

## 12. Unlicensed or Off-Label Use of Medicines

**12.1** UK medicines legislation requires that medicinal products be licensed before they are marketed in the UK. Accordingly no medicinal product may be placed on the market unless a Marketing Authorisation (formerly known as a Product Licence) has been issued by the Medicines and Healthcare Products Regulatory Agency (MHRA).

**12.2** Unlicensed products are not subject to any assessment by the UK Licensing Authority. Neither prescribers nor pharmacists can make the same assumptions of quality, safety and efficacy about unlicensed products as they do for licensed medicines. However, some medicines that are unlicensed in the UK may be licensed in their country of origin. Such medicines therefore will have a varying degree of quality, safety and efficacy assurance depending on the licensing regulations in the country of origin.

**12.3** Unlicensed medicines should only be used where the clinical needs of the patient cannot be met by a licensed medicinal product in UK or EU or when a licensed product cannot be used in an off-label manner (e.g. crushing of tablets or opening of capsules).

**12.4** When a licensed medicine is used, the liability for an untoward event caused by the medicine remains with the manufacturer or license holder, provided it has been used in accordance with the terms of its licence. However, when the medicine is unlicensed, or is used in an off-label manner, any untoward event becomes the responsibility of the prescriber, and therefore the Trust.

**12.5** Licensed medicines are utilised for off-label uses, and although situations vary it may be that there is a recognised body of evidence in support of such therapeutic use (e.g. BNF for Children).

**12.6** Whenever unlicensed medicines are prescribed, or licensed medicines are prescribed for off-label use, prescribers are professionally accountable for their judgement, and may be called upon to justify their actions. Prescribers will be expected to have an awareness of their responsibilities as outlined within the Trust's Unlicensed Medicines Policy.

**12.7** Those involved in the prescribing or administration of an unlicensed medicine or medicines used off-label should be aware of the product's status, and any known relevant risks associated with its use. Advice on the licensed status of a product can be obtained from a pharmacist.

The patient/parent/carer should, wherever possible, be involved in the discussion and implications of using medicines in this way explained to them.

**12.8** There is a hierarchy of preference / risk and medicines should be used with the lowest risk where possible ( lowest risk at the top )

- UK/ EU licensed product for licensed indication
- UK/EU licensed product for unlicensed indication
- product licensed in third country with mutual recognition agreement (MRA)
- product licensed in third country without MRA
- UK unlicensed 'Special' from a licensed 'Specials' manufacturer
- UK unlicensed extemporaneous preparation

## LEICESTERSHIRE MEDICINES CODE

- 12.9** For further details and guidance, consult Trust Unlicensed Medicines Policy or MHRA Guidance Note 14 “The supply of unlicensed relevant medicinal products for individual patients”.