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

DIPLOMA IN PHARMACEUTICAL MEDICINE PART 2 EXAMINATION
16 OCTOBER 2017

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 have 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 <1 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 their 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 2017

1 The European Medicines Agency (EMA) state on their website that they are committed to enabling early patient access to new medicines and offer various regulatory support mechanisms to facilitate this. The Medicines and Healthcare Products Regulatory Agency (MHRA) also offer a support mechanism.

a) List 4 different regulatory support mechanisms, offered either by the EMA or the MHRA to facilitate earlier patient access to medicines. **(2 marks)**

(*note: marketing authorisation under exceptional circumstances is not an earlier access mechanism*)

b) For 2 of the support mechanisms you have listed in a) above, briefly describe: **(8 marks)**

i. The eligibility criteria for medicines to use this regulatory support mechanism.
ii. Two key features of this mechanism that facilitate earlier access.
iii. The final marketing authorisation status of the medicine after using this early access support mechanism.

2 a) What is a medication error? **(2 marks)**

b) For the following 4 different potential sources of medication errors (prescribing, storing, dispensing, preparing/administering medicinal products) give 2 examples of medication errors and briefly describe how routine and additional risk minimisation measures can be used to prevent them. **(8 marks)**

3 a) List the minimum information required for an adverse event report to be valid. **(2 marks)**

b) Briefly describe what MedDRA is and its intended purpose. **(3 marks)**

c) What is a safety signal? **(2 marks)**

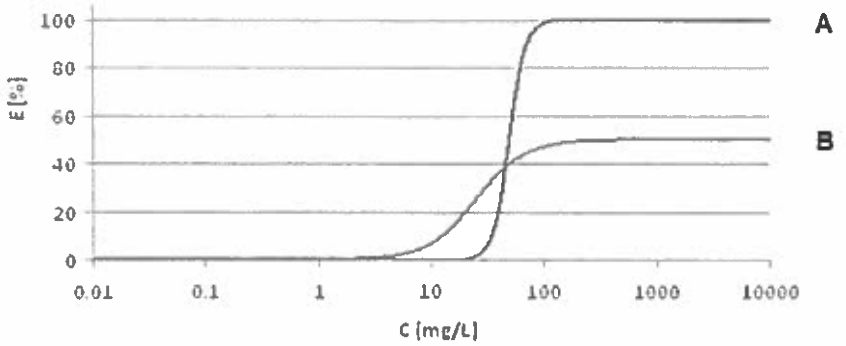
d) List 6 potential sources of safety signals for a marketed product. **(3 marks)**

4 With respect to the European Medicines Agency (EMA) *Guideline on strategies to identify and mitigate risks for first-in human and early clinical trials with investigational medicinal products*" briefly describe 10 risks factors (at least 3 must be from each of the headings below) that may predict the potential for severe adverse reactions in a first-in-human use of an investigational medicinal product. **(10 marks)**

a) Mode of action.
b) Nature of the target.
c) Non clinical safety studies / Relevance of animal models.

5 The graph below compares the concentration response for 2 different candidate agonist molecules A and B on the same receptor.

y axis = receptor effect [E] vs. x axis = drug concentration [C]



a) Define the affinity of a molecule. **(1 mark)**

b) Define Emax and EC50. **(1 mark)**

c) Describe the data and conclusions that can be made regarding these agonist molecules A and B with respect to: **(6 marks)**
- Emax.
- EC50.
- The slope of the concentration curves.

d) With respect to efficacy and safety considerations, under what 2 conditions would you favour molecule A? **(2 marks)**

6 For a first-in-human trial in healthy volunteers assessing single and multiple doses of a novel small molecule (Drug X):

a) What is the usual primary objective of this type of study? **(1 mark)**

b) Briefly describe 4 representative endpoints to assess this primary objective. **(4 marks)**

c) List 2 other typical objectives in such a trial. **(1 mark)**

d) For one of the objectives given in part c) above, briefly describe 2 representative endpoints used to assess this objective. **(2 marks)**

If this trial involved a biological medicinal product, instead of a small molecule:

e) Give a key additional objective and its associated endpoint that you would need to include. **(2 marks)**

7 a) With respect to the trial population defined in a study protocol, what do you understand by a "protocol waiver" and what is the Regulator Authorities' view of protocol waivers? **(2 marks)**

b) You are the medical monitor for a respiratory trial. What advice would you give for the following situations below:

i. The Site Investigator/Coordinator calls you. A patient they wish to randomise, who met all the eligibility criteria at the screening visit 1 week ago, now just fails on the FEV1 eligibility criterion required at the randomisation visit. The patient is keen to enter the study and the Investigator feels the trial is the best option for the patient so requests permission to randomise the patient. **(2 marks)**

ii. During a monitoring visit of the same trial, but at another site, your Clinical Research Associate (CRA) discovers a patient failed on the FEV1 eligibility criterion at the randomisation visit but was randomised and entered the study anyway. The patient is now 4 weeks into the trial. **(3 marks)**

c) For the patient described in part b ii), briefly describe what key analysis sets they should, or should not be included in. **(3 marks)**

8 a) What do you understand by an event driven (time to an event) study? **(2 marks)**

b) With respect to the assumptions made for the event rate, list 2 important trial logistics that must be in place for a time to an event trial. **(2 marks)**

c) If during the conduct of the trial the event rate is lower than expected, briefly describe 4 different options available to you to ensure the trial can be completed. **(4 marks)**

d) For 2 of the options you have listed in c), briefly describe what you must do to implement that option. **(2 marks)**

9 An advisory board meeting held by a company is a meeting at which invited experts are paid to give scientific advice on topics relevant to the company's products.

a) Briefly describe the key aspects to be aware of to ensure an advisory board is non-promotional. **(5 marks)**

b) Give 3 requirements that are the same for an advisory board and a promotional meeting under the ABPI Code of Practice. **(3 marks)**

c) List 2 other circumstances where healthcare professionals may be paid for their clinical expertise by companies. **(2 marks)**

10 Your company has just completed the phase 3 studies for Product X and is preparing for Health Technology Assessment (HTA) submissions.

a) List 8 essential types of information that need to be included in the HTA submission. **(4 marks)**

Due to the anticipated budget impact of the unlicensed Product X, the company plans to conduct an Advanced Budgetary Notification Programme.

b) Apart from having "an anticipated budget impact" briefly describe 3 other important considerations that are in accordance with an Advanced Budgetary Notification being conducted. **(3 marks)**

c) Product X is to be launched in partnership with another company.

i. What is co-promotion? **(1 mark)**

ii. List 2 requirements of co-promotion under the ABPI Code of Practice. **(2 marks)**