

North East Essex Medicines Management Committee

Statement of Good Practice

Supply of Unlicensed Medicines and Off Licence Usage

Under the Medicines Act 1968, all medicinal products should be marketed for sale, or supply with an appropriate Marketing Authorisation (MA), although there are exemptions. The MA is intended to guarantee the quality, safety and efficacy of medicinal products and states the indication, dose, route of administration and the age group of patients for which the drug may be used. To some extent, it places liability on the MA holder for adverse effects arising from the use of their product.

In effect, licensing arrangements apply to pharmaceutical companies, but not prescribers or pharmacists, as the Medicines Act and European legislation make provision for doctors to use either 'off-licence' or unlicensed medicines. The law allows a pharmacist to dispense medication without an MA or to dispense items to be used outside their product licence in response to a prescription.

The use of unlicensed and off-licence medicines is an area of potentially increased risk, since it means that the MHRA has not examined the risks or benefits of using these drugs.

There may, atypically, be situations where unlicensed medicines are approved for use by the North East Essex Medicines Management Committee (NEEMMC) in specific indications where there is no licensed alternative. In these cases, the NEEMMC will approve a clear local policy to support the use.

Unlicensed and 'Off-licence' Medicines

Off-licence: Medicines may be being used outside the terms of their product licence, e.g. in children, the elderly or for an unlicensed indication.

Unlicensed: Medicine is not licensed for human use for any indication or age group.

A medicine may be unlicensed for a variety of reasons. For example:

- It is undergoing clinical trials.
- It has been imported from another country.
- It has been prepared extemporaneously (i.e. mixtures made by pharmacists against a prescription, or when products are mixed together before being administered, e.g. mixing a local anaesthetic with a steroid prior to injecting a joint).
- It has been prepared under a specials licence (frequently liquid preparations for those with swallowing difficulties, low dose products for children, colour or allergen free formulations).
- Products where the licence has been suspended, revoked or not renewed (usually for commercial reasons), but where the company continues to make product available for named individuals
- The product is not a medicine but is being used to treat a rare condition (e.g. a metabolic disease)

Practical Considerations

1. For Prescribers:

When prescribing off-licence or unlicensed drugs the following points need to be considered:

- Tell the patient that the drug is unlicensed or off-licence. Record the conversation in the notes. Patients or carers should be given clear information on the use of an unlicensed or 'off-licence' drug; otherwise the patient information leaflet (PIL) given at dispensing will be confusing.
- Prescribing of unlicensed drugs should only be considered if there is no practical licensed alternative. This may include using a licensed drug in an off-licence manner. It should be noted that there are some situations where a simple dose adjustment of a licensed product may suffice.
- Prescribing of an unlicensed drug should be in accordance with the list in Part VIII B of the Drug Tariff if practically possible
- Tell the patient about known side effects and explain why the drug is not licensed for this particular indication by the MHRA. Written consent before starting treatment may be appropriate, see Appendix 1.

- Discuss with colleagues, especially a (or another) specialist to ensure that there is a responsible body of medical opinion supporting the use of the drug in this manner.
- Consultants should take responsibility for ensuring that GP's are informed in writing of any "off-licence" or unlicensed prescribing.
- Prescribing of unlicensed and off-licence drugs will generally be by the consultant and continued by the consultant. In some circumstances prescribing may be transferred to primary care by mutual agreement between the consultant and the GP. The prescribing of these drugs should be regularly reviewed and monitored as appropriate by the clinician who initiated prescribing.
- Primary care prescribers refusing to prescribe an unlicensed or off-licence drug should return a completed "Inappropriate unlicensed medicines letter" to the consultant stating the reasons for refusal. (Appendix 2)
- Patients should not be advised to expect their GP to prescribe as a matter of routine
- If appropriate discuss the drug, condition and possibly the patient (with their consent) with the medical officer of the drug company.
- Keep timely and detailed notes of reasons for use and of the consultations.
- Some companies may try to ask prescribers to sign agreements saying the company cannot be held responsible if the patient dies or suffers harm. Prescribers are liable if they prescribe or administer negligently in the face of current medical consensus, but should not be held responsible if the product itself is faulty or of poor quality.

2. For Pharmacists:

Every pharmacist assumes a duty of care to the patient when he or she supplies medication to a patient.

When supplying a product without marketing authorisation or outside the product licence the supplying pharmacist may assume some liability, with the prescribing doctor, if an adverse reaction is suffered to it. However, the **RPSGB Code of Ethics** provides an obligation not to deviate from the prescriber's intention except when necessary to protect the patient.

- As a minimum the pharmacist must ensure that the prescriber knew that he was using a product outside its Marketing Authorisation and the possible consequences or that the product supplied was an unlicensed medicinal product (special) and is aware of the possible consequences.
- MHRA guidance is that the use of unlicensed medicinal products (specials) should only be used where no suitable licensed product is available. Unlicensed products can be made in the pharmacy (i.e. extemporaneously dispensed), obtained from a "licensed specials" company (e.g. hospital production unit, BCM, Rosemont, Idis Pharma).
- Supplies of unlicensed drugs should be obtained on a named patient basis only and used only for that patient.
- When obtaining a supply of an unlicensed drug a record should be made of the name of the product, its specification; prescribers name (if appropriate) manufacturer and (if different) supplier, date ordered, quantity ordered and batch number received.
- When supplying a special, the pharmacist should keep a record of the source of the product, person to whom **supplied and the date on which the product was sold or supplied, prescriber's details**, quantity of each sale or supply, batch number of the product, details of adverse reactions to the product.
- **These records must be kept for 5 years and be available for inspection by the Licensing Authority.**
- In addition to the above community pharmacists are required **to stamp, date, initial and endorse the Certificate of Analysis (CoA)/ Certificate of Conformity (CoC) with the invoice price and prescriber's details for unlicensed specials or imports not listed in Part VIII B. At the end of the month, the pharmacy must then send a copy of the CoA/CoC to the local NHS England team of the prescriber along with the prescriber's details.**
 - **Where a CoA/CoC is not available for imported unlicensed products not listed in Part VIII B, the contractor must stamp, date, initial and endorse the invoice with the invoice price less discount (where not clearly detailed by the supplier) and the prescriber's details.**
- Before supplying a 'special' the pharmacist may wish to discuss with the prescriber whether a licensed product administered by an "off-licence" method (e.g. crushed tablets) may be a suitable alternative to an unlicensed special.

Monitoring

Prescribers and pharmacists should both be aware when unlicensed and off-licence drugs are used, and use the MHRA "Yellow Card" system to notify any unexpected or adverse reactions as well as notifying the pharmaceutical company concerned.

Appendix 1

Treatment with Unlicensed/off-licence Medication*

Patient name: _____ Patient Number /NHS number _____

Name of Medication: _____

Indication: _____

I hereby acknowledge I am aware of the monitoring and side-effects or risks associated with the above medication. I take responsibility for prescribing it and have informed the patient/and or carer of its unlicensed/off license status, discussed known side effects and why the drug is not licensed for this particular indication.

Name of Prescriber _____

Signature _____ Date _____

I _____ hereby accept treatment with this unlicensed/off license medication.

Signature of patient _____ Date _____

*Unlicensed medicines are also known as 'Specials' and may have been specially manufactured or imported for the treatment of an individual patient.
Please scan to notes once completed.