



FACULTY OF PHARMACEUTICAL MEDICINE

OF THE ROYAL COLLEGES OF PHYSICIANS OF THE UNITED KINGDOM

DIPLOMA IN PHARMACEUTICAL MEDICINE

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 the Diploma in Pharmaceutical Medicine* in Part 2 of this document and the *Examination Regulations and Procedures* in Part 3.

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 intended to test knowledge and its application relating to all parts of the syllabus (see Part 2 of this booklet), 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. An example of the latter would be 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. The examination is held once a year over a period of two days.

It has a conventional format of written papers and an oral (viva voce) examination.

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 eligible pharmaceutical physicians to become Members of the Faculty. For those pursuing a Certificate of Completion of Training (CCT) 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, having completed a required period of general professional (clinical) training, have entered pharmaceutical medicine and received structured training in the discipline. Candidates for the 2007 Diploma examination are required to have qualified in medicine in or before 2002; thus, the new regulations relating to Modernising Medical Careers are not currently applicable.

Eligibility of all candidates to sit the Diploma examination will be assessed at the time of registration for the examination. The eligibility criteria that candidates must meet are consistent with the requirements for Membership of the Faculty of Pharmaceutical Medicine and those laid down by the three Royal Colleges of Physicians UK for specialist training and accreditation in the specialty. The criteria are given in the *Examination Regulations and Procedures* in Part 3 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 requires a minimum period of two years post-registration clinical experience in General Professional Training in posts that should normally involve direct patient care and experience of prescribing. Multidisciplinary rotations are highly recommended. This period does not include the compulsory pre-registration twelve-month period of house officer (intern) posts necessary for full registration in the UK or any time spent in clinical training as an undergraduate.

The most frequent reason for pharmaceutical physicians failing to meet the eligibility criteria for the Diploma and hence Membership of the Faculty and Pharmaceutical Medicine Specialty Training is an inadequate period of General Professional Training. It is far better to remedy this situation early

rather than waiting until it becomes almost impossible to return to clinical practice in a recognised training post.

The Faculty also requires that a candidate will have undergone 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.

A Diploma candidate should plan a training programme in pharmaceutical medicine, where appropriate with the advice of his or her Educational Supervisor (see below). The training should involve supervised courses and distance-learning packages or other tuition. Candidates are not required to have attended a postgraduate course covering the syllabus in pharmaceutical medicine, though most do. There are approximately ten such courses currently being run in Europe including two in the UK. In addition there are many courses covering specific areas that fall within the syllabus. Personal study should supplement other approaches to learning. In aggregate, a combination of these should cover all elements of the syllabus. Parts 1 and 2 of this publication should be consulted on the scope of training.

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 are not required to have an Educational Supervisor, it is strongly recommended that they do so.

Educational Supervisors must be medically qualified. It is recommended that they meet the following additional criteria, which have been set for Educational Supervisors in Pharmaceutical Medicine Specialty Training.

1. GMC registered physician or whose medical qualification would fulfil the GMC's requirements for registration
2. Minimum 5 years experience as a pharmaceutical physician
3. Member or Fellow of the Faculty of Pharmaceutical Medicine
4. Willing and able to undertake training as an Educational Supervisor
5. Employed in the same organisation and / or same locality as the trainee
6. Actively undertaking continuing professional development

7. A CCT in Pharmaceutical Medicine
8. Management expertise
9. Evidence of professional development in medical education
10. Contributions to the development of an organisation and delivery of education and training
11. Achievements in and contributions to the specialty of Pharmaceutical Medicine
12. Commitment to specialty training

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 and enables the candidate to gain access to personnel and information of relevance to their training and preparation for the examination. This would also help the candidate to 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 a suitable medical specialist with relevant experience in a local university or hospital, 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 and discussing recent developments in pharmaceutical medicine and issues often not covered in textbooks.

PREPARATION FOR THE EXAMINATION

Attendance at a postgraduate course in Pharmaceutical Medicine and 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. 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*

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

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 may also wish to study past 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. 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 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.

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 four 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 choices) 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 of the *MCQs* has a stem statement followed by five options and 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 and typically requires less than two sides of paper. Credit is given for good organisation. *No credit is given for providing information outside the scope of the question.*

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. 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. 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. Allowance is made for candidates whose mother tongue is not English although it is fair to state that a good standard of written English is expected. The *Essay* paper questions typically bring together several issues and subsections of the syllabus. *No credit is given for irrelevant information or discussion of topics outside the scope of the question.*

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 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. Up to three published papers will be provided and candidates are allowed 5 minutes to select one of the papers, which will form the basis of a discussion with the examiners. Candidates are 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 and 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

Pass marks of all written papers are set taking into account the difficulty of the questions. Standards for the written papers are set using an objective criterion-referenced procedure in which the pass mark is decided in advance. It 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, 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 with the candidates remaining anonymous. 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. Each examiner marks the question(s) independently. 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'. A standard reference range of marks corresponding to each grade is agreed prior to review of the marks.

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. The identity of candidates in the written parts of the examination remains unknown to the examiners at and 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 'Bare Pass' will not pass the examination. It is unusual for candidates 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.

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.