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

DIPLOMA IN PHARMACEUTICAL MEDICINE PART 2 EXAMINATION
20 OCTOBER 2014

SHORT ANSWER QUESTIONS - INSTRUCTIONS TO CANDIDATES

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

2. **Answer all 10 questions**.
   You do not have to answer the questions in numerical order.

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

4. Each **question is worth 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.

   Where a specific number of answers are requested, you can provide more and they will be marked, however you cannot score more than the maximum mark for that part of the question.

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

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

7. **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*	Short Answer Questions	Question No:	*5*	Page No:	*2*

8. When the Invigilator announces the end of the session, please stop writing **immediately** and stay in your seat until we've collected the question paper, your answer book and any other notes you have made.

SAQ Paper 2014

1 With respect to the European Union (EU) Paediatric Regulation which came into force on 26 January 2007:

a) Give two key reasons why the Paediatric Regulation was introduced. **(1 mark)**

b) Which body is now responsible for coordination of the Paediatric Regulation? **(1 mark)**

c) In the EU what age group is defined as children? **(1 mark)**

d) Which marketing authorisation applications have to include results of children's studies (unless a deferral or waiver has been granted)? **(2 marks)**

e) Give one situation when development of a medicine in children can be deferred. **(1 mark)**

f) Give one situation when development of a medicine in children can be waived. **(1 mark)**

g) Give three incentives for the development of paediatric medicines. **(3 marks)**

2 a) What are the differences between the Centralised Procedure (CP) and the Decentralised Procedure (DCP) with respect to the countries included in the European Union (EU) Marketing Authorisation Application? **(1 mark)**

b) Apart from timelines and cost, list two advantages of the DCP over CP. **(2 marks)**

c) List the <u>three categories,</u> with examples where appropriate, for which the applicant cannot choose the DCP. **(3 marks)**

d) Assuming that the DCP is chosen, list two ways can the applicant achieve marketing authorisations in <u>all</u> member states? **(2 marks)**

e) Give one alternative type of marketing authorisation procedure in the EU to the CP or DCP and give a situation when this can be used. **(2 marks)**

3 You have been contacted by a pharmacist at a hospital site which is conducting an oncology trial using your novel intravenously administered anti-cancer drug. On several occasions after injecting the anti-cancer drug into the infusion bag, the pharmacist has noticed particles in the infusion bag before administration to patients

a) List four pieces of information you need in order to help determine the significance of this finding. **(2 marks)**

b) Give six actions you should take as trial Sponsor with respect to the trial conduct. **(6 marks)**

c) Would your actions as trial Sponsor vary if this was observed in a trial using a new investigational intravenous diuretic? Give two reasons to support your answer. **(2 marks)**

4 a) Define Absolute Risk Reduction (ARR). **(1 mark)**

b) Define Relative Risk (RR), also known as a risk ratio. **(1 mark)**

c) What is a Hazard Ratio and when is it used in preference to a RR? **(2 marks)**

d)

i. In the context of a comparison between two treatments explain the term "null value".
ii. What would the null value be for an RR?
iii. What would the null value be for an ARR? **(2 marks)**

e) If the point estimate for a RR of drug X versus placebo for all-cause mortality was 0.5 (in favour of drug X), briefly explain, giving an example for each, what the 95% CI values for the RR could be when the p value for the result was:

i. highly statistically significant
ii. not statistically significant

(3 marks)

f) For the above scenario comparing drug X with placebo, give an example of a point estimate and the 95% CI if the RR result was now statistically significant in favour of placebo. **(1 mark)**

5 With reference to costs, logistics, safety and analysis, list

a) five advantages **(5 marks)**
and
b) five disadvantages **(5 marks)**

of using a parallel group design, compared to a cross-over design in a phase I healthy volunteer study.

6 For a first time in man study with a small molecule new chemical entity in healthy volunteers, list different 10 factors to consider when determining the starting dose. **(10 marks)**

7 a) Define:
   i. Women NOT of child bearing potential
   ii. Women of child bearing potential (WCBP)
   iii. Post-menopausal women **(3 marks)**

   b) List five pieces of information that you would expect to see to help inform a decision about including WCBP into a Phase III trial of a new chemical entity. **(5 marks)**

   c) List two circumstances where you could include WCBP with more limited data in early Phase studies. **(2 marks)**

8 Regarding Transfers of Value to healthcare professionals and organisations according to the The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry 2014:

   a) What must companies document and publicly disclose? **(2 marks)**

   b) What is covered by the transfers of values? **(6 marks)**

   c) How long do companies have to retain records of this disclosure? **(1 mark)**

   d) How long should the transfers of value remain in the public domain? **(1 mark)**

9 a) What are the objectives of Periodic Benefit Risk Evaluation Report (PBRER), formally known as Periodic Safety Update Reports (PSURs)? **(3 marks)**

   b) Give six sources of efficacy, effectiveness, and safety information which may be used in the preparation of PBRERs. **(3 marks)**

   c) According to Good Pharmacovigilance Practices (GVP) module VII give four factors that should be considered in the evaluation of the benefit-risk of a product. **(4 marks)**

10 a) What major mechanisms of drug-drug interaction are recognised? Provide examples for each type. **(4 marks)**

b) What factors make a drug-drug interaction more clinically relevant? **(3 marks)**

c) As the medical advisor for a marketed anti epileptic drug you receive a medical information enquiry relating to a patient who has been taking a constant dose of drug X for long standing epilepsy and has developed symptomatic hyponatraemia for the second time in 6 months. On both occasions it is noted that her anti-anginal drug treatment had been altered 2 weeks previously.

Describe the information you need in order to make a valid assessment of this case. **(3 marks)**