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JOHANNESBURG
ACADEMIC OFFICE

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R E G U L A T I O N S

FOR ADMISSION TO THE FELLOWSHIP OF

THE COLLEGE OF CLINICAL PHARMACOLOGISTS OF SOUTH AFRICA

FC Clin Pharm(SA)

1.0 EXIT LEVEL OUTCOMES

1.1 The candidate who passes these examinations must be able to fulfil the role of a specialist clinical pharmacologist in the medical and academic communities, and in society at large.

1.2 Central to these examinations is their licensing function: Persons awarded the fellowship who fulfil the other requirements of the Medical, Dental and Supplementary Health Services Act may register and practice as specialist clinical pharmacologists in terms of the Act.

1.3 The following sections briefly outline the range of competencies that can be expected of the specialist clinical pharmacologist. Knowledge and skills must be kept up-to-date. The specialist clinical pharmacologist should be competent to:

1.3.1 **Implement drug policy**

1.3.1.1 Apply rational drug selection principles for formulary and standard treatment guidelines development for different levels of care.

1.3.1.2 Critically evaluate the risks and benefits of all drugs, particularly new drugs and new information on available drugs, by applying the principles of evidence-based medicine, pharmaco-economics and pharmaco-epidemiology.

1.3.1.3 Provide guidance regarding key regulatory legislation (eg for drug regulation, dispensing, unregistered medicines and clinical trials).

1.3.1.4 Advise or assist other professionals where necessary on drug policy.

1.3.2 **Manage individual patients and health of communities/special risk populations**

1.3.2.1 Select appropriate, safe, effective, and cost-effective therapeutic regimens for patients presenting at different levels of healthcare.

1.3.2.2 Application of the principles and practice of prescribing in special risk groups of patients, eg children, elderly, obesity, malnutrition, pregnancy, lactation, renal failure, hepatic failure and porphyria.

1.3.2.3 Diagnosis and management of cases of suspected poisoning and overdose.

1.3.2.4 Detection and management of drug interactions.

1.3.2.5 Appropriate use of therapeutic drug monitoring.

1.3.2.6 Appropriate management, reporting, and evaluation of adverse events/adverse drug reactions and failed therapy.

1.3.2.7 Participate in treatment selection for individual patients as a member of multidisciplinary team.

1.3.2.8 Provide guidance on medico-legal aspects of drug use, substance abuse and prescriptions.

1.3.3…/

1.3.3 **Acquire new medicines information and critically evaluate its quality and utility**

1.3.3.1 Access information using electronic and traditional methods.

1.3.3.2 Engage in continuing professional development activities.

1.3.3.3 Critically appraise the quality, clinical relevance locally and utility of medicines information.

1.3.4 **Function as an effective team member in the broader context of health care**

1.3.4.1 Treat all healthcare workers (including traditional, alternative and complementary practitioners) with respect.

1.3.4.2 Recognise the roles other health care workers play and consult appropriately.

1.3.4.3 Effectively communicate with health care workers in verbal and written format.

1.3.4.4 Provide leadership as needed.

1.3.4.5 Maintain high ethical and professional standards.

1.3.5 **Play an active role in training other health care workers**

1.3.5.1 Regularly participate in academic undergraduate and postgraduate teaching activities and continuing professional development programmes.

1.3.5.2 Regularly participate in academic meetings.

1.3.5.3 Able to communicate health-related information effectively to colleagues.

1.3.6 **Engage in research**

Be able to design, conduct, analyse and report on studies of drug therapy. This may include pre-clinical research, as clinical pharmacology is a bridging discipline between basic and clinical sciences.

2.0 ADMISSION TO THE EXAMINATION

PART I (Basic science of clinical pharmacology)

2.1 A candidate may be admitted to Part I of the examination having:

2.1.1 A post-internship qualification to practice medicine that is registered or registrable with the Health Professions Council of South Africa (HPCSA).

2.1.2 Completed at least 15 months full-time post-internship training as a clinical pharmacology registrar/clinical assistant in a teaching hospital department of pharmacology at the time of applying to enter for the Part I. On a case-by-case basis, consideration will be given in special circumstances to allow candidates to sit Part I without formal experience in a teaching hospital, on approval by the College of Clinical Pharmacologists.

PART II (Clinical pharmacology and therapeutics)

2.2 A candidate may be admitted to Part II of the examination having:

2.2.1 A post-internship qualification to practice medicine that is registered or registrable with the Health Professions Council of South Africa (HPCSA).

2.2.2 Successfully completed Part I of the examination, or be exempt from Part I.

2.2.3 Completed at least three years full-time post-internship training as a registrar/clinical assistant in either of the following combinations.

2.2.3.1 All three years in a teaching hospital department of pharmacology.

OR

2.2.3.2 Two years in a teaching hospital department of pharmacology plus one year as a registrar in a satellite clinical teaching department.

2.2.4 Approval of logbook/portfolio of learning by the supervisor; the supervisor must be an HPCSA recognised specialist in Clinical Pharmacology. It is recommended that all candidates entering into their registrar training from 1 January 2019 use the LogBox online portfolio. This is a free service and the app is available in both Apple and Android format. Please register at www.logbox.co.za. [1]

2.3 The CMSA may accept part-time training from registrars who have completed 4½ years in a teaching hospital including 1½ years full-time training, provided the candidate submits evidence of prior approval by the Health Professions Council of South Africa of a part-time training programme acceptable for specialist registration.

The CMSA Senate…/

[1] LogBox recommendation effective for new Registrars – 1 January 2019

2.4 The CMSA Senate, through its Examination and Credentials Committee, will review every application for admission to the examination, and may also consider the professional and ethical standing of the candidate.

3.0 GUIDELINES FOR PREPARATION FOR THE EXAMINATION

(See Appendices A & B for core curriculum and recommended reading)

3.1 Training objectives

Candidates preparing for the examination are advised to pay particular attention to the following aspects of training and professional development:

3.1.1 Knowledge (See Core Curriculum in Appendix A)

In order to assist candidates preparing for the examination, a core curriculum has been outlined. While this is not intended to serve as an exhaustive list of topics in clinical pharmacology and therapeutics likely to be encountered by the specialist clinical pharmacologist in practice in South Africa, the listed topics have been prioritised to emphasise those topics where clinical pharmacology input is often required.

3.1.2 Skills

3.1.2.1 ***Critical appraisal***

- 3.1.2.1.1 Assess new drugs and new information on existing drugs.
- 3.1.2.1.2 Assess clinical trials, including research proposals.

3.1.2.2 ***Diagnostic and therapeutic procedures***

- 3.1.2.2.1 Interpretation of therapeutic drug monitoring.

3.1.2.3 ***Communication***

- 3.1.2.3.1 **Oral:** appropriate to patients, public, health care workers, academic audiences, policy-makers.
- 3.1.2.3.2 **Written:** record keeping, referral letters, medical reports, treatment guidelines, academic writing.

3.1.2.4 ***Information management***

- 3.1.2.4.1 Data access using traditional and electronic techniques.
- 3.1.2.4.2 Critical appraisal of information sources and information.

3.1.2.5 ***Research***

- 3.1.2.5.1 Critical appraisal of research methods.
- 3.1.2.5.2 Analysis and interpretation of data.
- 3.1.2.5.3 Presentation of data.

3.1.2.6 ***Teaching and training***

- 3.1.2.6.1 Education of patients and communities.
- 3.1.2.6.2 Teaching and training of students and colleagues.

3.1.3 Professional behaviour and personal attributes

- 3.1.3.1 Respect for the rights and values of others; treat everyone with dignity.
- 3.1.3.2 Capacity for self-reflection and critical appraisal.
- 3.1.3.3 Insight into personal strengths and recognition of personal limitations.
- 3.1.3.4 Ability to recognise and effectively deal with personal stress.
- 3.1.3.5 Ability to care for oneself, including seeking health care when needed.
- 3.1.3.6 Discipline and insight to continue learning to maintain clinical competencies.
- 3.1.3.7 Dedication to serving the interests of our patients and communities at all times.
- 3.1.3.8 Promotion of justice and equity in the health care system.
- 3.1.3.9 Maintenance of integrity and honesty in professional practice.
- 3.1.3.10 Adhere to the highest ethical standards, including recognising and avoiding any potential conflict of interest.

3.2 Recommended reading (See Appendix B)

4.0…/

4.0 FORMAT OF THE EXAMINATION

4.1 **Part I (Basic sciences related to the practice of clinical pharmacology)**

4.1.1 Two written papers in the basic sciences (3 hours each).

4.2 **Part II**

4.2.1 **Written:** Two written papers on the principles and practice of clinical pharmacology and therapeutics (3 hours each).

4.2.2 **Objective Structured Clinical Examination:** This may include clinical slides, interpretation of laboratory results, and short case-histories.

4.2.3 **Oral examination:** Candidates will be assessed on their ability to apply the principles of clinical pharmacology and therapeutics to complex clinical and policy-making scenarios as reflected in the portfolio of learning.

5.0 CONDUCT OF THE EXAMINATION

5.1 At least two examiners will participate in the oral examination of each candidate in Part II of the examination.

5.2 The examiners will submit their assessments with marks in percentages for Part I and Part II of the examination.

5.3 In order to pass the examination, candidates must obtain:

- 50% or more for Part I of the examination (2 written papers), AND
- 50% or more for each component of Part II of the examination, namely:
  - 50% or more for the combined mark from the two written papers, AND
  - 50% or more for the OSCE, AND
  - 50% or more for the oral examination in Part II of the examination.

5.4 The three components of Part II of the examination will be weighted as follows:

- Two written papers will contribute 50% to the final mark (i.e. 25% for each paper).
- The OSCE will contribute 20% to the final mark.
- Oral examination will contribute 30% to the final mark.

7.0 ADMISSION AS A FELLOW

7.1 Only candidates who have completed training in a CMSA recognised registrar post may be awarded a fellowship if successful in the examination.

7.2 **Candidates who have written the examination as a prerequisite from the HPCSA for inclusion on the specialist register are not eligible to be awarded a Fellowship but will be sent a letter confirming their success in the examinations**

All other candidates will be asked to sing a declaration as below:

I, the undersigned, …….…….....do solemnly and sincerely declare

that while a member of the CMSA I will at all times do all within my power to promote the objectives of the CMSA and uphold the dignity of the CMSA and its members

that I will observe the provisions of the Memorandum and Articles of Association, By-laws, Regulations and Code of Ethics of the CMSA as in force from time to time

that I will obey every lawful summons issued by order of the Senate of the said CMSA, having no reasonable excuse to the contrary

and I make this solemn declaration faithfully promising to adhere to its terms

Signed at ……..…….…… this ……..……....…. day of

…….. 20 ……..

Signature ……..…….

Witness ……
(who must be a Founder, Associate Founder, Fellow, Member, Diplomate or Commissioner of Oaths)

7.3 A two-thirds majority of members of the CMSA Senate present at the relevant meeting shall be necessary for the award to any candidate of a Fellowship

7.4 A Fellow shall be entitled to the appropriate form of certificate under the seal of the CMSA

7.5 In the event of a candidate not being awarded the Fellowship (after having passed the examination) the examination fee shall be refunded in full

7.6 The first annual subscription is due one year after registration (statements are rendered annually)

A P P E N D I X A

CORE CURRICULUM

1. BASIC SCIENCES RELATED TO THE PRACTICE OF CLINICAL PHARMACOLOGY (PART I)

Note that the following basic science core curriculum should be used as a guidance tool rather than a restricted outline of what is expected. It entails a review of the broad field of pharmacology including topics covered in the undergraduate pharmacology program, but at an advanced level with a strong clinical perspective and critical thinking.

- **Understand the general principles of pharmacokinetics, including:**
  - Comprehensive understanding of absorption, distribution, metabolism and elimination;
  - Major families of membrane transporters involved in drug disposition;
  - Basic mechanisms of membrane transport;
  - Regulation of transporter expression and inhibition;
  - Enzyme induction and inhibition;
  - Drug biotransformation;
  - Comprehensive understanding of first pass metabolism, volume of distribution, clearance, half-life, bioavailability and the variables that influence them;
  - Optimisation of dosage regimens;
  - The relationship between the volume of distribution and/or clearance and the target concentration;
  - Use appropriate formulas to derive relevant pharmacokinetic parameters such as a drug's half-life or clearance or dose or volume of distribution after single dose (bolus/infusion) and at steady state.
- **Understand the general principles of pharmacodynamics including:**
  - Definitions such as affinity, intrinsic activity, efficacy, potency, EC_{50} value, E_{max}, agonism, antagonism;
  - Drug receptors, signalling mechanisms, regulation of receptors (desensitization, tachyphylaxis, down regulation and up regulation);
  - Concentration effect-curves;
  - Drug-receptor interaction forces.
- **Drug interactions:**
  - Pharmacokinetic interactions (this includes drug interactions at the level of absorption, distribution, biotransformation, excretion and drug transporter proteins);
  - Pharmacodynamic interactions (this includes synergistic, antagonistic, neurotransmitter uptake, common drug-traditional / alternative and complementary medicine interaction, drug-food interactions).
- **Pharmacogenetics and pharmacogenomics:**
  - Principles relating to the importance of variability of drug response such as metabolism, transporters and targets;
  - Commonly used medicines in which the pharmacokinetics or pharmacodynamics are influenced by genetic variations;
  - Implementation of personalised medicine using genetic profiles to guide the prevention, diagnosis and treatment of disease.
- **Overview of all classes of medicines commonly used in clinical practice including:**
  - Understanding of basic principles of physiology and anatomy to explain the mechanism of action;
  - Place in therapy;
  - Main side effect profile.
- **Drug hypersensitivity:**
  - Types of hypersensitivity reactions including the basic pathophysiology, examples of major drug classes involved and clinical manifestations;
  - Basic principles of the management (and prevention) of drug hypersensitivity reactions.

- **Pharmacoeconomics:**
  - Understanding the major types of pharmaco-economic evaluations (cost minimization analysis, cost effectiveness analysis, cost utility analysis and cost benefit analysis);
  - Basic concepts of costing (direct, indirect and intangible costs, discounting);
  - Basic concepts of outcome measurement and valuation such as disability-adjusted life year (DALY), quality-adjusted life year (QALY).
- **Drug discovery, pre-clinical evaluation and clinical development:**
  - Principles of phase 1 clinical development including study design, objectives, challenges, risk, starting dose;
  - Principles of phase II including study design, objectives.
- **Evidence-based medicine related to clinical pharmacology:**
  - Types of studies including the differences in the measures of occurrence, measures of association, strengths and limitations;
  - Blinding, randomisation, types of analysis (intent-to-treat, per protocol), types of bias, confounding;
  - Sensitivity and specificity of tests;
  - Grading / rating of evidence;
  - Interpretation of data (event rate, relative risk, relative risk reduction, absolute risk reduction, number needed to treat);
  - Clinical interpretation of trial results;
  - Critical appraisal of publications.
- **Basic biostatistics:**
  - Types of variables (categorical, numerical), measures of central tendency (mean, median, mode), measures of dispersion (range, interquartile range, standard deviation, non-normal and normal distribution);
  - Sample size, power, significance, hypothesis testing;
  - Paired and non-paired tests, parametric and non-parametric tests, confidence interval.
- **Basic principles of pharmacovigilance and pharmaco-epidemiology:**
  - Reasons to perform pharmaco-epidemiology studies;
  - Study designs for pharmaco-epidemiology studies;
  - Definitions and reporting requirements for adverse event, side effect, adverse drug reaction, unexpected drug reaction, serious adverse event, suspected unexpected serious adverse event (SUSAR);
  - Classification of adverse drug reactions (alphabetical, time, dose);
  - Signal detection;
  - Causality assessment.
- **Ethical principles:**
  - Principles relevant to clinical research and good clinical practice;
  - History of the development of research ethics standards including the declaration of Helsinki;
  - Ethical review, informed consent and human dignity of research subjects;
  - Protection of research subject, balance of harm and benefit and minimising risk;
  - Ethical aspects of conflict of interest, subject recruitment, clinical trials in vulnerable populations, subject reimbursement, post-trial access and genetic sampling.
- **Dispensing, pharmaceutical laws and drug regulation:**
  - Health Professions act (56 of 1974), Medicines and related Substances Act (101 of 1965), National Health act (61 of 2003), Health act (63 of 1977);
  - Control of medicines and scheduled substances;
  - General regulations pertaining to prescribing and dispensing of medicines.

2.0 CLINICAL PHARMACOLOGY AND THERAPEUTICS (PART II)

i) Rational use of all major therapeutic classes of drugs including chemotherapy

Management of common medical conditions in adults and children in South Africa

ii) Prescribing in special risk patients

This includes but not limited to the principle of prescribing in the following groups of patients:

- Pregnant;
- Lactating;
- Paediatric patients;
- Geriatric patients;
- Critically ill;
- Patients with hepatic impairment;
- Patients with renal impairment;
- Patients with co-morbid disease including HIV, tuberculosis, malnutrition, obesity;
- Porphyria.

iii) Therapeutic drug monitoring (TDM): principles and practice

iv) Complementary and traditional medicines/natural medicinal products

- Identify traditional alternative and complementary medicines/products that are therapeutically and/or toxicologically important to patient care;
- Discuss the benefit-risk of commonly used traditional, alternative and complementary medicines including their efficacy and potential adverse effects and drug-drug interactions.

v) Poisoning and overdose: principles and management

- Describe the common clinical syndromes and their mechanism of toxicity;
- Management principles.

vi) Drugs / substances of abuse: principles and medical management.

vii) Drug discovery, evaluation and development

- Principles, designs and value of phase 3 & 4 clinical trials.

viii) Medico-legal and regulatory aspects of medicines in South Africa

- Discuss regulatory and legal aspects including but not limited to aspects of medicine registration which include complementary medicine, biosimilars and generics.
- Discuss the role of the regulatory authority in ensuring medicine safety.

ix) Adverse events / adverse drug reactions

- Appropriate management, reporting, and evaluation of adverse events / adverse drug reactions.

3.0 Clinical pharmacology experience (as reflected in candidate's logbook)

a) **Clinical patient care in a variety of healthcare contexts**

- to make up 25% of pharmacology training

Expected to undertake clinical rotations to meet the following criteria:

i) At least 2 months' rotation is each of the following:
   - Intensive care unit
   - Paediatrics or adult medical casualty/emergency department
   - Primary health care clinics run by the Department of Family Medicine or equivalent.

ii) At least 2 months' rotation in at least 4 of the following:
   - Endocrinology
   - Dermatology
   - Neurology
   - Rheumatology
   - Gastroenterology
   - Infectious diseases, including HIV care
   - Cardiology
   - Oncology
   - Psychiatry
   - Anaesthesia, including pain clinic
   - Pulmonology
   - Nephrology
   - Geriatrics.

b) **Contribution to:**

i) Education and training
- Contribution to undergraduate / postgraduate teaching and continuing professional development.

ii) Therapeutic service
- Assist in the providing of a therapeutic drug monitoring service, by interpreting clinical significance of drug levels reported.

iii) Research
- Actively participate in at least one research study relevant to clinical pharmacology.
- Critically review proposals on clinical trials submitted to a Research Ethics Committee.
- Presentation of critical appraisal of relevant journal articles.
- Research protocols.

vi) Implementation of drug policy
- Actively participate in a drug selection committee (eg hospital pharmaceutical and therapeutics committee, national or provincial essential medicines committee, development of treatment guidelines or medicines formulary);
- Principles of formulary development and standard treatment guidelines.

A P P E N D I X B

1.0 RECOMMENDED READING

1.1 General textbooks

- Katzung, BG. *Basic & Clinical Pharmacology*. Latest edition. Lange.
- Goodman and Gilman's. *The pharmacological basis of therapeutics.* Latest edition. McGraw Hill.
- Walley T et al. *Pharmacoeconomics.* Churchill Livingstone.
- Strom BL. *Pharmacoepidemiology.* Latest edition. John Wiley.
- *South African Medicines Formulary (SAMF).* Latest edition.
- Straus S et al. *Evidence-based medicine: How to practice and teach EBM.* Latest edition. Edinburgh, Churchill Livingstone.
- Stahl, SM. *Stahl's Essential Psychopharmacology.* Latest edition. Cambridge.
- *WHO monographs on selected medicinal plants;* volumes 1, 2 and 3.

1.2 Original articles and seminal reviews in leading medical and pharmacology journals, including:

- New England Journal of Medicine
- Lancet
- Pharmacological Reviews
- Clinical Pharmacology & Therapeutics
- British Journal of Clinical Pharmacology
- Annual Review of Pharmacology & Toxicology
- Drug Safety
- Annals of Pharmacotherapy