General Medical Council

Professional standards

In effect: 5 April 2021

Good practice in prescribing and managing medicines and devices

Summary

This guidance will help you make sure that you practise safe prescribing. It reminds you that where possible, you must avoid prescribing for yourself or those close to you. It goes through what you need to consider when repeat prescribing, prescribing controlled drugs or share the responsibility of your patient with a colleague.

The standards of good practice apply to all doctors working in all settings. That is why advice on face to face and remote prescribing is integrated throughout the guidance. We also set out things to consider if prescribing to patients who are overseas or if prescribing unlicensed medicines.

General Medical Council

Good practice in prescribing and managing medicines and devices

Professional standards: More detailed guidance

This guidance was published on 18 February 2021

This guidance came into effect 5 April 2021 and updated on 15 March 2022.

You can find the latest version of all our professional standards at www.gmc-uk.org/guidance.

Contents

About this guidance

1. In 'Good medical practice' (2024)[1] we say:

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

4. You must follow the law, our guidance on professional standards, and other regulations relevant to your work .

7. In providing clinical care you must:

d. propose, provide or 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 will meet their needs

e. propose, provide or prescribe effective treatment based on the best available evidence

14. You must make good use of the resources available to you, and provide the best service possible, taking account of your responsibilities to patients and the wider population.

39. You should ask patients about any other care or treatment they are receiving – including over-the-counter medications – and check that any care or treatment you propose, provide or prescribe is compatible.

69. You must make sure that formal records of your work (including patients' records) are clear, accurate, contemporaneous[1] and legible.

70. You should take a proportionate approach to the level of detail but patients' records should usually include:

a. relevant clinical findings

b. drugs, investigations or treatments proposed, provided or prescribed

c. the information shared with patients

d. concerns or preferences expressed by the patient that might be relevant to their ongoing care, and whether these were addressed

[1] Contemporaneous means making records at the same time as the events you are recording, or as soon as possible afterwards.

e. information about any reasonable adjustments and communication support preferences

f. decisions made, actions agreed (including decisions to take no action) and when/whether decisions should be reviewed

g. who is creating the record and when.

2. This guidance, which forms part of the professional standards, gives more detailed advice on how to comply with these principles when prescribing and managing medicines and medical devices. The guidance applies to all prescribing in whatever setting your interaction takes place, including remote consultations.

3. You are responsible for the prescriptions you sign. You are also accountable for your decisions and actions when supplying or administering medicines and devices, and when authorising or instructing others to do so.

4. 'Prescribing' is used to describe many related activities, including:

a. supplying prescription-only medicines
b. prescribing medicines, devices, dressings and activities, such as exercise
c. advising patients on the purchase of over the counter medicines and other remedies.

5. It may also be used to describe any written information (information prescriptions) or advice you give to patients. 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.

6. Prescribing happens in a range of contexts, including face to face and remotely using telephone, online and video-link or other technological platforms. If you can't meet the standards set out in this guidance through the mode of consultation you are using, you should offer an alternative if possible, or signpost to other services. If you think that systems, policies or procedures are, or may be, placing patients at risk of harm, you must follow the guidance in 'Raising and acting on concerns about patient safety'.

7. The professional standards describe good practice, and not every departure from them will be considered serious. You must use your professional judgement to apply the standards to your day-to-day practice. If you do this, act in good faith and in the interests of patients, you will be able to explain and justify your decisions and actions. We say more about professional judgement, and how the professional standards relate to our fitness to practise processes, appraisal and revalidation, at the beginning of *Good medical practice*

Keeping up to date and prescribing safely

8. As outlined in 'Good medical practice', you must recognise and work within the limits of your competence and you must keep your knowledge and skills up to date. You must maintain and

develop your knowledge and skills that are relevant to your role and practice in:

a. pharmacology and therapeutics

b. prescribing and managing medicines

c. any technology or processes you use to prescribe, for example via remote consultation.

9. 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.

10. The Medicines and Healthcare products Regulatory Agency's (MHRA) Drug Safety Update and Central Alerting 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.

11. The National Institute for Health and Care Excellence (NICE) brings together evidence on the safe, effective and efficient use of medicines from a range of organisations in Evidence Search. It also publishes a range of products to help you improve the safety, as well as the clinical and cost effectiveness, of your prescribing. This includes Patient Decision Aids. The electronic Medicines Compendium contains Summaries of Product Characteristics and Patient Information Leaflets (PILs).

12. If you are unsure about interactions or other aspects of prescribing and managing medicines, you should seek advice from experienced colleagues, including pharmacists, prescribing advisers and clinical pharmacologists.

13. 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.

14. 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. You should also make sure you include your name legibly.[3] As well, you should consider including clinical indications[4] on your prescriptions.

15. You should take account of the clinical guidelines published by:

a. National Institute for Health and Care Excellence (England)

b. Department for Health, Social Services and Public Safety (Northern Ireland)

c. Healthcare Improvement Scotland (including the Scottish Medicines Consortium and Scottish Intercollegiate Guidelines Network) (Scotland)

d. All-Wales Medicines Strategy Group (Wales)

e. medical royal colleges and other authoritative sources of specialty specific clinical guidelines.

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

17. You should make sure that anyone you delegate responsibility for dispensing or administering

medicines to is competent to do what you ask.[5] Advice on training for dispensing support staff can be obtained from the General Pharmaceutical Council and Pharmaceutical Society of Northern Ireland (PSNI).

18. Where relevant, if you don't wish to prescribe due to a conscientious objection, you should follow our explanatory guidance on 'Personal beliefs and medical practice'.

19. 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.[6]

Deciding if it is safe to prescribe

20. You should only prescribe medicines if you have adequate knowledge of the patient's health and you are satisfied that the medicines serve the patient's needs. You must consider:

a. the suitability of the mode of consultation you are using, for example face to face or remote, taking account of any need for physical examination or other assessments (see paragraphs 21 to 26)

b. whether you have sufficient information to prescribe safely, for example if you have access to the patient's medical records and can verify relevant information (see paragraphs 27 to 33)

c. whether you can establish two-way dialogue, make an adequate assessment of the patient's needs and obtain consent (see paragraphs 34 to 38)

d. whether you can share information appropriately after an episode of care (see paragraphs 53 to 58).

Does the mode of consultation meet the individual needs of the patient and support safe prescribing?

21. Patients may prefer to access healthcare services face-to-face or through remote consultations via telephone, video-link or online, depending on their individual needs and circumstances.[7] Where different options exist, and when it is within your power, you should agree with the patient which mode of consultation is most suitable for them.

22. Circumstances in which a face-to-face consultation may be more appropriate than a remote consultation include when:

a. you are unsure of a patient's capacity to decide about treatment (see paragraphs 41 to 44)

b. you need to physically examine the patient

c. you are not the patient's usual doctor or GP and they have not given you consent to

share their information with their regular prescriber; this is particularly important if the treatment needs following up or monitoring, or if you are prescribing medicines where additional safeguards are needed (see paragraphs 59 to 66)

d. you are concerned that a patient does not have a safe and confidential place to access healthcare remotely, for example due to domestic abuse

e. you are concerned that a patient may be unable to make a decision freely because they are under pressure from others (see paragraphs 69 to 75 of 'Decision making and consent').

23. If you are not the patient's regular prescriber, such as a GP, you should:

a. tell the patient your name, role and, if online, your GMC registration number

b. explain how the consultation is going to work and what they should do if they have any concerns or questions

c. follow the advice in paragraphs 27 to 33 and 53 to 58 on sharing information.

24. Before you prescribe, you must be satisfied that you can make an adequate assessment, establish a dialogue and obtain the patient's consent through the mode of consultation you are using (see paragraphs 34 to 44).

25. You must also consider and respond to the patient's communication needs and make reasonable adjustments to your practice, where necessary, so they can receive care that meets their needs.[8]

26. You must carry out a physical examination of patients before prescribing non-surgical cosmetic medicines, such as Botox, Dysport, Vistabel or other injectable cosmetic medicines. Therefore, you must not prescribe these medicines remotely.

Do you have enough information about the patient to prescribe a treatment that meets their needs?

27. You must only prescribe if it is safe to do so.

a. It's not safe to prescribe if you don't have sufficient information about the patient's health or if the mode of consultation is unsuitable to meet their needs.

b. It may be unsafe if relevant information is not shared with other healthcare providers involved in the patient's care – for example because the patient refuses consent.

28. Before prescribing, you must consider whether the information you have is sufficient and reliable enough to enable you to prescribe safely.

For example, whether:

a. you have access to the patient's medical records or other reliable information about their health and other treatments they are receiving

b. you can verify other important information by examination or testing

c. the patient would be at risk of death or serious harm if they are also obtaining medication from other sources.

29. If you are not the patient's regular prescriber, you should ask for the patient's consent to:

a. contact their GP or other treating doctors if you need more information or confirmation of the information you have before prescribing

b. share information with their GP when the episode of care is completed.[9]

30. If the patient objects to information being shared with you, or does not have a regular prescriber, you must be able to justify a decision to prescribe without that information.

31. If the patient refuses to consent to you sharing information with their GP, or does not have a GP, you should explain to the patient the risks of not sharing this information. This should be documented in their medical records.

32. If failing to share information could pose a risk to patient safety, you should explain to the patient that you cannot prescribe. You should outline their options and signpost them to appropriate alternative services. You should clearly document your reasons for any decisions made.

33. When treating vulnerable patients in any setting, such as children's homes, care homes or prisons, take particular care to follow relevant national protocols. You should support appropriate and effective information sharing between the setting and the community in order to ensure continuity of care.

Can you establish a dialogue and obtain consent?

Establishing a dialogue

34. You must establish a dialogue with your patient to help them consider information about their options and so they can decide whether or not to have care or treatment. Good dialogue should give both you and your patient the opportunity to ask questions to get the information you both need.

35. Together with the patient, you should assess their condition before deciding to prescribe a medicine. You must have or take an adequate history, which includes:

a. any previous adverse reactions to medicines

b. current and recent use of other medicines, including non-prescription and herbal medicines, illegal drugs and medicines purchased online or face to face

c. other medical conditions.

36. You should encourage your patient to be open about their use of alternative remedies, illegal substances and medicines obtained online or face to face, as well as whether or not they

have taken prescribed medicines as directed in the past.

37. If you need more information to help you decide which options would serve the patient's needs, you must ask for it before recommending an option or proceeding with treatment.

38. If it's not possible to clarify or ask for more information from the patient in the environment you are working, you should consider whether it is safe to prescribe, and raise concerns as appropriate. For example, it may be appropriate to raise concerns if the system in which you're working involves prescribing remotely on the basis of a questionnaire and there is no mechanism for two-way dialogue or communication with patients.

Assessing the patient's needs

39. You should identify the likely cause of the patient's condition and which treatments are likely to meet their needs.

40. You should reach agreement with the patient on the proposed treatment,[10] explaining:

a. the likely benefits, risks and impact, 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

d. how to use a medical device

e. the likely duration of treatment

f. any relevant 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.

Assessing a patient's capacity

41. You must begin with the presumption that every adult patient has capacity to make decisions about their care. Assessing capacity is a core clinical skill and doesn't necessarily require specialist input. You should be able to draw reasonable conclusions about your patient's capacity during your dialogue with them.

42. If you are unsure if a patient has capacity to make a decision, you should assess their capacity using the test under the relevant legislation. Our guidance on 'Decision making and consent' gives detailed advice on assessing capacity and making decisions where a patient is known not to have capacity, at paragraphs 76 to 91.

43. 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.

44. For patients under 18 this guidance should be read alongside '0–18: guidance for all

doctors'.[11]

Giving information to patients

45. 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 aids for disabled patients to help them understand and consider and retain information in a way suited to their needs.

46. 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, could play. Pharmacists can undertake medicine 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 overloading or confusing patients with excessive or inconsistent information.

47. You should refer patients to the information in PILs and other reliable sources of information.[12] PILs are useful supplements to the information you give patients about their medicines, but they are not a substitute for that information.

48. With the patient's consent, you should provide patients' carers with information about the medicines you prescribe. If the patient lacks capacity to consent, you should share this information with carers where, in your opinion, it would be of overall benefit to the patient.[13]

49. Some patients do not take medicines prescribed for them, or they do not follow the instructions as to the dose or the time medicines should be taken. You should try to understand the reasons for this and address them by providing reassurance and useful information. You should try to reach agreement with the patient on an appropriate course of treatment that they are able and willing to adhere to.[14]

Obtaining a patient's consent

50. You should be proportionate when obtaining a patient's consent. For most prescribing decisions, you can rely on a patient's verbal consent, as long as you are satisfied that they've had the opportunity to consider any relevant information and decided to go ahead. Sometimes a patient's signature is required on a form, for example to comply with an MHRA drug safety alert about a medicine with serious side effects.

Handling patient requests for medicine you don't think will benefit them

51. Sometimes, patients will ask for treatment or care that you don't think is in their clinical

interests. In these situations, you should explore the reasons for their request, their understanding of what it would involve and their expectations about the likely outcome. This discussion will help you take account of the factors that are significant to the patient and assess whether providing the treatment or care could serve the patient's needs.

52. If, after discussion, you still think the treatment or care would not serve the patient's needs, you should not provide it. You should explain your reasons to the patient and explore other options that might be available, including their right to seek a second opinion.

Sharing information after providing care

53. 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. This includes when you hand over care as you go off duty, when you delegate care, or when you refer patients to other health or social care providers. You should include all relevant information about the patient's current and recent use of medicines, as well as any other conditions, allergies and previous adverse reactions to medicines.

54. 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.[15]

55. If you are the patient's GP, you should make sure that changes to the patient's medicines, for example following hospital treatment, 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.[16]

56. If you are not the patient's GP, when an episode of care is completed, you must tell the patient's GP about:

a. changes to the patient's medicines along with reasons, including if existing medicines are changed or stopped, and new medicines are started

b. length of intended treatment

c. monitoring requirements, including who will carry this out

d. any new allergies or adverse reactions identified.

57. If a patient refuses to give consent for their information to be shared, or if the patient does not have a GP, you should follow the guidance at paragraph 31.

58. In some circumstances, such as in the provision of sexual health services, privacy concerns may override the need to share information.

Controlled drugs and other medicines where additional safeguards are needed

59. Some categories of medicine may pose particular risks of serious harm or may be associated with overuse, misuse or addiction. When prescribing, you should follow relevant clinical guidance, such as drug safety updates on the risk of dependence and addiction associated with opioids.[17]

60. If you don't have access to relevant information from the patient's medical records you must not prescribe controlled drugs or medicines that are liable to abuse, overuse or misuse or when there is a risk of addiction and monitoring is important.[18] Exceptions to this are when no other person with access to that information is available to prescribe without unsafe delay and it is necessary to:

a. avoid serious deterioration in health or avoid serious harm

b. ensure continuity of treatment where a patient is unexpectedly without access to medication for a limited period.

61. In these circumstances, you should provide a limited quantity and dose – one that is sufficient to make sure the patient receives suitable care until a) they are able to see an appropriate health professional who has access to the relevant information from their medical records or b) you are able to verify that information yourself. In making this decision you should consider the possibility that the patient may be obtaining medicines from other sources. You should also follow the guidance at paragraphs 56-58.

62. If you are prescribing remotely, you must also be satisfied that appropriate safeguards are in place to support safe prescribing. Relevant safeguards include:

a. robust identity checks to make sure medicines are prescribed to the right person

b. if you are not the regular prescriber, check to make sure the patient has given consent for their regular prescriber to be contacted about their prescription (see paragraph 27)

c. making sure all relevant information about the prescription is shared with the patient's GP or added to the primary care record (see paragraphs 56 to 57).

63. You should give the patient the names, roles and contact details of key people who will be involved in their care, as well as advice about who they can contact if they have any questions or concerns. This is particularly important if you are prescribing remotely.

64. You must not prescribe controlled drugs to yourself or someone close to you, except in the circumstances described in paragraph 69.

65. You must not prescribe medicines for your own convenience or the convenience of other health or social care professionals (for example, prescribing sedatives for the convenience of those caring for patients with dementia in care homes where there is no clinical justification.[19]

66. Pharmacies may not dispense some categories of medicine if they are prescribed remotely,

unless certain safeguards are met.[20]

Prescribing for yourself or those close to you

67. Wherever possible, you must avoid prescribing for yourself or anyone you have a close personal relationship with.

68. If you prescribe any medicine 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. follow the advice on information sharing and safe prescribing in paragraphs 27 to 33 and 53 to 58.

69. You must not prescribe controlled drugs 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

b. emergency treatment is immediately necessary to avoid serious deterioration in health or serious harm.

Prescribing remotely for patients in a care or nursing home or hospice

70. If you are prescribing remotely for a patient in a care or nursing home or hospice, you should communicate with the patient, or if that's not practicable, the person caring for them, to make your assessment and to provide the necessary information and advice. You should make sure any instructions, such as how to administer the drug or monitor the patient's condition, are understood. And you should send written confirmation to them as soon as possible.

Prescribing remotely for patients based overseas

71. In addition to the above guidance, before prescribing remotely to patients who are overseas, you should also consider:

a. how you or local healthcare professionals will monitor their condition

b. differences in a product's licensed name, indications and recommended dosage

c. whether you have adequate insurance or indemnity arrangements in place to cover your practice in all relevant countries

d. whether you need to be registered with multiple regulatory bodies, including in the country you are based, in the country the patient is based, and in the country where the prescribed medicines are to be dispensed.

72. You should also follow UK and overseas legal requirements as well as relevant guidance on import and export for safe delivery, including from the MHRA.

73. If you are considering working for service providers based outside the UK, it's important to be aware that there may not be established local mechanisms to provide effective systems of regulation and this may have an impact on patient safety.

Shared care

74. 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 convenience or the cost of the medicine and associated monitoring or follow-up.

75. Shared care requires the agreement of all parties, including the patient. It's essential that all parties communicate effectively and work together.

Prescribing at the recommendation of a colleague

76. If you prescribe based on the recommendation of another doctor, nurse or other healthcare professional, you must be satisfied that the prescription is needed, appropriate for the patient and within the limits of your competence.

77. If you delegate the assessment of a patient's suitability for a medicine, you must be satisfied that the person you delegate to 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. You must also make sure that they follow our guidance on 'Decision making and consent' in paragraphs 42 to 47.

78. In both cases (paragraphs 76 – 77), you will be responsible for any prescription you sign.

Recommending medicines for a colleague to prescribe

79. If you recommend that a colleague, for example a trainee doctor or GP, prescribes a particular medicine for a patient, you must consider their competence to do so. You must be satisfied they have sufficient experience (especially in the case of trainee doctors) and knowledge of the patient and the medicine in order to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required.

Shared care prescribing

80. 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.

81. In proposing a shared care arrangement, specialists may advise the patient's GP 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. You should also provide both the GP and the patient with sufficient information to permit the safe management of the patient's condition.[21]

82. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should ask for further information or advice from the clinician who is sharing care responsibilities 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

83. Prescribing and administration errors are common,[22] but harm is usually avoided by colleagues intervening before the errors can affect patients.

84. You must protect patients from risks of harm posed by colleagues' prescribing, administration and other medicine-related errors. You should question any decision or action that you consider may be unsafe.[23] You should also respond constructively to concerns raised by colleagues, patients and carers about your own practice.

85. You should make patient safety your first priority and raise concerns if the service or system you are working in does not have adequate safeguards, which are relevant to the nature and mode of the consultation. This includes appropriate identity and verification checks.[24] You should not prescribe unless it is safe to do so.

Reporting adverse drug reactions medical device incidents and other patient safety incidents

86. Early, routine reporting of adverse reactions, incidents and near misses involving medicines

and devices can ensure performance and systems issues are investigated, problems rectified and lessons learned.[23] You must make reports in accordance with your employer or contracting body's local clinical governance procedures.[25]

87. You must use the Yellow Card Scheme[26, 27] to inform the MHRA about:

a. serious suspected adverse reactions to a medicine

b. any suspected adverse reactions to products marked with a Black Triangle symbol (▼).[28]

88. 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 must be reported to the medical device safety lead in your organisation (if there is one) and the relevant national body:

a. in England and Wales – MHRA reporting adverse incidents

b. in Northern Ireland – Northern Ireland Adverse Incident Centre.

c. in Scotland – Health Facilities Scotland online incident reporting

89. You should give patients information about how they can report suspected side effects directly to the MHRA.

90. You should also check that patient safety incidents are reported to the relevant national body or system, especially if such incidents are not automatically reported through clinical governance arrangements where you work. For instance:

a. In England and Wales, patient safety incidents are reported to the National Reporting and Learning System (NRLS), or its replacement, the Learn from patient safety events (LFPSE) service.[29]

b. In Northern Ireland, serious adverse incidents are reported to the Regional Health and Social Care Board (HSCB) and the Regional Public Health Agency.[30]

c. In Scotland, significant adverse event reviews commissioned by NHS boards for a category one adverse event should be reported to Healthcare Improvement Scotland.[31]

91. Where appropriate, you should also report relevant adverse drug reactions and patient safety incidents to the patient's GP, the pharmacy that supplied the medicine, the local controlled drugs accountable officer and the medicine manufacturers.

92. 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

93. 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. You should take account of

the patients' needs and any risks arising from the medicines.

94. When you review a patient's medicines, you should reassess their need for any unlicensed medicines (see paragraph 103 to 106) they may be taking, for example antipsychotics used for the treatment of behavioural and psychological symptoms in dementia.

95. Reviewing medicines will be particularly important where:

a. patients may be at risk, for example, those 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.

96. Pharmacists can help improve safety, efficacy and adherence in medicine use, for example by advising patients about their medicines and carrying out medicines reviews. This does not replace your duty to ensure you are prescribing and managing medicines appropriately.

97. You should consider and act appropriately on information and advice from pharmacists and other healthcare professionals who have reviewed a patient's use of medicines. This is especially the case if there are changes to a patient's medicines, or if they report problems with tolerance, side effects or with taking medicines as directed.

Repeat prescribing and prescribing with repeats

98. 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, and where possible, reduce repeat prescribing.

99. As with any prescription, you should agree with the patient which 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

b. stop taking the medicines before the agreed review date, or before a set number of repeats have been issued.

You must make clear records of these discussions and your reasons for repeat prescribing.[32]

100. 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.

101. 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.

102. 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.

Prescribing unlicensed medicines

103. In this guidance, the term 'unlicensed medicine' is used to describe medicines, which are used outside the terms of their UK licence or that have no licence for use in the UK.[33] Unlicensed medicines are commonly used in some areas of medicine, such as in paediatrics, psychiatry and palliative care. They are also used, albeit less frequently, in other areas of medicine.

104. 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.

105. Prescribing unlicensed medicines may be necessary in the following instances.

a. There is no suitably licensed medicine that will meet the patient's need. Examples include – but are not limited to – where:[34]

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

II. a medicine licensed to treat a condition or symptom in children would nonetheless not meet the specific assessed needs of the particular child, but a medicine licensed for the same condition or symptom in adults would do so

III. the dosage specified for a licensed medicine would not meet the patient's need

IV. the patient needs a medicine in a formulation that is not specified in an applicable licence.

b. 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.

c. The prescribing forms part of a properly approved research project.

d. There is a serious risk to public health and the MHRA has temporarily authorised the sale or supply of an unlicensed medicine, such as a vaccine or treatment, in response.[35]

e. A prescription only medicine that is unlicensed in Northern Ireland has been supplied under the Northern Ireland MHRA Authorised Route (NIMAR).[36]

106. 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 make sure that arrangements are in place 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

107. 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.

108. 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.[37] In the case of a medicine supplied under NIMAR, it's not usually necessary to draw attention to it being unlicensed in Northern Ireland. This is because the medicine will be licensed in Great Britain and have met the MHRA's requirements for safety, quality and efficacy. You must always answer questions from patients, or their parents or carers, about medicines fully and honestly.

109. If you intend to prescribe unlicensed medicines where it's not routine or if there are suitably licensed alternatives available, you should explain this to the patient, and give your

reasons for doing so.

Sports medicine

110. You must not prescribe or collude in the provision of medicines or treatment with the intention of improperly enhancing an individual's performance in sport. This does not preclude the provision of any care or treatment where your intention is to protect or improve the patient's health.

Endnotes

1. ‘Good medical practice’ (2024) London, General Medical Council
2. ‘Raising and acting on concerns about patient safety’ (2012) London, General Medical Council
3. 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) , Scottish Government. Electronic prescribing services may be introduced in Northern Ireland in the future.
4. See Clinical Indications.
5. See 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.
6. See Chapter 14 of the Human Medicines Regulations 2012 Number 1916 – SI 2012/1916 and ‘The Blue Guide: Advertising and Promotion of Medicines in the UK’ (MHRA, 3rd edition, 2nd revision, July 2019). The MHRA is an Agency of the Department of Health and Social Care with regulatory responsibility for medicines (for human use), blood and medical devices in the UK.
7. ‘The doctor will zoom you now: getting the most out of the virtual health and care experience’ insight report, July 2020, Healthwatch, Traverse, National Voices.
8. Our ethical hub has resources on applying our guidance in practice to help you decide if face-to-face or remote consultations are appropriate in other situations.
9. In some circumstances, such as in the provision of sexual health services, privacy concerns may override the need to share information.
10. ‘Decision making and consent’ (2020) London, General Medical Council
11. ‘0–18: guidance for all doctors’ (2018) London, General Medical Council
12. NHS Choices and information bearing The Information Standard quality mark, for example. Also see the electronic medicines compendium.
13. The concept of overall benefit is consistent with the legal requirements to consider whether treatment ‘benefits’ a patient (Scotland), or is in the patient’s ‘best interests’ (England, Northern Ireland and Wales). General Medical Council (2020) ‘Decision making and consent’ London, General Medical Council (paragraph 87).

    Also see ‘Confidentiality: Good practice in handling patient information’ (paragraphs 44 to 49).
14. The NICE website includes information, guidance and tools for understanding and improving adherence. See also NICE’s guideline on medicines adherence.
15. See ‘Keeping patients safe when they transfer between care providers – getting the

medicines right' (2011) Royal Pharmaceutical Society.

16. NICE's guideline on Medicines optimisation provides relevant recommendations, including in relation to medicines reconciliation.
17. See MHRA safety drug update on opioids and risk of dependence and addiction.
18. General Pharmaceutical Council (GPhC) guidance on providing pharmacy services at a distance, including on the internet (April 2019) provides examples of relevant medicines. These include: opiates, sedatives, laxatives, pregabalin, gabapentin.
19. See 'The use of antipsychotic medication for people with dementia: Time for action' (Department of Health, 2009) and NICE's guideline on dementia. The NICE website, 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.
20. For further information see GPhC guidance on providing pharmacy services at a distance, including on the internet (April 2019). The Pharmaceutical Society of Northern Ireland (PSNI) provides guidance for pharmacies based in Northern Ireland.
21. For more information about shared care prescribing see resources published by NHS England, Welsh Medicines Information Centre, NHS Scotland health boards and Health and Social Care in Northern Ireland.
22. See the EQUIP (Errors – Questioning Undergraduate Impact on Prescribing) study regarding inappropriate delegation of responsibility for writing up discharge summaries to junior staff with insufficient pharmacology training or knowledge of patients.
23. 'Raising and acting on concerns about patient safety' (2012) London, General Medical Council
24. NHS Digital has published 'The Identity and Verification standard for Digital Health and Care Services' (2018). For primary care providers, see guidance issued by NHS England and NHS Improvement Digital First Primary Care Team. For guidance on safe and appropriate online and remote provision of sexual health services please refer to Faculty of Reproductive Sexual Health (FRSH) and British Association for Sexual Health and HIV (BASHH) Standards for Online and Remote Providers of Sexual and Reproductive Health Services.
25. You should anonymise or code the information, or seek consent, if practicable. If necessary, see our explanatory guidance 'Confidentiality: good practice in handling patient information' (2017) for more advice.
26. You must 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. You must follow local procedures for reporting and learning from similar issues.
27. The MHRA provides guidance for healthcare professionals, patients and the public on reporting adverse incidents with medicines and medical devices to the Yellow Card scheme.
28. New medicines and vaccines that are under additional monitoring may be marked with an

inverted black triangle symbol (▼). The symbol appears in the British National Formulary (BNF), summaries of product characteristics, patient information leaflets and elsewhere.

29. The LFPSE service was launched in July 2021 and will eventually replace the NRLS. During the transition period professionals will need to identify which system their organisation is using to report incidents. Further information on the LFPSE service is available on NHS England and Improvement's website.

30. The Health and Social Care Board provides detailed guidance in its procedure for the reporting and follow-up of serious adverse incidents in Northern Ireland.

31. Healthcare Improvement Scotland provides guidance on managing adverse events and reporting requirements.

32. The MHRA collects data on licensed and unlicensed prescription-only, pharmacy and over-the-counter medicines.

33. 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.

34. 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 you are in any doubt, consult the MHRA or seek legal advice.

35. Regulation 174 of the Human Medicines Regulations 2012 allows the MHRA (the licensing authority) to permit a temporary authorisation for the supply of an unlicensed medicinal product for use in response to specific types of public health threat. This includes the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation.

36. The Department of Health and Social Care will be publishing guidance on NIMAR.

37. 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'.

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