

(REVISED OCTOBER 2007)

SPECIALTY SPECIFIC GUIDANCE ON EVIDENCE IN SUPPORT OF APPLICATIONS UNDER ARTICLE 14 – PHARMACEUTICAL MEDICINE

Good Medical Practice and Good Pharmaceutical Medical Practice

An overview

Specialists must be judgement-safe and competent in their field of specialist practice. They must be able to demonstrate the qualities and abilities to manage a project unit or team, ensuring high standards of professional activity and effective working relationships with colleagues across professional disciplines. The Specialist will be able to monitor plans and initiatives, to evaluate them and ensure that modifications are made where appropriate. Specialists may take on leadership roles within teams and organisations and will have the vision and foresight to develop new ways of working and the commitment to see projects and teamwork through to the end. Specialists will demonstrate the personal capacity and qualities to respond positively to feedback from colleagues, clients and others, to take and accept responsibility for decisions, and to manage and respond to complaints from clients and fellow professionals in a professional manner. They have the potential to teach and to support training programmes for trainees, departments and staff under their supervision. Specialists demonstrate a commitment to the highest standards of medical work and ethical and professional behaviour within the specialty of pharmaceutical medicine and within the medical profession as a whole.

Standards to be met are as set out in the [Curriculum for Pharmaceutical Medicine Specialty Training \(PMST\)](#) (Faculty of Pharmaceutical Medicine) which leads to the award of the Certificate of Completion of Training (CCT) by the Postgraduate Medical Education and Training Board (PMETB), [Good Medical Practice \(GMP\)](#) (General Medical Council) and [Good Pharmaceutical Medical Practice \(GPMP\)](#) (Faculty of Pharmaceutical Medicine).

(This version of Specialty Specific Guidance incorporates revised PMETB Generic Guidance August 2007, revised Pharmaceutical Medical Specialty Training Curriculum August 2007 and revised GMC Good Medical Practice 2006)

1. Providing good practice and care

Specialists will maintain high standards of practice and care in their specialist field and will be able to demonstrate strong analytical skills and insight in the decisions that they make in the course of their practice. Specialists practice safely within their specialist field and acknowledge when situations go beyond their expertise and when they should refer to others for advice. Specialists ensure that they and their colleagues work within current legal and ethical guidelines in their field. They monitor practice in their specialist field and modify protocols in the light of evidence-based research and audit findings. Specialists will ensure clear and effective systems for sharing information, record keeping and report-writing in a timely fashion

Pharmaceutical physicians play a key role in patient care by:

- a) 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.*
- b) Designing clinical research programmes and protocols in areas of medical need working to the ICH Guidelines, regulatory requirements and the Declaration of Helsinki.*
- c) 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.*
- d) 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.*
- e) 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.*
- f) Ensuring that the information provided in the Summary of Product Characteristics (SmPC) is consistent with the terms of the Marketing Authorisation.*
- g) Ensuring that patient information leaflets are clear and can be understood by the end user.*
- h) Ensuring that all promotional material and representative product training is consistent with the SmPC.*

Criteria	Standards to be met:	Suggested examples of possible documentary evidence to submit:
<p>Specialists will have knowledge and skills to undertake safe, effective and independent practice across the breadth and depth of pharmaceutical medicine to the standards set out in the PMST curriculum for CCT-UK.</p>	<p>The entry and selection criteria for Pharmaceutical Medical Specialty Training (PMST) as set out in the Person Specification (Appendix 3 of the Curriculum for PMST)</p> <p>All of the standards defined within the curriculum for PMST which leads to award of CCT in pharmaceutical medicine. These are:</p> <p><u>Part A - Specialty Knowledge Base</u></p> <p>All nine sections of the knowledge-based syllabus of the UK Diploma in Pharmaceutical Medicine (Medicines Regulation, Clinical Pharmacology, Statistics and Data Management, Clinical Development, Healthcare Marketplace, Drug Safety,</p>	<p>Evidence of Specialty Training & Qualifications:</p> <ul style="list-style-type: none"> • Evidence of success in a relevant test of knowledge will be required. • Evidence of courses followed e.g. curriculum/programme of training. • Evidence of the methods, frequency and outcomes of assessment e.g. syllabi of examinations, assessment documentation and outcomes. • Evidence that specialty training was supervised by relevant authorities e.g. accredited. • Log books / training records / work-based assessments.

	<p>Role of the Medical Department, Discovery of New Medicines, Therapeutics);</p> <p><u>Part B – Practical Competencies in PMST</u></p> <p>The knowledge, skills (cf. application of knowledge), attitudes / behaviour and associated competencies as set out in the first six practical modules of the PMST curriculum: Medicines Regulation (RGN), Clinical Pharmacology (CLP), Statistics and Data Management (SDM), Clinical Development (CLD), Healthcare Marketplace (HMP) and Drug Safety Surveillance (DSS)</p> <p><u>Part C - Generic Curriculum in Pharmaceutical Medicine</u></p> <p>The knowledge, skills (cf. application of knowledge), attitudes / behaviour and associated competencies as set out in the Generic Curriculum in Pharmaceutical Medicine (Module 7 of PMST). This module comprises Interpersonal and Management Skills (Items IPM1, IPM2, IPM3) and Good Pharmaceutical Medical Practice (IPM4 with seven Focus Areas corresponding to those in Good Medical Practice)</p> <p>It is essential to obtain a full copy of the Curriculum for PMST in order to prepare your application. It is available on the Faculty website http://www.fpm.org.uk/ or from the Faculty office.</p>	<p>Evidence of Experience:</p> <ul style="list-style-type: none"> • Full, detailed Curriculum Vitae with dates and job description/s. • Validated employment record for each post giving details of type of post, work place, size, factors such as staff, facilities and dates. • Evidence of satisfactory achievement in post(s) of performance/competency in module components (see PMST Curriculum six practical modules and generic module) as assessed by designated representative(s) of the Institution(s). • Satisfactory current appraisal / revalidation portfolio. • Structured Reports / References. • Participation in continuing professional development (CPD). • Multi-source feedback (MSF) assessment and appraisal outcomes. • Membership of professional bodies / learned societies which work towards the improvement in standards in medical practice.
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<p>Specialists will recognise and work within the limits of their competence and when it is appropriate to refer to other senior colleagues for advice.</p> <p>Specialists will have the potential (or ability) to take responsibility for governance activities, risk management and audit in order to improve the quality of practice and care.</p>	<p>In providing care you must recognise and work within the limits of professional competence and be willing to consult and take advice from colleagues when appropriate (GMP Paragraph 3(a & i)).</p> <p>Work with colleagues to maintain and improve the quality of your work and promote patient safety by following the guidance set out in paragraph 14 of Good Medical Practice (GMP Paragraph 14).</p> <p>Take part in regular team reviews and audits of standards and performance of the team, taking steps to remedy any deficiencies (GMP Paragraph 41 (d)).</p> <p>Use benchmarking techniques, either internal or external, that ensure the highest standards of practice are being maintained as required by national and international regulations (GPMP – Maintaining Good Medical Practice Paragraph 2).</p>	<ul style="list-style-type: none"> • Evidence of CPD. • Appraisal and / or revalidation portfolio. • Evidence of participation in governance activities, risk management, audit and / or other relevant activities which include the use of benchmarking techniques and are in a team setting. • Structured reports.
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2. Relationships with research subjects and patients

Specialists will demonstrate the capacity to build trust and to develop and maintain effective relationships with research subjects and / or patients. They will be good listeners and show respect and understanding for research subjects' and / or patients' perspectives on their condition or situation. They must demonstrate a commitment to the principles and practice of consent and confidentiality and patients' / subjects' rights to privacy.

Pharmaceutical Physicians work with research subjects in early studies in man in Phase 1 Units and with healthy volunteers and sometimes patients in exploratory clinical studies in the development phase and throughout the life-cycle of a medicine. It is unusual for pharmaceutical physicians to have direct contact with patients in the context of clinical care for an individual patient.

Criteria	Standards to be met:	Suggested examples of possible documentary evidence to submit:
<p>Specialists will demonstrate the ability to build relationships of trust with research subjects and / or patients through effective listening and interpretation skills, a courteous and compassionate approach, respect for their privacy and dignity, and cultural and religious beliefs.</p> <p>Specialists will follow the principles and legal aspects of consent and confidentiality.</p> <p>Specialists will demonstrate the ability to manage difficult and complex situations with patients and / or research subjects to advise them appropriately and manage complaints effectively and be open and honest if things go wrong.</p>	<p>Standards set out in GMP relating to relationships with patients (and/or research subjects) obtaining consent and respecting confidentiality and relationships with research subjects and / or patients (GMP Paragraphs 20 - 37).</p> <p>Demonstrate ability to draft an informed consent form that includes all the required elements (Cross reference to PMST Module Ref: CLD 5).</p> <p>Demonstrate involvement in writing and approving subject information sheets and consent forms in appropriate language for study subjects and their relatives and incorporating all elements of informed consent as specified in ICH guidelines on GCP (Cross reference to PMST Module Ref: CLP 5 & 6.2).</p> <p>Cross reference to PMST Module Ref: IPM4 Focus Area 4.3 (Relationships with Patients and Research Subjects).</p>	<ul style="list-style-type: none"> • Appraisal and / or revalidation portfolio. • Evidence from cases (anonymised) and relevant activities. • Structured reports. • Evidence of knowledge, skills, attitudes & behaviours as set out in PMST Module Reference IPM4 Focus Area 4.3 (Relationships with Patients and Research Subjects).

3. Maintaining Good Pharmaceutical Medical Practice

Keeping up to date

Specialists set high standards in their medical care and ensure that they remain fully competent to practise through their commitment to continuing professional development and the process of revalidation. They foster the skills and abilities of colleagues and encourage their professional development by identifying and ensuring their participation in further training and research opportunities. Specialists are reflective practitioners and strive to improve standards in all aspects of their work. They demonstrate the ability to seek and respond constructively to feedback and have a duty to maintain a folder of information and evidence drawn from their medical practice.

Pharmaceutical physicians are required to keep themselves informed of and up to date on scientific advances that will have a major impact on the development of the new medicines of the future.

Criteria	Standards to be met:	Suggested examples of possible documentary evidence to submit:
<p>Specialists will reflect and take responsibility for and keep up to date in their own relevant professional and self development and maintain a folder of information and evidence drawn from their medical practice.</p> <p>Specialists will acknowledge that the balance of their skills and expertise will change as their careers progress and they specialise in certain areas of pharmaceutical medicine.</p> <p>Specialists will take part in regular audit, quality assurance, quality improvement and appraisals.</p>	<p>Standards relating to maintaining good medical practice as set out in GMP (GMP Paragraph 12, 13, 14 a - e).</p> <p>Standards relating to maintaining good medical practice as set out in GPMP. (GPMP Maintaining Good Pharmaceutical Medical Practice).</p> <p>Cross reference to PMST Module Reference IPM4 Focus Area 4.2 (Maintaining Good Pharmaceutical Practice).</p>	<ul style="list-style-type: none"> • Evidence of recent CPD and that a folder of information and evidence drawn from your medical practice is being maintained. • Evidence of participation in activities such as teaching, lecturing, educational supervision and performance management. • Evidence of participation in evidence based learning. • Multi-source feedback (MSF) assessment and appraisal outcomes. • Evidence of reflective practice. • Structured reports. • Revalidation material. • Evidence of participation in audit, quality assurance, quality improvement, appraisals and / or other relevant activities, and constructive responses to their outcomes. • Evidence of knowledge, skills, attitudes & behaviours as set out in PMST Module Reference IPM4 Focus Area 4.2 (Maintaining Good Pharmaceutical Practice).

4. Teaching and training, appraising and assessing

Making assessments and providing references

Specialists may be expected to teach and train students, trainees and colleagues and to appraise colleagues and assess their work. They will demonstrate effective communication skills in all of these activities, in the presentation and discussion of topics and in their personal interactions. Specialists will be able to demonstrate an understanding of and a commitment to the principles and practice of effective teaching and learning in medical contexts. They must be able to take responsibility for the supervision of trainees and ensure that effective arrangements are in place. They must demonstrate the ability to be open, honest and objective in appraisals and in written references for colleagues.

Pharmaceutical physicians are also often involved in the training of members of the company's sales team and when doing so will pass on only accurate and verifiable information.

Criteria	Standards to be met:	Suggested examples of possible documentary evidence to submit:
<p>Specialists will be able to demonstrate the potential to teach and train effectively at all levels of undergraduate and postgraduate education where required.</p> <p>Specialists will ensure staff who they are responsible for are properly supervised.</p> <p>Specialists will demonstrate skills and strategies in the process of feedback to colleagues and trainees, ensuring positive and constructive outcomes.</p> <p>Specialists will be capable of judging competence and professional attributes in others.</p>	<p>Standards relating to teaching, training, appraising and assessing as set out in GMP (GMP Paragraph 15 -19).</p> <p>Standards relating to teaching, training, appraising and assessing as set out in GPMP (GPMP Teaching, Training, Appraising and Assessing).</p> <p>Cross Reference to PMST Module Reference IPM4 Focus Areas 4.5 (Teaching, Training, Appraising & Assessing).</p>	<ul style="list-style-type: none"> • Evidence of participation in teaching, lecturing and educational supervision. • Evidence of CPD. • Evidence of successful attendance at relevant courses. • Evidence of participation in appraisal and performance management. • Evidence of peer opinion, structured reports. • Evidence of participation in the conduction of work-based assessments and / or examining. • Evidence of knowledge, skills, attitudes, behaviours as set out in PMST Module Reference IPM4 Focus Area 4.5 (Teaching, Training, Appraising & Assessing).

5. Working with colleagues

Specialists work as members of a number of teams and within organisations. They demonstrate an understanding of the roles of others and a respect for the knowledge, skills and experience they bring to a team and to an organisation. They demonstrate strong interpersonal skills and an open and non-discriminatory approach to professional working relationships with colleagues. They will support colleagues who have problems with performance, conduct or health and protect research subjects and patients from risk of harm posed by another colleague's conduct.

Criteria	Standards to be met:	Suggested examples of possible documentary evidence to submit:
<p>Specialists will strive for continuing improvement in all aspects of their work and that of colleagues while mindful of priorities and high standards.</p> <p>Specialists will have effective interpersonal skills which enable them to bring out the best in colleagues, to resolve conflicts when they arise and to develop and maintain productive working relationships within the team.</p> <p>Specialists will support teams that bring together different professions and disciplines and other agencies, to provide high quality health care.</p>	<p>Standards relating to working in teams, the conduct and performance of colleagues and respect for colleagues as set out in GMP (GMP paragraphs 41-47).</p> <p>Standards relating to treating colleagues fairly, working in teams, leading teams arranging medical cover and taking up appointments as set out in GPMP (GPMP Working with Colleagues).</p> <p>Demonstrates an understanding of the principles and practices of people management and leadership, and competency to apply these within their own working environment (Cross Reference to PMST Module Ref: IPM 2 (People Management & Leadership)).</p> <p>Cross reference to PMST Module Ref: IPM4 Focus Area 4.4 (Working With Colleagues).</p>	<ul style="list-style-type: none"> • Evidence of CPD. • Evidence of participation in performance management activities. • Multi-source feed back assessment and appraisal outcomes. • Structured Reports. • Appraisal and revalidation material. • Evidence of knowledge, skills, attitudes, behaviours as set out in PMST Module Reference IPM4 Focus Area 4.4 (Working with Colleagues) and to PMST Module Ref: IPM 2 (People Management & Leadership).

6. Probity

Protecting patients, clients, colleagues and the profession

Specialists are honest and trustworthy, act with integrity and recognise the privileges and responsibilities of their position. They ensure the standards of Good Medical Practice (GMP) as set out by the General Medical Council and Good Pharmaceutical Medical Practice (GPMP) as set out by the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK and any other relevant professional bodies are met.

Pharmaceutical physicians may 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.

Criteria	Standards to be met:	Suggested examples of possible documentary evidence to submit:
<p>Specialists will always act in their personal and professional lives to maintain public trust in the profession.</p> <p>Specialists will act quickly and effectively if they have reason to believe that their own or a colleague's conduct or performance does not meet the highest standards of integrity.</p> <p>Specialists will undertake duties such as writing reports, giving evidence and completing and signing documents in a timely, honest and conscientious way.</p> <p>Specialists will through their leadership encourage the development and practice of these qualities in their colleagues.</p>	<p>Standards relating to probity as set out in GMP (GMP paragraphs 56 – 76).</p> <p>Standards relating to raising concerns about patient safety as set out in GMP (GMP Paragraph 6).</p> <p>Standards relating to the conduct and performance of colleagues as set out in GMP (GMP Paragraphs 43 – 45).</p> <p>Standards relating to writing reports and CVs, giving evidence and signing documents as set out in GMP (GMP paragraph 63-69).</p> <p>Standards relating to writing reports and signing documents, research, financial and commercial dealings and conflicts of interest and financial interest in commercial organisations as set out in GPMP (GPMP Probity).</p> <p>Ensures that medical team members meet the standards of conduct and care set out in GPMP (GPMP Leading Teams).</p> <p>Cross reference to PMST Module Ref. IPM4 Focus Area 4.6 (Professional Behaviour and Probity).</p>	<ul style="list-style-type: none"> • Probity statement (see UK GMC Revalidation documents for example). • Structured reports. • Certificate of current good standing with medical registration body. • Evidence from any cases (anonymised) • Revalidation material. • Letters of appreciation. • Multi-source feedback assessment and appraisal outcomes • Evidence of participation in teaching, lecturing, performance management. • Evidence of knowledge, skills, attitudes, behaviours as set out in PMST Module Reference IPM4 Focus Area 4.6 (Professional Behaviour & Probity).

7. Health

Protecting patients, clients, colleagues and the profession

Whilst the risk of transmitting communicable diseases is only an issue for pharmaceutical physicians working in direct contact with research subjects or patients, their own work and that of others may be affected by stress, depression, alcohol etc. Pharmaceutical physicians should be vigilant about these problems, both in themselves and colleagues.

Criteria	Specialist Standards	Suggested Evidence
<p>Specialists will always act in their personal and professional lives to maintain public trust in the profession.</p> <p>Specialists will act quickly and effectively if they have reason to believe that their own or a colleague's health may put their performance or conduct at risk.</p>	<p>Standards relating to health as set out in GMP (GMP paragraphs 77-79).</p> <p>Standards relating to the conduct and performance of colleagues as set out in GMP (GMP Paragraphs 43 – 45).</p> <p>Standards relating to health as set out in GPMP (GPMP Health).</p> <p>Cross reference to PMST Module Ref. IPM4 Focus Area 4.7 (Health).</p>	<ul style="list-style-type: none">• Health Statement (see UK GMC Revalidation documents, for example).• Structured Reports.• Evidence from any cases (anonymised).• Revalidation material.• Evidence of knowledge, skills, attitudes, behaviours as set out in PMST Module Reference IPM4 Focus Area 4.6 (Professional Behaviour & Probity).