



# Good practice in prescribing and managing medicines and devices

## **Draft for consultation**

Background, draft guidance  
and consultation questions

General  
Medical  
Council

Regulating doctors  
Ensuring good medical practice

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**Please return your responses by Friday 27 May 2011 to:**

Prescribing Consultation  
Standards and Ethics Team  
General Medical Council  
Regents Place, 350 Euston Road  
London NW1 3JN

Email: [standards.consult@gmc-uk.org](mailto:standards.consult@gmc-uk.org)

Telephone: 020 7189 5404

### Other formats

Our consultations are also available, on request, in alternative formats such as large print or audio. If you would like to receive a copy of a consultation in an alternative format please contact us to discuss your specific requirements in more detail.

### Freedom of information

The information you provide in your response may be subject to disclosure under the Freedom of Information Act 2000, which allows public access to information held by the GMC. This does not necessarily mean that your response will be made available to the public as there are exemptions relating to, for example, information provided in confidence and information to which the Data Protection Act 1998 applies. You may request confidentiality by ticking the box below. We will take this into account if a request for your response is made under the Freedom of Information Act 2000.

Please tick this box if you want us to treat your response as confidential

### Data protection

The information you supply will be stored and processed by the GMC in accordance with the Data Protection Act 1998 and will be used to analyse the consultation responses and help us to consult more effectively in the future. Any reports published using this information will not contain any personally identifiable information. We may provide anonymised responses to the consultation to third parties for quality assurance or approved research projects on request.

# Consultation summary and background

We are holding this consultation to seek your views on new draft guidance, *Good practice in prescribing and managing medicines and devices*.

The consultation will interest patients, doctors, other healthcare professionals, employers and organisations that represent their interests.

The draft guidance and the relevant questions are presented together for ease of reference.

The consultation closes on **Friday 27 May 2011**.

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## Background

The General Medical Council issues guidance to doctors on the standards of conduct and ethics expected of them by patients, the public and the profession. We regularly review our ethical guidance to ensure that it is up to date and fit for purpose.

The GMC's core guidance *Good Medical Practice* (2006) sets out the principles of good practice and the standards expected of all doctors registered with the GMC. *Good Medical Practice* is supplemented by a range of more detailed guidance covering specific issues, including consent, confidentiality, raising concerns and conflicts of interests. You can read our guidance on our website [www.gmc-uk.org/guidance/index.asp](http://www.gmc-uk.org/guidance/index.asp).

The draft guidance, *Good Practice in prescribing and managing medicines and devices*, is intended to replace *Good practice in prescribing medicines*, which was published in 2008. The guidance is for all doctors, whatever their specialty and wherever they work.

The draft guidance was approved by the GMC's Standards and Ethics Committee following consideration of relevant queries received; fitness to practise cases heard; and a scoping consultation from September 2010 to January 2011 involving approximately 80 key organisations to identify key themes and issues for the content of the draft guidance.

## Why is the GMC consulting?

The purpose of this questionnaire is to seek your views on the draft guidance, *Good practice in prescribing and managing medicines and devices*.

The consultation is also open to anyone with an interest in these issues who wishes to respond.

## How can I respond?

You can submit your response to the consultation through the GMC consultation website <https://gmc.e-consultation.net/econsult/default.aspx>.

Alternatively, you can reply by post to the address above or email your response to [standards.consult@gmc-uk.org](mailto:standards.consult@gmc-uk.org). Please mark emails 'Prescribing consultation'.

You can find a PDF version of this consultation document and on the consultation website.

The consultation runs until Friday 27 May 2011. We will analyse and report on the response to the consultation with a view to publishing the new guidance in late 2011.

## Questions about the draft guidance

This consultation asks for your views on *Good practice in prescribing and managing medicines and devices*.

There are 35 questions in this consultation broken down as follows:

- questions 1 to 26 relate to sections of *Good practice in prescribing and managing medicines and devices*
- questions 27 to 35 are general questions about the guidance and the consultation documents and process.

We do not ask questions about every paragraph of the draft guidance but at the end of each section, you have the opportunity to provide any further relevant comments.

You can also give us your comments about the clarity, level of detail and any links you think we should include in your answers to the general questions at the end of this questionnaire (questions 27 to 30).

If you require hard copies of any of the consultation documents please contact us using the contact details on page 1.

When answering the questions, please bear in mind that the GMC has a UK-wide remit and our guidance applies to all doctors on the medical registers regardless of specialty, grade and whether they work in the private or public sector.

# Good practice in prescribing and managing medicines and devices – a draft for consultation

## About this guidance

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- 1 In our core guidance, *Good Medical Practice*, we say:
  - 2 Good clinical care must include:
    - a. adequately assessing the patient's conditions, taking account of the history (including the symptoms, and psychological and social factors), the patient's views, and where necessary examining the patient.
  - 3 In providing care you must:
    - a. recognise and work within the limits of your competence
    - b. 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.
    - c. provide effective treatments based on the best available evidence.
    - f. keep clear, accurate and legible records, reporting the relevant clinical findings, the decisions made, the information given to patients, and any drugs prescribed or other investigation or treatment
    - g. make records at the same time as the events you are recording or as soon as possible afterwards
    - j. make good use of the resources available to you.
  - 13 You must keep up to date with, and adhere to, the laws and codes of practice relevant to your work.
- 2 This supplementary guidance is intended to provide 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 or when authorising or instructing others to do so. You must be prepared to explain and justify your decisions and actions when prescribing, administering and managing medicines. So far as it is relevant and applicable, this guidance should be followed in relation to medical devices as well as medicines, although there are obvious differences.
- 4 Serious or persistent failure to follow this guidance will put your registration at risk.

## About this guidance: questions

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'Prescribing' is used to describe many similar activities, ranging from authorising the supply of prescription only medicines, through prescribing medicines, devices and dressings on the NHS, to advising patients to purchase over-the-counter medicines and other remedies. It may also be used to describe written information provided for patients (information prescriptions) or advice given, for example about diet, exercise or refraining from exertion ('the doctor prescribed bed rest').

While some of the guidance is particularly relevant to prescription only medicines, we did not think it would be helpful to include a definition in the guidance; but instead allow for the sensible interpretation and application of the principles and advice to the range of activities doctors undertake.

**Q1. Do you think it would be helpful to define 'prescribing' in the guidance?**

Yes

No

Not sure

If yes, please suggest an appropriate definition.

**Q2. Do you have any other comments on the *About this guidance* section?**

Yes

No

Not sure

Comments



## Keeping up to date and prescribing safely

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- 5 *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 throughout your working life. You must maintain and further develop your competence in pharmacology and therapeutics, relevant to your role and prescribing practice.
- 6 You should utilise electronic and other systems to improve the safety of your prescribing practice, for example by highlighting interactions and allergies and by ensuring consistency and intelligibility of medicines prescribed, supplied and administered. Registering with the MHRA's **Drug Safety Update** can help you get information and advice to support the safer use of medicines relevant to your practice. The **National Prescribing Centre** publishes a range of material to help prescribers improve the safety and clinical and cost effectiveness of their prescribing.
- 7 You should seek advice from experienced colleagues, including pharmacists, prescribing advisers and clinical pharmacologists, if you are unsure about interactions or other aspects of prescribing and medicines management.
- 8 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.
- 9 You should follow the advice in the BNF on prescription writing and make sure your prescriptions and orders are clear and in accordance with the relevant statutory requirements and include your name. You should consider including clinical indications<sup>1</sup> on your prescriptions.
- 10 You should take account of the clinical guidelines published by the:
  - a. National Institute for Health and Clinical Excellence (NICE)
  - b. Scottish Medicines Consortium and NHS Quality Improvement Scotland (including the Scottish Intercollegiate Guidelines Network (SIGN))
  - c. Department for Health, Social Security and Public Safety (Northern Ireland)
  - d. All-Wales Medicines Strategy Group
  - e. Medical Royal Colleges and other authoritative sources of specialty-specific clinical guidelines.
- 11 You should make sure that anyone to whom you delegate responsibility for preparing, supplying or dispensing medicines or devices has the qualifications, skills and experience necessary to undertake the task. Those to whom you delegate responsibility for dispensing medicines should be registered with or trained to the standard that would be required by the General Pharmaceutical Council.

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1 See [www.clinicalindications.com](http://www.clinicalindications.com)

## Keeping up to date and prescribing safely: questions

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**Q3. Do you think it is reasonable, at paragraph 11, to expect those to whom doctors delegate responsibility for dispensing medicines to be registered with or trained to the standard that would be required by the General Pharmaceutical Council?**

Yes

No

Not sure

If no, please say why not and suggest what alternative guidance we should give.

**Q4. Do you have any other comments on the *Keeping up to date and prescribing safely* section?**

Yes

No

Not sure

Comments

## Need and objectivity

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- 12 You should only prescribe medicines to meet your patient's identified needs, and never for your own convenience or the convenience of those caring for patients (for example, those caring for patients with dementia in care homes), or simply because patients demand them.
- 13 In *Good Medical Practice*, we say that you should not treat yourself and, whenever possible, you should avoid providing medical care to anyone with whom you can have close personal relationship.
- 14 Doctors who prescribe for themselves or those close to them can lose objectivity, act outside their competence, treat symptoms without investigating the underlying cause, and may fail to keep accurate records or communicate with the patient's general practitioner or other treating doctors.
- 15 Controlled drugs present particular dangers, occasionally associated with drug misuse, addiction and misconduct. You must not prescribe a controlled drug for yourself or someone close to you unless:
  - a. no other person with the legal right to prescribe is available to assess the patient's clinical condition and to prescribe without a delay which would put the patient's life or health at risk, or cause the patient unacceptable pain or distress, and
  - b. that treatment is immediately necessary to:
    - i. save a life
    - ii. avoid serious deterioration in the patient's health, or
    - iii. alleviate otherwise uncontrollable pain or distress.
- 16 If you do prescribe for yourself or somebody close to you, you must:
  - a. be able to justify your actions
  - b. make a clear record at the same time or as soon as possible afterwards, including your relationship and the circumstances that necessitated your prescribing for yourself or someone close to you
  - c. tell the patient's general practitioner<sup>2</sup> what treatments you have provided and any other information necessary for the continuing care of the patient, unless the patient objects.

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2 and others treating the patient, where relevant

# Need and objectivity: questions

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**Q5. Do you agree with the advice at paragraph 12 on prescribing to meet patients' identified needs?**

Yes

No

Not sure

Comments

A wide range of views were expressed during the scoping consultation to develop this draft about doctors prescribing for themselves, their families and others close to them, including, for example, colleagues. Some recommended a complete prohibition, similar to the Nursing and Midwifery Council's *Code*, pointing to evidence of substance misuse and poor health among doctors. They cited potential lack of objectivity, prescribing beyond competence and poor record keeping as features of doctors who prescribe for

themselves and those close to them. Other respondents suggested that doctors should be permitted to prescribe for minor ailments and self-limiting conditions and that the guidance should consider the demands placed on doctors in rural and isolated communities. None thought it appropriate for doctors to prescribe controlled drugs for themselves or those close to them other than in the exceptional circumstances described in paragraph 15.

**Q6. Do you think the guidance at paragraphs 13 to 16 on doctors prescribing for themselves and those close to them is appropriate?**

Yes

No

Not sure

If not, what guidance should we should give to doctors?

**Q7. Do you have any other comments on the *Need and objectivity* section?**

Yes

No

Not sure

Comments

## Consent to prescribe

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- 17 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.
- 18 Together with the patient<sup>3</sup>, you should make an assessment of their condition before deciding to prescribe a medicine. You must be in possession of or take an adequate history, including: any previous adverse reactions to medicines; recent use of other medicines, including non-prescription and herbal medicines; and other medical conditions.
- 19 You should identify the likely cause of the patient's condition and which treatments are likely to be in their best interests.
- 20 You should reach agreement with the patient on the treatment proposed, 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
  - d. arrangements for monitoring, follow-up and review, including further consultation, blood tests or other investigations, processes for adjusting the type or dose of medication; and issuing repeat prescriptions.
- 21 The amount of information you should give to each patient will vary according to the nature of their condition, risks, 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 and other aids to help patients to digest information at their own speed and to retain the information you give them. You should also provide carers with information about the medicines you prescribe with the patient's consent or if it is in the best interests of a patient who lacks capacity to consent.
- 22 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<sup>4</sup>, might play. Pharmacists can undertake medicines reviews, explain how to take medicines and offer advice on interactions and side-effects. You should also refer patients to the information in Patient Information Leaflets (PILs) and other reliable sources of relevant information<sup>5</sup>. PILs are useful supplements to the information you give patients about their medicines; but they are not a substitute or a guide to their condition.
- 23 Patients regularly do not take medicines prescribed for them as indicated, or at all. 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 a treatment regimen that they are able and willing to adhere to<sup>6</sup>.

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3 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.

4 including community pharmacists; see our guidance on confidentiality for advice on who comprises the healthcare team.

5 Information Prescriptions and information bearing *The Information Standard* quality mark, for example.

6 **NPCI** includes information, guidance and tools for understanding and improving adherence.

## Consent to prescribe: questions

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In the scoping consultation to develop this draft, respondents suggested some doctors may be less explicit about the risks and side effects of the medicines they prescribe to outpatients and in the community than similar risks associated with in-patient treatment, such as surgery or anaesthesia. Others questioned the capacity and helpfulness of doctors providing more

extensive information about the risks and side effects of medicines; and there were widely differing views about the usefulness of Patient Information Leaflets (PILs). We have used our guidance on consent as the basis for this advice on the information doctors should give patients about their medicines and the partnership approach to decision-making.

**Q8. Do you think pharmacists and other healthcare professionals are well placed to provide patients with the information, advice and services suggested in paragraph 22?**

Yes

No

Not sure

Comments

**Q9. Do you have any other comments on the *Consent to prescribe* section?**

Yes

No

Not sure

Comments

## Sharing information with colleagues

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- 24** In *Good Medical Practice*, we say that, when you refer a patient, you should provide all relevant information about the patient, including their medical history and current condition. This should include complete information, where relevant, about their current and recent use of other medicines, other conditions, allergies and previous adverse reactions to medicines.
- 25** If you are not the patient's general practitioner, you should provide their general practitioner with a timely and accurate discharge summary or other record of changes to their medication (changes to existing medication and new medicines started, with reasons), unless the patient objects.
- 26** If you are the patient's general practitioner, you should make sure that changes to the patient's medication are critically 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.
- 27** If a patient has not been referred to you by their general practitioner, you should ask for the patient's consent to liaise with their general practitioner before prescribing for them, except in emergencies or when it is not practicable to do so. If they object, you must:
- a. check that the patient is not suffering from any medical condition, receiving any other treatment, or has an allergy or had an adverse reaction to medicines that would make your prescription unsuitable
  - b. provide or arrange all necessary after-care.

## Sharing information with colleagues: questions

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There are long-standing concerns about the quality and timeliness of hospital discharge summaries, the quality of information sent to hospitals on admission, and the processes for critically reviewing medication changes and

other information and updating patients' records after they are discharged from hospital\*. This goes beyond prescribing and will be considered as part of the review of *Good Medical Practice* in 2011 and 2012.

**Q10. Does the guidance at paragraph 24 accurately describe the information that should be provided with referrals?**

Yes

No

Not sure

If not, what information should be provided with referrals to help ensure safe prescribing by specialists?

**Q11. Do you have any other comments on the *Sharing information with colleagues* section?**

Yes

No

Not sure

Comments

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\* See the Care Quality Commission's 2009 national study, *Managing patients' medicines after discharge from hospital* and 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.



## Prescribing at the recommendation of a professional colleague

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- 28** 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 concerned and within the limits of your competence.
- 29** If you delegate assessment of a patients' 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 share enough information about the patient and the assessment required. You must also make sure that they follow the guidance in paragraphs 17 to 23.
- 30** In both cases, you will be responsible for any prescription you sign.
- 31** In circumstances in which you are unable to speak to or examine patients, you should consider the alternatives to prescribing, including patient group directions<sup>7</sup>.

## Prescribing at the recommendation of a professional colleague: questions

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**Q12.** Do you have any comments on the *Prescribing at the recommendation of a professional colleague* section?

Yes

No

Not sure

Comments

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<sup>7</sup> See *Patient Group Directions: A practical guide and framework of competencies for all professionals using patient group directions* (National Prescribing Centre, 2009).

## Shared care prescribing

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- 32** If you share responsibility for a patient's care with a colleague, you must be fully competent to exercise your share of clinical responsibility. You should:
- keep yourself informed about the medicines that are prescribed for the patient
  - be able to recognise serious and frequently occurring adverse side-effects
  - keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition<sup>8</sup>.
- 33** The decision 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.
- 34** Shared care requires the agreement of all parties, including the patient. In proposing a shared care arrangement, specialists may advise the patient's general practitioner which medicine to prescribe. Where a new, or rarely prescribed, medicine is being recommended, its dosage and administration should be specified. A protocol for treatment should normally be agreed. Explanation should be given for the use of off-label or unlicensed medicines, departures from authoritative guidance or recommended treatments; and sufficient information to permit the safe management of the patient must be provided to both the patient and their general practitioner.
- 35** If you are uncertain about your own 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 an 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.

## Shared care prescribing: questions

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**Q13.** Do you have any comments on the *Shared care prescribing* section?

Yes

No

Not sure

Comments

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<sup>8</sup> NPCi has case studies and learning materials to support better shared care prescribing.

## Raising concerns and reporting adverse reactions

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- 36** Prescribing and administration errors by doctors are common<sup>9</sup>, but harm is usually avoided by professional colleagues intervening before they can affect patients.
- 37** You must protect patients from risks of harm posed by colleagues' prescribing, administration and other medication-related errors. You should question any decision or action that you consider might be unsafe<sup>10</sup>. You should also respond constructively to concerns raised by colleagues, patients and carers about your own practice.
- 38** Early, routine reporting of adverse incidents and near misses can allow performance and systems issues to be investigated, problems rectified and lessons learned. You should make sure that all serious patient safety incidents are reported to the **National Reporting and Learning System** (in England and Wales), 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.
- 39** You should inform the Medicines and Healthcare products Regulatory Agency (MHRA) about:
- suspected adverse reactions to all medicines<sup>11</sup> using the **Yellow Card Scheme**
  - adverse incidents involving medical devices.
- 40** You should also provide patients with information about how to report adverse reactions and incidents directly to the MHRA.

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9 See the **EQUIP** (Errors—Questioning Undergraduate Impact on Prescribing) study.

10 See *Raising concerns about patient safety*.

11 The MHRA are particularly interested in serious suspected adverse reactions and all reactions to products marked with a Black Triangle in the BNF and elsewhere. It collects Yellow Card data on licensed and unlicensed, including pharmacy and over-the-counter, medicines.

## Raising concerns and reporting adverse incidents: questions

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**Q14.** In addition to those mentioned in paragraph 38, are there other organisations to which reports of medicines-related adverse incidents or near misses should be sent?

Yes

No

Not sure

If yes, who are they?

**Q15.** Do you have any other comments on the *Raising concerns and reporting adverse incidents* section?

Yes

No

Not sure

Comments

## Repeat prescribing and prescribing with repeats

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- 41 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.
- 42 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 to the patient what they should do if they suffer side-effects or adverse reactions or stop taking the medicines before the agreed review date (or a set number of repeats have been issued); and why regular reviews are important. You should make clear records of these discussions and your reasons for initiating medicines for repeat prescribing<sup>12</sup>.
- 43 You must be satisfied that arrangements 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 with appropriate training prepare prescriptions for authorisation
- e. patients who need further examination or assessment do not receive medicines without being seen by an appropriate healthcare professional (especially in the case of medicines with potentially serious side effects).
- 44 Each time you issue a repeat prescription, you should first check that the medicines are still needed, effective, tolerated and that the patient's condition is stable enough to warrant the repeat prescription without further examination or assessment. This may be particularly important following a hospital stay, or changes to medication 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.
- 45 As with repeat prescribing, you should make sure that secure procedures are in place to monitor patients' continuing need and suitability for medicines when you prescribe with repeats. Repeat dispensing is likely to be appropriate for patients with chronic conditions that are likely to remain stable for the duration of the dispensing period. Patients on a large number of medicines, or who are likely to require hospital treatment, may be less suitable. You should keep a record of dispensers holding original repeat dispensing prescriptions so that you can contact them if necessary.

## Repeat prescribing and prescribing with repeats: questions

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**Q16.** Do you have any comments on the *Repeat prescribing and prescribing with repeats* section?

Yes

No

Not sure

Comments

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<sup>12</sup> See *Saving time, helping patients: A good practice guide to quality repeat prescribing* (2004), *Dispensing with repeats: a practical guide to repeat dispensing* (2008) and service improvement guides and other resources available at [www.npci.org.uk](http://www.npci.org.uk).

## Reviewing medicines

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- 46** 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 tailor your review according to the needs and risks of the patient and their medication, with a particular focus on patients on long-term medication, controlled drugs, elderly patients and those with poor adherence to medication regimens.
- 47** You should actively consider reduction or cessation of medicines and alternative (non-drug) approaches to care for patients upon review, especially when prescribing unlicensed medicines, for periods longer than medicines are licensed for, or outside clinical guidelines, for example antipsychotics used for the treatment of behavioural and psychological symptoms in dementia<sup>13</sup>.
- 48** Pharmacists can help improve safety, efficacy and adherence in medicines use by carrying out medicines reviews. This does not relieve you of your duty to ensure that your prescribing and medicines management is appropriate. You should be particularly careful with regard to:
- medicines with potentially serious or common side effects
  - patients whose condition is not stable
  - patients on complex medication regimes, including many older patients and care home residents
  - otherwise vulnerable patients, who may be less likely to contact you to review their medication regime in the event of non-adherence, side effects of other problems

## Reviewing medicines: questions

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**Q17. Do you have any comments on the *Reviewing medicines* section?**

Yes

No

Not sure

Comments

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<sup>13</sup> 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. NPCi](#) also contains guides, case studies and other materials to support good prescribing practice for patients with dementia.

## Remote prescribing via telephone, video-link or online

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- 49** 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 17 to 23.
- 50** You should prescribe only when you have adequate knowledge of the patient's condition, and are satisfied that the medicines serve the patient's needs. You should consider:
- the limitations of the medium through which you are communicating with the patient
  - the need for physical examination or other assessments
  - whether you have access to the patient's medical records.
- 51** You should explain to the patient how the remote consultation will work and what to do if they have any concerns or further questions.
- 52** 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 nurse 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 whenever practicable.
- 53** 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:
- give your name and GMC number
  - ask for the patient's consent to liaise with their general practitioner before starting treatment, except in emergencies or when it is not practicable to do so
  - tell the patient's general practitioner the results of any investigations, medicines prescribed and any other information necessary for the continuing care of the patient, unless the patient objects.
- 54** Sharing information with the patient's general practitioner is important for safe and effective prescribing and other aspects of patient care. You must not encourage the patient to object to such liaison and information sharing with their general practitioner; and you must not rely on them to communicate the information. This will be particularly important if you have a commercial or financial interest in providing care or if you think your patient's general practitioner will discourage them from accepting your treatment. If liaison with the patient's general practitioner is essential to the provision of safe care but the patient objects, you should explain that you cannot prescribe for them and what their options are.
- 55** You should be careful not to collude in the unlawful advertising of prescription only or unlicensed medicines to the public by prescribing via websites that breach advertising regulations<sup>14</sup>.
- 56** If you prescribe for patients who are overseas, you should also have regard to differences in a product's licensed name, indications and recommended dosage regimen. The [Medicines and Healthcare products Regulatory Agency](#) issues guidance on import/export requirements and safety of delivery, which you might also need to consider. You should make sure that you have adequate indemnity cover for such practice. You may need to be registered with a local regulatory body in the country in which the prescribed medicines are to be dispensed.

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<sup>14</sup> *The Medicines (Advertising) Regulations 1994* and *The Medicines (Monitoring of Advertising) Regulations 1994*, both as amended; see also *The Blue Guide: Advertising and Promotion of Medicines in the UK* (MHRA, 2005).

## Remote prescribing via telephone, video-link or online: questions

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Many respondents to the scoping consultation to develop this draft were in favour of a 'ban' on doctors prescribing remotely (particularly online) for patients they had not met and whose records they did not have access to, especially without liaison with the patients' general practitioners.

Others questioned the evidence of harm arising from

online and other remote prescribing practices. They also questioned the significance of differences between this and other forms of medical practice (in the NHS and private practice) where patients consult without referral or liaison, albeit with face-to-face consultation. A few were concerned about the impact any 'ban' might have on patients' access to the medical care of their choosing and their rights to control information about themselves.

**Q18. Do you think the draft guidance on remote prescribing represents a reasonable balance between patients' autonomy and safety?**

Yes

No

Not sure

If not, please say why not and suggest what guidance we should give.



## Remote prescribing via telephone, video-link or online: questions continued

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In our [existing guidance](#), we advise that doctors should not prescribe Botox® and similar treatments without an assessment of individual patients' suitability and should not delegate administration without patient specific directions. That summarises advice in the MHRA's [Supply and administration of Botox®, Vistabel®, Dysport® and](#)

[other injectable medicines in cosmetic procedures](#).

The remote prescription and supply of Botox® for administration by nurses and beauty therapists continues to be a cause of some concern; but it is an unusually specific, clinical issue for the GMC to advise on, and we have removed all mention from this draft.

**Q19. Do you think we should give advice on the remote prescription of Botox® and similar treatments?**

Yes

No

Not sure

If yes, please say why and what advice we should give.

**Q20. Do you have any other comments on the *Remote prescribing via telephone, video-link or online* section?**

Yes

No

Not sure

Comments

## Prescribing off-label and unlicensed medicines

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- 57** Off-label prescribing is most frequently undertaken in treating children, because many medicines are not licensed for use in the treatment for children. Unlicensed medicines may be prescribed in accordance with a research protocol or when two or more licensed medicines are mixed prior to administration, for example in palliative care. 'Specials' are also unlicensed medicines, use of which may be appropriate in some cases, usually for patients who cannot take licensed formulations and for whom licensed or off-label alternatives are not suitable.
- 58** You should usually prescribe licensed medicines for their licensed uses; but you may prescribe off-label or unlicensed medicines outside an approved research protocol if:
- there is no appropriately licensed alternative available or you are satisfied, on the basis of authoritative clinical guidance, that it is as safe and effective as an appropriately licensed alternative
  - you have adequate insurance or indemnity cover or are covered by an employer's indemnity scheme to prescribe in this way.
- 59** You must make a clear record of all off-label and unlicensed medicines you prescribe, and your reasons for doing so.
- 60** Some medicines are routinely used off-label. When this is the case and there is authoritative clinical guidance to support your prescribing decision, it may not be necessary to draw the patient's attention to the licensing status of the medicine. You should, however, give patients the information they want or need when seeking consent to prescribe. If a patient is concerned, you should explain why the medicine you intend to prescribe is not licensed for the use you intend<sup>15</sup>.
- 61** You should also be careful about using medical devices for purposes for which they were not intended, which can risk patient safety and may limit manufacturers' liability for injuries.

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<sup>15</sup> The leaflets on off-label and unlicensed medicines use 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*.

## Prescribing off-label and unlicensed medicines: questions

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As the draft guidance explains, some medicines are routinely prescribed off-label, usually because there is no appropriately licensed alternative; but also because there are cheaper medicines that are as safe and effective. Most respondents to the scoping consultation to develop this draft agreed that doctors should be able to prescribe off-label or unlicensed medicines, even when there is an appropriately licensed alternative, when authoritative

clinical guidelines support such use. Examples of what many regarded as acceptable or good practice include amitriptyline as a first line treatment for neuropathic pain (see [NICE clinical guideline 96](#)) and sertraline, if drug treatment is chosen, for generalised anxiety disorder and panic ([NICE clinical guideline 113](#)). In both cases there are licensed alternatives, but they are not considered by NICE to be as cost-effective.

**Q21. Do you agree with the draft guidance at paragraph 58 that doctors can prescribe off-label or unlicensed medicines if satisfied, on the basis of authoritative clinical guidance, that it is as safe and effective as an appropriately licensed alternative?**

Yes

No

Not sure

If not, please say why not and what guidance we should give.

## Prescribing off-label and unlicensed medicines: questions continued

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**Q22.** Do you agree with the guidance at paragraph 60 that it may not be necessary to draw patients' attention to the licensing status of medicines routinely used off-label and for which there is authoritative clinical guidance?

Yes

No

Not sure

Comments

**Q23.** Do you have any other comments on the *Prescribing off-label and unlicensed medicines* section?

Yes

No

Not sure

Comments

## Conflicts of interest

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- 62** *Good Medical Practice* makes clear that trust between you and your patients is essential to successful professional relationships, and that your conduct must justify your patients' trust in you and the public's trust in the profession. You must not damage that trust by prescribing or supplying medicines or devices in a way that conflicts with your duties to:
- a. make the care of your patient your first concern
  - b. make efficient use of the resources available to you.
- 63** You must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect the way you prescribe or supply medicines or devices. You must not offer such inducements to colleagues<sup>16</sup>.
- 64** Health service financial incentives and similar schemes to improve the cost-effective use of medicines have a legitimate role to play in helping you to make good use of the resources available to you. This can benefit the wider community of patients; but you should also consider the safety and needs of the individual patient for whom you prescribe. In particular you should:
- a. consider the benefits and risks associated with your choice of medication and subsequent changes for reasons of cost (patients' adherence to medicines can be harmed by frequent switching, for example)
  - b. consider what communication, explanation and support should accompany your choice and change of medicines (you should not change patients' medication without informing them; and you should consider their needs for information, reassurance and other assistance in the event of a new suspected side effect, for example).
- 65** You should follow authoritative clinical guidelines or be prepared to justify your decision not to; and raise concerns if you have good reason to think that patient safety is or may be seriously compromised by financial incentives and similar schemes that encourage deviation from such guidelines.
- 66** You should be open and honest with your patients about any financial or commercial interests you or your employer has in a pharmacy or pharmaceutical or medical devices company that could affect or be seen to affect the way you prescribe.
- 67** You should not seek to influence patients' choice of where to have their medicines dispensed for your own or your employer's benefit.
- 68** If you also dispense medicines, you should not allow your financial or commercial interests affect the way you prescribe.

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<sup>16</sup> The advertising of medicines is controlled by a combination of statutory measures (with both criminal and civil sanctions) enforced by the [Medicines and Healthcare products Regulatory Agency](#) and self-regulation. The Prescription Medicines Code of Practice Authority is responsible for administering The [Association of the British Pharmaceutical Industry's Code of Practice](#). See also the [Association of British Healthcare Industries' Code of Business Practice](#) for its members in the medical technology sector.

## Conflicts of interest: questions

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**Q24. Do you think we have identified the main conflicts of interest relevant to doctors' prescribing?**

Yes

No

Not sure

If not, what conflicts are missing and what should we say about them?

**Q25. Do you have any other comments on the *Conflicts of interest* section?**

Yes

No

Not sure

Comments

## Sports medicine

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**69** 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.

**70** If you discover or suspect that a sportsperson's performance is improperly enhanced in this way, you should follow our guidance on confidentiality and, specifically, disclosures in the public interest.

## Sports medicine: questions

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**Q26.** Do you have any comments on the *Sports medicine* section?

Yes

No

Not sure

Comments

# General questions about the guidance



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**Q27. Do you think the draft guidance contains the right level of detail?**

Too detailed

About right

Not detailed enough

Please indicate the issues on which you think there is too much or too little detail.

**Q28. Do you think the guidance is clear?**

Very clear

Clear

Neutral

Unclear

Very unclear

Please say which parts of the guidance are unclear and suggest how they could be made clearer.

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**Q29. Do you think the guidance accurately reflects the law that applies where you live or work (in the UK)?**

Yes

No

Not sure

If not, please say why not.

**Q30. Can you point to any other guidance documents, information or resources that it would be useful for us to refer to in the published guidance?**

Yes

No

Not sure

Please identify any other documents, information or resources as specifically as you can.

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**Q31. Can you point to any important inconsistencies between the draft guidance and guidance published by other relevant organisations? These might include, for example, the health departments, the Medicines and Healthcare products Regulatory Agency or the National Prescribing Centre.**

Yes

No

Not sure

Please indicate any inconsistencies as specifically as you can.

**Q32. Can you identify any changes to practice that would be needed in order to meet the standards set out in the guidance?**

Yes

No

Not sure

Please identify any changes as specifically as you can.

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**Q33. Do you think that applying the standards in this guidance will have an adverse impact on particular groups of people? For example, will there be an adverse impact on particular groups of patients in any of the equality strands (age, disability gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation)?**

Yes

No

Not sure

If you can, please describe any adverse impact that you can identify.

## Questions about the consultation documents and process

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**Q34. Do you have any comments on the consultation documents?**

Yes

No

**Q35. Do you have any comments on the consultation process?**

Yes

No

**Thank you for taking the time to send us your comments.**

# About you

Finally, we would appreciate you providing the following information about yourself to help us analyse the consultation responses.

# Your details

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Name
Job Title
Organisation
Address
Email
Contact Tel

Would you like to be contacted about GMC consultations in the future?

Yes

No

If you would like to know about upcoming GMC consultations, please let us know which areas of the GMC's work you are interested in:

Education

Standards and ethics

Fitness to practise

Registration

Licensing and revalidation

## Data protection

The information you supply will be stored and processed by the GMC in accordance with the Data Protection Act 1998 and will be used to analyse the consultation responses and help us to consult more effectively in the future. Any reports published using this information will not contain any personally identifiable information. We may provide anonymised responses to the consultation to third parties for quality assurance or approved research projects on request.

# Responding as an individual

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Are you are responding as an individual?

Yes

No

If yes, please complete the following questions.

If not, please complete the 'responding on behalf of an organisation' section below.

Which of the following categories best describes you?

Doctor

Medical educator (teaching, delivering or administrating)

Medical student

Member of the public

Other healthcare professional

Other (please give details)

---

What is your country of residence?

England

Northern Ireland

Scotland

Wales

Other – European Economic Area

Other – rest of the world

If other, please specify \_\_\_\_\_

## Information about you

To help ensure that our consultations are reflecting the view of the diverse community, please fill in the information below. Although we will use this information in our analysis of the consultation response, it will not be linked to your response.

What is your age?

Under 24

25 – 34

35 – 44

45 – 54

55 – 64

65+

Are you:

Female

Male

Would you describe yourself as having a disability?

Yes  No



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**What is your ethnic origin? (Please tick one)**

**Asian or Asian British**

- Bangladeshi                       Indian                       Pakistani
- Any other Asian background, please specify \_\_\_\_\_

**Black or Black British**

- Black or Black British                       African                       Caribbean
- Any other Black background, please specify \_\_\_\_\_

**Chinese or other ethnic group**

- Chinese
- Any other background, please specify \_\_\_\_\_

**Mixed**

- White and Asian                       White and Black African                       White and Black Caribbean
- Any other Mixed background, please specify \_\_\_\_\_

**White**

- British                       Irish
- Any other White background, please specify \_\_\_\_\_

# Responding as an organisation

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## Are you responding on behalf of an organisation?

Yes

No

If yes, please complete the following questions. If not, please complete the 'responding as an individual' section above.

Which of the following categories best describes your organisation?

Body representing doctors

Body representing patients or public

Government department

Independent healthcare provider

Medical School (undergraduate)

Postgraduate medical institution

NHS/HSC organisation

Regulatory body

Other (please give details)

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## In which country is your organisation based?

UK wide

England

Scotland

Northern Ireland

Wales

Other (European Economic Area)

Other (rest of the world)



### **London**

Regent's Place, 350 Euston Road, London NW1 3JN

### **Manchester**

3 Hardman Street, Manchester M3 3AW

### **Scotland**

5th Floor, The Tun, 4 Jackson's Entry, Holyrood Road, Edinburgh EH8 8PJ

### **Wales**

Regus House, Falcon Drive, Cardiff Bay CF10 4RU

### **Northern Ireland**

9th Floor, Bedford House, 16-22 Bedford Street, Belfast BT2 7FD

Telephone: 0161 923 6602

Email: [gmc@gmc-uk.org](mailto:gmc@gmc-uk.org)

Website: [www.gmc-uk.org](http://www.gmc-uk.org)

Outside the UK telephone: +44(0)161 923 6602

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