

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.