THE USE OF MEDICINAL PRODUCTS BEYOND (OFF LABEL) AND WITHOUT (UNAUTHORISED) MARKETING AUTHORISATION POLICY

1.0 **Introduction**

1.1 In specialist palliative care the treatment of many symptoms involves the use of off-label medicinal products. Up to one quarter of all prescriptions in palliative care come under this category. [1]

1.2 A marketing authorisation (MA), previously called a product licence, is granted by a regulatory body to a pharmaceutical company for a specific medicinal product. It specifies the terms of use, including indications, doses, routes and patient populations for which it can be marketed.

1.3 'Off-label' describes the use of a medicinal product beyond the specifications of its MA, e.g. for an indication, route or patient population not covered by the MA.

1.4 Unauthorised medicinal products are products that do not have an MA for medicinal use on humans. Unauthorised medicinal products include:

- Two or more medicinal products mixed together for administration in a syringe for CSCI
- 'Specials' – special order manufactured formulations by a manufacturer with a specials manufacturing licence and medicinal products that require importation
- Medicinal products made in a local pharmacy at the request of a prescriber (e.g. dilution of cream)
- New medicinal products undergoing clinical trials or awaiting MA.

1.5 There are exemptions specifically incorporated into the Medicines Act (1968) which preserve a prescriber's clinical freedom.

1.6 In the UK, Medicines prescribed outside the licence can be dispensed by pharmacists (Ph) and administered by registered nurses (RN).

1.7 In the UK an independent prescriber may legally:

prescribe off-label use or unauthorised medicinal products
use or advise use of off-label or unauthorised medicinal products, the consequence of these actions lies with the prescriber.

1.8 When prescribing off label or unauthorised medicinal products, 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.

1.9 When prescribing a drug beyond or without MA, 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 beyond or without MA is so widespread that such an approach is impractical.[2]

1.10 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 off-label or unauthorised medicinal products. 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. [2]

1.11 At Lindsey Lodge the essence of the recommendations of the Association for Palliative Medicine and the Pain Society on the use of drugs beyond and without marketing authorisation in palliative care and pain management will be adopted. (Appendix 1)

2.0 Policy

2.1 Documentation in the notes of the off-label or unauthorised medicinal product use 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) or on the formulary of the website 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 prescriber or Pharmacist.

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

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

3.0 Procedure

3.1 " The Use of Drugs Beyond Licence" (off-label) 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 :

- informs patient or carer that they are proposing to prescribe a medicine off-label.
- 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 independent prescriber or Pharmacist if requested as per patient preference, to discuss issues further. Prescriber or Pharmacist makes a record of the discussion in the patient record.

References

1. Palliative Care Formulary version 7; Robert Twycross, Andrew Wilcock and Paul Howard;2020
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.

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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.