ST GEMMA'S HOSPICE
POLICIES AND GUIDANCE

Category:	Medicines
Title:	Using licensed medicines for unlicensed purposes
Responsibility of:	Director of Medicine
HLT Member Accountable:	Director of Medicine
Developed in consultation with:	Hospice Pharmacist
Staff with operational responsibility for development, implementation and review:	Pharmacy Group
Target audience:	Doctors Registered Nurses Pharmacists
Key words:	Medicines, prescribing, licensed, unlicensed, policy
Associated policies:	Medicines – Prescribing Medicines – non medical prescribing
Date most recently validated:	December 2011
Date originally validated:	July 2003
Review date:	December 2014

MEDICINES: USING LICENSED MEDICINES FOR UNLICENSED PURPOSES

1.0 Preamble

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 two thirds of patients receive drugs in this way. (1)

1.2 The licensing process regulates the use of pharmaceuticals and not an authorised practitioner's prescribing 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 (Dr)/non medical prescriber (NMP) 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. (2)

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.

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 [3]

1.8 At St Gemma's 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) 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 (Ph). The medicine chart will be annotated appropriately and initialled by the Dr/ NMP or Ph.

2.4 Patients or carers requiring further explanation or reassurance are referred to the Dr/NMP 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 in the Pharmacy folder in each drug room and in Day Service, should a patient or carer require any written information or is available on line at:

www.britishpainsociety.org/book_usingdrugs_patient.pdf

3.0 Procedure

3.1 Ward secretary ensures that current "The Use of Drugs Beyond Licence" leaflet is in the Pharmacy Folder in the drugs room on each inpatient ward and in Day Services.

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 "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 RN refers patient or carer to the Consultant, Dr, NMP or Ph if requested as per patient preference, to discuss issues further. Consultant, Dr, NMP or Pharmacist makes a record of the discussion in the multidisciplinary notes.

References:

(1) Pain Society and Association for Palliative Medicine Leaflet – The Use of Drugs Beyond Licence – Information for Patients.

(2) www.palliativedrugs.com

(3) (Ref: Pavis H and Wilcock A (2001) Prescribing of drugs for use outside their licence in palliative care: survey of specialists in the United Kingdom. British Medical Journal. 323: 484–485.

Appendix 1

The recommendations of the Association for Palliative Medicine and the Pain Society

The use of drugs beyond licence in palliative care and pain management

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 management.
2. The use of drugs beyond licence should be seen as a legitimate aspect of clinical practice.
3. The use of drugs beyond licence in palliative care and pain management practice is currently both necessary and common.
4. Choice of treatment requires partnership between patients and health professionals, and informed consent should be obtained, whenever possible, before prescribing any drug. Patients should be informed of any identifiable risks and details of any information given should be recorded. It is often unnecessary to take additional steps when recommending drugs beyond licence.
5. Patients, carers and health professionals need accurate, clear and specific information that meets their needs. The Association for Palliative Medicine and the Pain Society should work in conjunction with pharmaceutical companies to design accurate information for patients and their carers about the use of drugs beyond licence.
6. Health professionals involved in prescribing, dispensing and administering drugs beyond licence should select those drugs that offer the best balance of benefit against harm for any given patient.
7. Health professionals should inform, change and monitor their practice with regard to drugs beyond licence 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.
9. Organizations providing palliative care and pain management services should support therapeutic practices that are underpinned by evidence and advocated by a responsible body of professional opinion.
10. There is urgent need for the Department of Health to assist healthcare professionals to formulate national frameworks, guidelines and standards for the use of drugs beyond licence. The Pain Society and the Association for Palliative Medicine should work with the Department of Health, NHS Trusts, voluntary organizations and the pharmaceutical industry to design accurate information for staff, patients and their carers in clinical areas where drugs are used beyond their licence (off-label). Practical support is necessary to facilitate and expedite surveillance and audit which are essential to develop this initiative.