Examination Handbook

Diploma in Human Pharmacology

Guidance and Regulations for Candidates: Online Remote Invigilated Exams

Faculty of
Pharmaceutical
Medicine

19 Angel Gate, 326a City Road
London, EC1V 2PT
+44(0) 20 3696 9040

Registered Charity No 1130573
Company No 6870644

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PART I: DIPLOMA IN HUMAN PHARMACOLOGY EXAMINATION GUIDANCE NOTES

Introduction

These notes are intended to help candidates prepare for the examination for the Diploma in Human Pharmacology (DHP). Candidates should read the notes in conjunction with the Syllabus, together with the examination Regulations.

The examination is designed to test knowledge and the application of that knowledge, such as the ability to interpret preclinical and clinical data relating to an investigational medicinal product (IMP). Questions in the examination may relate to any part of the syllabus, but some parts are likely to be represented to a greater extent than others.

A pass in the examination and all other parts of the curriculum indicates that the individual has successfully completed a period of training, and should qualify them to serve as a Principal Investigator (PI) for Exploratory Development (Phase 1/2) studies of IMP in humans. However, the decision to appoint an individual as PI for a particular study, and the extent of supervision deemed necessary, are always matters for that individual's manager and employer, irrespective of qualifications.

Format of the examination

The DHP examination is prepared and conducted by a subcommittee of the FPM Board of Examiners. The examination comprises 3 written papers: there is no oral or practical clinical examination. The format of the papers is set out in Regulation A.4.

Paper 1 is intended mainly to test factual knowledge and the application of that knowledge, including interpretation of data relating to any part of the syllabus but excluding topics of a strictly clinical nature*.

Paper 2 is intended mainly to test knowledge relating to clinical safety and medical care of subjects participating in Phase 1 & 2 studies, including the management of adverse reactions and the interpretation of vital signs, ECG, laboratory safety tests, and pharmacokinetic and pharmacodynamic data. Candidates are expected to have a working knowledge of the mechanism of action, therapeutic benefit, and adverse effects of commonly used drugs and representatives of major drug classes.

Paper 3 is intended to test candidates' knowledge and understanding of human pharmacology, including the design of typical studies and the interpretation of pharmacokinetic and pharmacodynamic data. Paper 3 is also intended to test candidates' ability to apply their knowledge to ethical and safety aspects of Phase 1 & 2 studies.

Candidates usually sit Paper 1 on one day. On a second day, candidates usually sit Paper 2 in

the morning and Paper 3 in the afternoon. If candidates wish to sit Paper 1 as soon as they are eligible, the examination days may be separated by 1 or more years – see below.

The time allowed for each of part of the examination is enough to complete the papers, working at a reasonable pace.

*The Diploma Paper 1 is also the Certificate in Human Pharmacology question paper.

Eligibility

The eligibility criteria for the DHP examination are set out in Regulations A.14 – A.16. DHP examination candidates will already have met the criteria for entry into the DHP programme, as defined in the *DHP Candidate Guide and Syllabus*.

Preparation for the examination

DHP candidates should note that the examination may include questions relating to any part of the syllabus. Candidates should plan a programme of at least 6 months' preparation for the examination. Material studied should include:

- Presentation slides and lecture notes from the mandatory courses listed above.
- Recommended reading material distributed or listed by the organisers of the above courses, including journal articles and regulatory guidelines.
- Other regulatory guidelines relevant to human pharmacology.
- Appropriate medical books and articles.
- Editorials and articles in relevant journals *eg International Journal of Pharmaceutical Medicine, British Journal of Clinical Pharmacology, European Journal of Clinical Pharmacology, Clinical Pharmacology and Therapeutics.*

Recommended reading

- *Pharmacokinetics Made Easy*, DJ Birkett. 2nd edition, 2010.
- *Adult Advanced Life Support,* Resuscitation Council (UK) Guidelines, 2015. http://www.resus.org.uk/pages/als.pdf.
- Textbooks of Pharmacology eg
  - *Integrated Pharmacology*, CP Page et al. 3rd edition, 2006.
  - *Basic and Clinical Pharmacology,* ed BG Katzung. 14th edition, 2017.
  - *Rang & Dale's Pharmacology*, JM Ritter et al. 9th edition, 2019.
  - *Textbook of Receptor Pharmacology,* JC Foreman et al. 3rd edition, 2011.
- Textbooks of Clinical Pharmacology eg
  - *Clinical Pharmacology and Therapeutics - Lecture Notes,* GA McKay, MR Walters. 9th edition, 2013.
  - *Clinical Pharmacology* MJ Brown, P Sharma, FA Mir, PN Bennett. 12th edition, 2018.

- Other reference texts eg
  - *Clinical Pharmacokinetics and Pharmacodynamics,* M Rowland and TN Tozer. 4th edition, 2011.
  - *Essentials of Pharmacokinetics and Pharmacodynamics,.* TN Tozer and M Rowland. 2nd edition, 2015.
  - *Goodman and Gilman's The Pharmacological Basis of Therapeutics,* L Brunton, BC Knollman and R Hilal-Dandan. 13th edition 2018.
  - *The Textbook of Pharmaceutical Medicine* ed JP Griffin, J Posner, GR Barker. 7th edition, 2013.

Candidates for the DHP must have an Educational Supervisor (ES) who should help them prepare for the Diploma examination by suggesting reading material, checking that the candidate has comprehensive knowledge in all areas of the syllabus, and clarifying any areas of difficulty or weakness. Please refer to DHP enrolment pack for details of the ES.

Assessments

The standard-setting and marking procedures are described in Regulations A.18 – A.21.

There is no negative marking of the MCQ papers: a correct response earns 1 mark; an incorrect answer receives 0 marks; and no response receives 0 marks. Thus candidates should enter a response to every question: they have nothing to lose by doing so, and they might gain 1 mark by chance alone.

Candidates should note the maximum number of marks available for each short answer question, and the distribution of marks within a question: they should generally allocate their time in rough proportion to the number of marks available. If a question consists of more than 1 part, candidates should take care to answer all parts.

In the Short Answer Question paper (Paper 3), candidates should write their answers in note form, using bulleted or numbered lists where appropriate. Answers must be legible and the meaning clear, but poor spelling or grammar are not penalised. No credit is given for irrelevant information or for discussion of topics outside the scope of the question. Marks may be deducted for important errors of commission, particularly if they relate to unsafe and/or unethical practice.

Adjudication

The adjudication process is described in Regulations A.22 – A.25. Candidates should note particularly that the Examiners' decision is final, with respect to each paper and to the examination as a whole.

Resits

The procedures for resits are described in Regulations A.29 – A.30.

PART 2: CERTIFICATE IN HUMAN PHARMACOLOGY EXAMINATION REGULATIONS AND PROCEDURES

Examination

A.1 The Diploma in Human Pharmacology (DHP) is awarded by FPM on the recommendation of the Board of Examiners.

A.2 A Diploma Examination is conducted annually by the Board of Examiners at a time and place announced by FPM.

A.3 The examination is held over 2 days, which may be consecutive or separate. The date and times are available from FPM about 9 months before the examination and are advertised at least 3 months before the closing date for registration.

A.4 The examination comprises 3 written papers:

Paper 1: *Multiple Choice Question* paper in **'True/False' format** comprising 100 questions (stems), each with 5 completions (a total of 500 statements). The candidate is required to identify which statements are 'true' and which are 'false'. Any number may be true or false. The time allowed for the paper is 3 hours (180 minutes).

Paper 2: *Multiple Choice Question* paper in **'Best of Five' format** comprising 75 questions, each with 5 possible answers of which the single 'best' answer is to be selected. Only 1 of the 5 is the correct answer. The time allowed for the paper is 2.5 hours (150 minutes).

Paper 3: *Short Answer Question* paper comprising 6 to 10 questions to be answered in the form of short notes, bullet points, and/or prose, as specified in the question. Candidates should attempt all questions. The time allowed for the paper is 2.5 hours (150 minutes).

A.5 A candidate may sit Paper 1 as soon as they are eligible; see A.15. Candidates who pass Paper 1 are awarded the Certificate in Human Pharmacology.

A.6 Candidates must sit Papers 2 and 3 together at their first attempt. Candidates who pass one paper but fail the other need not retake the paper they passed at their next attempt; they only need to retake the paper they failed. A pass in Papers 2 and 3 will be valid for 3 further exam settings*. For example, if a candidate passed Paper 2 but failed Paper 3 in 2020:

- Assuming the exams are held annually, the next three exam settings to resit Paper 3 are 2021, 2022 and 2023. Therefore, if a candidate does not attempt or does not pass Paper 3 by 2023, then Paper 2 will need to be resat together with Paper 3 in 2024.

* The validity of a pass in Papers 2 or 3 for three exam settings is effective from the 2020 exam setting. Candidates who have passed Paper 1 will never be required to re-sit Paper 1.

A.7 Exam protocols for online remote invigilated exams are provided, they include information on computer requirements, the process prior to the exam and how the exam is conducted.

A.8 Candidates will be remotely supervised under examination conditions throughout the exam and the entire exam is recorded. The recording of the exam is destroyed 6 weeks after the exam date unless it is to be used as evidence in a case of misconduct. Candidates have the right to request a copy of their exam recording.

A.9 Candidates are advised to be in their chosen exam location 20 to 30 minutes before their scheduled exam start time in order to login, enter exam and go through the system checks. Candidates will be permitted to commence the exam up to 30 minutes after the scheduled start time. The duration of their exam remains the same. If a candidate has not connected within 30 minutes, their exam will expire and they will not be able to do the exam.

A.10 Situations such as long-term sickness may prevent a candidate from re-sitting Papers 2 and/or 3 in a particular year. The candidate may then be entitled to an extension of the validity of their pass in one of the papers. The extension of the validity of the pass will be considered on a case by case basis by the Board of Examiners. Candidates who wish to request an extension should submit their justification to the FPM Examinations and Standards Manager (exams@fpm.org.uk).

Exam registration

A.11 FPM supplies a Diploma Examination pack containing all necessary forms, the *Candidate Guidance and Syllabus* and these *Examination Regulations and Procedures*.

A.12 Candidates must complete the application form and submit it to the FPM office by the announced closing date.

A.13 When attending an examination, candidates are required to provide photographic identity (e.g., passport, driving licence, identity card) at registration.

Eligibility

A.14 Eligibility of candidates to sit the Diploma examination is decided by the Board of Examiners.

A.15 Paper 1 of the examination is open to candidates who have attended the two 5-day mandatory courses at King's College London, on 'Exploratory Drug Development' and 'Drug Development Pharmacology', with completion of related assignments to a satisfactory standard.

A.16 Papers 2 and 3 are open to candidates who meet the above criteria for Paper 1 and have attended a 1-day course on prevention and management of adverse reactions in Phase I studies. Candidates must also have completed at least 2 years of workplace training, with portfolio, and must have achieved a satisfactory standard in the rest of the curriculum. The Senior Specialty Advisor or the Educational Supervisor must verify on the application form that the candidate meets those requirements.

Syllabus

A.17 In the examination, a Diploma candidate should expect questions on any section of the Syllabus.

Assessment

A.18 Standards for the papers are set using a criterion-referenced procedure in which the pass marks are decided before the examination. The procedure takes into account the difficulty of the paper and the standard expected of candidates at this level. There is no limit to the proportion of candidates who may pass.

A.19 The *multiple-choice* questions of Papers 1 and 2 are marked by computer. Each correct response earns 1 mark, no response receives 0 marks, and an incorrect answer receives 0 marks.

A.20 Answers to the *short answer questions* of Paper 3 are marked by 3 examiners independently. To maximise standardisation, the answers of all candidates to each individual question are marked by the same 3 examiners, who use a guide to the core answer and the allocation of marks.

A.21 Candidates are identified only by their candidate numbers throughout the examination, until after the adjudication.

Adjudication

A.22 When all results are available, an adjudication meeting of the Diploma/Certificate in Human Pharmacology Examinations Subcommittee is held to examine any inconsistencies among examiners in a candidate's marks for individual questions.

A.23 Candidates must meet all the eligibility criteria set out in A.14 – A.16, and must pass all 3 parts of the examination, to gain an overall 'Pass'.

A.24 At the adjudication meeting, the examiners review the examination procedures and the overall results. Particular attention is paid to candidates who are close to the boundary between pass and fail in Paper 2 or 3.

A.25 The examiners' decision is final with respect to the outcome of any individual paper and of the examination as a whole.

Communication of results

A.26 FPM informs all candidates of the outcome by email. Unsuccessful candidates receive a detailed summary of their performance in the different sections of the Syllabus.

A.27 A Diploma certificate is issued as appropriate.

A.28 Candidates are not entitled to the return of their answer papers after the examination. The Chair cannot enter into detailed discussion with a candidate, but will be as constructive as possible in any correspondence.

Resits

A.29 Candidates must pass all 3 papers to obtain the Diploma, but can resit any paper that they fail. Candidates resit only the paper(s) previously failed.

A.30 Candidates will have a maximum of 6 attempts at each of the Examination papers Candidates who do not pass Papers 2 and 3 within the first 3 settings of the examination that follow their first attempt at these papers must then resit both papers 2 and 3; see A.6.

Fees

A.31 Fees for 1 sitting of the DHP examination are included in the overall prepaid fees for the DHP programme. Unsuccessful candidates who register to resit the examination pay an additional fee.

Compliance

A.32 FPM may refuse to register a person as a Diploma candidate, and may withdraw such registration at any time, if that person does not comply with regulations or instructions before or during the examination.

A.33 Mobile phones, calculators, smart watches and other electronic devices that can access the internet may not be used during the examination. Only ordinary 'clock face' watches will be allowed.

A.34 FPM will investigate any suspected dishonesty or misconduct by a candidate in relation to the DHP examination and, if appropriate, may revoke the Diploma and report the candidate to the GMC. An anomaly monitoring system may be used to detect instances of copying or collusion.

Exceptional circumstances and appeals

A.35 Any candidate who wishes the Examiners to take account of exceptional circumstances or conditions present before the start of the examination that might affect his or her performance should refer to the Reasonable Adjustment Policy for Candidates with Special Requirements, details of which are available on the FPM website or from the FPM office. The candidate must notify such circumstances to the Examinations and Standards Manager before sitting the examination. Such information cannot be taken into account if it be passed to FPM after sitting the examination. The information will be kept confidential.

A.36 Any candidate who wishes account to be taken of exceptional conditions or circumstances arising AFTER THE START of the examination must make the invigilator aware of such circumstances AT THE TIME of the examination AND make representation in writing as described in the Appeals Procedure. Information provided after the day of the examination shall not be taken into account.

A.37 The *Appeals Procedure* must also be followed for any representations by candidates on the conduct of the CHP Examination. Details are available on the FPM website or from the FPM office.

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