Patient Information

University Hospitals Coventry and Warwickshire NHS Trust

# The Palliative Care Team

# Unlicensed Medication

## Information for patients regarding Medications being used outside their UK licence

The use of medicines beyond their Marketing Authorisation (MA) is widespread, particularly in specialties such as paediatrics and palliative care. Specialist textbooks, such as the Palliative Care Formulary, highlights such use as common place in this field.

Marketing Authorisation means that a medicine has been approved by a regulatory body for use in humans and licensed for specific indications and patient populations, and can be marketed for these purposes by the relevant pharmaceutical company.

Off-label describes the use of a medicine beyond the specifications of its MA, e.g. for an unlicensed indication, or in doses, preparations, patient population or route of administration not covered by the MA. For example in Palliative Care the subcutaneous route is often used but the MA may be for intravenous route which is more common for other specialities.

An unlicensed medicine is a drug which does not have MA for medicinal use in humans. Unlicensed medicines include:

- A mixture of two or more medicines in a syringe for administration by continuous infusion
- Medicines with MA in another country, but not the UK, which are imported

The use of unlicensed medicines is widespread in palliative care because the mixing of two or more licensed medicines in a syringe driver is now officially considered to produce an unlicensed preparation as stated above.

A joint statement by the British Pain Society and the Association for Palliative Medicine of Great Britain and Ireland similarly regards such use of medicines in palliative care and pain medicine to be in the best interests of the patient and generally represents standard practice.

The MA does not limit what the medicine could be used for (i.e. off-label use), and clinical experience may reveal other indications. For these to receive MA, additional evidence would need to be gathered and submitted to licencing authorities. The considerable expense of this, perhaps coupled with a small market for a new indication, often means that a revised application is not made.

The responsibility for the consequences of prescribing a medicine beyond or without MA lies with the prescriber, who must be competent, operate within the professional codes and ethics of their statutory bodies and the prescribing practices of their employers. The prescriber must be fully informed about the actions and uses of the medicine, be assured of the quality of the particular product, and in the light of published evidence, balance both the potential good and the potential harm which might ensue.

The Product Information Leaflet prepared by the manufacturer will only contain information about licensed indications. Thus, it is important that prescribers (or those authorizing treatment on their behalf) provide sufficient information to patients about the expected benefits and potential risks of using a medicine beyond or without MA (undesirable effects, drug interactions, etc.)

**Useful information**

- Please speak to the ward nurses and doctors if you have any questions, concerns or worries at any time.

The Trust has access to interpreting and translation services. If you need this information in another language or format please contact and we will do our best to meet your needs. Please contact the Palliative Care team on 02476 965498

The trust operates a smoke free policy.

**Help us to get it right**

If you have a complaint, concern, comment or compliment please let us know by speaking to a member of our staff. We learn from your feedback and use the information to improve and develop our services.
If you would like to talk to someone outside the service contact the Patient Advice and Liaison Service (PALS) on 0800 028 4203 or email your queries on feedback@uhcw.nhs.uk

**Document History**

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