



FACULTY OF PHARMACEUTICAL MEDICINE
OF THE ROYAL COLLEGES OF PHYSICIANS OF THE UNITED KINGDOM

CONTINUING PROFESSIONAL DEVELOPMENT GUIDANCE NOTES

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Good Pharmaceutical Medical Practice		



1. **INTRODUCTION**

Physicians have a duty to keep their knowledge and skills up to date throughout their career.

WHAT IS CONTINUING PROFESSIONAL DEVELOPMENT (CPD)?

CPD is a continuing learning process that helps physicians to keep up to date and develop new skills, enabling them to maintain and improve their professional practice to the highest possible standard. CPD should support changes in a physician's practice and career and should also help physicians to keep up to date when they are not practising.

2. **BACKGROUND**

The Faculty's Continuing Medical Education (CME) scheme in pharmaceutical medicine was introduced in 1998. Since 1998, the Faculty has had a place on the committee of Directors of CPD (formally Directors of CME), which co-ordinates the CPD schemes of most Medical Royal Colleges and associated Faculties. During this time, CME has broadened from a process principally concerned with keeping up to date with medical/scientific and specialist knowledge to one of Continuing Professional Development (CPD), which also takes account of the development of skills which reflect the full range of practice of an individual physician and these may include teaching, research, management etc. The Faculty's scheme was revised in 2003 and now focuses on CPD.

With Revalidation being introduced in the near future, physicians wishing to retain a licence to practise will need to demonstrate amongst other things that they have kept their knowledge and skills up to date. Collecting evidence about their CPD activities will help them to fulfil that part of the requirements.

3. **GENERAL INFORMATION**

Yearly appraisal arranged within the workplace or independently (which may or may not be a Revalidation appraisal), provides a formal, structured opportunity for physicians to discuss their CPD needs and agree personal development objectives. Appraisal should ensure that any CPD identified is relevant to a physician's practice, career and learning needs. Physicians wishing to retain a licence to practise should aim to collect evidence to cover all areas of the Good Pharmaceutical Medical Practice (GPMP) document (Annex A).

The Faculty of Pharmaceutical Medicine allocates credits as measures of CPD. Generally, one credit will correspond to one hour of learning (excluding travelling and breaks). In line with other Faculties and Colleges, the Faculty of Pharmaceutical Medicine recommends that participants in its scheme should aim for a target of 250 CPD credits in any 5-year period i.e. 50 credits per year, although it is recognised that this might not always be possible. There should also be a balance between the various CPD activities (see section 4 below) as well as external and internal CPD activities.

It is important for all physicians to note that they have the responsibility for taking part and recording their own relevant CPD activities. It is also the responsibility of the physician to collect verifiable evidence to support each entry in their CPD diary.

4. CPD ACTIVITIES

The following list of CPD activities provides the basis for accumulating CPD credits. This list is for illustrative purposes only and is not exhaustive. Participants with queries are actively encouraged to contact the CPD Co-ordinator or the CPD Director via the Faculty office.

- Professional meetings, symposia, workshops (1 credit per hour)
- Presentations (3 credits per qualifying presentation)
- Authorship (editing 15 credits; chapter 10 credits; publication 5 credits)
- Training courses (1 credit per hour)
- Structured self-learning programmes (1 credit per hour)
- Reading (1 credit per hour; maximum 10 credits per year)
- Membership of ethics committees (1 credit per hour; maximum 20 credits per year)
- Specified clinical attachment (0.5 credits per hour; maximum 5 credits per year)
- Ward rounds and clinical meetings (1 credit per hour; maximum 10 credits per year)

Participants should note that the maximum number of credits that can be recorded for a single activity at any one time is 25 credits (excluding activities with other restrictions imposed). For example, if a doctor attended a training course that was 30 hours in duration, only 25 credits could be recorded in their CPD diary.

5. DETAILS OF CPD ACTIVITIES

For information regarding what activities need approval please refer to section 6 below.

PROFESSIONAL MEETINGS, SYMPOSIA, WORKSHOPS (1 CREDIT PER HOUR)

Professional meetings, symposia, workshops that are relevant to a physician's professional practice can be recorded for CPD.

Those that are medical/scientific related need to be approved for CPD by the Faculty or one of the other Medical Royal Colleges or associated Faculties in the UK. Please refer to section 7 below, for further information.

Evidence/certificate of attendance, programme/agenda and approval confirmation from the CPD Co-ordinator (if appropriate) must be retained for audit purposes.

PRESENTATIONS (3 CREDITS PER QUALIFYING PRESENTATION)

Presentations relevant to a physician's professional practice will count for 3 credits provided that the presentation is 30 minutes or more in duration. If it is a shorter presentation dictated by the time limits imposed by particular meetings or societies, then evidence must be produced to show that it is based on material that would normally require 30 minutes or more for presentation.

Presentations qualify provided they are not based on material previously submitted for credits under this or another category in a calendar year.

Individuals who present at and attend the whole meeting will be entitled to claim for both.

Presentations that are medical/scientific related need to be approved for CPD by the Faculty or one of the other Medical Royal Colleges or associated Faculties in the UK.

A copy of the presentation, the programme/agenda where the presentation took place and approval confirmation from the CPD Co-ordinator (if appropriate) must be retained for audit purposes.

AUTHORSHIP (EDITING 15 CREDITS; CHAPTER 10 CREDITS; PUBLICATION 5 CREDITS)

- Being an Editor of a book qualifies for 15 credits
- Writing a chapter of a book qualifies for 10 credits
- Authors will receive 5 credits for an original publication if they meet the Vancouver guidelines for definition of authorship
- Abstracts or posters merit 2 credits but if the work is subsequently published as a full paper, only a further 3 credits will be awarded at that stage

The reference should be inserted into the CPD diary and a copy of the publication must be retained.

AUTHORSHIP – OTHER THAN JOURNAL PUBLICATIONS AND BOOKS

From time to time participants might write documents during the course of their work for which they would like to claim CPD credits.

Please contact the CPD Co-ordinator for information about how to apply for CPD approval for these activities.

TRAINING COURSES (1 CREDIT PER HOUR)

Training courses, which are relevant to a physician's professional practice, can be recorded for CPD.

Those that are medical/scientific related need to be approved for CPD by the Faculty or one of the other Medical Royal Colleges or associated Faculties in the UK.

Postgraduate courses in pharmaceutical medicine, which prepare for the Diploma in Pharmaceutical Medicine, are eligible for CPD, along with courses approved for Pharmaceutical Medicine Specialty Training (PMST – formerly Higher Medical Training [HMT]). A maximum of 25 credits per annum can be recorded for these activities. Other postgraduate courses that are relevant to a physician's professional practice, e.g. MBA, can also be recorded. A maximum of 25 credits per annum can be recorded for these activities. Those that are medical/scientific related that are not mentioned above, need to be approved by the Faculty if they have not been approved already.

Evidence/certificate of attendance, programme/agenda and approval confirmation from the CPD Co-ordinator (if appropriate) must be retained for audit purposes.

PMST/HMT

Participants who are undertaking PMST can count their training towards CPD and claim a maximum of 50 credits per annum for this activity. If participants wish to count their training towards CPD they must notify the CPD Co-ordinator so that they can be registered into the CPD scheme and the credits can be recorded.

For the period of the participant's training, the Training Record will also act as the CPD folder.

STRUCTURED SELF-LEARNING PROGRAMMES (1 CREDIT PER HOUR)

Web-based and journal structured self-learning programmes are eligible for CPD. Individuals must retain records of the self-learning activities they have undertaken together with the records of their scoring.

Company internal approved training programmes may also be included under this heading, please ensure that completion documents are kept in your CPD file.

READING (1 CREDIT PER HOUR; MAXIMUM 10 CREDITS PER YEAR)

CPD participants will frequently be required to read and obtain information from various publications and such reading will by its very nature involve "learning". A sample of articles/papers read and brief reflective notes of what was learnt (showing topics covered) or verifiable evidence of how that reading was applied practically must be retained for audit purposes.

MEMBERSHIP OF ETHICS COMMITTEES (1 CREDIT PER HOUR; MAXIMUM 20 CREDITS PER YEAR)

Participation in an ethics committee as a full participant is an activity that may be counted towards CPD. Given the confidential nature of the items discussed only brief information will be required as to the particular work undertaken.

SPECIFIED CLINICAL ATTACHMENT (1 CREDIT PER HOUR; MAXIMUM 5 CREDITS PER YEAR)

Routine clinical attachments will not be eligible for credits. Special learning-oriented clinical attachments may be eligible for credits if approved by the CPD Director. Written confirmation from the participant's Medical Director or Head of Department that the clinical attachment is a 'learning experience' must be provided. The participant should request and retain a letter from the Consultant in charge of the clinic, which needs to document the clinical activities undertaken and the total time spent on them.

WARD ROUNDS AND CLINICAL MEETINGS (1 CREDIT PER HOUR; MAXIMUM 10 CREDITS PER YEAR)

Ward rounds and clinical meetings provide an excellent opportunity for those with clinical specialisation to keep up to date and participants must keep brief notes of topics discussed and evidence/certificate of attendance in their CPD file for audit purposes.

6. WHAT ACTIVITIES NEED APPROVAL?

Professional meetings, symposia, workshops, presentations and training courses that are medical/scientific related, whether internal or external, that have not already been approved for CPD by the Faculty or one of the other Medical Royal Colleges or associated Faculties in the UK, must be submitted for approval. Applications for approval can be submitted by the event organiser or by an attendee.

Other activities that are medical/scientific related for e.g. ward rounds and all non-medical activities for e.g. training courses in computer skills, whether internal or external, do not need to be submitted for approval.

7. APPROVAL OF ACTIVITIES

If an event has been approved for CPD by the Faculty or one of the other Medical Royal Colleges/Faculties in the UK, a statement will be entered on to the programme/agenda noting that the event has been approved, by whom and the credits that have been allocated.

If the programme/agenda does not have this information then firstly, contact should be made to check this with the event organiser. If the event organiser has not got approval for the activity then contact should be made to check this with the Faculty.

If it has not been approved the participant should notify the Faculty CPD Co-ordinator, enclosing a copy of the programme/agenda together with a CPD approval application form and request approval. The CPD Director will decide whether the activity is eligible and will decide the credit allocation. The participant will be informed of the outcome.

RETROSPECTIVE APPROVAL

Activities needing approval should be submitted for approval prior to attendance. Approval on a retrospective basis may be given under certain circumstances, for example if an event provided an unexpected learning opportunity, but requests for approval should be submitted to the CPD Co-ordinator at the Faculty within two weeks after attendance.

DOCUMENTATION

The participant must record the number of hours spent on CPD activities and enter the corresponding number of credits in the CPD diary. The participant must retain all evidence of CPD activities including copies of the programmes/agendas, approval confirmations from the Faculty CPD Co-ordinator, evidence/certificates of attendance and reflective learning notes (for activities such as reading and ward rounds) in the CPD file.

8. COMPLETING THE CPD DIARY

PAPER DIARY

The diary is provided in order to keep a record of the participants CPD activities. The number of credits claimed for each activity should be entered in the "credits earned" column. Credits should be rounded up or down to the nearest half hour/credit. Totals can be carried forward to the following pages. The entries are the responsibility of the participant and it is recommended that the diary information be reviewed on a weekly basis and updated as approved.

Each participant will be sent a summary document to be completed and returned to the Faculty office at the end of every 12 months.

If you do not have a copy of the paper CPD diary please contact the CPD Co-ordinator who will provide you with a copy.

ONLINE DIARY

The number of credits claimed for each activity should be entered on to the online diary when the participant "reviews" the activity. Credits should be rounded up or down to the nearest half hour/credit. The entries are the responsibility of the participant and it is recommended that the activities be reviewed immediately after the activity has taken place or on a weekly basis.

The deadline for completing the previous year's diary (January to December) will be 31 January. For example, the diary for 2006 (January 2006 to December 2006) would need to be completed by 31 January 2007. The activities for the previous year will be locked from this date and participants will not be able to make any further amendments.

9. CPD AUDIT

A random sample of participants' folders will be audited per annum. It is obligatory to participate in the audit if selected.

It will be necessary to keep a well-organised CPD file with the supporting documentation (programmes/agendas, approval confirmations, evidence/certificates of attendance and any notes made where applicable) for each entry in the CPD diary. This may also form part of the Revalidation folder.

Annex A

Good Pharmaceutical Medical Practice – Jan 2003

Executive summary

The UK General Medical Council is introducing revalidation of medical registration on a five year cycle. This will confer a licence to practise medicine.

The underlying principle is that the physicians will be revalidated on the basis of the medical work they are doing, broadly defined. If a physician changes jobs e.g. to or from a job in the National Health Service and the pharmaceutical industry it will be for the new employer to decide whether the qualifications are appropriate for the position. For revalidation, a physician will need to demonstrate that he or she has made the change in their field of practice in a professional and responsible manner. Revalidation will apply to the job being done and should not impede free movement of physicians provide they have appropriate qualifications.

A number of general principles laid down by the GMC will apply to all physicians seeking revalidation and this document explains their particular implications for physicians in the pharmaceutical industry.

All physicians will be expected to provide evidence that they carry out their work to a good standard and keep themselves up to date in their fields of expertise. Their duty as a medical doctor is to their patients whether they provide direct patient care or do so indirectly by participating in the research and development of new therapies.

Physicians will be expected to maintain a high standard of personal conduct and integrity in relations with patients, other healthcare professionals and colleagues, whether they do so as managers, medical advisers, team members or individual consultants.

Personal and professional probity is essential, especially when commercial pressures and priorities might seem to be in conflict with medical decisions.

The most straightforward way in which most pharmaceutical physicians can demonstrate their fitness to practise for revalidation will be through maintaining a personal revalidation folder of which important components will be an annual appraisal report, a description of the work done in the post held and evidence of regular participation in continuing professional education. They should also include in their revalidation folder opinions from peers and, where relevant, patients (this includes healthy volunteers).

Introduction

All physicians registered with the General Medical Council (GMC) and working in the pharmaceutical industry adhere to the principles of Good Medical Practice (GMP). However, because of the nature of their work most of them do not come into direct contact with patients, although those working in clinical pharmacology units may be responsible for the clinical care of subjects participating in studies. Thus, there is a need to define GMP as it applies to this group of doctors.

Pharmaceutical medicine is a discipline that involves the discovery, development, evaluation, registration, monitoring and ethical marketing of medicinal products and medical devices. The responsibility of the pharmaceutical physician within this process is to guard the interests of patients by working to standards which ensure that research studies are conducted according to Good Clinical Practice (GCP), that safety data are collected, acted upon and reported to the highest international standards and that all communication with medical professionals and patients is

accurate and ethical. Delaying the entry of effective new medicines into the market is as much a public health issue as allowing unsafe ones to come onto, or remain on, the market.

This document does not supersede the GMC guidance on Good Medical Practice, rather it is meant to augment it to cater for the needs of the pharmaceutical industry.

Good clinical care

Providing a good standard of practice and care

Pharmaceutical physicians play a key role in patient care by:

1. Having a thorough understanding of the therapeutic areas in which they work. This includes the current state of knowledge of medical science in the area, the epidemiology of the conditions of interest, the natural history of the specific diseases, the current modes of investigation and treatment and what other therapies are under investigation.
2. Designing clinical research programmes and protocols in areas of medical need, working to the ICH Guidelines, regulatory requirements and the declaration of Helsinki.
3. Ensuring that they fulfil their obligations in clarifying, evaluating and reporting adverse events, whether they come from research protocols, spontaneous reports or as part of a formal surveillance programme.
4. Ensuring that documents submitted to the regulatory authorities accurately reflect the data that have been gathered in the development process. Where they have direct responsibility for writing part of the dossier, e.g. a clinical expert opinion, they do not make any statement that they know to be false or a claim that cannot be supported by the evidence. This does allow for there being different interpretations of the same data, which are reasonable until further clarification is obtained.
5. Ensuring that relevant data are made available for publication and that articles submitted to journals accurately reflect the data on which they are based and no conclusions are drawn that are inconsistent with the data.
6. Ensuring that the information provided in the Summary of Product Characteristics (SPC) is consistent with the terms of the Marketing Authorisation.
7. Ensuring that patient information leaflets are clear and can be understood by the end user.
8. Ensuring that all promotional material and representative product training is consistent with the SPC.

Maintaining good medical practice

Pharmaceutical physicians are required by the nature of their job to keep themselves abreast of scientific advances that will have a major impact on the development of the new medicines of the future. They will be able to maintain this essential role by:

1. Ensuring that they remain well informed about current scientific and medical knowledge in the areas of therapeutics in which they work, by attending internal or external scientific meetings, reading relevant medical journals or by using such other means that are available and that they can demonstrate allows them to remain well informed.

2. By using benchmarking techniques, either internal or external, that ensure that they are maintaining the high standards required by national and international regulations.
3. By assimilating constructive feedback from their management, internal review committees, ethics committees and the regulatory authorities.

Teaching, training, appraising and assessing

1. Pharmaceutical physicians are often involved in the training of members of the company's sales team. They will ensure that they pass on only accurate and verifiable information to the sales department.
2. Pharmaceutical physicians who are responsible for training other members of the medical department will respect the professional integrity of those being trained and ensure that they are trained in the skills necessary to be able to carry out their functions.
3. Pharmaceutical physicians who have managerial responsibility for colleagues will ensure that they are adequately trained for their job function and that appraisals are carried out objectively and in accordance with company policies. Evidence of peer opinion will be obtained where available.

Relationships with patients

1. It is unusual for pharmaceutical physicians to have direct contact with patients, the exception being those working in clinical pharmacology departments.

Working with colleagues

Treating colleagues fairly

1. Pharmaceutical physicians must always treat colleagues fairly. In accordance with the law, a pharmaceutical physician must not discriminate against colleagues, including those applying for posts, on grounds of their sex, race or disability, and must not allow views of colleagues' lifestyle, culture, beliefs, colour, gender, sexuality, or age to prejudice a professional relationship with them.
2. Pharmaceutical physicians must not undermine subjects' trust in the care or treatment they receive, or in the judgment of those treating them, by making malicious or unfounded criticisms of colleagues.

Working in teams

1. Pharmaceutical research is increasingly provided by multi-disciplinary teams. Working in a team does not change personal accountability for professional conduct and the care provided. When working in a team, a pharmaceutical physician must:
 - Respect the skills and contributions of colleagues;
 - Communicate effectively with colleagues within and outside the team;
 - Participate in regular reviews and audit of the standards and performance of the team, taking steps to remedy any deficiencies;
 - Be willing to deal openly and supportively with problems in the performance, conduct or health of team members.

Leading teams

1. A pharmaceutical physician who leads a team must ensure that:
 - Medical team members meet the standards of conduct and care set in this guidance;
 - Any problems that might prevent colleagues from other professions following guidance from their own regulatory bodies are addressed;
 - All team members understand their personal and collective responsibility for the safety of patients, and for openly and honestly recording and discussing problems;
 - Arrangements are in place to provide medical cover at all times;
 - Regular reviews and audit of the standards and performance of the team are undertaken and any deficiencies are addressed;

Systems are in place for dealing supportively with problems in the performance, conduct or health of team members.

Arranging medical cover

1. There are a few critical situations where it is necessary for a pharmaceutical physician to arrange medical cover. These include, but may not be limited to, those working in a clinical pharmacology unit where subjects stay in overnight, those responsible for clinical trials where contact needs to be maintained for urgent action on a potentially serious adverse event. For such situations the pharmaceutical physician must make suitable arrangements for a colleague, with the necessary qualifications and experience, to cover the situation.

Taking up appointments

It is bad practice to fail to take up an appointment that has been accepted without giving the future employer adequate time to make alternative arrangements.

Probity

Pharmaceutical physicians usually work for a commercially driven operation. They must, therefore, be extra vigilant that their decisions and practices are not in any way influenced by any personal financial gain that could result from the movement of share price etc.

Writing reports and signing documents

1. Pharmaceutical physicians write the key clinical sections of final study reports. They must ensure that the document accurately reflects the data and that any publication that flows from the data is wholly consistent with the report. They must stand by the principles that all relevant reports should lead to a publication and not be persuaded by the argument that adverse data will have a negative impact on the finances of the company.
2. Pharmaceutical physicians are responsible for ensuring that advertising and promotional material is both legal and ethical. They must balance the need to make the material interesting and attractive against the need for scientific and medical accuracy. Under no circumstances must they allow statements into promotional material that is not supported by the available data.
3. Safety reporting is a key tool in the protection of public health and pharmaceutical physicians must never allow the commercial interest of a company to take precedence over the

requirement to ensure that all safety data are reported to the authorities and any new adverse drug reactions are included in the prescribing information according to the legal and ethical requirements prevailing at the time.

Research

1. Clinical research protocols must be designed to answer genuine scientific questions and not to be promotional tools.
2. All clinical research must be carried out according to the ICH guidelines on GCP.
3. No clinical research protocol can be implemented without the approval of an independent research ethics committee.
4. In all protocols the protection of subjects must take priority over scientific interest.

Financial and commercial dealings

1. Pharmaceutical physicians must not accept gifts or hospitality that are designed to influence their professional judgement.
2. The recompense offered to investigators for carrying out a clinical trial must be commensurate with the work required and not structured in such a way as to encourage coercive behaviour.

Conflicts of interest and financial interest in commercial organisations

The areas of potential conflicts of interest are described above and pharmaceutical physicians must always declare their financial interests in their dealings with professional colleagues, the editors of scientific journals and the general public.

Health

Whilst the risk of transmitting communicable diseases is only an issue for pharmaceutical physicians working in direct contact with patients or volunteers, the work of others may be affected by such things as stress, depression etc, so pharmaceutical physicians should be vigilant about these problems, both in themselves and colleagues.