

Recommendations to Prescribers for the Use of Unlicensed Medicines and Licensed Medicines for Unlicensed Indications

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Approved by	Medicines Commissioning Group
Name of author/originator	Debbie Bunn, Pharmacist SDCCG
Name of reviewer	Rachel Mackay
Owner (director)	
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This guideline has been endorsed by the Medicines Commissioning Group on behalf of its constituent CCGs (see header). CCGs may wish to adopt or adapt locally as a guideline or a policy (subject to following local policy-making processes)

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1 Executive summary

A marketing authorisation or product licence defines a medicine's terms of use: its Summary of Product Characteristics outlines, among other things, the indication(s), recommended dose(s), contraindications, and special warnings and precautions for use on which the licence is based, and it is in line with such use that the benefits of the medicine have been judged to outweigh the potential risks. Furthermore, a licensed medicine: has been assessed for efficacy, safety, and quality; has been manufactured to appropriate quality standards; and when placed on the market is accompanied by appropriate product information and labelling.

Prescribers would normally be expected to prescribe a licensed product, if available, as information on the product's safety is more freely available.

There are many situations in which it is appropriate to prescribe, dispense and administer unlicensed medicines or licensed medicines for unlicensed indications.

In GMC guidance the term 'unlicensed medicines' refers to both medicines with no UK licence, and those being used outside of the terms of their licence (commonly referred to as 'off-label'). It is recognised that unlicensed medicines are commonly used in many areas of medicine such as paediatrics, psychiatry and palliative care.

2 Introduction

The majority of medicines have a Marketing Authorisation (formerly a product licence) issued by the Medicines and Healthcare Products Regulatory Agency (MHRA) or the European Medicines Evaluation Agency (EMA) and are usually used in ways that are consistent with their marketing Authorisation or Summary of Product Characteristics.¹

A Marketing Authorisation (product license) certifies the drug manufacturers claims for the quality, safety and effectiveness of its product. Any failure for defects associated with the quality, safety or effectiveness of the medicine or its use in an approved clinical situation transfers liability back to the manufacturer.

The Medicines Act does not prohibit the use of unlicensed medicines (medicines without a Marketing Authorisation).

The safeguards that apply to products with a marketing authorisation should be extended as far as possible to the use of unlicensed medicines. The quality, safety, and efficacy (including labelling) of unlicensed medicines should be assured by means of clear policies

¹ <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con025908.pdf>

on their prescribing, purchase, supply and administration. Extra care is required with unlicensed medicines as less information may be available for the drug or its formulation.

3 Purpose and scope

This document is to provide information and guidance on the clinical and prescribing responsibilities for unlicensed medicines and the off-label use of licensed medicines.

The guidance is for use within *the CCG*, by doctors, independent prescribers, supplementary prescribers (within a clinical management plan) and dentists.

Pharmacists can dispense such medicines, and nurses, midwives and others can administer them to patients.

4. Liability

There is a question over who has liability when a medicine is prescribed, dispensed or administered for a purpose for which it has not been licensed.

The manufacturer would be liable for any defect in a licensed product **or** if it did not do what the manufacturer claimed. They would also be liable for harm caused to the patient due to adverse drug reactions and side effects.

Prescribers may also be liable for harm caused by a licensed medicine if they have made an inappropriate diagnosis, an inappropriate choice of medicine or the patient is not warned of potential adverse drug reactions and side effects.

In the case of an unlicensed medicine or unlicensed use of a licensed medicine the liability would lie with the prescriber unless the way in which the medicine was produced was defective in which case the manufacturer **may** be liable.

The responsibility that falls on healthcare professionals when prescribing an unlicensed medicine or a medicine off-label may be greater than when prescribing a licensed medicine within the terms of its licence. Prescribers should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label. These risks may include: adverse reactions; product quality; or discrepant product information or labelling (e.g. absence of information for some unlicensed medicines, information in a foreign language for unlicensed imports, and potential confusion for patients or carers when the Patient Information Leaflet is inconsistent with a medicine's off-label use).

This guidance does not address the prescribing of medicines in relation to the conduct of clinical trials.

The GMC produced provided some information in a Hot Topics bulletin in November 2015 answering the question of: “**Am I putting my registration at risk when I prescribe unlicensed medicines?**”

Their reply states: “Doctors are often worried about prescribing unlicensed medicines as we say that they must take responsibility for the prescription, but of course we expect this whether the medicine is licensed or not. You are responsible for all prescriptions you sign and your decisions and actions when supplying and administering medicines and devices (or when they authorise or instruct others to do so).

Contrary to recent suggestions, GMC guidance does not include reference to any extra personal liability in relation to prescribing unlicensed medicines.

We expect you to carefully consider any treatment that you prescribe, and we expect you to be able to justify your decisions and actions when prescribing, administering and managing medicines regardless of whether they are licensed or unlicensed.

Importantly, prescribing unlicensed medicines will not put your registration at risk any more than other areas of practice covered by our guidance.”

5. Prescribing in a patient’s best interest

There are clinical situations when the use of unlicensed medicines or use of medicines outside the terms of the license (i.e. ‘off-label’) may be judged by the prescriber to be in the best interest of the patient on the basis of available evidence.

Such practice is particularly common in certain areas of medicine: for instance, in paediatrics where difficulties in the development of age-appropriate formulations means that many medicines used in children are used off-label or are unlicensed.

Healthcare professionals may regard it necessary to prescribe or advise on the use of an unlicensed medicine (ie, through the so-called ‘specials’ regime when no licensed suitable alternative is available, or when a medicine is prepared in a pharmacy by, or under the supervision of, a pharmacist), or the use of a licensed medicine outside the terms defined by the license (e.g. outside defined indications, doses, routes of administration, or contrary to listed warnings).

6. What does a prescriber need to consider when prescribing unlicensed medicines?

When deciding on the best treatment for a patient the prescriber should weigh up all of the options, taking into account the evidence available. You should be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy.

Decisions should be made in collaboration with the patient by discussing the options with them and ensuring that they have sufficient information about the medicine to allow them to make an informed decision.

The GMC expects the prescriber to use their judgment when deciding on the level of information needed. Some medicines are routinely used outside the terms of their license, 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 license. In other cases, where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe to the patient in general terms, why the medicine is not licensed for the proposed use.

The prescriber must always answer questions from patients (or their parents or carers) about medicines fully and honestly. Listen to their concerns, ask for and respect their views, and encourage them to ask questions.

Consider discussing the options with colleagues or experts and getting advice from them on the appropriateness of the treatment.

7. Implications for patients

Patients should be made aware that there are situations where the prescribing or administration of an unlicensed medicine or unlicensed use of a licensed medicine is clinically appropriate as indicated above.

If a patient considers that they have been harmed by an unlicensed medicine or unlicensed use of a licensed medicine they will have no redress against the manufacturer of the product unless the product can be shown to be defective. They would, however, have redress against the prescriber who prescribed the medication.

Patients or their carers, who are prescribed such medicines, should be able to expect their prescriber and the pharmacist or other supplier of the medicine to ensure that they receive sufficient information to use the product safely and effectively, as such medicines are not usually supplied with a patient information leaflet.

Where a product is used off-label, i.e. an unlicensed use of a licensed medicine, the prescriber has the responsibility to make patients aware of the fact that the way the medicine

is being used will not be reflected in any patient information leaflet provided with the medicine. However there may be situations where it may not be practical or necessary to draw attention to the license as indicated by the GMC guidance. The GMC expects the prescriber to use their judgment when deciding on the level of information needed. Where possible a pharmacist should bring to the attention of the patient that the product is being used outside the terms of its marketing authorisation and therefore will not be reflected in the patient information leaflet. As far as possible this should be done without undermining the patient's confidence in either the prescriber or the prescribed medicine.

8. Implications for CCGs, hospitals and prescribing groups

Advice given to prescribers to support the prescribing of an unlicensed medicine or unlicensed use of a licensed medicine should be evidence based.

9. Key questions for prescribers and prescribing advisors

The body or individual clinician responsible for recommending the prescribing of an unlicensed medicine or off-label use of a licensed medicine is likely to be seen as reasonable and to have acted appropriately if they can answer at least one but preferably both of the following key questions:

1. Is there evidence that other prescribers, skilled in the therapeutic area being treated, would recommend this product? e.g. is it included in the British National Formulary (BNF) or Children's BNF, national guidelines. [Bolam Principle – Bolam v Friern Hospital Management Committee 1957]
2. Can the prescriber provide a rationale for using this approach?, e.g. local evidence based guidance, considered by local Drugs and Therapeutics Committees, Local Medical Committee or Prescribing Group. [Bolitho Principle – Bolitho v City & Hackney Health Authority 1997]

10. Duties

Prescribers remain professionally accountable for their judgement in the prescribing of unlicensed medicines or off-label use of licensed medicines and may be called upon to justify their actions.

The decision to prescribe an unlicensed medicine or off-label use of a licensed medicine is the responsibility of the healthcare professional accountable for the patient's care.

Prescribers should consider alternative treatment options and explore whether there is a medicine with a product licence which would be an equally appropriate treatment option for the patient

Where there are concerns regarding the level of risk (see Appendix A) or the appropriateness of prescribing of an unlicensed medicine or off-label use of a licensed medicine, advice should be sought from the local Trust or Medicines Management team.

Where the use of an unlicensed medicine or off-label use of a licensed medicine does not reflect current, accepted good practice (informed by expert opinion or robust literature) it is the responsibility of the initiating healthcare professional to provide a level of detailed information that would enable a GP to make an informed decision as to whether they will take on prescribing responsibility, using the “Key questions for prescribers and prescribing advisors in section 9.

Unlicensed medicines may be extemporaneously prepared, manufactured as specials or imported from abroad. Unlicensed medicines are not covered by a marketing authorisation and therefore the Medicines for Human Use Regulations 1994 & 2012 which require all the holders of marketing authorisations for relevant medicinal products to supply a patient information leaflet does not apply and as such would not be required to be dispensed with a patient information leaflet.²

11. Frequently asked questions

Do I need to inform my patient that the treatment I am proposing is for an unlicensed/off label medicine?

Yes – prescribers have a responsibility to advise their patient/carer that they are being treated with an unlicensed/off-label medicine. The patient should be provided with accurate and clear information on the use and side effects of the medicine.

Where other clinical staff are involved in the treatment of a patient with an unlicensed or off-label drug the prescriber has a responsibility to ensure that:

- They are aware of its unlicensed/off-label status
- They are informed of any problems and risks involved and how to deal with them
- They are given appropriate information to administer and use the product safely and correctly.

Do I need to obtain consent from patients when supplying an unlicensed medicine or off label use of a licensed medicine?

Yes – as with any product, it should be ensured that the patient or their carer/guardian is able to make a balanced judgement on whether to give or withhold consent. The patient or their carer/guardian should be informed of any material or significant risks in the proposed treatment, any alternatives to the proposed treatment and the risks incurred by doing nothing.

The patient’s individual needs and priorities should be established before providing information about treatment options but it should be noted that an individual patient’s preference for a treatment should be secondary to clinical appropriateness.

² http://www.legislation.gov.uk/ukxi/2012/1916/pdfs/ukxi_20121916_en.pdf

It is recommended that consent for the prescribing of an unlicensed medicine should be recorded in the patient's notes. Patients, or those authorising treatment on their behalf, must be given sufficient information about the proposed course of treatment including any known serious or common side effects or adverse reactions to enable informed consent. The medicine prescribed and, where the prescriber is not following common practice, the reasons for choosing this medicine should also be documented in the patient's notes.

Is there any occasion where consent would not be required?

Where the proposed treatment is to be used in an emergency situation and it is not possible to gain consent.

When is it appropriate for me to prescribe an unlicensed medicine or off label use of a licensed medicine?

An unlicensed medicine or off-label use of a licensed medicine may be recommended where there is no licensed alternative to meet the clinical needs of the patient.

Or

Where the clinical and pharmaceutical needs of the patient cannot be met by a suitably licensed product and where the benefits of treatment using the unlicensed or off-label product are considered to outweigh the potential risks, for example where a patient has an intolerance or allergy to an ingredient in a licensed product or an inability to tolerate the formulation of the licensed product e.g. if they need an unlicensed liquid formulation of a drug as they are not able to ingest a licensed solid oral dosage form.

Or

Use of an unlicensed medicine in line with the protocol for an approved clinical study

What evidence do I need to provide to support my prescribing of an unlicensed medicine or off label use of a licensed medicine?

The body or individual clinician responsible for recommending the prescribing of an unlicensed medicine or off-label use of a licensed medicine is likely to be seen as reasonable and to have acted appropriately if they can answer at least one but preferably both of the following key questions:

1. Is there evidence that other prescribers, skilled in the therapeutic area being treated, would recommend this product? e.g. is it included in the British National Formulary (BNF) or Children's BNF, national guidelines. [Bolam Principle – Bolam v Friern Hospital Management Committee 1957]
2. Can the prescriber provide a rationale for using this approach?, e.g. local evidence based guidance, considered by local Drugs and Therapeutics Committees, Local Medical Committee or Prescribing Group. [Bolitho Principle – Bolitho v City & Hackney Health Authority 1997]

When is it not appropriate to prescribe an unlicensed medicine or off label use of a licensed medicine?

- Where there is a licensed alternative available to meet the clinical needs of the patient.
- When there is little or no evidence of clinical benefit
- Where the acquisition costs may deem a medicine not to be cost-effective (prescribers may wish to contact their local Medicines Management teams for cost information – many “specials” cost around £200 -£500 per prescription item). It should be noted that there may be a large variation between the costs of obtaining an unlicensed medicine in primary care and the costs of obtaining it in secondary care.
- Where potential risks outweigh benefits

What should a GP do if requested to prescribe an unlicensed medicine or off-label use of a licensed medicine by a secondary care clinician?

When considering whether to accept clinical and legal responsibility for prescribing of such medicines it would be advisable to take into account the level of risk involved. (see Appendix A).

Secondary care clinicians are expected to request the agreement of the primary care clinician to prescribe and inform them of the unlicensed or off-label status of the proposed treatment and the level of risk attached to the prescribing of the medicine. The secondary care clinician also has a responsibility to ensure that the requested treatment has been approved by the relevant Drugs and Therapeutics Committee.

The primary care clinician should be provided with a copy of any shared care protocol (approved by *the CCG* and the Prescribing Clinical Network) or detailed information regarding how the medicine is used, the risks involved, any monitoring arrangements and where to obtain supplies of the product.

A primary care prescriber is under no obligation to take on prescribing of a secondary care initiated drug if they feel it to be inappropriate or feel unable to take on clinical responsibility. The implications for the patient of not prescribing should be considered and information gathered from secondary care clinicians and/or Medicines Management Pharmacists to help inform the final choice of treatment.

What information should I provide when prescribing an unlicensed medicine or off label use of a licensed medicine?

Patient information leaflets are not required for unlicensed medicines and manufacturers' patient information leaflets for licensed medicines do not contain information about off-label uses for these medicines. This should be clearly explained to the patient/carer to avoid misunderstandings.

It may take longer to obtain some unlicensed medicines and the patient or their carer should be made aware of this. Some imported medicines or specially manufactured medicines can take up to 2 weeks to obtain.

What are my responsibilities regarding adverse drug reactions in relation to the prescribing of an unlicensed medicine or off label use of a licensed medicine?

All adverse drug reactions that occur in patients treated with unlicensed medicines or unlicensed uses of licensed medicines should be reported to the Committee on Safety of Medicines (CSM) using the Yellow Card Scheme. Report card available at <https://yellowcard.mhra.gov.uk/>

Can Unlicensed Medicines be supplied on a long-term basis?

If a pharmaceutically equivalent licensed product is not available through normal distribution channels in a reasonable time then it may be necessary to supply an unlicensed product, however, long-term supply should be avoided, where possible.

Unlicensed products should not be included in repeat dispensing schemes but be dealt with on a case by case basis.

It should be noted that liability for prescribing of unlicensed medicines or off-label use of licensed medicines lies with the prescriber (unless the medicine can be shown to be defective) and prescribers may wish to check with their medical defence organisation before prescribing any unlicensed products.

12. Supply of unlicensed medicines or medicines for which the use will be unlicensed

As a supplying, procuring pharmacist, do I have any liability for the supply of an unlicensed medicine or the off-label use of a licensed medicine? (see Appendix D)

Yes - pharmacists who supply an unlicensed medicine or a licensed medicine for an unlicensed use are professionally accountable for any harm caused by a defect in the medicine that is attributable to their own actions or omissions.

Pharmacists should take reasonable steps to satisfy themselves that the prescriber is fully aware of the unlicensed status of the product and that its unlicensed use is appropriate in the circumstances.

A pharmacist has a duty of care to the patient when supplying them with **any** medicinal product.

How should unlicensed products be obtained or supplied?

Supplies of unlicensed medicines should be obtained from appropriately licensed manufacturers or wholesalers (either with a specials manufacturing licence or an importer's licence) or be otherwise prepared in a registered pharmacy.

The pharmacist or dispensing doctor should be satisfied that the importer has made the necessary written notifications to the Medicines and Healthcare products Regulatory Agency (MHRA).

Unlicensed medicines should be labelled in English and supplied with patient information in English (applies especially to unlicensed medicines imported from abroad).

Prescribers, dispensing doctors and pharmacists should keep adequate records relating to purchase, preparation and supply of unlicensed products. Such records should be kept for at least five years.

When ordering an unlicensed medicine the pharmacist should declare their professional status and confirm that the supply of the unlicensed medicine is in accordance with a prescription from an authorised prescriber.

There is no requirement to give the supplier the name and/or address of the patient.

Are there any variations to the guidance for dispensing doctors?

Where medicines are extemporaneously prepared, there are exemptions to the licensing requirements for products prepared in a registered pharmacy under the supervision of a pharmacist, in accordance with:

- A medical prescription for an individual patient
- The specification or monograph of a pharmacopoeia and intended to be supplied directly to patients of a Pharmacy.

- A specification furnished by the person to whom the product is to be sold where the product is prepared or dispensed for administration to that person or a person under his care.

A marketing authorisation or manufacturer's licence is not required to produce and supply such products. These exemptions **do not** apply to dispensing doctors.

Where dispensing doctors and pharmacists procure an unlicensed medicine, adequate records relating to the purchase, preparation and supply of the unlicensed medicinal products, including the source of the product, the person to whom the product was sold or supplied, the quantity of each sale or supply, the batch number of the product and details of any adverse reactions to the product sold or supplied should be kept. These details should be retained for **five years**.

RPSGB guidance on unlicensed specials:

<http://www.rpharms.com/pharmacy-practice-resource/specials.asp>

13. Review of the guidance

This document will be subject to review after two years and at any stage at the request of the Governing Body.

The guidance may be adopted as a policy following approval through an appropriate body or committee of the CCG.

14. APPENDIX A - Potential Risks Associated with the Prescribing and Supply of Unlicensed Medicines or Off-label Use of Licensed Medicines

This guidance is an aid to prescribers in making decisions as to the risk: benefit profile associated with the use of unlicensed or off-label use of licensed medicines.

It is recommended, in considering the information available to establish the level of risk for an unlicensed medicine or the off-label use of a licensed medicine and where there is no currently accepted local NHS protocol or guidance approved by *the CCG*, that advice is sought from the Medicines Management Team.

Higher Risk – these products are unlikely to be suitable for use within Primary Care for one or more of the following reasons:

- They have very limited evidence to support their use.
- There is limited evidence of toxicity or other risks.
- They have been withdrawn from the market due to concerns over safety.
- There is little or no assurance of pharmaceutical quality.
- Where the product is a vaccine, blood product or other biological.
- Where the product is of animal origin.

Intermediate Risk - could be considered for use in primary care but should be supported by either a local NHS protocol or guidance document approved by *the CCG*. These may include:

- Drugs being used in a complicated disease area or where there are requirements for monitoring beyond those normally dealt with in primary care.
- Drugs never licensed in the UK or discontinued on economic grounds.
- Drugs where there is limited assurance of pharmaceutical quality due to potentially sub UK standard quality assurance in the exporting country or an inadequate supply chain environment.

Lower Risk – prescribing should be suitable for GPs and other primary care prescribers. This may include:

- Off-label use of licensed products where consideration has been given to any precautions or warnings.
- Off-label use of licensed products where consideration has been given to the quality aspect of intended use of a product in relation to an alternative route of administration.
- Specials manufactured in premises licensed by the MHRA.

When considering these levels of risk, precedence should be given to the highest category of potential risk in determination of the overall risk.

15. APPENDIX B – Definitions

Licensed medicines are medicines with a UK marketing authorisation (product license). When prescribed within the terms of the marketing authorisation the manufacturer is likely to be found liable for any harm caused by that medicine.

Off-label medicines are medicines which have a current UK marketing authorisation but where the prescriber elects for an indication, age group, dose and/or route of administration that is outside those recommended in the licence or which override any of the contra-indications, precautions or warnings. If a patient is harmed by such use of a medicine then the manufacturer is unlikely to be found liable, unless the harm is directly attributable to a defect in the medicine, rather than the way in which it was prescribed, e.g. sodium valproate as a mood stabiliser or use of medicines licensed for use only in adults, for the treatment of children.

Unlicensed medicines are medicines, or substances used as medicines without a UK marketing authorisation and include:

Medicines prepared by a UK manufacturer but not for sale in the UK and may include medicines undergoing clinical trial, medicines awaiting a UK marketing authorisation, medicines withdrawn from the UK market, or medicines manufactured for export. Such medicines are usually available on an “individual patient basis”, e.g. Primidone tablets, Pyrazinamide tablets, Naproxen suspension.

Medicines prepared outside of the UK with a marketing authorisation from the country of origin. Such medicines are imported into the UK, e.g. Formepizole (ethylene glycol antidote)

“Specials” obtained from a hospital or commercial supplier with a manufacturer’s “specials” licence. Such medicines can be supplied against an unsolicited order or prescription e.g. Sodium chloride 1mmol/ml solution (salt replacement for cystic fibrosis patients), Captopril suspension.

Extemporaneously dispensed medicines prepared for a specific patient under the supervision of a pharmacist in accordance with a practitioner’s prescription, including TPN compounding, IV additive & cytotoxic reconstitutions, e.g. Azathioprine suspension.

Re-packed medicines. These are medicines which are removed from their original containers and re-packed during dispensing, e.g. Flucloxacillin capsules 250mg for a 5 day treatment course packed down from a larger manufacturers pack.

Chemicals used to treat rare metabolic disorders, e.g. Dichloroacetic acid for Leigh’s encephalopathy, L-Arginine Powder for Urea cycle disorder, Copper Histidine injection for Menkes disease / syndrome

Some of the above examples are common practice (e.g. repackaged medicines) and raise little concern for prescribers or patients, whereas others, though sometimes accompanied by published evidence of efficacy, raise concerns over unfamiliarity with prescribing, quality assurance and liability.

16 APPENDIX C – The GMC Guidance

The GMC guidance is as follows:

http://www.gmc-uk.org/Prescribing_guidance.pdf_59055247.pdf

Prescribing unlicensed medicines

67 The term ‘unlicensed medicine’ is used to describe medicines that are used outside the terms of their UK license or which have no for use in the UK.³ Unlicensed medicines are commonly used in some areas of medicine such as in paediatrics, psychiatry and palliative care. They are also used, less frequently, in other areas of medicine.

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

69 Prescribing unlicensed medicines may be necessary where:

- a There is no suitably licensed medicine that will meet the patient’s need, for example, where⁴:
 - i there is no licensed medicine applicable to the particular patient. For example, if the patient is a child and a medicine licensed only for adult patients would meet the needs of the child; or
 - ii a medicine licensed to treat a condition or symptom in children would nonetheless not meet the specific assessed needs of the particular child patient, but a medicine licensed for the same condition or symptom in adults would do so; or
 - iii the dosage specified for a licensed medicine would not meet the patient’s need; or
 - iv the patient needs a medicine in a formulation that is not specified in an applicable licence.
- b Or where a suitably licensed medicine that would meet the patient’s need is not available. This may arise where, for example, there is a temporary shortage in supply; or
- c The prescribing forms part of a properly approved research project.

70 When prescribing an unlicensed medicine you must:

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

³ This definition is based on information published by the MHRA, which is the licensing and regulatory body for the supply and use of medicines and medical devices. MHRA guidance on the lawful supply and use of unlicensed medicines is set out in the MHRA publication *The supply of unlicensed medicinal products ('specials')*, MHRA Guidance Note 14 available at www.mhra.gov.uk/home/groups/is-lic/documents/publication/con413520.pdf.

⁴ We cannot foresee every circumstance in which it may be necessary to prescribe an unlicensed medicine to meet a particular patient's assessed needs. If in doubt, consult the MHRA (www.mhra.gov.uk) or seek legal advice.

following common practice, your reasons for prescribing an unlicensed medicine.

Information for patients about the licence for their medicines

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

72 Some medicines are routinely used outside the terms of their licence, for example in treating children. In emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the licence. In other cases, where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population.⁵ You must always answer questions from patients (or their parents or carers) about medicines fully and honestly.

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

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

See also paragraphs 35-43 on shared care prescribing within the GMC guidance on Prescribing, not listed here, but available at:

http://www.gmc-uk.org/Prescribing_guidance.pdf_59055247.pdf

17 APPENDIX D - RPSGB Specials Guidance

RPSGB guidance on unlicensed specials:

<http://www.rpharms.com/pharmacy-practice-resource/specials.asp>

18 APPENDIX E - Therapeutic options for patients unable to take solid oral dosage form

<http://pad.res360.net/Content/Documents/Guide%20to%20crushing%20and%20use%20of%20specials%20Mar%202015.pdf>

19 APPENDIX F - Off-label use or unlicensed medicines: prescribers' Responsibilities

Dug Safety Update; MHRA: Volume 2 Issue 9 April 2009



Drug Safety Update
off label Rx Apr 09.px

⁵ 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*.