HERPC

Hull & East Riding Prescribing Committee

GUIDELINE ON USE OF UNLICENSED MEDICINES IN PRIMARY CARE

Introduction

Medicines legislation requires that medicinal products be licensed before they are marketed in the UK. The Marketing Authorisation provides assurance of the safety and efficacy of the drug in relation to a specified use, which has been reviewed and accepted by an official expert body. It also defines the legal status of the product and ensures its quality.

Circumstances may arise where it is necessary to prescribe a patient an unlicensed product or a licensed product outside its licensed use (off-label). This guideline provides recommendations for prescribing in such circumstances.

It is important to note that responsibility for prescribing unlicensed products or unlicensed use of licensed medicines remains with the prescriber, including over-seeing the patient's care, monitoring and any follow up treatment. Prescribers have a right to refuse to take over prescribing responsibilities where circumstances do not fulfil criteria set by GMC in Good Practice in Prescribing and Managing Medicines and Devices 2013

Definitions

1. Unlicensed products

These are products without a Market Authorisation.
Unlicensed products are not subject to stringent control by the Licensing Authority (The MHRA), and neither prescribers nor pharmacists can make the same assumptions of quality, safety and efficacy about unlicensed products as they do for licensed medicines. They may be licensed in another country via their licensing body e.g. EMA/FDA.

"Specials" are included within this definition.
Specials are unlicensed medicinal products manufactured in the UK for human use which have been specially prepared to meet a prescription ordered for individual patients without the need for the manufacturer to hold a marketing authorisation for the medicinal product concerned.
Specials are prescribed where the licensed medicinal product is not available in a formulation or strength required for an individual patient e.g. liquid preparation for patients with swallowing difficulties.

2. Unlicensed use of a licensed medicinal product ("off-label")

This is where a licensed medicinal product is prescribed for an indication or otherwise in a manner that is not recommended in its Marketing Authorisation (often referred to as "off-label" use).

Although there are a number of circumstances in which this may arise, it is likely to occur most frequently in prescribing for children and prescribing in palliative care. Currently, pharmaceutical companies do not usually test their medicines on children and, as a consequence, cannot apply to license their medicines for use in the treatment of children. The use of medicines that have been licensed for adults, but not for children, is often necessary in paediatric practice. Often in prescribing in

palliative care unlicensed routes of administration are used e.g. subcutaneous usage of product licensed for intravenous or intramuscular use.

Recommendations for prescribing in Primary Care

1. Unlicensed products

Unlicensed products are classified as **RED** drugs within Hull and East Riding.
Except for circumstances listed below, unlicensed products should NOT be prescribed in primary care.
Where unlicensed product is initiated in secondary care, prescribing and monitoring of patient should remain with specialist team.

Exceptions where unlicensed products may be prescribed in primary care:

1. Where there is a HERPC approved guideline for prescribing specific unlicensed product

2. Where product prescribed is a "special"
Before a special is prescribed, prescriber should ensure there is no licensed alternative which would better serve the patient's needs.

3. Where prescribing is part of specialist service operating in primary care.

2. Unlicensed use of a licensed medicine ("off-label")

Unlicensed use of a licensed medicinal product may be recommended in the following circumstances:

1. Where there is a recognised body of evidence in support of such therapeutic use e.g. listed in BNF or BNF for children, NICE guidance, and other national guidance

2. Where there is a HERPC approved guideline e.g. Verapamil for cluster headache

3. Where treatment is initiated by consultant or consultant provided
   - The primary care prescriber has previous knowledge on the use of the medicine 'off label' for the condition being treated.

The secondary care provider is able to provide the primary care provider with sufficient information on evidence base to demonstrate safety and efficacy on the use of the medicine 'off label' for the condition being treated.
N.B. The prescriber will bear responsibility for treatment; it is therefore important that, the prescriber, understands the patient's condition as well as the treatment prescribed and can recognise any adverse side effects of the medicine, should they occur.

For information on licensed indications for medicines healthcare professionals should refer to the BNF (www.bnf.org), BNF for Children (www.bnfc.org) and Summary of Product Characteristics (www.medicines.org.uk)

Further good practice guidance
(from GMC Good Practice in Prescribing Medicines, Feb 2013)

When prescribing any unlicensed medicines or licensed medicine for unlicensed use, the prescriber must

- be satisfied that an alternative, licensed medicine would not meet the patient's needs or where a suitably licensed medicine that would meet the patient's need is not available (for example if there is a temporary shortage in supply) or the prescribing forms part of a properly approved research project.
- be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy
- 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
- make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine

Information for patients about the licence for their medicines

- Prescribers 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.
- 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. You must always answer questions from patients (or their parents or carers) about medicines fully and honestly.
- 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.
- You should be careful about using medical devices for purposes for which they were not intended.

APPROVAL PROCESS

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