FACULTY OF PHARMACEUTICAL MEDICINE
of the Royal Colleges of Physicians of the United Kingdom

EXAMINATION FOR THE DIPLOMA IN PHARMACEUTICAL MEDICINE

14 OCTOBER 2010

SECTION B

SHORT ANSWER QUESTIONS

INSTRUCTIONS TO CANDIDATES

1. **Two hours and 30 minutes** are allowed for answering this section.
   Allow 15 minutes for each question.

2. **Answer all ten (10) questions** in this section.
   You do not have to answer the questions in numerical order.

3. Each **question is worth a maximum of 10 marks.**
   Where questions comprise more than one part, the number of marks available for each part is shown.

4. Complete the **front cover of the answer book** with your last name, forename(s), candidate number and signature.

5. **Begin each SAQ on a new page and write only on one side.**
   Please do not write outside the margins of the pages.

6. **On each page of your answer book**, write your candidate number, the Section as "B", the question number and the page number:

   e.g. candidate 12 starting his second page in answer to question 5 would complete the answer book page as:

Candidate No:	*12*	Section:	*B*	Question No:	*5*	Page No:	*2*

7. We advise you to **write your answers as brief notes / bullet points**, not in the form of essays.

1. With respect to the legal status of medicines in the UK
   a) List the criteria that require a medicine to be a Prescription Only Medicine (POM) (6 marks)
   b) What is the criterion for switching from Pharmacy (P) to General Sales List (GSL) status? (1 mark)
   c) What will the legal status of a newly approved new active substance be? (1 mark)
   d) Who can request a change in legal status (reclassification) of the drug? (2 marks)

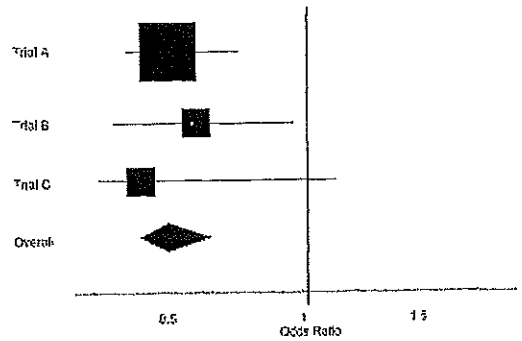
2. Enzyme inhibition may result in drug interactions.
   a) Give one example, and the underlying mechanism, of a clinically important drug-drug interaction resulting from enzyme inhibition. (1 mark)
   b) Briefly describe the *in vitro* assessment of the potential of a new drug (Drug X) to be a cytochrome P450 (CYP450) enzyme inhibitor. (2 marks)
   c) Outline the design of a clinical study to assess whether Drug X causes enzyme inhibition in man. (7 marks)

3. Using diagrams where appropriate and giving one example for each topic, write short notes on the following:
   a) Competitive antagonism (4 marks)
   b) Receptor up regulation (2½ marks)
   c) Partial agonist activity (3½ marks)

4. With respect to the evaluation of the cardiac safety of new drugs:
   a) What is the QT interval on the ECG and what does it represent? (1 mark)
   b) List the non-clinical studies by which the QT/QTc prolongation potential of a new drug is evaluated. (1 mark)
   c) Summarise when and how the QT/QTc prolongation potential is evaluated in the clinical development of a new active substance. (8 marks)

5. a) What is a serious breach of GCP or the trial protocol, as defined by the Medicines and Healthcare products Regulatory Agency (MHRA)? (2 marks)
   b) What action should a Sponsor take if fraud is suspected at a trial site in a multi-centre trial? (8 marks)

6. Below is a Forest Plot *(with some of the normal detail deliberately missing)* showing the treatment effect, using odds ratio (OR), of Drug X versus placebo in 3 trials – trial A, B & C and their overall meta-analysis effect.



a) What does this Forest Plot tell us about the individual trials A, B & C? (6 marks)
b) What does this Forest Plot tell us about the overall treatment effect of Drug X in the meta-analysis? (2 marks)
c) How do you calculate an odds ratio? (2 marks)

7. List the key principles governing provision of medicinal samples in the UK. (10 marks)

8. a) What is a Health Technology Assessment (HTA), its aim and focus? (6 marks)
b) What is the main difference in focus of a HTA compared to a marketing authorisation review? (2 marks)
c) List 2 countries and the name of the body in that country that conducts Health Technology Assessments. (2 marks)

9. Outline the package of safety data typically required to support a first administration study in humans of a novel small molecule by the intravenous route at doses around the expected therapeutic dose. (10 marks)

10. a) List the minimum information required for an adverse event report to be valid. (2 marks)
b) You are responsible for the pharmacovigilance activities relating to a flu vaccine. Three fatal seizures have been reported within three weeks of launch of the vaccine. What do you need to know in order to evaluate these cases fully? (8 marks)