Mid Essex CCG Statement of Good Practice for Prescribing Unlicensed and Off Label Medicines

Introduction

Under the Medicines Act 1968 and more recent European Community legislation, medicines must be granted a Marketing Authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA) before they can be used in the UK. The MHRA reviews clinical trial data to satisfy itself that the product, as well as the manufacture, distribution and supply arrangements, meets quality and safety standards. The Marketing Authorisation (MA) states the indication, dose, route of administration and the age group of patients which are covered by the licence and places some liability on the holder (the manufacturer) when the product is used within those terms. The regulation of medicines on the UK market is undertaken by MHRA in accordance with the Human Medicines Regulations 2012 (SI 2012/1916).

Doctors can legally use medicinal products 'off label'[1] or which are not licensed at all, and pharmacists can dispense off label and unlicensed[2] products, but the prescriber is professionally responsible for any adverse effects which arise. The risk is increased because the safety, quality and efficacy of the products in those circumstances have not been reviewed by the MHRA.

Health professionals involved in the prescribing, procurement and supply of unlicensed and 'off label' medicines are expected to adhere to the relevant professional code.

Responsibilities

Prescribers

- Unlicensed medicines should only be prescribed when there is no alternative licensed alternative that would meet the patient's needs
- A medicine should only be prescribed off-label if it will meet the patient's needs better than a licensed alternative
- Some unlicensed medicines are recommended by the CCG as part of pathways developed in conjunction with the relevant specialist and approved by the Area Prescribing Committee. Prescribers acting in line with this guidance are acting in line with an evidence base
- Informing the patient that the drug is unlicensed or off-label and documenting the conversation. Written consent before starting treatment may be appropriate.
- Give the patient or carer clear information on the use of an unlicensed or 'off-label' drug, otherwise the patient information leaflet (PIL) may be confusing.
- Informing the patient about known side effects and explaining why the drug is not licensed for this particular indication by the MHRA.
- Prescribing of unlicensed and off-label drugs will generally be by a consultant / accredited practitioner with special interest who will have been required to complete the necessary risk assessment document required by the MEHT Unlicensed Medicines Policy[3]. In some circumstances prescribing may be transferred to primary care by mutual agreement and copies of the associated risk assessment will need to be requested. The prescribing should be regularly reviewed and monitored by the

consultant / accredited practitioner with special interest who initiated prescribing.

- If appropriate, discuss the drug, condition and possibly the patient (with their consent) with colleagues, specialists and / or the medical officer of the drug company to determine whether there is an established experience.
- Keep contemporaneous and detailed notes of reasons for use and of the consultations.
- If drug company is contacted for advice they may request a signed agreement to absolve the company of responsibility if the patient dies or suffers harm. Prescribers are advised to consider very carefully the consequences of doing this.

Pharmacists

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 experienced as a result of the treatment..

- The pharmacist should ensure that the prescriber is aware of the unlicensed status of the medicine, and advise on the availability of a licensed alternative that would meet the patient's needs
- Before supplying a 'special'[4] 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.
- MHRA guidance is that the use of unlicensed medicinal products (specials) should only be used where no suitable licensed product is available.
- Supplies of unlicensed drugs should be obtained on an individual patient basis only on the basis of a prescription
- 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, person to whom product was supplied, fate of supply, quantity supplied, batch number, details of adverse reactions to the product.
- Community pharmacists are required to forward copies of the CoC/CoA[5] to the NHS England Area Team as part of their Terms of Service

Administering Health Professionals

- Should ensure that the patient's informed consent has been obtained before administering an unlicensed medicine against the manufacturer's instructions.
- Before administering an unlicensed or off label medicine, need to ensure that enough information has been obtained to administer the medication safely.

Definitions and Policy

[1]Off-label Prescribing

The Summary of Product Characteristics (SPC) of a medicinal product lists the indications, dose ranges, methods of administration, age restrictions and contra-indications which are covered by the Marketing Authorisation. Any use not in accordance with SPC is "off-label" or an unlicensed use.

[2]Unlicensed medicines

A medicine may be unlicensed (i.e. not licensed in the UK for human use in any age group or for any indication) because:

- It is undergoing clinical trials
- It has been imported from another country.
- It has been prepared extemporaneously
- It has been prepared under a 'specials license'
- The license has been suspended, revoked or not renewed (usually for commercial reasons)
- The product is not a medicine but is being used to treat a rare condition (e.g. a metabolic disease).
- The license of a particular brand doesn't cover the indication it is prescribed for
- A licensed medicine has been repacked or modified e.g. a tablet is crushed before administration

See Appendix One and Two MHRA Guidance Note 14 The Supply of Unlicensed Medicinal Products ('Specials') for more in depth information.
https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials

[3] **MEHT Unlicensed Medicines Policy**

08111 Unlicensed Medicines 3 0.pdf

[4]**Specials** Specials are unlicensed medicines created for patients for whom there are no existing suitable licensed products available, for reasons of formulation and/or presentation.

[5] CoC/CoA Specials Certificates of Conformity

Liability

The use of unlicensed and off-label medicines is an area of potentially increased risk, since it means that the Medicines and Healthcare Regulatory Agency (MHRA) has not examined the risks or benefits

Considering the prescribing of unlicensed or 'off-label' medications by general practitioners on recommendation of hospital consultants, it is believed that a doctor will not be found negligent in a court of law if he can demonstrate that he acted in accordance with a responsible body of relevant professional opinion and where appropriate has prescribed the drug in accordance with a pathway which has been approved by an Area Prescribing Committee. Several pathways involving the use of unlicensed or 'off-label' medications have been developed for use in the Mid Essex Locality and can be accessed on the Medicines Management website, http://www.midessexccg.nhs.uk

If a GP has: taken steps to become familiar with the drug; is able to monitor that drug completely; has access to effective consultant support, then it is unlikely that they will be found negligent if a problem subsequently develops.

The ultimate responsibility for prescribing rests with the prescriber who signs

the prescription and is professionally accountable for his/her action.

Monitoring

Prescribers and pharmacists should both be aware when unlicensed and off-label drugs are used, and use the Yellow Card systems (www.yellowcard.gov.uk tel.no: 0203 080 6000 (9am to 5pm Monday-Friday only) to notify any unexpected or adverse reactions, as well as notifying the pharmaceutical company concerned.

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