Faculty of
Pharmaceutical Medicine
of the Royal Colleges of Physicians of the United Kingdom

Advancing the science and practice of pharmaceutical medicine for the benefit of the public

Good Pharmaceutical Medical Practice

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Introduction

Good Pharmaceutical Medical Practice provides all doctors practising pharmaceutical medicine around the world with specific guidance and direction on expected standards, conduct and behaviour. The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom (FPM) advocates that the principles outlined in this document are appropriate for all those involved in the practice of pharmaceutical medicine anywhere in the world. This represents a code for the membership of the FPM.

Good Pharmaceutical Medical Practice complements international and national legislation.[i-vii] We have chosen *Good Medical Practice 2013*[viii] (GMC) as its foundation. *Good Pharmaceutical Medical Practice* is guidance, rather than a statutory code. Its intention is to provide additional direction to doctors who specialise or participate in the practice of pharmaceutical medicine. **The text in blue within this document has been added by the FPM.**

Good Pharmaceutical Medical Practice has been written to apply to all circumstances to ensure that it contains universal standards of good medical practice in pharmaceutical medicine. *Good Pharmaceutical Medical Practice* extends upon the principles first outlined in *Good Pharmaceutical Medical Practice* (2008)[ix] and the *Guiding Principles for Pharmaceutical Physicians (2010)*.[x] It also takes account of the results of the *FPM survey of members on transparency in clinical trials* (2014).[xi]

What is pharmaceutical medicine?

Pharmaceutical medicine involves understanding and promoting the interests of patients, society and public health. It involves the discovery, development, licensing, ethical marketing and safety of medicines, diagnostics and medical devices. *Good Pharmaceutical Medical Practice* makes clear the relationship between pharmaceutical medicine and patients. Patient safety must always be the primary concern of doctors. Although many doctors practising pharmaceutical medicine do not have direct contact with patients, the doctor's responsibility extends to any individual whose care may be affected by their actions.

Pharmaceutical medicine has a global impact on healthcare. It is practised in diverse environments, including academic centres, clinical pharmacology and clinical trial units, pharmaceutical, biotechnology, and service companies, regulatory authorities and independent practice. Pharmaceutical medicine may also involve commercial, managerial and business activities. The principles of *Good Pharmaceutical Medical Practice* apply in all of these settings. In pharmaceutical medicine, decisions taken locally may have implications either globally or in an individual country or territory.

Why develop additional guidance?

Doctors practising pharmaceutical medicine are bound by the same ethical standards that apply to all doctors. Their work, however, leads to some special situations with ethical considerations that may not be fully explored in general ethical codes designed for clinical medicine.

All doctors must understand the balance between the benefits and the potential risks and adverse effects of medical interventions. However, doctors practising pharmaceutical medicine may also be involved in the development of experimental treatments, which may have a limited knowledge base and are not yet approved for licensure by the relevant regulatory authorities. This is unlike medicines used in everyday medical practice, which are approved by regulatory authorities and typically may have been evaluated in long-term use in medical practice. Thus the efficacy and safety profile of a novel or experimental treatment will continue to evolve and will require ethical management throughout its lifecycle.

Good Pharmaceutical Medical Practice is a code of practice for the membership of the FPM. Consequently, if you are a member of the FPM, you are expected to follow this guidance. If you contribute to the practice of pharmaceutical medicine but are not a member of the FPM, we trust that you will read this guidance and apply its principles. At a minimum, *Good Pharmaceutical Medical Practice* assumes compliance with international legislation. However, we consider that mere compliance is not enough. The need for higher standards must be applied to the care of the individual and public health.

Probity, ethics and pharmaceutical medicine

You should promote probity, namely adherence to the highest ethical principles and ideals, wherever you practice. Probity is at the centre of the practice of medicine, education and ethics. *Good Pharmaceutical Medical Practice* involves a duty of care to society in respect of the research and delivery of medical interventions. Concerns regarding areas such as ethical practice, patient safety and data integrity must be highlighted to the appropriate governance structure. You must act as an advocate for the patient.

The definition of 'patient' within this document

Throughout this document, the term 'patient' means those receiving a licensed or unlicensed medical intervention, including those in clinical trials. The term 'patient' is used to mean both healthy volunteers and people living with disease.

A medical intervention may include a medicine used in the diagnosis, treatment or prevention of disease. The term medicine may include a drug, vaccine, diagnostic or device.

The GMC document *Good Medical Practice*[viii] is specifically focused on the needs of the patient. Therefore the commentary inserted here by the FPM (blue print) follows the same principle of putting the patient first but in the practice of pharmaceutical medicine.

The duties of a doctor registered with the General Medical Council

Patients must be able to trust doctors with their lives and health. To justify that trust you must show respect for human life and make sure your practice meets the standards expected of you in four domains:

Knowledge, skills and performance

- Make the care of your patient your first concern.
- Provide a good standard of practice and care.
    - Keep your professional knowledge and skills up to date.
    - Recognise and work within the limits of your competence.

Safety and quality

- Take prompt action if you think that patient safety, dignity or comfort is being compromised.
- Protect and promote the health of patients and the public.

Communication, partnership and teamwork

- Treat patients as individuals and respect their dignity.
    - Treat patients politely and considerately.
    - Respect patients' right to confidentiality.
- Work in partnership with patients.
    - Listen to, and respond to, their concerns and preferences.
    - Give patients the information they want or need in a way they can understand.
    - Respect patients' right to reach decisions with you about their treatment and care.
    - Support patients in caring for themselves to improve and maintain their health.
- Work with colleagues in the ways that best serve patients' interests.

Maintaining trust

- Be honest and open and act with integrity.
- Never discriminate unfairly against patients or colleagues.
- Never abuse your patients' trust in you or the public's trust in the profession.

You are personally accountable for your professional practice and must always be prepared to justify your decisions and actions.

Professionalism in action

1. Patients need good doctors. Good doctors make the care of their patients their first concern: they are competent, keep their knowledge and skills up to date, establish and maintain good relationships with patients and colleagues,* are honest and trustworthy, and act with integrity and within the law.

You may not have direct patient contact, but you must still put the needs and well-being of patients first.

2. Good doctors work in partnership with patients and respect their rights to privacy and dignity. They treat each patient as an individual. They do their best to make sure all patients receive good care and treatment that will support them to live as well as possible, whatever their illness or disability.

3. *Good medical practice* describes what is expected of all doctors registered with the General Medical Council (GMC). It is your responsibility to be familiar with *Good medical practice* and the explanatory guidance† which supports it, and to follow the guidance they contain.

The principles contained within *Good Pharmaceutical Medical Practice* apply internationally. You should be familiar with and follow *Good Pharmaceutical Medical Practice*.

4. You must use your judgement in applying the principles to the various situations you will face as a doctor, whether or not you hold a licence to practise, whatever field of medicine you work in, and whether or not you routinely see patients. You must be prepared to explain and justify your decisions and actions.

5. In *Good Medical Practice*, we use the terms 'you must' and 'you should' in the following ways.

   'You must' is used for an overriding duty or principle.

   'You should' is used when we are providing an explanation of how you will meet the overriding duty.

   'You should' is also used where the duty or principle will not apply in all situations or circumstances, or where there are factors outside your control that affect whether or how you can follow the guidance.

Good Pharmaceutical Medical Practice is guidance rather than a statutory code. However, throughout this document the definitions of 'you must' and 'you should' apply as described above. Decisions are frequently made by a team. You must be prepared to explain and justify your contribution to decisions that may affect the safety and well-being of patients.

6. To maintain a licence to practise, you must demonstrate, through the revalidation process, that you work in line with the principles and values set out in this guidance. Serious or persistent failure to follow this guidance will put your registration at risk.

You should use *Good Pharmaceutical Medical Practice* as an adjunct to *Good Medical Practice* when revalidating in the United Kingdom. For other doctors you should use the principles of *Good Pharmaceutical Medical Practice* as the standard to judge your practice against.

* Colleagues include anyone a doctor works with, whether or not they are also doctors.
† You can find all the explanatory guidance on our website (www.gmc-uk.org/guidance).

Domain 1: Knowledge, skills and performance

Develop and maintain your professional performance

You should maintain membership of one or more professional bodies relevant to your practice of pharmaceutical medicine.

7. You must be competent in all aspects of your work, including management, research and teaching.[1, 2, 3]

8. You must keep your professional knowledge and skills up to date.

9. You must regularly take part in activities that maintain and develop your competence and performance.[4]

10. You should be willing to find and take part in structured support opportunities offered by your employer or contracting body (for example, mentoring). You should do this when you join an organisation and whenever your role changes significantly throughout your career.

This also applies to self-employed and independent pharmaceutical doctors.

11. You must be familiar with guidelines and developments that affect your work.

12. You must keep up to date with, and follow, the law, our guidance and other regulations relevant to your work.

13. You must take steps to monitor and improve the quality of your work.

In pharmaceutical medicine the terms 'monitor' and 'improve quality' can take many forms, such as audit, inspection and other feedback. You should use this feedback to identify both good and bad actions, learn and promote positive change.

Apply knowledge and experience to practice

14. You must recognise and work within the limits of your competence.

    14.1 You must have the necessary knowledge of the English language to provide a good standard of practice and care in the UK

Although the requirement for knowledge of English is included in *Good Medical Practice*, the principle of having language skills appropriate to your practice is relevant universally.

15. You must provide a good standard of practice and care. If you assess, diagnose or treat patients, you must:

    a. adequately assess the patient's conditions, taking account of their history (including the symptoms and psychological, spiritual, social and cultural factors), their views and values; where necessary, examine the patient

    b. promptly provide or arrange suitable advice, investigations or treatment where necessary

    c. refer a patient to another practitioner when this serves the patient's needs.[5]

16. In providing clinical care you must:

    a. prescribe drugs or treatment, including repeat prescriptions, only when you have adequate knowledge of the patient's health and are satisfied that the drugs or treatment serve the patient's needs[6]

    b. provide effective treatments based on the best available evidence

    c. take all possible steps to alleviate pain and distress whether or not a cure may be possible[7]

    d. consult colleagues where appropriate

    e. respect the patient's right to seek a second opinion

    f. check that the care or treatment you provide for each patient is compatible with any other treatments the patient is receiving, including (where possible) self-prescribed over-the-counter medications

    g. wherever possible, avoid providing medical care to yourself or anyone with whom you have a close personal relationship.[6]

Pharmaceutical medicine may affect clinical care in situations such as clinical trials.

Information provided to healthcare professionals and patients must permit objective clinical decision-making based on the benefit:risk profile of available medicines.

17. You must be satisfied that you have consent or other valid authority before you carry out any examination or investigation, provide treatment or involve patients or volunteers in teaching or research.[2, 8, 9]

Research may also include experimental treatments where the benefit:risk profile has not yet been clearly established and/or is evolving. If the benefit:risk profile has changed during the development programme then this should be shared with the involved patients. If necessary, you must obtain further consent from the patients participating in the research.

18. You must make good use of the resources available to you.[1]

You must also ensure that the necessary resources will be available to meaningfully conduct and complete any aspect of your work where it involves and affects patients.

Record your work clearly, accurately and legibly

19. Documents you make (including clinical records) to formally record your work must be clear, accurate and legible. You should make records at the same time as the events you are recording or as soon as possible afterwards.

20. You must keep records that contain personal information about patients, colleagues or others securely, and in line with any data protection requirements.[10]

21. Clinical records should include:

    a. relevant clinical findings

    b. the decisions made and actions agreed, and who is making the decisions and agreeing the actions

    c. the information given to patients

    d. any drugs prescribed or other investigation or treatment

    e. who is making the record and when.

Accurate documentation is essential to the practice of pharmaceutical medicine. Good Clinical Practice,[xii] Good Pharmacovigilance Practice,[xiii] Good Laboratory Practice[xiv-xv] and Good Manufacturing Practice[xvi] are the essential operational guidelines for our work. Other regulations enshrining the principles of paragraphs 19–21 in the practice of pharmaceutical medicine are referenced in the International Conference on Harmonisation (ICH) Guidelines.[xvii]

Domain 2: Safety and quality

Contribute to and comply with systems to protect patients

22. You must take part in systems of quality assurance and quality improvement to promote patient safety. This includes:

    a. taking part in regular reviews and audits of your work and that of your team, responding constructively to the outcomes, taking steps to address any problems and carrying out further training where necessary

    b. regularly reflecting on your standards of practice and the care you provide

    c. reviewing patient feedback where it is available.

In pharmaceutical medicine you should take account of feedback from other individuals and groups such as healthcare professionals, regulatory bodies and organisations representing patients, and when needed undertake quality improvement programmes.

23. To help keep patients safe you must:

    a. contribute to confidential inquiries

    b. contribute to adverse event recognition

    c. report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another person, at risk

    d. report suspected adverse drug reactions

    e. respond to requests from organisations monitoring public health.

    When providing information for these purposes you should still respect patients' confidentiality.[10]

You must take prompt action when you believe that patient safety may be compromised. You must report adverse events and other safety concerns to the relevant regulatory agencies according to established procedures. You must also cooperate with official investigations in relation to patient safety.

You must conduct the monitoring of product safety, the prompt management of safety signals, and the management of incidents, e.g. product quality issues, that could affect patient well-being.

Respond to risks to safety

24. You must promote and encourage a culture that allows all staff to raise concerns openly and safely.[1,11]

25. You must take prompt action if you think that patient safety, dignity or comfort is or may be seriously compromised.

    a. If a patient is not receiving basic care to meet their needs, you must immediately tell someone who is in a position to act straight away.

    b. If patients are at risk because of inadequate premises, equipment* or other resources, policies or systems, you should put the matter right if that is possible. You must raise your concern in line with our guidance[11] and your workplace policy. You should also make a record of the steps you have taken.

    c. If you have concerns that a colleague may not be fit to practise and may be putting patients at risk, you must ask for advice from a colleague, your defence body or us [GMC]. If you are still concerned you must report this, in line with our guidance and your workplace policy, and make a record of the steps you have taken.[11,12]

Outside the jurisdiction of the GMC, comparable responsibilities and actions should be taken.

You must always consider the needs of both the individual patient and public health. This is particularly relevant to doctors practising pharmaceutical medicine, who are frequently not involved directly in patient care and often make decisions related to how a population might respond to treatment.

26. You must offer help if emergencies arise in clinical settings or in the community, taking account of your own safety, your competence and the availability of other options for care.

27. Whether or not you have vulnerable† adults or children and young people as patients, you should consider their needs and welfare and offer them help if you think their rights have been abused or denied.[13,14]

You should consider the needs of vulnerable populations and, where appropriate, ensure that they are not excluded from clinical research either pre- or post- regulatory approval, recognising the special care that must be taken.

Protect patients and colleagues from any risk posed by your health

28. If you know or suspect that you have a serious condition that you could pass on to patients, or if your judgement or performance could be affected by a condition or its treatment, you must consult a suitably qualified colleague. You must follow their advice about any changes to your practice they consider necessary. You must not rely on your own assessment of the risk to patients.

29. You should be immunised against common serious communicable diseases (unless otherwise contraindicated).

30. You should be registered with a general practitioner outside your family.

Irrespective of your place of work or where you live, you should consult an independent medical practitioner regarding your own health.

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* Follow the guidance in paragraph 23c (page 10) if the risk arises from an adverse incident involving a medical device.

† Some patients are likely to be more vulnerable than others because of their illness, disability or frailty or because of their current circumstances, such as bereavement or redundancy. You should treat children and young people under 18 years as vulnerable. Vulnerability can be temporary or permanent.

Domain 3: Communication, partnership and teamwork

Communicate effectively

31. You must listen to patients, take account of their views, and respond honestly to their questions.

This may also include the carers of vulnerable and/or unconscious patients. You should also listen to others representing patient interests.

32. You must give patients* the information they want or need to know in a way they can understand. You should make sure that arrangements are made, wherever possible, to meet patients' language and communication needs.[15]

You should anticipate the information needs of the patient in the preparation of communications such as informed consent forms, patient information leaflets, patient support materials and social media. These should be accurate, complete and expressed in terms that are easily understood and not misleading.

33. You must be considerate to those close to the patient and be sensitive and responsive in giving them information and support.

34. When you are on duty you must be readily accessible to patients and colleagues seeking information, advice or support.

When you are responsible for providing information, advice or support you must be readily accessible for safety issues and medical monitoring activities.

Work collaboratively with colleagues to maintain or improve patient care

You should demonstrate leadership in the promotion of probity, namely the adherence to the highest ethical principles and ideals, wherever you practise.

35. You must work collaboratively with colleagues, respecting their skills and contributions.[1]

36. You must treat colleagues fairly and with respect.

37. You must be aware of how your behaviour may influence others within and outside the team.

You have a professional responsibility to uphold the highest standards of behaviour with colleagues. As pharmaceutical medicine is practised as a global specialty, consideration for cultural and linguistic differences is of particular importance at a regional, national and international level.

38. Patient safety may be affected if there is not enough medical cover. So you must take up any post you have formally accepted, and work your contractual notice period before leaving a job, unless the employer has reasonable time to make other arrangements.

*Patients here includes those people with the legal authority to make healthcare decisions on a patient's behalf.

Teaching, training, supporting and assessing

39. You should be prepared to contribute to teaching and training doctors and students.

To support the development and use of treatments, you should contribute to the training of both medical and non-medical staff. This will help to ensure that they have appropriate knowledge in pharmaceutical medicine.

40. You must make sure that all staff you manage have appropriate supervision.

41. You must be honest and objective when writing references, and when appraising or assessing the performance of colleagues, including locums and students. References must include all information relevant to your colleagues' competence, performance and conduct.[16]

42. You should be willing to take on a mentoring role for more junior doctors and other healthcare professionals.[1]

43. You must support colleagues who have problems with their performance or health. But you must put patient safety first at all times.[1]

Continuity and coordination of care

44. You must contribute to the safe transfer of patients between healthcare providers and between health and social care providers. This means you must:

    a. share all relevant information with colleagues involved in your patients' care within and outside the team, including when you hand over care responsibility as you go off duty, and when you delegate care or refer patients to other health or social care providers[5,10]

    b. check, where practical, that a named clinician or team has taken over responsibility when your role in providing a patient's care has ended. This may be particularly important for patients with impaired capacity or who are vulnerable for other reasons.

45. When you do not provide your patients' care yourself, for example when you are off duty, or you delegate the care of a patient to a colleague, you must be satisfied that the person providing care has the appropriate qualifications, skills and experience to provide safe care for the patient.[5]

Establish and maintain partnerships with patients

Patients and their representatives can offer unique insights into disease and illness. You have an obligation to work with patient advocates in the interests of public health. Care should be taken to manage potential conflicts of interest.

46. You must be polite and considerate.

47. You must treat patients as individuals and respect their dignity and privacy.[12]

48. You must treat patients fairly and with respect whatever their life choices and beliefs.

49. You must work in partnership with patients, sharing with them the information they will need to make decisions about their care,[15] including:

    a. their condition, its likely progression and the options for treatment, including associated risks and uncertainties

    b. the progress of their care, and your role and responsibilities in the team

    c. who is responsible for each aspect of patient care, and how information is shared within teams and among those who will be providing their care

    d. any other information patients need if they are asked to agree to be involved in teaching or research.[9]

50. You must treat information about patients as confidential. This includes after a patient has died.[10]

You must only share individual patient data with others after taking measures to protect patient privacy, including obtaining relevant consent and obtaining ethical advice.

51. You must support patients in caring for themselves to empower them to improve and maintain their health. This may, for example, include:

    a. advising patients on the effects of their life choices and lifestyle on their health and well-being

    b. supporting patients to make lifestyle changes where appropriate.

52. You must explain to patients if you have a conscientious objection to a particular procedure. You must tell them about their right to see another doctor and make sure they have enough information to exercise that right. In providing this information you must not imply or express disapproval of the patient's lifestyle, choices or beliefs. If it is not practical for a patient to arrange to see another doctor, you must make sure that arrangements are made for another suitably qualified colleague to take over your role.[17]

Domain 4: Maintaining trust

Show respect for patients

53. You must not use your professional position to pursue a sexual or improper emotional relationship with a patient or someone close to them.[12]

54. You must not express your personal beliefs (including political, religious and moral beliefs) to patients in ways that exploit their vulnerability or are likely to cause them distress.[17]

55. You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should:

    a. put matters right (if that is possible)

    b. offer an apology

    c. explain fully and promptly what has happened and the likely short-term and long-term effects.

An apology is an expression of regret that an event has occurred and is not necessarily an admission of liability or guilt. When conducting clinical research, it is often not possible to predict an adverse event or side effect of treatment or to be able to fully explain the likely long-term effects. It is important to express this uncertainty before treatment and not give unfounded reassurance. If a patient has suffered harm then you should express regret and empathy.

Treat patients and colleagues fairly and without discrimination

56. You must give priority to patients on the basis of their clinical need if these decisions are within your power. If inadequate resources, policies or systems prevent you from doing this, and patient safety, dignity or comfort may be seriously compromised, you must follow the guidance in paragraph 25b.

57. The investigations or treatment you provide or arrange must be based on the assessment you and your patient make of their needs and priorities, and on your clinical judgement about the likely effectiveness of the treatment options. You must not refuse or delay treatment because you believe that a patient's actions or lifestyle have contributed to their condition.

Pharmaceutical doctors are frequently involved in the conduct of clinical trials, either as sponsor representative or clinical investigator. You must ensure that the clinical trial has a reasonable probability of successfully answering the research question. The intervention in the clinical study must be justified. If you are acting as the clinical investigator, you must consider the likelihood of the individual completing the study as part of the enrolment process. As clinical investigator, you can only advise the patient on the potential outcome and must consider the safety of the patient throughout a clinical trial.

58. You must not deny treatment to patients because their medical condition may put you at risk. If a patient poses a risk to your health or safety, you should take all available steps to minimise the risk before providing treatment or making other suitable alternative arrangements for providing treatment.

59. You must not unfairly discriminate against patients or colleagues by allowing your personal views* to affect your professional relationships or the treatment you provide or arrange. You should challenge colleagues if their behaviour does not comply with this guidance, and follow the guidance in paragraph 25c if the behaviour amounts to abuse or denial of a patient's or colleague's rights.

* This includes your views about a patient's or colleague's lifestyle, culture or their social or economic status, as well as the characteristics protected by legislation: age, disability, gender reassignment, race, marriage and civil partnership, pregnancy and maternity, religion or belief, sex and sexual orientation.

60. You must consider and respond to the needs of disabled patients and should make reasonable adjustments† to your practice so they can receive care to meet their needs.

61. You must respond promptly, fully and honestly to complaints and apologise when appropriate. You must not allow a patient's complaint to adversely affect the care or treatment you provide or arrange.

62. You should end a professional relationship with a patient only when the breakdown of trust between you and the patient means you cannot provide good clinical care to the patient.[18]

63. You must make sure you have adequate insurance or indemnity cover so that your patients will not be disadvantaged if they make a claim about the clinical care you have provided in the UK.

You must ensure that the clinical trial sponsor holds adequate insurance for the study before the enrolment of patients.

As pharmaceutical medicine is practised globally, you must ensure that you have adequate insurance or indemnity cover for all the jurisdictions in which you are working.

64. If someone you have contact with in your professional role asks for your registered name and/or GMC reference number, you must give this information to them.

If you are not registered with the GMC, then you should provide adequate information according to your local guidelines.

Act with honesty and integrity

Honesty

65. You must make sure that your conduct justifies your patients' trust in you and the public's trust in the profession.

66. You must always be honest about your experience, qualifications and current role.

67. You must act with honesty and integrity when designing, organising or carrying out research, and follow national research governance guidelines and our guidance.[2]

When conducting research anywhere in the world, you should select investigational sites based upon the health needs and the principles of ethics and probity outlined in this document.

You should ensure that local regulations and low costs do not unduly influence the conduct of clinical trials.

You should give special consideration to the design and conduct of clinical trials in the developing world. This is because of the ethical and public health issues related to the continuing provision of treatment and care.

† 'Reasonable adjustments' does not only mean changes to the physical environment. It can include, for example, being flexible about appointment time or length, and making arrangements for those with communication difficulties such as impaired hearing. For more information see the EHRC website (www.equalityhumanrights.com/advice-and-guidance).

Communicating information

You must ensure that all communications comply with local regulations and standards and, where applicable, codes of promotional practice.

68. You must be honest and trustworthy in all your communication with patients and colleagues. This means you must make clear the limits of your knowledge and make reasonable checks to make sure any information you give is accurate.

69. When communicating publicly, including speaking to or writing in the media, you must maintain patient confidentiality. You should remember when using social media that communications intended for friends or family may become more widely available.[10,19]

70. When advertising your services, you must make sure the information you publish is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge.

71. You must be honest and trustworthy when writing reports, and when completing or signing forms, reports and other documents.[16] You must make sure that any documents you write or sign are not false or misleading.

    a. You must take reasonable steps to check the information is correct.

    b. You must not deliberately leave out relevant information.

The Faculty of Pharmaceutical Medicine advocates the following principles relating to disclosure and dissemination of information.

You must support and promote all of these principles.

- Timely registration of all clinical trials.
- Prompt communication of overall clinical trial results to all participants.
- Authors of documents that are released into the public domain must be fully conversant with the study results and supporting data.
- Summary results must be made public as soon as possible after completion of a clinical trial. The date of release of information should not be dependent upon market or pricing approval or the continuation or discontinuation of the clinical trial or the whole project.
- Release of anonymised patient-level data to third parties must be in line with national regulations.
- Promotional materials and/or information destined for patients, healthcare professionals, and pricing and reimbursement bodies must be complete, balanced and easily understood by the intended audience.

You are also required to comply with national and international legislation relating to clinical trial disclosure.

Openness and legal or disciplinary proceedings

72. You must be honest and trustworthy when giving evidence to courts or tribunals.[20] You must make sure that any evidence you give or documents you write or sign are not false or misleading.
    a. You must take reasonable steps to check the information.
    b. You must not deliberately leave out relevant information.

73. You must cooperate with formal inquiries and complaints procedures and must offer all relevant information while following the guidance in Confidentiality.

74. You must make clear the limits of your competence and knowledge when giving evidence or acting as a witness.[20]

75. You must tell us [GMC] without delay if, anywhere in the world:
    a. you have accepted a caution from the police or been criticised by an official inquiry
    b. you have been charged with or found guilty of a criminal offence
    c. another professional body has made a finding against your registration as a result of fitness to practise procedures.[21]

This is specific to those registered with the GMC. However, the same principles apply if you are registered with another regulatory body or bodies.

76. If you are suspended by an organisation from a medical post, or have restrictions placed on your practice, you must, without delay, inform any other organisations you carry out medical work for and any patients you see independently.

Honesty in financial dealings

Integrity in business dealings is a fundamental principle of pharmaceutical medicine.

77. You must be honest in financial and commercial dealings with patients, employers, insurers and other organisations or individuals.[22]

78. You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients.

79. If you are faced with a conflict of interest, you must be open about the conflict, declaring your interest formally, and you should be prepared to exclude yourself from decision making.

80. You must not ask for or accept – from patients, colleagues or others – any inducement, gift or hospitality that may affect or be seen to affect the way you prescribe for, treat or refer patients or commission services for patients. You must not offer these inducements.

You must operate within applicable local and international laws, regulations and guidelines relating to sponsorship, gifts, hospitality and the provision of grants and services allied to medical care.

References (GMC)

1	General Medical Council (2012) *Leadership and management for all doctors* London, GMC
2	General Medical Council (2010) *Good practice in research* London, GMC
3	General Medical Council (2011) *Developing teachers and trainers in undergraduate medical education* London, GMC
4	General Medical Council (2012) *Continuing professional development: guidance for all doctors* London, GMC
5	General Medical Council (2013) *Delegation and referral* London, GMC
6	General Medical Council (2013) *Good practice in prescribing and managing medicines and devices* London, GMC
7	General Medical Council (2010) *Treatment and care towards the end of life: good practice in decision-making* London, GMC
8	General Medical Council (2011) *Making and using visual and audio recordings of patients* London, GMC
9	General Medical Council ((2010) *Consent to research* London, GMC
10	General Medical Council (2009) *Confidentiality* London, GMC
11	General Medical Council (2012) *Raising and acting on concerns about patient safety* London, GMC
12	General Medical Council (2013) *Maintaining boundaries* London, GMC
	• *Intimate examinations and chaperones* (paragraphs 47, 25c)
	• *Maintaining a professional boundary between you and your patient* (paragraph 53)
	• *Sexual* behaviour and your duty to report(paragraphs 53, 25c)
13	General Medical Council (2007) *0-18 years: guidance for all doctors* London, GMC
14	General Medical Council (2012) *Protecting children and young people: the responsibilities of all doctors* London, GMC
15	General Medical Council (2008), *Consent: patients and doctors making decisions together* London, GMC
16	General Medical Council (2012), *Writing references* London, GMC
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