

Availability of Unlicensed Medicines Policy

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CONSULTATION AND DISTRIBUTION RECORD	
Contributing Author / Authors	<ul style="list-style-type: none"> • Director of Pharmacy •
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1. INTRODUCTION

This policy provides information on unlicensed medicines, off-label use of licensed medicines and responsibilities of prescribers and pharmacy.

The term 'unlicensed medicine' is normally applied to those medicines which do not have a UK Marketing Authorization, formerly a Product Licence (PL), granted by the Medicines and Healthcare products Regulatory Agency (MHRA) or European Agency for the Evaluation of Medicinal Products.

The term unlicensed may also be applied to licensed medicines when they are used for unlicensed applications, so-called 'off label' use.

The use of unlicensed medicines is often necessary and is common in many areas of medicine e.g. paediatrics, palliative care and psychiatry. It is important that such use continues, since if this practice were to be curtailed the treatment of many patients would be impeded.

2. AIM, PURPOSE and OUTCOMES

The aims of this document are to:

- Outline best practice in the use of unlicensed and off-label medicines.
- Provide support for prescribers and pharmacists in the use of unlicensed and off-label medicines.
- Endorse NHS Scotland Directors of Pharmacy and Scottish Association of Medical Directors consensus statement on use of unlicensed medicines and off-label medicines where a licensed medicine is available¹.

3. SCOPE

3.1 This policy applies to NHS Lanarkshire managed service and is commended to independent contractors for consideration.

This policy does NOT apply to investigational medicinal products which are being prescribed as part of a clinical trial – these are covered by separate policies and procedures.

3.2 Stakeholders are all prescribers authorised to practice within NHS Lanarkshire managed service. All registered pharmacy professionals within NHS Lanarkshire managed service.

NHS Lanarkshire take care to ensure your personal information is only accessible to authorised people. Our staff have a legal and contractual duty to keep personal health information secure, and confidential. In order to find out more about current data protection legislation and how we process your information, please visit the Data Protection Notice on our website at www.nhslanarkshire.scot or ask a member of staff for a copy of our Data Protection Notice.”

¹ NHS Scotland DoPS + SAMD Unlicensed and Off-label Medicines Consensus Statement Version 2 April 2014

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4. POLICY STATEMENT

The use of unlicensed medicines within NHS Lanarkshire is supported in accordance with the principles outlined below and any associated guidelines:

- 4.1 Where a licensed medicine is available, it should normally be prescribed in preference to any unlicensed alternative.
- 4.2 Where the prescribing of an unlicensed medicine is consistent with advice provided within current and recognised good practice guidelines then no further authorisation or consent will be required, for example paediatric prescribing consistent with the current BNF for Children, palliative care prescribing consistent with current NHS Scotland Palliative Care Guidelines etc.
- 4.3 There is an acceptable evidence base to support use and the risk-benefit assessment for the patient, or patient group, is in favour of prescription of the unlicensed medicine.
- 4.4 The Unlicensed Medicine Request Form will provide a mechanism for prescribers to seek approval for the use of either an unlicensed medicine or the off-label use of a licensed medicine in an individual patient or specified groups of patients.

5. LEGISLATION

The manufacture and sale or supply of medicines is controlled by national and EU legislation. This ensures that medicines are safe, effective and of the appropriate quality. In the UK this is regulated by the Medicines Act, 1968, which has been amended to comply with EEC directive 65/65/EC. This directive states that no relevant medicinal product may be placed on the market unless a marketing authorisation (formerly called a product licence) has been issued. This marketing authorisation (MA) details the indications for which the product is licensed and can be marketed. It also defines the form, dose, route of administration for the medicine and the container in which it is supplied. The summary or product characteristics only apply to licensed indications and doses. A pharmaceutical company cannot promote an unlicensed medicine or a licensed medicine for an unlicensed indication.

6. DEFINITIONS

- 6.1 **Licensed medicines** are medicines with a UK marketing authorisation. When prescribed within the terms of the marketing authorisation the manufacturer is likely to be found liable for any harm caused by that medicine.
- 6.2 **'Off-label'** medicines are medicines with a UK marketing authorisation, which are prescribed for a therapeutic indication outside the terms of its UK marketing authorisation, for example an unlicensed indication, or via a different route, or at a higher/ lower dosage, or in a patient group not covered by the marketing authorisation. If a patient is harmed by such use of a medicine then the manufacturer is unlikely to be found liable, unless the harm is directly attributable to

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an actual defect in the medicine, rather than the way in which it was prescribed.

6.3 **Unlicensed medicines** are medicines, or substances used as medicines without a UK marketing authorisation and include:

- Medicines prepared by a UK manufacturer but not for sale in the UK and may include medicines undergoing clinical trial, medicines awaiting a UK marketing authorisation, medicines withdrawn from the UK market, or medicines manufactured for export. Such medicines may be available from the manufacturer on an “individual named patient basis”.
- Medicines prepared out with the UK with a marketing authorisation from the country of origin and imported into the UK.
- “Specials” obtained from a hospital or commercial supplier with a manufacturer’s “specials” licence. Such medicines can be supplied against an unsolicited order or prescription.
- Extemporaneously dispensed medicines prepared for a specific patient under the supervision of a pharmacist in accordance with a practitioner’s prescription, including TPN compounding, IV additive & cytotoxic reconstitutions.
- Re-packed medicines. These are medicines which are removed from their original containers and re-packed during dispensing or ward stock “pack down” procedures.
- Chemicals used to treat rare metabolic disorders.

Some of the examples above are common practice (e.g. repackaged medicines) and raise little concern for prescribers or patients, whereas others, though sometimes accompanied by published evidence of efficacy, raise concerns over unfamiliarity with prescribing, quality assurance and liability.

7. RISK ASSESSMENT OF UNLICENSED MEDICINES

To manage the risk from the use of unlicensed (and off label) medicines a system has been adopted to risk assess and formally approve the use of these medicines. Prior to approval being given for an unlicensed medicine to be used for the first time, a clinical risk assessment is carried out. A number of factors are taken into consideration when undertaking the risk assessment and include, for example, the evidence base for its use, the route of administration of the medicine, the patient group where it is to be used, the supplier, manufacturing process, product packaging and labelling etc.

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The medicine will be categorised as below:-

Category Description	Risk Category
White	Exempt
Green	Low
Yellow	Medium
Red	High
Double Red	Special cases assessed to be a particularly high risk to patients e.g. imported products labelled in a foreign language

In the event of clinician wishing to prescribe an unlicensed medicine which pharmacy does not think appropriate, arbitration will be required. In the first instance, the site manager / lead clinical pharmacist will be involved. The clinical director may also be contacted to review the suitability of the request. In the event of an agreement not being reached, the request and associated information is forwarded to the Area Drug & Therapeutics Committee (ADTC).

8. REQUESTS

Where the prescribing of an unlicensed medicine is consistent with advice provided within current and recognised good practice guidelines then no further authorisation or consent is required, for example paediatric prescribing consistent with the current BNF for Children, palliative care prescribing consistent with current NHS Scotland Palliative Care Guidelines etc.

- 8.1 Requests to use an unlicensed medicine should be made by the prescriber using the Unlicensed Medicine Request Form to seek approval. Unlicensed medicine request forms are available via FirstPort and from pharmacy. A request form should be completed:-
- each time a new unlicensed medicine is required
 - each time a different consultant wants to use the same product for the same indication unless the original application was submitted and signed by a named group of consultants.
 - when an existing unlicensed medicine is to be used for a different indication, or different dose than previously approved.
- 8.2 The requesting clinician is required to prepare a treatment protocol, particularly if the care of the patient receiving a non-licensed drug is to be shared with the General Practitioner.
- 8.3 This process is endorsed by the ADTC and appeals are dealt with by the ADTC.

9. RESPONSIBILITIES

With a licensed medicines for a licensed indication if an untoward incident occurs as the result of a product defect, or a problem with its use in an approved clinical situation (as defined in the marketing authorisation) any liability arising may in part or whole be transferred to the holder of the marketing authorisation.

However should a patient suffer harm as a result of the effects of an unlicensed / off-label

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medicine then the manufacturer is not liable and either the prescriber or the pharmacist may be liable. Any legal action may also involve NHS Lanarkshire as a result of employer's vicarious liability if staff are acting within NHS Lanarkshire policy.

9.1 Prescriber Responsibilities

Where it is intended that prescribing of an unlicensed or off-label medicine initiated in secondary care will be continued in primary care clear arrangements must be agreed between primary and secondary care regarding clinical and prescribing responsibilities. The Consultant recommending the unlicensed medicine is responsible for ensuring that sufficient information about the product and its availability is provided to allow safe and appropriate prescribing. There may be occasions where retention of prescribing responsibility within secondary care may be considered or required.

- 9.1.1 Initiation of treatment using unlicensed medicines must be undertaken by the consultant, or a specialist registrar, or a specialty doctor of the consultant responsible for the care of the patient.
- 9.1.2 Subsequent prescribing may be carried out by the consultant or fully registered medical staff or a supplementary prescriber under the guidance of the initiating consultant.
- 9.1.3 Independent non-medical prescribers may prescribe unlicensed and off label medicines where it is accepted clinical practice or, for high risk off label prescribing, within an approved protocol.
- 9.1.4 Supplementary prescribers may prescribe unlicensed medicines within an approved clinical management plan
- 9.1.5 Unlicensed / off-label medicines should only be used where the use is clearly justified and the clinical / pharmaceutical benefits are considered to outweigh any risks involved.
- 9.1.6 A practitioner prescribing an unlicensed product, or a licensed product for an unlicensed indication, does so on his/her own responsibility. They are professionally accountable for this judgement, and may be called upon to justify their actions. Prescribers should satisfy themselves that they could obtain a professional body of support for their practice in relation to the use of the unlicensed product.
- 9.1.7 Prescribers have a responsibility to advise the patient that they are being treated with an unlicensed / off-label medicine. The prescriber should provide the patient with accurate and clear information that meets their needs, including information on side effects.

For use of an unlicensed medicine the prescriber should obtain written informed consent from the patient/carer. Patients will be asked to sign a duplicate consent form once the therapy has been explained; one copy is retained in the medical notes and the second copy sent to pharmacy with the prescription.
- 9.1.8 Other staff involved in the treatment of a patient with an unlicensed/off-label medicine should be made aware of its unlicensed/off-label status; risks involved and be given information on how to administer the product safely.
- 9.1.9 In clinical areas where there is a requirement for high levels of usage of such

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medicines (e.g. neonatal units, intensive care units) staff should be fully aware of the issues.

9.2 Pharmacy Staff Responsibilities

The use of unlicensed medicines is the joint responsibility of the prescriber and the ordering pharmacist. When procuring unlicensed medicines, the ordering pharmacist is considered to be the manufacturer and is responsible for the quality of the medicine.

9.2.1 A pharmacist will share responsibility:

- As the purchaser of the product, particularly where this involves specifying the product to be purchased;
- If his/her actions or omissions have contributed to the harm

9.2.1 Pharmacy staff should ensure that the prescriber is aware that a medicine they have requested is only available on an unlicensed basis and that advice is given on alternative licensed products.

9.2.2 Pharmacy should complete section 2 of the Unlicensed Medicines Form and carry out the unlicensed medicines risk assessment.

9.2.3 The ordering pharmacist must follow the standard operating procedure for supplying and ordering unlicensed medicines. For higher risk products this includes contacting the prescriber to inform them of the unlicensed status of the medicine.

9.2.4 A pharmacist must not feel that they have discharged their potential liability where the prescriber is prepared to sign a declaration to the effect that they are accepting full responsibility for any adverse effects of the prescribed medicine. The potential liability would be shared between the prescriber and pharmacist in any event.

9.2.5 Pharmacy staff must keep purchasing and general issue records of all unlicensed medicines for a period of at least 5 years.

9.2.6 Pharmacy staff should notify prescribers about alternative licensed products becoming available where appropriate and notify clinicians of any serious problems that they are alerted to with individual unlicensed medicines.

9.2.7 Where appropriate hospital pharmacy staff should ensure that information regarding sourcing of unlicensed medicines is available so that community pharmacy is able to maintain continuity of supply post discharge.

9.2.8 If in the professional opinion of a pharmacist the use of an unlicensed medicine would be unsafe for a given patient and would not command the support of a peer group it is their professional responsibility not to supply it and seek arbitration. In the first instance, the site manager / lead clinical pharmacist will be involved. The clinical director may also be contacted to review the suitability of the request. In the event of an agreement not being reached, the request and associated information is forwarded to the Area Drug & Therapeutics Committee (ADTC).

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10. ADVICE and INFORMATION for PATIENTS (ADULT)

Prescribers have a responsibility to advise the patient that they are being treated with an unlicensed / off-label medicine. Patients must sign the patient consent form prior to initiating the treatment; a copy should be filed in the patient's medical notes and the second copy forwarded to pharmacy with the prescription. In addition, it is required that the prescriber provide the patient with accurate and clear information that meets their needs, including information on side effects.

11. ADVICE and INFORMATION REGARDING PAEDIATRICS & NEONATES

As far as possible medicines should be prescribed within the terms of their licence. However many children require medicines not specifically licensed for paediatric/ neonatal use. The BNF for Children is the preferred reference source as it provides detailed dosing information on all medicines, including those which are unlicensed or being used off label. It also lists the licensed status of each medicine so that health care professionals are aware when they are prescribing.

Attention is drawn to the Policy Statement produced jointly by the Royal College of Paediatrics and Child Health and the Neonatal & Paediatric Pharmacists Group (RCPCH/NPPG updated Dec 2013) - The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice.

"Health professionals respect the right of children and their parents to participate in decisions on the health care of the child, and seek to ensure that those decisions are properly informed. In normal paediatric practice no additional steps, beyond those taken when prescribing licensed medicines, are required to obtain the consent of patients and parents / carers for the use of unlicensed medicines"

There are circumstances when a clinician may decide to give fuller information than is usually judged necessary. These may arise when a medicine is new or experimental; or when the balance of risk versus benefit is less clear or when the concerns of some parents, carers or patients suggest a more detailed discussion is needed. In each instance, practice is guided by clinical judgement.

12. INCLUSION IN NHSL FORMULARY

Where the use of an off label medicine has become established practice within a defined patient group, who have been shown to benefit from the medicine, it may be appropriate for the Area Drugs and Therapeutics Committee to consider this medicine for inclusion in the NHS Lanarkshire Formulary for this use.

13. RESOURCE IMPLICATIONS

Resource implications of each unlicensed medicine request are considered as part of the assessment of that request.

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13. COMMUNICATION PLAN

Please contact ward pharmacist or on site pharmacy department Pharmacy for advice on use of an unlicensed medicine.

14. QUALITY IMPROVEMENT – Monitoring and Review

Pharmacy will monitor and advise on the use of unlicensed medicines on an ongoing basis

15. EQUALITY AND DIVERSITY IMPACT ASSESSMENT

This policy meets NHS Lanarkshire's EDIA

Yes

Appendix 1 - Request to Use an Unlicensed Medicine Application Form

Liability for the use of a preparation which does not have a UK Market Authorisation, or use of a product out-with its UK Market Authorisation falls to NHS Lanarkshire.

Non-licensed categories:

- Prescribing of a licensed medicine outwith the terms of its Marketing Authorisation.
- Prescribing a product which is at the pre-marketing stage or is discontinued, for a named patient on compassionate grounds.
- A drug not marketed in the UK, e.g. a 'pharmaceutical special' or it is imported from abroad at the request of a Consultant. In the case of imported medicines the supplying companies may require that separate paperwork be completed before a drug in this category can be supplied.
- A medicinal preparation, which incorporates a laboratory chemical, which has no product licence and cannot be guaranteed to be of pharmaceutical quality
- Living product for medical treatment.

Please submit your request for such a medicine by completing the section below and send it to the onsite Hospital Pharmacy Manager.

Section 1 : To be completed by the consultant assuming responsibility for the patient.

Patient Name: Ward/Clinic:

CHI Number: Multiple Patients Yes/No

Drug Name	
Strength	Formulation
Route & Dosage	
Indication	
Non-licensed category - a, b, c, d or e	
Reason why a licensed product not suitable	
Duration of therapy	
Side effects, adverse reactions, toxicity	
Other therapy already tried	
References to primary published work	

I undertake to report any adverse drug reactions to the Committee on Safety of Medicines via the yellow card scheme

I attach a copy of the treatment protocol I will give to the patient to gain patient consent and I attach a copy of the signed patient consent form.

I undertake to discuss this medicine with the patient's General Practitioner who may be asked to continue to prescribe it in the community.

Consultant's Signature - Date

Please print name here

Section 2 – RISK ASSESSMENT (To be completed by pharmacy when product not licensed in the UK)

Unlicensed / Off-label use Consensus on use Yes/ No

Manufacturer Protocol Yes/ No

Evidence base

Risk category

Preparation/ Formula –

Manufacturer / supplier –

Grade of ingredients –

Formula reference –

Stability –

Report of Quality Assurance on non-pharmacoepial standard ingredients –

Potential harmful impurities –

Storage condition / shelf life –

Pharmacist signature **Date**

In situations where there is not a clear agreement between the supplying pharmacy and the consultant requesting the unlicensed medicine this document will be presented at the Area Drugs and Therapeutic Committee for consideration and if approval is granted section 3 will be completed.

Section 3 – To be completed by the Chairman of the Drug and Therapeutics Committee

Date application received -

Recommendations -

Signature **Date**
(Chairman of the Drug and Therapeutics Committee)