the organisation, implementation, and quality assurance of PHC services in line with national and international guidelines.)

Organisation of PHC services
Interprofessional collaboration
Health promotion & Disease pr

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

Monitoring and evaluation of PHC services

infrastructure, equipment, information and

The ideal health facility realisation and

Service delivery factors & allocation Resources (Financial-, Human-, and

maintenance

Factors that Influence Implementation of PHC

(This area focuses on the resource, policy, and operational factors that affect effective PHC delivery.)

Human resources

technology factors)

Policies and procedures

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,

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.)

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

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.)

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

DETAILED KNOWLEDGE FIELDS

Scientific writing techniques for research

Oral presentation skills for research findings

Principles of Scientific and Professional Communication

(This area focuses on the foundational skills and standards required for clear, accurate, and ethical research communication.)

cal Communication of data and results Timeliness Health literacy in research communication

papers and reports

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



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</u> therapy (PIT).

Curriculum Outline:

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)

Continuous Professional Development (CPD)
Quality Assurance

Patient Assessment (Comprehensive Evaluation)

(This area emphasises the ability to gather thorough patient information to inform pharmaceutical care decisions, considering medical history, physical findings, medicines, and cultural factors.)

Comprehensive patient history taking and medication use (including patient's name, date of birth, medical conditions, medicines, allergies and sensitivities)

Physical examination techniques.
Interpretation of laboratory and diagnostic data
Cultural competence and sensitivity

Medication History and Reconciliation (Ensuring Accuracy)

(This area focuses on obtaining a complete medication history and reconciling discrepancies to prevent medication errors and adverse events, including prescription and non-prescription products.)

Medication review techniques

Identification of medication-related problems
Drug-drug and drug-disease interactions
Reconciliation across care transitions
Documentation of current medications (including
OTC and supplements)

Expiry dates of medications

Dispensing

(Safe Medication Supply)

(This area emphasises the accurate interpretation, preparation, and provision of medications, adhering

Interpretation and evaluation of prescriptions Preparation and labelling of prescribed medicines.

Extemporaneous compounding

to legal and ethical standards to ensure patient safety and medication efficacy.)

Patient Education and Counselling

(This area focuses on effectively communicating

medication information to patients, promoting adherence, and addressing their questions and

concerns to improve health literacy and self-

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 questions and concerns

Patient's questions and concerns

Medicine information and education

Health promotion and disease prevention (GPP guidelines FIP publication)

Monitoring and Follow-up (Optimising Outcomes)

(Empowering Patients)

management skills.)

(This area focuses on assessing the effectiveness and safety of medication therapy, identifying adverse effects, and making necessary adjustments to achieve desired therapeutic outcomes.)

Therapeutic drug monitoring

Adverse drug reaction identification and

management

Treatment outcome evaluation

Continuous care planning and adjustment

Medication reviews

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.)

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 quality 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

ΑI

Machine learning

considerations

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 promotion of medication adherence in the community

Financial management

Pharmacy leaders may also be responsible for 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.)

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)

Professionalism

(This area emphasises the importance of integrity, responsibility, and continuous learning for effective and ethical pharmacy leadership.)

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 **inter-professional 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.)

Effective teamwork, Effective communication, Respect and recognition

Interprofessional Collaboration

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

<u>Primary Health Care (PHC)</u> – Services Delivery

& Collaborative Practice in PHC
Patient-specific information and therapeutic

principles - Pharmaceutical Care

<u>Business Acumen</u> – 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.)

Patient-centred care and medication safety, Patient education

Collaborative Medication Review

(This area focuses on collaborative medication management to reduce errors and enhance patient outcomes and safety.)

Medication safety and management within a professional team,
Detailed medicine review and safety Quality
Management System
(skills to collaborate)

Roles and Responsibilities within the Interprofessional Team, including taking into account the scope of practice

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 Pharmacy Practice (Pharmacy Business Management) |
| Strategic and Analytical Skills (This area focuses on developing strategic thinking, analytical problemsolving, 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.)

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)

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.)

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 s

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 | DETAILED 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.) | 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 |
| Operational Quality Assurance (This area focuses on implementing standardised procedures, ensuring staff competency, and maintaining facilities/equipment to support medication safety and quality.) | 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/Customer-Centred Quality and Risk Mitigation | Patient counselling and education Patient privacy and data security - Medication error prevention |

(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 patient-centred care, as well as reducing risk and mitigating 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

DETAILED 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.)

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, and medication safety.

Integration of technology (e.g., medication management systems) to optimise therapeutic outcomes.

Medication review

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.)

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.)

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.

Culture and Health Promotion

(This area focuses on building strong relationships through culturally sensitive communication and strategies designed to promote health behaviour change.)

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

DETAILED KNOWLEDGE FIELDS



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-KNOWI EDGE FIELDS

| 30D-NINOWELDGE I ILLD3 | DETAILED KNOWLEDGE FILEDS |
|--|---|
| 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 |

Cultural Competence: Sensitivity to diverse backgrounds
Medication counselling
Behavioural change techniques

Professionalism, Ethics, and Collaboration (This area focuses on promoting ethical conduct and effective teamwork among healthcare professionals to ensure responsible patient care.)

Ethics and professionalism (Confidentiality, privacy, POPIA, informed consent).
Interprofessional collaboration
Feedback and evaluation: Improving techniques and materials
Behavioural change techniques: Using patient-centred counselling to motivate change

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)

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

4

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.) The CPD cycle Submitting CPDs Compliance with CPD requirements Planning for CPD

Critical Self-assessment Skills

(This area focuses on developing critical selfassessment skills to identify individual learning needs and professional growth areas.) 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 objectives)

Mentorship and Guidance for CPD

(This area focuses on guiding pharmacists and other pharmaceutical support personnel to enhance their competencies.)

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 sales 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 | DETAILED 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.) | See ETHICAL AND LEGAL ISSUES Exercising professional autonomy without infringement of the patient's right |
| 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) | Educate and prepare patients to be knowledgeable and well-informed and have the skills to manage their own health |

