



The ROYAL COLLEGE of
OPHTHALMOLOGISTS

Ophthalmic Service Guidance

Prescribing Unlicensed Medicines – A brief guide

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1 Introduction

In the UK, eye units use a wide range of licensed medicines to treat their patients, but it is recognised that for some patients their needs may only be met by unlicensed medicines or licensed medicines used outside their product licence ('off label use').

A UK marketing authorisation (MA), formerly known as a product licence, provides assurance that a medicine conforms to agreed standards and guidance that a product has been manufactured, stored and distributed in compliance with the required standards. A licensed medicine may be identified by the presence of a licence number prefixed by PL, MA, EMEA (European Medicines Evaluation Agency) or EU (European Union). The MA is issued by the Medicines and Healthcare products Regulatory Agency (MHRA). The existence of an MA guarantees the quality, safety and efficacy of medicinal products and helps to protect the prescriber from liability if adverse effects arise from the use of the drug. In the case of unlicensed products, a product licence/marketing authorisation is not present. Using unlicensed medicines, or using licensed medicines outside the boundaries of that licence, places additional responsibility on the prescriber, and the organisation supplying the medication to the patient, with regard to the quality, record keeping and justification of use.

2 Licensed medicines used for unlicensed indications ('off licence' or 'off label')

The SPC (Summary of Product Characteristics) is the legal document approved as part of the MA of each medicine. It lists indications, dose ranges, methods of administration, age restrictions, contraindications and side effects. Any use not in accordance with the SPC is 'off label' or unlicensed use. Common examples include: unlicensed indication, unlicensed dose, unlicensed method of delivery, unlicensed route of administration, and many medicines prescribed for children and neonates. The term also includes licensed medicines which have been re-packed and supplied to, or received from, an external organisation. An ophthalmic example is the use of Avastin, licensed for cancer treatment, to treat macular degeneration.

If a prescriber uses a licensed medicine for an unlicensed indication or in a manner not compatible with the SPC, the manufacturer is unlikely to be found liable for any harm caused by the medicine, unless harm is directly attributed to a defect in it, rather than the way it was prescribed. The ultimate responsibility for prescribing rests with the prescriber who signs the prescription and is professionally accountable for his/her action.

3 Unlicensed medicines

An unlicensed medicine is a medicine without a European or UK MA and is not licensed to be marketed in the UK. Such medicines may be manufactured for export, licensed to use elsewhere in the world, or may have been withdrawn from the UK market. This category also includes medicines which are awaiting the grant of a UK MA.

Occasionally a prescriber will identify that a patient requires a medicine which does not have a licence. For example the patient may be allergic to an additive, requires a stronger or

weaker form or a different form such as unlicensed liquid formulation to overcome swallowing difficulties.

The medicine used may be imported or a 'special'. A special is an unlicensed product that has been obtained from either a hospital or commercial manufacturing unit which has a special manufacturing licence. They will have either a Manufacturing Licence (ML), or Manufacturing Specials (MS) number according to individual unit policy. A pharmaceutical special is defined by law as a medicine made to satisfy an individual patient need. An ophthalmic example is amphotericin 0.15% eye drops for the treatment of fungal keratitis.

The Medicines Act allows appropriate prescribers to prescribe medicines without a licence providing they are happy to assume full liability for the prescription.

4 Professional Obligations

General Principles of use

Unlicensed or off license medicines should usually only be used when there is no suitable licensed medicine that will fulfil the patients need at the time the patient needs it. It is in the interests of patients and hospital trusts that licensed medicines be used whenever possible and the primary obligation of prescribers and pharmacists is to ensure the safety of the patient.

However, for good clinical reasons, the use of unlicensed and off-label medicines is widespread in hospitals. The prescriber may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, the consultant concludes, for medical reasons, that it is necessary to do so to meet the specific needs of the patient. When prescribing for this group of patients, the prescriber must exercise professional judgment that the patient must have an unlicensed medicinal product rather than a licensed product because the licensed product will not meet the clinical need of the patient. They must therefore be aware of the associated legal implications to avoid exposing patients under their care to unnecessary risk and themselves to unnecessary liability.

Prescribers of unlicensed products carry their own responsibility and are professionally accountable for their judgment in doing so. Prescribers are responsible for the patient's welfare and in the case of adverse events, they may be called upon to justify their actions.

Individual trusts carry liability for their employees and would be expected to accept liability for the use of unlicensed and off-label medicines provided that the trust's drug and therapeutics policy is followed.

When a licensed medicine becomes unavailable due to a short-term shortage, it is permitted to use an unlicensed pharmaceutical equivalent. This should only be considered as a temporary solution and should not be taken as justification for a long-term supply. Supply in these circumstances should cease as soon as possible, following re-instatement of the licensed product.

The prescriber must document the reason (eg 'licensed product has supply issues') in the patient record as per GMC guidance.

Prescriber's obligations

Prescribers are professionally accountable for prescribing all medicines including unlicensed medicines. It is the prescriber's responsibility to decide whether the patient has special pharmaceutical needs, which a licensed product cannot meet.

Following amendments to the Medicines for Human Use Regulations 2009, independent nurse or pharmacist non-medical prescribers are also permitted to prescribe unlicensed medicines, with the same requirements for prescribing such drugs as doctors. Optometry independent prescribers are NOT allowed to prescribe unlicensed medicines.

A consultant must initiate all prescribing of new unlicensed medicines but afterwards other prescribers can continue its use Other prescribers may initiate unlicensed medicines if agreed by their individual trust.

In addition, prescribers must:

- Prescribe unlicensed medicines knowingly and after careful consideration
- Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy
- Document the reasons for choosing the unlicensed medicine in the patient's records
- Ensure the patient is aware that the medicine is unlicensed and document in the patient records informed consent for the use of unlicensed medicines and also for off-label use when this is not routine, accepted practice
- Explain to the GP and/or other colleagues the recommendation for the use of an unlicensed product together with any requested supporting evidence, and to ensure that they have all necessary prescribing information. The full agreement of the patient's GP must be obtained before prescribing is transferred to ensure continuity of therapy. A GP is not obliged to prescribe in such circumstances
- Review treatment if appropriate licensed medication becomes available
- Inform the relevant trust drugs, therapeutics or medicine management committee of the medicine's licensing state before a request to use an unlicensed medicine is made. The requesting consultant should also confirm whether or not junior medical staff will be permitted to prescribe it
- Consider what relevant information the patient will receive with the dispensed unlicensed medicine and ask the pharmacist to counsel the patient on the licensing issues if felt to be helpful

Responsibilities of the medical/clinical staff administering an unlicensed medicine

- As with all medicines, to be familiar with what the medicine is being used for, the normal dose range and administration details, common side effects and cautions/contraindications
- Where applicable, to question the prescriber (or contact a pharmacist) if an instruction to administer a medicine is thought to be outside its licence ('off-label' use) with regard to dose, route of administration or other aspect to ensure that the prescriber is aware of this and considers that it is in the best interests of the patient

5 Other Useful References/Evidence Base

[The Medicines Act 1968](#)

[The Human Medicines Regulations 2012](#)

MHRA Guidance Note14: The supply of unlicensed medicinal products (“specials”). Medicines and Healthcare products Regulatory Agency (May 2014)

Good Practice in Prescribing Medicines and Managing Medicines and Devices, General Medical Council (2013)

Guidance for the Purchase and Supply of Unlicensed Medicinal Products, Notes for Prescribers and Pharmacists (third edition). NHS Pharmaceutical Quality Control Committee, June 2004

[GMC guidance update about prescribing unlicensed medicines](#)

[GMC statement on the use of Avastin for the management of macular degeneration](#)

RCOphth statements on the use of Avastin:

[New NICE Age Related Macular Degeneration guidance supports potential cost savings for the NHS](#)

[RCOphth welcomes EU Court of Justice Advocate General’s new opinion on the use of ‘off-label’ drug Avastin](#)

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