



**USING LICENSED MEDICINES  
FOR UNLICENSED PURPOSES  
POLICY**

## 1.0 Introduction

- 1.1 In specialist palliative care the treatment of many symptoms involves the use of medicines for unlicensed indications or by unlicensed routes. Up to one quarter of all prescriptions in palliative care come under this category. <sup>1</sup>
- 1.2 The licensing process regulates the use and marketing of pharmaceuticals and not a prescriber's clinical practice. There are exemptions specifically incorporated into the Medicines Act (1968) which preserve a prescriber's clinical freedom.
- 1.3 Medicines prescribed outside the licence can be dispensed by pharmacists (Ph) and administered by registered nurses (RN).
- 1.4 In the UK a doctor may legally :
  - prescribe unlicensed medicines
  - in a named patient, use unlicensed medicines specially prepared, imported or supplied
  - use or advise use of licensed medicines for indications, doses, or routes of administration outside licensed recommendations. Usually in cases where there is strong evidence of efficacy and safety, or where there is no strong evidence in conditions for which there are no other treatments
  - override the warnings and precautions given in the licence
  - prescribe generic formulations, for which indications are not described
  - use medicines in individuals not covered by licensed indications e.g. children and the elderly

The consequence of these actions lies with the prescriber.

- 1.5 When prescribing outside the terms of the licence the prescriber must be fully informed about the actions and uses of the drug. The greater the risk of harm from the medicine and the relative absence of evidence, the more difficult it is to justify its prescription.
- 1.6 When prescribing a drug outside its licence, it is best practice for a prescriber to document in the patient's records the reasons for the decision to prescribe the specific drug for the specific indication and where possible, explain the position to the patient (and family as appropriate) in sufficient detail to allow them to give informed consent. The prescriber should also inform other healthcare professionals involved in the care of the patient to avoid misunderstandings. However, in palliative care, the use of drugs for unlicensed uses or by unlicensed routes is so widespread that such an approach is impractical. <sup>2</sup>
- 1.7 A UK survey showed that only <5% of palliative medicine consultants always obtain verbal or written consent, document in the notes or inform other professionals when using licensed drugs for unlicensed purposes/routes. Concern was expressed that not only would it be impractical to do so, but it would be burdensome for the patient, increase anxiety and might result in refusal of beneficial treatment. Some half to two-thirds indicated that they would sometimes obtain verbal consent (53%), document in the notes (41%) and inform other professionals (68%) when using

treatments which are not widely used within the specialty, e.g. ketamine, octreotide, ketorolac. <sup>2</sup>

1.8 At Lindsey Lodge Hospice the essence of the recommendations of the Association for Palliative Medicine and the Pain Society on the use of drugs beyond licence in palliative care and pain management will be adopted. (Appendix 1)

## 2.0 Policy

2.1 Documentation in the notes of the unlicensed use of a licensed medicine and verbal consent from a patient to be administered the medicine in this way is only necessary when the prescribing is considered by the prescriber as not usual in palliative care.

2.2 “Usual” prescribing of a medicine is as described in the current edition of the Palliative Care Formulary (Twycross and Wilcock, [palliativedrugs.com](http://palliativedrugs.com)) or on the formulary of the website [www.palliativedrugs.com](http://www.palliativedrugs.com)

2.3 Crushing or dissolving tablets, opening capsules or changing the prescribed route of medicines renders them “unlicensed”. These activities are not undertaken without consulting the prescriber or pharmacist. The medicine chart will be annotated appropriately and initialled by the Dr or Pharmacist.

2.4 Patients or carers requiring further explanation or reassurance are referred to the Dr or pharmacist as per patient preference.

2.5 “The use of Drugs Beyond Licence” leaflet produced by The Pain Society and Association for Palliative Medicine is available on the inpatient unit and in the day care unit, should a patient or carer require any written information or is available on line at:

[www.palliativedrugs.com/download/PCF4\\_Prelims\\_xxi-xxvi.pdf](http://www.palliativedrugs.com/download/PCF4_Prelims_xxi-xxvi.pdf)

## 3.0 Procedure

3.1 “ The Use of Drugs Beyond Licence” leaflet is available on Inpatient Unit and in Day care unit. The senior nurse in charge of the area should ensure these leaflets are readily available.

3.2 Authorised prescriber, when prescribing a medicine outside of the recommended prescribing guidelines in the current edition of the Palliative Care Formulary or at [www.palliativedrugs.com](http://www.palliativedrugs.com) :

- informs patient or carer that they are proposing to prescribe a medicine “outside of their licence”,
- explains to patient/carer what that means
- Offers patient/carer the “The Use of Drugs Beyond Licence” leaflet.
- Gains verbal consent from patient where possible
- Documents conversation and outcome in patient record

- 3.3 The registered nurse should refer the patient or carer to the Consultant, Dr or Pharmacist if requested as per patient preference, to discuss issues further. Consultant, Dr or Pharmacist makes a record of the discussion in the patient record.

<p>References</p> <ol style="list-style-type: none"> <li>1. Palliative Care Formulary version 5; Robert Twycross, Andrew Wilcock and Paul Howard;2014</li> <li>2. Use of Medicines outside their UK Marketing authorisation in pain management and palliative medicine; British Pain Society and Association of Palliative Medicine of great Britain and Ireland Consensus document; 2012.</li> </ol>
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## Appendix 1

### **Recommendations of the British Pain Society and Association for Palliative Medicine of Great Britain and Ireland**

Use of medicines beyond (off-label) and without (unlicensed) Marketing Authorisation (MA) in palliative care and pain medicine

1. This statement should be seen as reflecting the views of a responsible body of opinion within the clinical specialties of palliative medicine and pain medicine
2. The use of medicines beyond and without a MA in palliative care and pain medicine practice is both necessary and common and should be seen as a legitimate aspect of clinical practice.
3. Organisations providing palliative care and pain medicine services should support therapeutic practices that are underpinned by evidence and advocated by a responsible body of professional opinion.
4. Health professionals involved in prescribing medicines beyond or without MA should select those medicines that offer the best balance of benefit against harm for any given patient.
5. Choice of treatment requires partnership between patients and health professionals, and informed consent should be obtained, whenever possible, before prescribing any medicine.
6. Patients should be offered accurate, clear and specific information that meets their needs about the use of medicines beyond or without a MA in accordance with professional regulatory body guidance. The information needs of carers and other health professionals involved in the care of the patient should also be considered and met as appropriate. The use of information cards or leaflets may help with this. It is often unnecessary to take additional steps when recommending medicines beyond or without MA.
7. Health professionals should inform, change and monitor their practice with regard to medicines beyond or without MA in the light of evidence from audit and published research.
8. The Department of Health should work with health professionals and the pharmaceutical industry to enable and encourage the extension of product licences where there is evidence of benefit in circumstances of defined clinical need.