THE COLLEGES OF MEDICINE OF SOUTH AFRICA

Incorporated Association not for gain
Reg No 1955/000003/08

Part I Examination for the Fellowship of the College of Clinical Pharmacologists of South Africa

30 June 2016

Paper 1 (3 hours)

All questions are to be answered. Each question to be answered in a separate book (or books if more than one is required for the one answer)

---

1 a) Redraw and complete the table below comparing the objectives, sample sizes and inclusion / exclusion criteria for Phase 1, 2a and 2b clinical trials on a novel inhaled bronchodilator. (12)

	Phase 1	Phase 2a	Phase 2b
Primary objective/s			
Sample size range (approximate)			
Inclusion criteria			
Exclusion criteria			

b) Discuss how the objectives, sample sizes and inclusion / exclusion criteria for a Phase 1 study of a novel chemotherapy for pancreatic cancer would differ from those for a novel inhaled bronchodilator. (3)

[15]

2 Outline your analysis plan to compare the cost effectiveness of a fixed dose combination (FDC) inhaler containing the inhaled long acting beta-agonist salmeterol and the inhaled corticosteroid fluticasone with the co-administration of two inhalers, one containing salmeterol and the other fluticasone (dual inhalers). You have access to individual patient data from 16 500 patients enrolled in Phase 2, 3 and 4 studies comparing the FDC inhaler with the dual (co-administered) inhalers.

a) What are the main factors that you consider could alter the cost-effectiveness of the FDC over dual inhaler therapy? (3)

b) List key study end points that you would cost. (7)

c) Discuss the limitations of your cost-effectiveness evaluation for informing policy for the South African Essential Medicines List. (5)

[15]

3 Briefly describe the function of three voltage-gated ion channels and give two examples of drugs targeting each ion channel. [15]

4 Describe the different types of agonists and antagonists, and give one example of a drug for each group. [25]

5 Discuss the principal investigator's responsibilities after an approved prospective study of human subjects has been concluded. [10]

6 Describe the principles of obtaining informed consent. [10]

7 a) A new treatment for stroke provides a good outcome in 20% of those treated compared with a good outcome in 10% of those treated with placebo. A major bleeding complication occurs in 10% of those treated with the new drug and 5% of those treated with placebo. Determine the numbers needed to treat and to harm, and indicate how you calculated these. (5)

b) Briefly discuss key points important in the critical evaluation of a meta-analysis. (5)

[10]

FC Clin Pharm(SA) Part I

THE COLLEGES OF MEDICINE OF SOUTH AFRICA

Incorporated Association not for gain
Reg No 1955/000003/08

Part I Examination for the Fellowship of the College of Clinical Pharmacologists of South Africa

1 July 2016

Paper 2 (3 hours)

All questions are to be answered. Each question to be answered in a separate book (or books if more than one is required for the one answer)

---

1 Discuss the actions of morphine and describe the pharmacological mechanisms of opiate tolerance and dependence. [20]

2 Describe the three main mechanisms of action of the anti-epileptic drugs, giving one example of a drug for each mechanism. [15]

3 Predict the effects of the muscarinic antagonist atropine by using first principles of explaining the effect of acetylcholine on muscarinic receptors. [15]

4 Discuss the steps involved in adrenergic neurotransmission. [10]

5 Describe five common genetic disorders/polymorphisms that predispose to abnormal drug response and illustrate each one with the clinical effect on one drug example. [15]

6 Answer the following questions about spontaneous reporting systems for suspected adverse drug reactions

a) What is meant by the term “signal” in a spontaneous reporting system? (1)

b) List four limitations of spontaneous reporting systems for suspected adverse drug reactions. (4)

c) Outline two study designs which you might use to confirm or refute a signal. List the strengths and weaknesses of each study design. (10)

[15]

7 Write short notes on drug desensitisation for drug hypersensitivity reactions. [10]