



FACULTY OF PHARMACEUTICAL MEDICINE

OF THE ROYAL COLLEGES OF PHYSICIANS OF THE UNITED KINGDOM

DIPLOMA IN PHARMACEUTICAL MEDICINE

**GUIDANCE FOR CANDIDATES
AND SUPERVISORS**

**EXAMINATION REGULATIONS
AND PROCEDURES**

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**PART ONE: GUIDANCE NOTES FOR CANDIDATES AND
SUPERVISORS FOR THE DIPLOMA IN
PHARMACEUTICAL MEDICINE**

PREFACE

These notes are intended to provide guidance to physicians studying for the Diploma in Pharmaceutical Medicine (candidates). It is hoped that these notes will clarify the requirements and avoid misunderstandings, thereby enabling candidates to prepare themselves adequately and efficiently. These guidance notes should be read in conjunction with the *Syllabus for Pharmaceutical Medicine* which is available on the Faculty website and enclosed in the examination pack along with the *Examination Regulations and Procedures* in Part 2.

INTRODUCTION

From 1976, the three UK Royal Colleges of Physicians awarded the Diploma in Pharmaceutical Medicine. In 1994, five years after the creation of the Faculty, responsibility for the Diploma examination was transferred to the Faculty.

The examination is held once a year over a period of two days. It currently comprises a written examination consisting of three parts and an oral (viva voce) examination.

The examination is intended to test knowledge and its application relating to all parts of the syllabus, though more weight is given to those areas for which a pharmaceutical physician is likely to be responsible or which have a direct impact on the physician's decision making.

In terms of career progression, passing the examination indicates that the individual has reached a certain level of achievement and has completed a period of training. Possession of the Diploma allows pharmaceutical physicians to apply for Membership of the Faculty of Pharmaceutical Medicine (MFPM). For those pursuing a Certificate of Completion of Training (CCT) or Certificate of Eligibility for Specialist Registration (CESR) in the specialty of Pharmaceutical Medicine in the UK, success in the examination also indicates completion of the required period of basic Pharmaceutical Medicine Specialty Training (PMST).

ELIGIBILITY

The Diploma examination is open to doctors who have entered pharmaceutical medicine and received structured training in the discipline.

Eligibility of candidates to sit the Diploma examination will be assessed at the time of registration for the examination. The criteria are given in the *Examination Regulations and Procedures* in Part 2 of this booklet and are

explained below. Where there is doubt, prospective candidates, particularly those from outside the UK, are encouraged to seek advice from the Faculty early in their training rather than at the time of submitting their application to sit the examination.

The Faculty admits only medical graduates to sit the Diploma examination. In this regard, it accepts undergraduate training that leads to the award of a medical qualification recognised by the General Medical Council (GMC) in the UK. All candidates must be registered as medical practitioners in the country where they qualified or where they are presently practising.

The Faculty also requires that a candidate has completed full-time training in pharmaceutical medicine for at least two years at the time of sitting the Diploma examination, whether or not the candidate is enrolled in Pharmaceutical Medicine Specialty Training. An equivalent amount of part-time training is accepted provided that the trainee has worked at least 2½ days/week. This experience will almost always be acquired within the pharmaceutical industry, in a contract research organisation or in a drug regulatory authority. Time spent in research within an academic department of a medical school or hospital is rarely appropriate. A senior line manager at the company at which this experience was gained who, ideally, is also a Member or Fellow of the Faculty and/or Educational Supervisor, is required to verify on the application form that the candidate has met this requirement.

Applicants for Membership of the Faculty or for specialty registration are reminded that they must meet additional eligibility requirements. Success in the Diploma examination is necessary but not sufficient.

EDUCATIONAL SUPERVISOR

Candidates who are undertaking Pharmaceutical Medicine Specialty Training (PMST) must have an Educational Supervisor to help them prepare for the Diploma examination. Whilst other candidates for the Diploma examination are not required to have an Educational Supervisor, it is strongly recommended that they do so. Educational Supervisors should meet the criteria that have been set for Educational Supervisors in Pharmaceutical Medicine Specialty Training. These are available on the Faculty's website.

It is sensible for the Educational Supervisor to be employed in the same organisation and / or the same locality as the candidate. This aids communication, facilitates a one-to-one teacher-pupil relationship, enables the candidate to gain access to personnel and information of relevance to their training and preparation for the examination and helps the candidate obtain the necessary time and resources for their training. If the candidate and their line manager cannot identify an appropriate supervisor within their organisation or locally, the Faculty may be asked to assist in finding a supervisor.

The role of an Educational Supervisor is important. The supervisor should assist in devising the training of a novice pharmaceutical physician, taking into account his or her earlier postgraduate training and past experience. A programme can be outlined to remedy perceived deficiencies in exposure to

particular areas of the syllabus. Attendance at training courses, congresses or symposia, provision of CPD teach-in material, distance learning and secondment to other departments of the company or to an external institution may all be considered. The programme should be tailored to the individual's needs and will take into account his or her likely career development. Thereafter, the supervisor should monitor the programme, helping to identify other needs that come to light and how they can be met. The supervisor should also assist the trainee by suggesting reading material, discussing recent developments in pharmaceutical medicine and issues often not covered in textbooks, and providing feedback on practice examination questions.

PREPARATION FOR THE EXAMINATION

A Diploma candidate should plan a training programme in pharmaceutical medicine, where appropriate with the advice of his or her Educational Supervisor. The training in pharmaceutical medicine should involve courses, distance-learning packages, other tuition and personal study.

Candidates are not required to have attended a postgraduate course covering the syllabus for pharmaceutical medicine, though most do. There are many such courses currently being run in Europe including several in the UK. In addition, several courses cover specific areas that fall within the syllabus.

Personal study should supplement other approaches to learning. Study of a current edition of one of the published comprehensive texts such as *The Textbook of Pharmaceutical Medicine*¹ is highly recommended as preparation for the examination. Textbooks on key topics in the syllabus such as clinical trials, pharmacokinetics, medical statistics, safety assessments, etc, are also essential reading. Regulatory guidelines, particularly those issued by ICH, can also be a valuable source of up-to-date information. Regular reading of editorials and articles in the *International Journal of Pharmaceutical Medicine*, *British Journal of Clinical Pharmacology* and general medical journals such as the *New England Journal of Medicine* and *The Lancet* provides part of the pharmaceutical physician's lifelong learning and can provide a guide to 'hot topics' which might feature in the examination.

Candidates are advised to study past Short Answer Question and Essay papers, which are available from the Faculty office at a small cost, though, as with all examinations, they should not be taken as an absolute guide to future examinations. It is particularly helpful to practice answering past questions under conditions mimicking the examination and obtaining feedback from an Educational Supervisor or comparing one's answer with those of a colleague. Past MCQ examination papers are not available to candidates as some questions may be used again.

It is suggested that a valuable exercise by way of preparation for the oral examination is to undertake critical review of published clinical pharmacology studies, larger clinical trials and epidemiological studies. Making a detailed record of one's views about the Methods and Results before reading the

¹ The Textbook of Pharmaceutical Medicine. 5th edition Editors Griffin JP, O'Grady J, BMJ Publ. 2005

Discussion section makes the process active rather than just accepting the views of the authors. It is particularly useful to critique a paper that forms the subject of an accompanying editorial, again completing the exercise before reading the editorial, which serves as feedback. Comparison of one's responses with those of a colleague can add great value to this exercise.

In addition to reviewing published papers, much can be gained by spending time with colleagues working in different areas of the industry. Like any other medical specialty, pharmaceutical medicine is learned through examples in practice.

The examination tests knowledge and its application relating to *ALL* parts of the syllabus and, in aggregate, a combination of these approaches to preparation must cover all elements of the syllabus. However, some sections are given greater emphasis in the examination and, therefore, require more study. More weight is given to those areas for which a pharmaceutical physician is likely to be responsible such as the management and reporting of serious adverse events occurring during a clinical trial. Knowledge of both principles and practice of therapeutics is considered an essential requirement for pharmaceutical physicians and features prominently in the written examination.

FORMAT OF THE EXAMINATION

The three written parts of the examination, consisting of a *Multiple Choice Question (MCQ)* paper, a *Short Answer Question* paper and an *Essay* paper, together with the oral examination are prepared by panels of examiners and the Officers of the Board of Examiners. Core features of the answers and the allocation of marks are also prepared prior to the examination and distributed for guidance to examiners when the scripts and oral examination are marked.

The three papers comprising the **Written** examination are as follows:

- an *MCQ* paper of 250 questions (50 stems each with 5 statements) all to be completed in 1 hour 30 minutes;
- a *Short Answer Question* paper of ten questions all to be completed in 2 hours 30 minutes;
- an *Essay* paper of four questions of which candidates are required to attempt two in 1 hour 30 minutes.

The time allowed for the written examination is sufficient to complete the papers working at a reasonable pace.

The *MCQ* is intended primarily to test factual knowledge. Each *MCQ* has a stem followed by five statements, any number of which may be true. The candidate is required to identify which are 'true' and which are 'false'.

The *Short Answer Question* paper tests factual knowledge. The questions can bring together several issues and subsections of the syllabus. The candidate is expected to identify the major relevant points and thereby show their understanding of the topic. Candidates should read each question

carefully and answer it. Each answer should be written in note or bullet point form.

In total, 10 marks are available for each question (100 marks for the full paper). Candidates should note any guidance provided on the distribution of marks within a question and, if a question consists of more than one part, take care to answer every part.

It is important to attempt every question since 10% of the possible marks will be lost for each question not answered. Candidates who do not attempt or fail to score on three or more questions will fail this paper (and hence the whole examination) whatever their aggregate score is on the remainder of the paper.

The *Essay* paper also requires knowledge but is designed primarily to test the ability of the candidate to present reasoned argument, expressed in a coherent manner. It is recommended that candidates spend a few moments planning their answer before beginning to write. A substantial proportion of the marks is allotted specifically to demonstration of the ability to analyse a problem, offer solutions and management options and to exercise judgement. Credit is given for good organisation. Some questions may present scenarios and invite a problem-solving answer while others may seek a response showing appreciation of a series of related issues. Answers should *not* be written in an abbreviated style e.g. listings. The *Essay* paper questions typically bring together several issues and subsections of the syllabus.

It is emphasised that no credit is given in any part of the examination for irrelevant information or discussion of topics outside the scope of the question. Where a question has more than one part, all parts must be answered to gain maximum marks. Marks may be deducted for important errors of commission, particularly if they relate to statements of unsafe and/or unethical actions.

Answers must be legible and the meaning clear; however, poor spelling or grammar are not penalised.

The *Oral* examination is held on the day following the written papers. Candidates should note that the time of their oral examination will not be allocated until after the closing date for entry for the Diploma examination and allow for a full half-day for this part of the examination as they may be detained before or after their oral examination while examination of other candidates is in progress. Examiners conducting the oral part of the examination are not aware of the candidate's marks in the written papers, which will not have been marked at this time. The oral examination is designed to test the ability of candidates to summarise verbally and critique the important components of work published in a scientific paper of direct relevance to the role of a pharmaceutical physician. The abstracts of up to three published papers will be provided and candidates are allowed 5 minutes to select one of the papers. Candidates are then given approximately 40 minutes to study the selected paper, preparing notes if they wish. This period of preparation is followed immediately by the *viva voce* conducted by two examiners, which will occupy a period of 20 minutes. The candidate will be asked to begin the *viva* by summarising the important features of the

publication in one to two minutes. Subsequent questioning will be shared between the two examiners. To standardise the examination as far as possible, examiners are required to adhere reasonably closely to a sequence of prepared question topics to assist the candidate to critique the design, analysis and results as presented by the authors. Candidates will also be invited to discuss the interpretation and significance of the results for clinical practice and further research. Examiners are free to modify or extend these topics as appropriate. An observer may be present but will take no part in the examination or in its assessment.

ASSESSMENTS

Standards for the written papers are set using an objective criterion-referenced procedure in which the pass mark and the ranges of marks corresponding to each grade are decided in advance. The procedure takes into account the difficulty of the paper and the standard expected of candidates at Diploma level. There is no limit to the number of candidates who may pass.

The *MCQ* paper is marked by computer. Each correct response earns one mark (maximum of 250 marks overall), no response receives zero marks and an incorrect answer receives zero marks.

The *Short Answer* and *Essay* papers are each marked by pairs of examiners marking independently. Each question is generally marked by the same two examiners for all candidates using the core features of the answer and guide to allocation of marks provided to maximise standardisation. A moderating procedure exists for any individual questions for which a discrepancy arises in the marks awarded by the two examiners. Candidates are identified by their candidate numbers only.

Immediately after each *Oral* examination, the examiners independently assess the candidate's performance and then confer to agree a final grade.

A meeting of the Officers and Panel Convenors of the Board of Examiners is held prior to a full meeting of the Board to award grades for each part of the written examination. The possible grades are: 'Excellent', 'Good', 'Pass', 'Bare Pass', 'Bare Fail' or 'Fail'. It is unusual for a candidate to fail on a single part of the examination but when this does occur the part in question is re-assessed to verify the initial agreed mark or otherwise.

ADJUDICATION

The final decision on 'Pass' or 'Fail' is made at an adjudication meeting of the full Board of Examiners held about four weeks after the examination. Candidates are identified by their candidate numbers only throughout the examination until after the adjudication.

The grades of each candidate in all four parts of the examination are listed and each is considered in turn and a decision reached. A candidate must obtain at least a 'Bare Pass' in each of the four parts to pass the examination.

Candidates given a single 'Bare Fail' will pass the exam if the grades in the other three parts are 'Pass' or higher. Candidates with one 'Bare Fail' and one or more 'Bare Pass' will not pass the examination.

The Board of Examiners may award the Diploma with Distinction to candidates who obtain consistently high grades in the examination.

After completion of the adjudication, a detailed review of the overall results and of the examination procedures is conducted.

Re-marking of written examination papers after completion of the moderation and adjudication processes will only be undertaken at the request of the Appeals Panel in response to a well-founded appeal.

PART TWO: EXAMINATION REGULATIONS AND PROCEDURES

DIPLOMA EXAMINATION

- A.1 The Diploma in Pharmaceutical Medicine (DipPharmMed) is awarded by the Faculty on the recommendation of the Board of Examiners.
- A.2 A Diploma Examination is conducted annually by the Board of Examiners at a fixed time and place announced by the Faculty.
- A.3 The Diploma candidate is required to sit a written examination and to attend an oral examination.
- A.4 Membership of the Faculty may be granted to pharmaceutical physicians who possess the Diploma, meet other eligibility criteria, and have their application approved by the Board of the Faculty (see A.43).

DIPLOMA REGISTRATION

- A.5 The Faculty will provide a Diploma Examination pack containing all necessary forms with *Guidance Notes for Candidates and Supervisors*, *Syllabus for Pharmaceutical Medicine* and the *Examination Regulations and Procedures*.
- A.6 Candidates must complete the application form and submit it with a recent photograph for identity, along with supporting documents, to the Faculty office by the announced closing date.
- A.7 When attending the examination, candidates are required to provide photographic identity (passport, driving licence or ID from place of work) at registration on both days.

ELIGIBILITY OF CANDIDATES

- A.8 Eligibility of candidates to sit the Diploma examination will be decided by the Board of Examiners.
- A.9 Candidates must possess full registration with the General Medical Council (GMC) in the UK or possess a medical qualification recognised by the GMC and be registered in the country in which the qualification was granted or where currently working.
- A.10 When submitting the application form, candidates must provide evidence of registration as a medical practitioner by provision of their GMC registration number. Candidates not registered in the United Kingdom should provide the original or a notarised (legally validated) copy and translation of their medical registration certificate. If this does not show current registration then a certificate of good standing will also need to be produced.

- A.11 A Diploma candidate must have completed, by the time of the Diploma Examination, at least two years in a post that provides practical experience and training in pharmaceutical medicine. A senior line manager at the company at which this experience was gained, who, ideally, is also a Member or Fellow of the Faculty and / or the Educational Supervisor, is required to verify on the application form that the candidate has met this requirement.
- A.12 The practical experience in pharmaceutical medicine may be obtained by working in a pharmaceutical company, contract research organisation or drug regulatory authority or, exceptionally, in an academic department. An equivalent amount of part-time training is accepted, provided the candidate has worked at least 2½ days / week in a relevant position.

EDUCATIONAL SUPERVISOR

- A.13 Candidates who are enrolled with the Faculty and Joint Royal Colleges of Physicians Training Board (JRCPTB) for Pharmaceutical Medicine Specialty Training must have an Educational Supervisor to assist in planning their training in pharmaceutical medicine. In addition, a Senior Specialty Adviser will be allocated to these candidates. It is recommended that candidates who are not enrolling for Pharmaceutical Medicine Specialty Training also have an Educational Supervisor.

SYLLABUS

- A.14 The *Syllabus for Pharmaceutical Medicine* is presented in detail on the Faculty's website and is enclosed in the examination pack.
- A.15 A Diploma candidate should expect questions during the examination on any section of the syllabus. The discipline of pharmaceutical medicine is ever evolving and a Diploma candidate should be aware of important recent changes and current issues.

WRITTEN EXAMINATION

- A.16 The written examination is held during one day. The place and time are available from the Faculty about 10 months before the examination and are advertised about 3 months before the closing date for registration.
- A.17 The written examination comprises three separate papers with a rest period between each and consists of:

Multiple Choice Question (MCQ) paper. All 250 questions (50 stems each with 5 choices) should be answered in 1 hour 30 minutes

Short Answer Question paper. All ten questions should be answered in 2 hours 30 minutes

Essay paper with a choice of four questions of which two should be answered in 1 hour 30 minutes

- A.18 The final selection of questions for the papers is made by the Officers and Panel Convenors of the Board of Examiners. The Board ensures that the written examination as a whole covers the syllabus appropriately. Core features of the *short answers* and guidance notes for the markers of the essays are checked and agreed.
- A.19 Candidates will not be allowed to leave the room within the first 15 minutes of any written paper and candidates arriving late will not be admitted after this time. Any candidate wishing to leave and return to the examination hall will be accompanied.
- A.20 Mobile phones, calculators and other electronic devices may not be used during the examination and, if brought into the examination hall, must be switched off and placed to the side of the room out of sight of all candidates.

ORAL EXAMINATION

- A.21 The oral (*viva voce*) examination is held the day following the written examination.
- A.22 Suitable scientific papers for the oral examination are selected and topics for discussion with candidates are identified by the Officers and Panel Convenors of the Board of Examiners.
- A.23 Candidates are allocated a time for arrival and must arrive at that scheduled time. Candidates who arrive late will not be given any additional time and may not be able to take the oral examination. Candidates should note that the time of their oral examination will not be allocated until after the closing date for the Diploma examination and allow for a full half-day for this part of the examination as they may be detained before or after their oral examination while examination of other candidates is in progress.
- A.24 Candidates will have 5 minutes to select one of up to three published papers on which they will be examined. Approximately 40 minutes are allotted for preparation. Candidates are expected to demonstrate an ability to summarise critically the important features of the paper in a brief oral presentation, to answer questions focusing on its design, conduct and results and to discuss their relevance to clinical practice and research. Candidates will not be expected to have specialist knowledge of the particular scientific material or therapeutic area.
- A.25 The oral examination lasts 20 minutes and is conducted by two examiners, each asking questions and each adjudicating the replies for equal periods.
- A.26 An observer may be present at each table, but will take no part in the examination or in its assessment.

- A.27 Examiners will not request the candidate's company identification or confidential information.

ASSESSMENT

- A.28 Candidates must attend and attempt all four sections of the examination.
- A.29 The multiple-choice questions are marked by computer and grades are then assigned according to pre-set standards.
- A.30 Pairs of examiners mark candidates' answers in the *short answer* and *essay* sections of the written examination. Individual questions will generally be marked by two examiners acting independently.
- A.31 For each section of the examination, one of the following possible grades are awarded: 'Excellent', 'Good', 'Pass', 'Bare Pass', 'Bare Fail', and 'Fail'. The Board of Examiners approves the correspondence between marks and grades.

ADJUDICATION

- A.32 Before the meeting of the full Board, the Officers and Panel Convenors examine any inconsistencies in a candidate's marks on individual questions and grades and re-assess the relevant papers identified through this process.
- A.33 The Board of Examiners holds its annual meeting approximately four weeks after the examination. The adjudication of the Diploma Examination is a major item, followed by a detailed review of the overall results and of the examination procedures.
- A.34 Candidates are identified by their candidate numbers only throughout the examination until after the adjudication.
- A.35 Each candidate's grades in all four sections are listed and each is considered in turn and a decision reached.
- A.36 An outright 'Fail' in any part of the examination will lead to an overall fail of the examination.
- A.37 Candidates given one 'Bare Fail' may pass the examination if the grades in the other three sections are 'Pass' or higher. A 'Bare Pass' indicates precisely that and candidates with one or more 'Bare Fail' and one or more 'Bare Pass' grades will not pass the examination. Similarly, a candidate with two 'Bare Fails' will fail the examination. During the adjudication process, care is taken by the examiners to review papers with critical borderline grades with re-marking and possible re-grading if considered appropriate.

- A.38 The Board of Examiners may award the Diploma with Distinction to a candidate who has consistently high grades (generally 'Good' or 'Excellent') in all four sections of the examination.

COMMUNICATION OF RESULTS

- A.39 The Faculty will advise all candidates of the outcome in writing.
- A.40 A Diploma certificate will be provided as appropriate.
- A.41 Candidates are not entitled to the return of their answer papers after the examination. Written papers will only be re-marked after the adjudication at the request of the Appeals Panel in response to a well-founded appeal. The Chair cannot enter into detailed discussion with a candidate but will try to be as constructive as possible in any correspondence.
- A.42 An unsuccessful candidate may re-sit the Diploma Examination.

MEMBERSHIP OF THE FACULTY

- A.43 A pharmaceutical physician who has been awarded the Diploma in Pharmaceutical Medicine, meets other eligibility criteria and wishes to become a Member of the Faculty must complete an application form and submit it to the Faculty office.

FEES

- A.44 The Faculty will maintain a schedule of fees, which will be included in the Diploma Examination pack with the conditions that apply clearly stated.

CONDUCT

- A.45 The Faculty may refuse to register a person as a Diploma candidate and may withdraw such registration at any time if the candidate's behaviour is prejudicial before or during the examination by not complying with examination regulations or instructions.
- A.46 The Faculty will investigate any suspected dishonesty or misconduct by a candidate in relation to the Diploma Examination and, if appropriate, revoke the Diploma and Membership.
- A.47 Any candidate who wishes account to be taken of exceptional circumstances or conditions present *BEFORE* the start of the examination that may affect his or her performance must refer to the *Policy for Candidates with Special Requirements*, details of which are available on the Faculty website or from the Faculty office. Such circumstances must be notified to the Chair of the Board of Examiners or the Education Administrator *BEFORE SITTING* the examination; such information passed to the Faculty after sitting the examination

cannot be taken into account. This information will be kept confidential.

- A.48 Any candidate who wishes account to be taken of exceptional conditions or circumstances arising *AFTER THE START* of the examination must make the invigilator / examiners 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.49 The Appeals Procedure should also be followed for any representations by candidates on the conduct of the Diploma Examination. Details are available on the Faculty website or from the Faculty office.

The Faculty of Pharmaceutical Medicine is committed to promoting equal opportunity and eliminating discrimination in all areas of its activity