MIL

Oxford University Hospitals NHS
NHS Foundation Trust

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This Medicines Information Leaflet is produced locally to optimise the use of medicines by encouraging prescribing that is safe, clinically appropriate and cost-effective to the NHS.

Unlicensed medicines and 'off-label' uses

A marketing authorisation (MA) or product licence (PL) defines a medicine's terms of use. The licensing process provides certain degree of assurance that a medicine has been assessed for efficacy, safety, and quality; has been manufactured to appropriate quality standards; and when placed on the market is accompanied by appropriate product information and labelling.

Prescribing medicines outside the recommendations of their marketing authorisation increases the prescriber's professional responsibility and potential liability.

All prescribing, supply and administration of unlicensed or off-label medicines at the Oxford University Hospitals NHS Foundation Trust must be in accordance with the Procedure for the use of unlicensed and 'off-label' medicines. The **prescriber** must be able to justify, and be competent in the use of an unlicensed medicine or a licensed medicine off-label; the **pharmacist** is professionally accountable for supplying these. Prescriptions should be endorsed in accordance with the Clinical Pharmacy Procedure to indicate that a medicine is unlicensed or its being used off-label.

Prescribing unlicensed medicines

Prescribing unlicensed medicines may be necessary when there is no suitable licensed medicine that will meet the patient's need, for example where:

- there is no licensed medicine applicable to the particular patient;
- the dosage specified for a licensed medicine would not meet the patient's need;
- the patient needs a medicine in a formulation that is not specified in an applicable licence.

When prescribing an unlicensed medicine the prescriber **must**:

- be satisfied that there is sufficient evidence and/or experience of using the medicine to demonstrate safety and efficacy;
- take responsibility 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;
- document reasons for prescribing an unlicensed medicine in the clinical notes; inform the patient/carer about the unlicensed medicine, including the *Patient information Leaflet (PIL) on unlicensed medicines.* The patient/carer should also give informed consent for the use of the unlicensed medicine, in accordance with the Procedure for the use of unlicensed and 'off-label' medicines and the Trust consent policy;
- arrangements for continuing supplies, for the duration of the prescription, involving the general practitioner (GP) when appropriate.

The Trust maintains a Register of Unlicensed Medicines (and off-label uses) which have been approved for use in the Trust, by the Medicines Management and Therapeutics Committee (MMTC) and will form part of the Trust's Medicines Formulary.

Adverse Drug Reactions

Pharmacy and medical staff should be informed about any *adverse drug reactions* or *significant interactions* that occur with the unlicensed medicine and these should be reported to the MHRA through the Yellow Card reporting scheme and a Trust incident report completed on Datix.

What is an unlicensed medicine?

The term '*unlicensed medicine*' is used to describe medicines that are used outside the terms of their UK licence or which have no licence for use in the UK. They are commonly used in some areas of medicine such as in paediatrics, psychiatry and palliative care. They are also used, less frequently, in other areas of medicine.

- **Medicines without a UK MA** – these may include medicines that have been imported, have been withdrawn from the UK market, etc.
- **"Off-label" uses** - licensed medicines being used outside their terms of use (indication, dose, age of the patient, route or method of administration).
- **"Specials"** - medicines manufactured and supplied by a hospital or commercial supplier with a manufacturers 'specials' licence.
- **Extemporaneous (Extemp) –** medicines that are prepared extemporaneously by the Pharmacy Department in accordance with section 10 of the Medicines Act 1968.
- **Re-packaged medicines (Pre-packs)** - These are medicines which are removed from their original containers and re-packed (or relabelled), such as ward pre-packed discharge *packs*.
- **Food Supplements -** When a health supplement is used as a medicine, it must be treated as an unlicensed medicines and risk assessed like any other unlicensed medicine.

Inclusion of an unlicensed medicine onto the Register

All requests for the inclusion of an unlicensed medicine onto the Register must be considered by MMTC. Unlicensed medicines approved by MMTC for routine use will be added to the Register with a *restricted* formulary status.

A disclaimer Unlicensed Medicinal Product use form for *ROUTINE USE* must be completed by the prescriber (or a member of their team may sign on their behalf). This form is valid for five years.

All **off-label** use of medicines doses, indications and routes of administration recommended in the following resources will automatically be eligible for inclusion on the Register where the medicine has a formulary status of **'Formulary (Y) – for use as per license'**:

- British National Formulary (BNF)
- British National Formulary for Children (BNFc)
- British Association of Dermatology (BAD) list
- Palliative Care Formulary (PCF)

All off-label medicines being used for skin-prick allergy testing will automatically be eligible for inclusion on the Register.

Any other off-label use of medicines is non-formulary and will require additional supporting information at the time a request is made or a formulary application submitting to the MMTC if to be used routinely.

See the Procedure for the use of Unlicensed medicines and Off-label uses for additional information.

One-off approval

When an unlicensed medicine that is not in the Register, therefore *non-formulary*, is required in an emergency, one-off use for a specific patient may be obtained by the Chair of MMTC (or a nominated deputy) – this is subject to Pharmacy being able to obtain a product of suitable quality from an approved supplier. This might not be readily available; please check with pharmacy before prescribing or scheduling treatment.

If approval is granted by MMTC then:

- a *non-formulary form* has to be completed by the requesting pharmacist
- a Unlicensed Medicinal Product form for *one-off use* must be signed on the patient's EPR by the requesting consultant (or a member of their team); guidance on completing a declaration can be found here.
- an unlicensed medicine risk assessment must be completed on SharePoint

References

1. Prescribing guidance: Prescribing unlicensed medicines, General Medical Council. http://www.gmc-uk.org/mobile/news/14327_(accessed 2 April 2014).
2. Drug Safety Update: Off-label or unlicensed use of medicines: prescribers' responsibilities. MHRA. http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON087990 (accessed 2 April 2014).
3. Medicines Policy. Oxford University Hospitals NHS Trust, Version 9.1 – November 2018.

Prepared by:

Carlos García Torres, Clinical Effectiveness Pharmacist.

Colm Mckenzie, Clinical Effectiveness Pharmacist.

Grant Sugiura, Clinical Effectiveness Pharmacist.

(Updated Dec 2018)

With advice from:

Victoria Mott, Lead Medicines Information Pharmacist

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