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

EXAMINATION FOR THE
DIPLOMA IN PHARMACEUTICAL MEDICINE

12 OCTOBER 2009

SECTION A

SHORT ANSWER QUESTIONS

INSTRUCTIONS TO CANDIDATES

1. **Two hours and 30 minutes** are allowed for answering this section.
2. Answer all ten (10) questions in this section.
3. Allow 15 minutes for each question.
4. To be eligible for a Pass you must attempt at least eight (8) questions.
5. You must complete the front cover of the answer book with your last name, forename(s), candidate number and signature.
6. Please begin each SAQ on a new page and only write on one side. Please do not write under the bottom line of each page. The questions do not have to be answered in numerical order.
7. On each page used, you must fill in your candidate number and the section (A). On each page of each SAQ, please also fill in the question number and the page number, e.g. Ques1/Page1, Ques1/Page 2.

Question No	Question	Available Marks
1.	With respect to orphan medicinal drugs: a) What are the criteria for orphan medicinal drug status in the EU? b) Who considers and grants orphan medicinal drug status in the EU? c) What are the benefits to a company of developing one in the EU? d) What are the criteria and benefits with respect to orphan medicinal drug development in the US?	 2 marks 2 marks 3 marks 3 marks
2	a) Define a phase I trial. b) What are the main objectives of a phase I trial? c) You wish to outsource a first in man study. Apart from cost, what factors should you take into account in choosing a site?	1 mark 2 marks 7 marks
3.	List the factors which should be considered in developing a medicine, which was originally approved for the treatment of illness in adults, for use in children.	10 marks
4.	According to ICH GCP, what information must be provided in the subject/patient information sheet and consent form?	10 marks
5	a) Draw and label a box and whisker plot for the results of a hypothetical distribution in which the values are 65, 65, 70, 75, 75, 80, 80, 85, 90, 95 and 100. Indicate the median, interquartile range, and extreme values. Show your working. b) Draw and label a hypothetical Kaplan-Meier curve for an effective treatment for heart failure (drug H) and its placebo comparator.	6 marks 4 marks
6.	List the provisions that must be in place when a pharmaceutical company works with a patient organisation in the UK.	10 marks
7.	List the criteria by which you would evaluate the validity of a pharmacoeconomic study.	10 marks
8.	Outline the package of pre-clinical studies that are typically required to allow first administration to man of a novel biological product. Give brief details of important considerations for each type of study. Indicate how this package might differ from that for a typical small molecule.	10 marks
9.	a) List potential sources of reports of adverse reactions available to a Marketing Authorisation Holder (MAH) for inclusion in a Periodic Safety Update Report (PSUR). b) List the main responsibilities of the qualified person for pharmacovigilance (QPPV).	5 marks 5 marks
10.	a) What are 'special populations' in the context of the Summary of Product Characteristics (SPC)? b) List the different types of special populations, and for each, briefly outline the key information that should be stated in the SPC to allow for the safe use of a product.	1 mark 9 marks