

References to Good medical practice updated in March 2013

Good practice in prescribing and managing medicines and devices (2013)

- 1 In *Good medical practice (2013)*¹ we say:
 - 12 You must keep up to date with, and follow, the law, our guidance and other regulations relevant to your work.
 - 14 You must recognise and work within the limits of your competence.
 - 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.
 - b provide effective treatments based on the best available evidence
 - 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
 - 18 You must make good use of the resources available to you.
 - 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.
 - 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.

About this guidance

- 2 This guidance provides more detailed advice on how to comply with these principles when prescribing and managing medicines and medical devices, including appliances.
- 3 You are responsible for the prescriptions you sign and for your decisions and actions when you supply and administer medicines and devices or authorise or instruct others to do so. You must be prepared to explain and justify your decisions and actions when prescribing, administering and managing medicines.
- 4 'Prescribing' is used to describe many related activities, including supply of prescription only medicines, prescribing medicines, devices and dressings on the NHS and advising patients on the purchase of over the counter medicines and other remedies. It may also be used to describe written information provided for patients (information prescriptions) or advice given. While some of this guidance is particularly relevant to prescription only medicines, you should follow it in relation to the other activities you undertake, so far as it is relevant and applicable. This guidance applies to medical devices as well as to medicines.
- 5 Serious or persistent failure to follow this guidance will put your registration at risk.
- 7 You should make use of electronic and other systems that can improve the safety of your prescribing, for example by highlighting interactions and allergies and by ensuring consistency and compatibility of medicines prescribed, supplied and administered. The Medicines and Healthcare Products Regulatory Agency's (MHRA) Drug Safety Update and the NHS Central Alert System provide information and advice to support the safer use of medicines relevant to your practice and alert you to safety information about medicines you prescribe. The National electronic Library for Medicines has extensive information on the safe, effective and efficient use of medicines. The National Prescribing Centre (now part of the National Institute for Health and Clinical Excellence (NICE)) publishes a range of materials to help you improve the safety and clinical and cost effectiveness of your prescribing. The electronic Medicines Compendium lists Summaries of Product Characteristics and Patient Information Leaflets.
- 8 If you are unsure about interactions or other aspects of prescribing and medicines management you should seek advice from experienced colleagues, including pharmacists, prescribing advisers and clinical pharmacologists.
- 9 You must be familiar with the guidance in the British National Formulary (BNF) and British National Formulary for Children (BNFC), which contain essential information to help you prescribe, monitor, supply, and administer medicines.

Keeping up to date and prescribing safely

- 6 *Good medical practice* says that you must recognise and work within the limits of your competence and that you must keep your knowledge and skills up to date. You must maintain and develop the knowledge and skills in pharmacology and therapeutics, as well as prescribing and medicines management, relevant to your role and prescribing practice.
- 10 You should follow the advice in the BNF on prescription writing and make sure your prescriptions and orders are clear, in accordance with the relevant statutory requirements and include your name legibly.² You should also consider including clinical indications³ on your prescriptions.

- 11** You should take account of the clinical guidelines published by the:
- a** NICE (England)
 - b** Scottish Medicines Consortium and Health Improvement Scotland (including the Scottish Intercollegiate Guidelines Network) (Scotland)
 - c** Department for Health, Social Services and Public Safety (Northern Ireland)
 - d** All-Wales Medicines Strategy Group (Wales)
 - e** medical royal colleges and other authoritative sources of specialty specific clinical guidelines.
- 12** You should make sure that anyone to whom you delegate responsibility for dispensing medicines in your own practice is competent to do what you ask of them. Advice on training for dispensing support staff can be obtained from the General Pharmaceutical Council.
- 13** You should make sure that anyone to whom you delegate responsibility for administering medicines is competent to do what you ask of them.⁴

Need and objectivity

- 14** You should prescribe medicines only if you have adequate knowledge of the patient's health and you are satisfied that they serve the patient's needs.

15 *In Consent: patients and doctors making decisions together,⁵ we say:*

- 5d If a patient asks for a treatment that the doctor considers would not be of overall benefit to them, the doctor should discuss the issues with the patient and explore the reasons for their request. If, after discussion, the doctor still considers that the treatment would not be of overall benefit to the patient, they do not have to provide the treatment. But they should explain their reasons to the patient, and explain any other options that are available, including the option to seek a second opinion.

- 16** You must not prescribe medicines for your own convenience or the convenience of other health or social care professionals (for example, those caring for patients with dementia in care homes⁶).

Prescribing for yourself or those close to you

- 17** Wherever possible you must avoid prescribing for yourself or anyone with whom you have a close personal relationship.
- 18** Controlled medicines present particular dangers, occasionally associated with drug misuse, addiction and misconduct. You must not prescribe a controlled medicine for yourself or someone close to you unless:
- a** no other person with the legal right to prescribe is available to assess and prescribe without a delay which would put your, or the patient's, life or health at risk or cause unacceptable pain or distress, and

- b the treatment is immediately necessary to:
 - i save a life
 - ii avoid serious deterioration in health, or
 - iii alleviate otherwise uncontrollable pain or distress.

19 If you prescribe for yourself or someone close to you, you must:

- a make a clear record at the same time or as soon as possible afterwards. The record should include your relationship to the patient (where relevant) and the reason it was necessary for you to prescribe.
- b tell your own or the patient's general practitioner (and others treating you or the patient, where relevant) what medicines you have prescribed and any other information necessary for continuing care, unless (in the case of prescribing for somebody close to you) they object.

20 *In Consent: patients and doctors making decisions together, we say:*

- 3 For a relationship between doctor and patient to be effective, it should be a partnership based on openness, trust and good communication. Each person has a role to play in making decisions about treatment or care.

Consent

21 Together with the patient,⁷ you should make an assessment of their condition before deciding to prescribe a medicine. You must have or take an adequate history, including:

- a any previous adverse reactions to medicines
- b recent use of other medicines, including non-prescription and herbal medicines, illegal drugs and medicines purchased online, and
- c other medical conditions.

22 You should encourage your patients to be open with you about their use of alternative remedies, illegal substances and medicines obtained online, as well as whether in the past they have taken prescribed medicines as directed.

23 You should identify the likely cause of the patient's condition and which treatments are likely to be of overall benefit to them.

24 You should reach agreement with the patient on the treatment proposed,⁸ explaining:

- a the likely benefits, risks and burdens, including serious and common side effects
- b what to do in the event of a side effect or recurrence of the condition
- c how and when to take the medicine and how to adjust the dose if necessary, or how to use a medical device
- d the likely duration of treatment
- e arrangements for monitoring, follow-up and review, including further consultation, blood tests or other investigations, processes for adjusting the type or dose of medicine, and for issuing repeat prescriptions.

25 The amount of information you give to each patient will vary according to the nature of their condition, the potential risks and side effects and the patient's needs and wishes. You should check that the patient has understood the information, and encourage them to ask questions to clarify

any concerns or uncertainty. You should consider the benefits of written information, information in other languages and other aids for patients with disabilities to help them understand and consider information at their own speed and to retain the information you give them.

- 26** You should also provide patients' carers with information about the medicines you prescribe, either with the patient's consent or, if the patient lacks capacity to consent, if it is in their best interests.
- 27** It is sometimes difficult, because of time pressures, to give patients as much information as you or they would like. To help with this, you should consider the role that other members of the healthcare team, including pharmacists, might play. Pharmacists can undertake medicines reviews, explain how to take medicines and offer advice on interactions and side effects. You should work with pharmacists in your organisation and/or locality to avoid the risks of overburdening or confusing patients with excessive or inconsistent information.
- 28** You should also refer patients to the information in patient information leaflets (PILs) and other reliable sources of relevant information.⁹ PILs are useful supplements to the information you give patients about their medicines, but they are not a substitute for that information.
- 29** Some patients do not take medicines prescribed for them, or do not follow the instructions on the dose to take or the time medicines should be taken. You should try to understand the reasons for this and address them by providing reassurance and information, and by negotiating with the patient to reach agreement on an appropriate course of treatment that they are able and willing to adhere to.¹⁰

Sharing information with colleagues

- 30** You must contribute to the safe transfer of patients between healthcare providers and between health and social care providers. This means you must share all relevant information with colleagues involved in your patient's care within and outside the team, including when you hand over care as you go off duty, when you delegate care or refer patients to other health or social care providers. This should include all relevant information about their current and recent use of other medicines, other conditions, allergies and previous adverse reactions to medicines.
- 31** It is essential for safe care that information about medicines accompanies patients (or quickly follows them, for example on emergency admission to hospital) when they transfer between care settings.¹¹
- 32** If you prescribe for a patient, but are not their general practitioner, you should check the completeness and accuracy of the information accompanying a referral. When an episode of care is completed, you must tell the patient's general practitioner about:
 - a** changes to the patient's medicines (existing medicines changed or stopped and new medicines started, with reasons)
 - b** length of intended treatment
 - c** monitoring requirements
 - d** any new allergies or adverse reactions identified,¹² unless the patient objects or if privacy concerns override the duty, for example in sexual health clinics.

- 33** If a patient has not been referred to you by their general practitioner, you should also:
- a** consider whether the information you have is sufficient and reliable enough to enable you to prescribe safely; for example, whether:
 - i** you have access to their medical records or other reliable information about the patient's health and other treatments they are receiving
 - ii** you can verify other important information by examination or testing
 - b** ask for the patient's consent to contact their general practitioner if you need more information or confirmation of the information you have before prescribing. If the patient objects, you should explain that you cannot prescribe for them and what their options are.
- 34** If you are the patient's general practitioner, you should make sure that changes to the patient's medicines (following hospital treatment, for example) are reviewed and quickly incorporated into the patient's record. This will help to avoid patients receiving inappropriate repeat prescriptions and reduce the risk of adverse interaction.¹³

Shared care

- 35** Decisions about who should take responsibility for continuing care or treatment after initial diagnosis or assessment should be based on the patient's best interests, rather than on your convenience or the cost of the medicine and associated monitoring or follow-up.
- 36** Shared care requires the agreement of all parties, including the patient. Effective communication and continuing liaison between all parties to a shared care agreement are essential.

Prescribing at the recommendation of a professional colleague

- 37** If you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence.
- 38** If you delegate assessment of a patient's suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required. You must also make sure that they follow the guidance in paragraphs 21–29 on consent.
- 39** In both cases, you will be responsible for any prescription you sign.

Recommending medicines for prescription by colleagues

- 40** If you recommend that a colleague, for example a junior doctor or general practitioner, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required.

Shared care prescribing

- 41** If you share responsibility for a patient's care with a colleague, you must be competent to exercise your share of clinical responsibility. You should:
- a** keep yourself informed about the medicines that are prescribed for the patient
 - b** be able to recognise serious and frequently occurring adverse side effects

- c make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
 - d keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- 42** In proposing a shared care arrangement, specialists may advise the patient's general practitioner which medicine to prescribe. If you are recommending a new, or rarely prescribed, medicine, you should specify the dosage and means of administration, and agree a protocol for treatment. You should explain the use of unlicensed medicines, and departures from authoritative guidance or recommended treatments and provide both the general practitioner and the patient with sufficient information to permit the safe management of the patient's condition.¹⁴
- 43** If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.

Raising concerns

- 44** Prescribing and administration errors by doctors are common,¹⁵ but harm is usually avoided by professional colleagues intervening before the errors can affect patients.
- 45** You must protect patients from risks of harm posed by colleagues' prescribing, administration and other medicines-related errors. You should question any decision or action that you consider might be unsafe.¹⁶ You should also respond constructively to concerns raised by colleagues, patients and carers about your own practice.

Reporting adverse drug/device and other patient safety incidents

- 46** Early, routine reporting of adverse reactions, incidents and near misses involving medicines and devices can allow performance and systems issues to be investigated, problems rectified and lessons learned.¹⁷ You must make reports in accordance with your employer or contracting body's local clinical governance procedures.¹⁸
- 47** You must inform the MHRA about:
- a serious suspected adverse reactions to all medicines and all reactions to products marked with a Black Triangle in the BNF and elsewhere using the Yellow Card Scheme.¹⁹
 - b adverse incidents involving medical devices, including those caused by human error that put, or have the potential to put, the safety of patients, healthcare professionals or others at risk.²⁰ These incidents should also be reported to the medical device liaison officer within your organisation.
- 48** You should provide patients with information about how they can report suspected side effects directly to the MHRA.
- 49** You should also:
- a check that all serious patient safety incidents are reported to the National Reporting and Learning System (in England and Wales), especially if such incidents are not automatically reported through clinical governance arrangements where you work
 - b where appropriate, inform the patient's general practitioner, the pharmacy that supplied the medicine, the local controlled drugs accountable officer and the medicines manufacturers of relevant adverse drug reactions and patient safety incidents.

- 50** You should respond to requests from the Drug Safety Research Unit for prescription-event monitoring data and information for studies on specific safety or pharmacovigilance issues.

Reviewing medicines

- 51** Whether you prescribe with repeats or on a one-off basis, you must make sure that suitable arrangements are in place for monitoring, follow-up and review, taking account of the patients' needs and any risks arising from the medicines.

- 52** When you review a patient's medicines, you should re-assess the patient's need for unlicensed medicines (see paragraphs 67–70), for example antipsychotics used for the treatment of behavioural and psychological symptoms in dementia.

- 53** Reviewing medicines will be particularly important where:

- a** patients may be at risk, for example, patients who are frail or have multiple illnesses.
- b** medicines have potentially serious or common side effects
- c** the patient is prescribed a controlled or other medicine that is commonly abused or misused
- d** the BNF or other authoritative clinical guidance recommends blood tests or other monitoring at regular intervals.

- 54** Pharmacists can help improve safety, efficacy and adherence in medicines use, for example by advising patients about their medicines and carrying out medicines reviews. This does not relieve you of your duty to ensure that your prescribing and medicines management is appropriate. You should consider and take appropriate action on information and advice from pharmacists and other healthcare

professionals who have reviewed patients' use of medicines, especially following changes to their medicines or if they report problems with tolerance, side effects or with taking medicines as directed.

Repeat prescribing and prescribing with repeats

- 55** You are responsible for any prescription you sign, including repeat prescriptions for medicines initiated by colleagues, so you must make sure that any repeat prescription you sign is safe and appropriate. You should consider the benefits of prescribing with repeats to reduce the need for repeat prescribing.

- 56** As with any prescription, you should agree with the patient what medicines are appropriate and how their condition will be managed, including a date for review. You should make clear why regular reviews are important and explain to the patient what they should do if they:

- a** suffer side effects or adverse reactions, or
- b** stop taking the medicines before the agreed review date (or a set number of repeats have been issued),

You must make clear records of these discussions and your reasons for repeat prescribing.

- 57** You must be satisfied that procedures for prescribing with repeats and for generating repeat prescriptions are secure and that:

- a** the right patient is issued with the correct prescription
- b** the correct dose is prescribed, particularly for patients whose dose varies during the course of treatment
- c** the patient's condition is monitored, taking account of medicine usage and effects

- d only staff who are competent to do so prepare repeat prescriptions for authorisation
- e patients who need further examination or assessment are reviewed by an appropriate healthcare professional
- f any changes to the patient's medicines are critically reviewed and quickly incorporated into their record.

58 At each review, you should confirm that the patient is taking their medicines as directed, and check that the medicines are still needed, effective and tolerated. This may be particularly important following a hospital stay, or changes to medicines following a hospital or home visit. You should also consider whether requests for repeat prescriptions received earlier or later than expected may indicate poor adherence, leading to inadequate therapy or adverse effects.

59 When you issue repeat prescriptions or prescribe with repeats, you should make sure that procedures are in place to monitor whether the medicine is still safe and necessary for the patient. You should keep a record of dispensers who hold original repeat dispensing prescriptions so that you can contact them if necessary.

Remote prescribing via telephone, video-link or online

60 Before you prescribe for a patient via telephone, video-link or online, you must satisfy yourself that you can make an adequate assessment, establish a dialogue and obtain the patient's consent in accordance with the guidance at paragraphs 20–29.

61 You may prescribe only when you have adequate knowledge of the patient's health, and are satisfied that the medicines serve the patient's needs. You must consider:

- a the limitations of the medium through which you are communicating with the patient
- b the need for physical examination or other assessments
- c whether you have access to the patient's medical records.

62 You must undertake a physical examination of patients before prescribing non-surgical cosmetic medicinal products such as Botox, Dysport or Vistabel or other injectable cosmetic medicines. You must not therefore prescribe these medicines by telephone, video-link, or online.

63 If you are prescribing for a patient in a care or nursing home or hospice, you should communicate with the patient (or, if that is not practicable, the person caring for them) to make your assessment and to provide the necessary information and advice. You should make sure that any instructions, for example for administration or monitoring the patient's condition, are understood and send written confirmation as soon as possible.

64 If the patient has not been referred to you by their general practitioner, you do not have access to their medical records, and you have not previously provided them with face-to-face care, you must also:

- a give your name and, if you are prescribing online, your GMC number
- b explain how the remote consultation will work and what to do if they have any concerns or questions
- c follow the advice in paragraphs 30–34 on Sharing information with colleagues.

65 You should not collude in the unlawful advertising of prescription only or unlicensed medicines to the public by prescribing via websites that breach advertising regulations.²¹

66 If you prescribe for patients who are overseas, you should consider how you or local healthcare professionals will monitor their condition. You should also have regard to differences in a product's licensed name, indications and recommended dosage regimen. You may also need to consider:

- a** MHRA guidance on import/export requirements and safety of delivery,
- b** whether you will need additional indemnity cover
- c** whether you will need to be registered with a regulatory body in the country in which the prescribed medicines are to be dispensed.

Prescribing unlicensed medicines

67 The term 'unlicensed medicine' is used to describe medicines that are used outside the terms of their UK licence or which have no licence for use in the UK.²² Unlicensed medicines are commonly used in some areas of medicine such as in paediatrics, psychiatry and palliative care. They are also used, less frequently, in other areas of medicine.

68 You should usually prescribe licensed medicines in accordance with the terms of their licence. However, you may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient.

69 Prescribing unlicensed medicines may be necessary where:

- a** There is no suitably licensed medicine that will meet the patient's need. Examples include (but are not limited to), for example, where:²³
 - i** there is no licensed medicine applicable to the particular patient. For example, if the

patient is a child and a medicine licensed only for adult patients would meet the needs of the child; or

- ii** a medicine licensed to treat a condition or symptom in children would nonetheless not meet the specific assessed needs of the particular child patient, but a medicine licensed for the same condition or symptom in adults would do so; or
- iii** the dosage specified for a licensed medicine would not meet the patient's need; or
- iv** the patient needs a medicine in a formulation that is not specified in an applicable licence.

- b** Or where a suitably licensed medicine that would meet the patient's need is not available. This may arise where, for example, there is a temporary shortage in supply; or
- c** The prescribing forms part of a properly approved research project.

70 When prescribing an unlicensed medicine you must:

- a** be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
- b** take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so
- c** make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.

Information for patients about the licence for their medicines

71 You must give patients (or their parents or carers) sufficient information about the medicines you propose to prescribe to allow them to make an informed decision.

72 Some medicines are routinely used outside the terms of their licence, for example in treating children. In emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the licence. In other cases, where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population.²⁴ You must always answer questions from patients (or their parents or carers) about medicines fully and honestly.

73 If you intend to prescribe unlicensed medicines where that is not routine or if there are suitably licensed alternatives available, you should explain this to the patient, and your reasons for doing so.

74 You should be careful about using medical devices for purposes for which they were not intended.

References

- 1 General Medical Council (2013) *Good medical practice* London, General Medical Council, available at www.gmc-uk.org/gmp
- 2 Electronic prescribing services can also be used. In England prescriptions can be sent electronically to a pharmacy; in Wales and Scotland, information is held in a barcode on a paper prescription. For more details see *Get Started with EPS*, Health and social Care information Centre; *Prescriptions electronically*, NHS Wales Informatics Service; *Electronic Transfer of Prescriptions (ETP)* (pdf), Scottish Government
- 3 See clinicalindications.com
- 4 See explanatory guidance on *Delegation and referral* (2013). See also Supply and administration of Botox®, Vistabel®, Dysport® and other Injectable medicines in cosmetic procedures, Medicines and Healthcare products Regulatory Agency.
- 5 General Medical Council (2008) *Consent: patients and doctors making decisions together* London, General Medical Council, available at www.gmc-uk.org/consent
- 6 See *The use of antipsychotic medication for people with dementia: Time for action* (Department of Health, 2009), which reported that 'around 180,000 people with dementia are treated with antipsychotic medication across the country per year... use at this level equates to an additional 1,800 deaths, and an additional 1,620 cerebrovascular adverse events, around half of which may be severe, per year', and NICE *clinical guideline 42: Dementia*. The National Prescribing Centre website and the joint NHS Institute and Dementia Action Alliance's *Call to action: the use of antipsychotic drugs for people with dementia* also contains guides, case studies and other materials to support good prescribing practice and alternative care strategies for patients with dementia.
- 7 or, where appropriate, parents or carers with authority to make decision on behalf of patients. Medicines may be prescribed without consent if it is likely to be of overall benefit to adults who lack capacity, or in accordance with mental health legislation.
- 8 A number of patient decision aids are available on the National Prescribing Centre website.
- 9 NHS Choices and information bearing The Information Standard quality mark, for example.
- 10 The National Prescribing Centre website includes information, guidance and tools for understanding and improving adherence. See also NICE's Clinical guidelines CG76 on medicines adherence.

- 11 See *Keeping patients safe when they transfer between care providers – getting the medicines right* (Royal Pharmaceutical Society, July 2011).
- 12 See the EQUIP (Errors – Questioning Undergraduate Impact on Prescribing) study (pdf) regarding inappropriate delegation of responsibility for writing up discharge summaries to junior staff with insufficient pharmacology training or knowledge of patients.
- 13 See *Medicines Reconciliation: A guide to implementation* (pdf) (National Prescribing Centre, 2008)
- 14 Shared care resources are available from the National Prescribing Centre; Midlands Therapeutics Review & Advisory Committee, which has produced 16 'Effective Shared Care Agreements' covering a variety of medicines/indications; UK Medicines Information, which has published many shared care protocols/agreements; and Keele School of Pharmacy which publishes an Effective Shared Care Agreement Toolkit 'to assist healthcare professionals in the development of their own shared care agreements to support locally agreed prescribing'.
- 15 See the EQUIP (Errors – Questioning Undergraduate Impact on Prescribing) study (pdf) and Investigating the prevalence and causes of prescribing errors in general practice: The PRACtICE study.
- 16 See *Raising and acting on concerns about patient safety* (2012).
- 17 You should anonymise or code the information or seek consent, if practicable, or see our confidentiality guidance for more advice.
- 18 You must also make sure dangerous occurrences and accidents are reported to the Health and Safety Executive in accordance with the *Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995*, and that local procedures for reporting and learning from similar issues are followed.
- 19 The MHRA collects data on licensed and unlicensed prescription-only, pharmacy and over-the-counter medicines.
- 20 Further guidance on reporting is available from the MHRA: Reporting Adverse Incidents. Incidents involving medical devices in England and Wales should be reported to MHRA reporting adverse incidents. In Northern Ireland they should be reported to Northern Ireland Adverse Incident Centre; and in Scotland to Health Facilities Scotland online incident reporting.
- 21 See *The Medicines (Advertising) Regulations 1994* and *The Medicines (Monitoring of Advertising) Regulations 1994*, both as amended, and *The Blue Guide: Advertising and Promotion of Medicines in the UK* (MHRA, 2005).
- 22 This definition is based on information published by the Medicines and Healthcare Products Regulatory Authority (MHRA) which is the licensing and regulatory body for the supply and use of medicines and medical devices. MHRA guidance on the lawful supply and use of unlicensed medicines is set out in the MHRA publication *The supply of unlicensed medicinal products ("specials")*, MHRA Guidance Note 14.
- 23 We cannot foresee every circumstance in which it may be necessary to prescribe an unlicensed medicine to meet a particular patient's assessed needs. If in doubt consult MHRA or seek legal advice.
- 24 The Medicines for Children leaflets on unlicensed medicines produced by the Royal College of Paediatrics and Child Health/Neonatal and Paediatric Pharmacists Group Standing Committee on Medicines may be helpful in explaining to children and parents why such practice is common in caring for children. The British Pain Society publishes *Using medicines beyond licence: Information for patients*.