Unlicensed medicines or medicines used "off-label" (use out with their licensed indications) - responsibilities

The responsibility that falls on healthcare professionals when prescribing an unlicensed medicine or a medicine "off-label" is greater than when prescribing a licensed medicine within the terms of its marketing authorisation. Prescribers should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine "off-label". These risks may include: adverse reactions; product quality; or discrepant product information or labelling e.g. absence of information for some unlicensed medicines, information in a foreign language for unlicensed imports and potential confusion for patients or carers when the Patient Information Leaflet is inconsistent with a medicine's off-label use.

The following information outlines the responsibilities associated with prescribing unlicensed or "off-label" medicines and **these apply irrespective of the formulary status of the medicine**.

Responsibilities

Prescriber (signing and issuing the prescription) [1]

- Before prescribing an unlicensed medicine, be satisfied that an alternative, licensed medicine would not meet the patient's needs
- Before prescribing a medicine "off-label", be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative
- Before prescribing an unlicensed medicine or using a medicine "off-label":
  - be satisfied that there is a sufficient evidence base and/or experience of using the medicine to show its safety and efficacy
  - take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring and follow-up
  - record the medicine prescribed and, where common practice is not being followed, the reasons for prescribing this medicine; you may wish to record that you have discussed the issue with the patient
- Communicate with patients or those authorising treatment on their behalf sufficient information about the proposed course of treatment including any known serious or common side effects or adverse reactions

Pharmacist

- Will assume responsibility for the purchasing of the medicine and the development of a product specification against which the product can be assessed for quality.
- Pharmacists share responsibility with the prescriber for the supply of any prescribed medicine.

Manufacturer

- For a licensed medicine prescribed and administered in accordance with the products marketing authorisation, the manufacturer will accept liability if an adverse event occurs.
- For unlicensed medicines with no marketing authorisation then the manufacturer is not liable for any adverse events encountered.
- When a medicine is used "off-label", then the manufacturer is unlikely to be found liable for harm caused by that medicine.

The prescribing of medicines that are unlicensed, “off-label” (use out with their licensed indications), is generally considered to be for exceptional use. However where unlicensed or “off-label” medicines are prescribed or recommended by an appropriate specialist as per the relevant specialist formulary list, this use is not considered exceptional. Use of these medicines in the appropriate circumstances and by the appropriate specialist, or on their recommendation, is considered to be formulary prescribing. For information on prescribing medicines unlicensed or “off-label” that are not within the Tayside Area Formulary see Non-formulary (including IPTRs) Policy

Unlicensed or “off-label” medicines have been included within a specialist formulary list on the basis of commonality of approach adopted by a wide range of clinicians or local specialists. In any case of liability assessment, this would be the basis of defence i.e. that peer group practice clearly supported the prescriber. However this does not remove the risk and responsibility that rests with prescribers when prescribing unlicensed medicines or using a licensed medicine “off-label”. For unlicensed medicines the quality, safety and efficacy will not have been evaluated and the **risk of use rests with the prescriber**.

Definitions

Unlicensed Medicine – Is a medicine that does not hold a marketing authorisation within the UK. There are two sources of unlicensed medicines;

1. Some patients may have special clinical needs that cannot be met by licensed medicinal products. So that these special needs may be met, the law allows manufacture and supply of unlicensed medicinal products (commonly known as '**specials**') subject to certain conditions [(2)].The conditions are that there is a bona fide unsolicited order, the product is formulated in accordance with the requirement of a doctor or dentist registered in the UK, and the product is for use by their individual patients on their direct personal responsibility. If a 'special' is manufactured in the UK, the manufacturer must hold a manufacturer's (specials) license issued by the MHRA. A 'special' may not be advertised and may not be supplied if an equivalent licensed product is available which could meet the patient's needs. Essential records must be kept and serious adverse drug reactions reported to the MHRA. For further information on the use of Specials – see What’s so ‘Special’ – Tayside Prescriber Issue 121, August 2011.

2. A second type of unlicensed medicine is an imported unlicensed relevant medicinal product which may only be supplied under the same defined conditions as ‘specials’.

“Off-Label” Use – Is where a product is used out with the marketing authorisation granted by the licensing authority an example in routine practice would be amitriptyline which is licensed for the treatment of symptoms of depression but commonly prescribed for the treatment of neuropathic pain.

References

1. General Medical Council; Good Practice in Prescribing Medicines, supplementary guidance. September 2008.
2. MHRA, Medicines that do not need a license (Exemptions from licensing) accessed at http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Medicinesthatdonotneedalicence/index.htm on 7th September 2012.