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

EXAMINATION FOR THE
DIPLOMA IN PHARMACEUTICAL MEDICINE

2 OCTOBER 2012

SECTION C

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.

   The number of marks shown for each part should be taken as a guide to the relative extent of the answer required.

   For some questions, a full answer will require more points to be given than the number of marks available because some questions are marked in increments of 0.5 marks

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

5. **Begin each question 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 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: C** ***SAQ***	Question No:	*5*	Page No:	*2*

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

SAQ Paper 2012

1 a) Outline the package of Good Laboratory Practice (GLP) pre-clinical safety studies that are typically required in the European Union (EU) to allow first administration of a new chemical entity in a single ascending dose study to healthy male volunteers. **(8 marks)**

b) How might this package differ if your novel product was a biological product? **(2 marks)**

2 Your company has a new oral drug for development in all age groups:

a) What is a Paediatric Investigation Plan (PIP) and what are the key elements that should be addressed in it? **(4 marks)**

b) When do the guidelines recommend that you should first submit your PIP? **(1 mark)**

c) In what ways do factors which affect the disposition of drugs (pharmacokinetics) differ between neonates/infants and older patients? **(5 marks)**

3 Write short notes on:

a) The elimination half-life of a drug and how this pharmacokinetic parameter maybe used in clinical pharmacology. **(3 marks)**

b) The volume of distribution of a drug and what might affect it. **(3 marks)**

c) Absolute oral bioavailability and what might influence it **(4 marks)**

4 You are conducting a randomised, controlled, double-blind, double-dummy clinical trial:

a) What is meant by the term double-blind, double-dummy? **(2 marks)**

b) Give a scenario where you might use a double-blind, double-dummy design. **(1 mark)**

c) What factors relating to trial Investigational Medicinal Product (IMP) do you need to consider that may (unintentionally) result in unblinding your study? **(7 marks)**

5 Write short notes on all the different mechanisms that are in place to protect the rights and well-being of human subjects participating in clinical trials. **(10 marks)**

6 a) Draw and label a histogram showing a normally distributed population. Label the histogram with the key summary statistics. **(4 marks)**

b) What is meant by the term "95% confidence interval" and how is it derived? **(2 marks)**

c) What is meant by a p-value of 0.01? **(1 mark)**

d) What is a hazard ratio? What does a hazard ratio of 1 mean? Give one example of when it may be appropriate to use a hazard ratio? **(3 marks)**

7 Your company is the Marketing Authorisation Holder (MAH) for drug X, granted by mutual recognition in 12 countries in the European Union (EU).

a) In relation to the EU Summary of Product Characteristics (SmPC) for drug X, list the:

i. clinical particulars that should be set out in section 4. **(4 marks)**

ii. pharmacological properties that should be set out in section 5. **(1 mark)**

iii. pharmaceutical properties that should be set out in section 6. **(2 marks)**

b) Your company discovers a rare adverse reaction of drug X. Outline the steps you should undertake to update the SmPC. **(2 marks)**

c) Which parts of the SmPC (if any) allow differences between countries? **(1 mark)**

8 a) Why do we need Risk Management Plan (RMP) in drug safety? **(5 marks)**

b) List the four steps of risk management. **(2 marks)**

c) List the major sections that should be included in the RMP (*you do not need to mention annexes*). **(3 marks)**

9 With regards to the United Kingdom's Prescription Medicines Code of Practice Authority (PMCPA) Code of Practice:

a) You are revising an 8-sided promotional leavepiece for a new product your company launched 12 months ago in the UK.

i. Apart from including prescribing information, what other obligatory information should be included or requirements met? **(6 marks)**

ii. What piece of information should be included in the prescribing information of your leave piece that is not found in the Summary of Product of Characteristics? **(1 mark)**

b) When certifying promotional material, what qualifications and/or status must each signatory hold? **(1 mark)**

c) Clause 2 of the PMCPA code states "*Activities or materials associated with promotion must never be such as to bring discredit or reduce confidence in the pharmaceutical industry*"
What are the possible additional sanctions of a breach of this clause? **(2 marks)**

10 What factors need to be taken into account when prescribing medicines for the following patients:

a) A three year old child. **(3 marks)**

b) A thirty year old woman who is twenty four weeks pregnant. **(3 marks)**

c) An eighty year old male. **(4 marks)**