Policy and procedures for the use of unlicensed medicines

Unique ID: NHSL.
Category/Level/Type:
Status: DRAFT
Date of Authorisation: 6 June 2014
Date added to Intranet:
Key Words: policy; unlicensed medicines
Comments: **Only relevant on day of printing**

Author (s): Unlicensed Medicines Short-Life Working Group
Version: 3.0
Authorised by: Area Drug and Therapeutics Committee
Review Date: June 2016

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Introduction

Legal position
The Medicines and Healthcare Products Regulatory Agency (MHRA) is responsible for ensuring that medicines and medical devices work, are safe and of an appropriate quality. The regulation of medicines in the UK market is undertaken by MHRA in accordance with the Human Medicines Regulations 2012 (SI 2012/1916).[1]

A marketing authorisation or product licence defines a medicine's terms of use. A licensed medicine has been assessed for efficacy, safety and quality, has been manufactured to appropriate high standards, and when placed on the market is accompanied by appropriate product information and labelling.[2]

Updated MHRA guidance on the supply of unlicensed medicinal products ('specials') better known as MHRA Guidance Note 14 was published in May 2014.[1] This guidance was updated following the consolidation of medicines legislation into the Human Medicines Regulations 2012 and takes into account the outcomes of relevant European court cases. It provides advice on the manufacture, importation, distribution and supply of unlicensed medicinal products for human use (commonly described as 'specials') which have been specially manufactured or imported to the order of a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber for the treatment of individual patients.

Key points from MHRA Guidance Note 14[1]

An unlicensed medicinal product may only be supplied in order to meet the special needs of an individual patient. An unlicensed medicinal product should not be supplied where an equivalent licensed medicinal product can meet the special needs of the patient. Responsibility for deciding whether an individual patient has 'special needs' which a licensed product cannot meet should be a matter for the doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber responsible for the patient's care. Examples of 'special needs' include an intolerance or allergy to a particular ingredient, or an inability to ingest solid oral dosage forms. These examples are not exhaustive.

The requirement for a 'special need' relates to the special clinical needs of the individual patient. It does not include reasons of cost, convenience or operational needs. Anyone supplying an unlicensed medicinal product, where an equivalent licensed medicinal product is available must be satisfied as to the existence of a special need for the unlicensed medicinal product. MHRA expects that documentary evidence of this special need should be obtained by manufacturers, importers or distributors and that this evidence should be made available on request of the Licensing Authority. This may take the form of a prescriber's letter, however an alternative fully documented audit trail through the supply chain confirming special need may be acceptable.

Although MHRA does not recommend 'off-label' (outside the licensed indications) use of products, if a UK licensed product can meet the clinical need, even off-label, it should be used instead of an unlicensed product.

Guidance on the hierarchy for the use of unlicensed medicines is included as an appendix. This is provided for guidance only and each case should be considered on its individual merit.

General Medical Council guidance
General Medical Council guidance[3] recommends that doctors should **usually prescribe licensed medicines in accordance with the terms of their licence. However, they may prescribe unlicensed or off-label medicines where, on the basis of an assessment of the individual patient, they conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient**. It also states that unlicensed medicines 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.

Royal Pharmaceutical Society professional standards
The Royal Pharmaceutical Society's professional standards for hospital pharmacy services[4] states that **medicines should be used in accordance with their marketing authorisations wherever possible** and that **unlicensed medicines are used only where licensed or off-label medicines are inappropriate for an individual patient's needs**. It also states that selection between different licensed options for individual patients is guided by considerations of safe use, effectiveness, tolerability and value, and that if individual clinical need cannot be addressed safely or appropriately by a licensed option, the off label use of a licensed medicine is the first alternative.

Nursing and Midwifery Council guidance
Nurse prescribers should also consider any relevant Nursing and Midwifery Council guidance, which advises that there are clinical situations when the use of unlicensed medicines may be judged by the nurse or midwife independent prescriber to be in the best interest of the patient on the basis of available evidence. Such practice is particularly common in certain areas of medicine such as paediatrics where difficulties in the development of age-appropriate formulations means that some medicines used in children are unlicensed.[5]

1.1 Liability

If an untoward incident occurs with a licensed medicine that is 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 manufacturer.

Should a patient suffer harm as a result of the effects of an unlicensed medicine then the manufacturer is not liable (unless the medicine was shown to be defective).

Prescribing medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescriber's professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines, and also inform the patient or the patient's carer that the prescribed medicine is unlicensed.[6]

Prescribers should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label. These risks may include: adverse reactions; product quality; or discrepant product information or labelling (e.g. absence of information for some unlicensed medicines, information in a foreign language for unlicensed imports, and potential confusion for patients or carers when the Patient Information Leaflet is inconsistent with a medicine's off-label use).[2]

NHS Indemnity applies to staff in the course of their NHS employment. It does not apply to independent contractors under contract for services.[7]

1.2 Definitions

Licensed medicines: 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.

Unlicensed medicines: medicines without a UK marketing authorisation and include medicines prepared by a UK manufacturer but without a UK product licence and may include medicines undergoing clinical trial, medicines awaiting UK marketing authorisation, medicines withdrawn from the UK market, or medicines manufactured for export.

'Specials': medicines obtained from a hospital or commercial supplier with a manufacturer's 'specials' licence. MHRA Guidance Note 14 provides advice on the manufacture, importation, distribution and supply of unlicensed medicinal products for human use (commonly described as 'specials'), which have been specially manufactured or imported to the order of a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber for the treatment of individual patients.[1] An unlicensed medicinal product may only be supplied in order to meet the special needs of an individual patient. An unlicensed medicinal product should not be supplied where an equivalent licensed medicinal product can meet the special needs of the patient. Responsibility for deciding whether an individual patient has 'special needs' which a licensed product cannot meet should be a matter for the doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber responsible for the patient's care. Examples of 'special needs' include an intolerance or allergy to a particular ingredient, or an inability to ingest solid oral dosage forms. These examples are not exhaustive. The requirement for a 'special need' relates to the special clinical needs of the individual patient. It does not include reasons of cost, convenience or operational needs. Anyone supplying an unlicensed medicinal product, where an equivalent licensed medicinal product is available must be satisfied as to the existence of a special need for the unlicensed medicinal product.

Off-label medicines: licensed medicines, prescribed for an indication not covered by the licence, or via a different route that is out with the terms of 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 a defect in the medicine, rather than the way in which it was prescribed.

Medicines prepared out with the UK with a licence in the country of origin: medicines imported into the UK.

Extemporaneously dispensed medicines: prepared for a specific patient under the supervision of a pharmacist in accordance with a practitioner's prescription, including Total Parenteral Nutrition compounding, intravenous additive and cytotoxic reconstitutions.

Re-packed medicines: medicines removed from their original containers and repacked during dispensing or ward stock 'packdown' procedures.

Chemicals used to treat rare metabolic disorders: chemicals used for a medicinal purpose and treated as medicines for the clinical treatment of patients; these agents have not been approved for safety, quality and efficacy; any such agents purchased for treating patients should be of an appropriate quality.

1.3 Aim of the Policy

The aim of this policy is to support medicines governance to provide safe procurement, supply and use of unlicensed medicines.

1.4 Policy Objectives

The objectives of this policy are to:

- Provide guidance on the prescribing and use of unlicensed medicines in adults and children across NHS Lothian.
- Provide support for primary and secondary care prescribers in the use of unlicensed medicines, including continuity of supply when transferring patients between the sectors.
- Describe the responsibilities of healthcare professionals when prescribing an unlicensed medicine.
- Describe the system of categorisation of unlicensed medicines and formulary classification in NHS Lothian.

1.5 Scope

This policy is applicable to patients being treated with unlicensed medicines within primary care and secondary care across NHS Lothian.

2.0 Philosophy, Principles and Objectives

This policy supports high quality, safe and appropriate prescribing across NHS Lothian in line with the Medicines Governance Strategy.[8] It describes good practice and provides support for prescribers in the use of unlicensed medicines.

3.0 Roles and Responsibilities

3.1 Patients, Relatives and Carers

Informing the specialist team, GP or other healthcare professional if he or she does not have a clear understanding of the treatment.

Reporting any adverse effects to the specialist team, GP or other healthcare professional involved in their care.

Sharing any concerns about their treatment and compliance with the specialist team, GP or other healthcare professional involved in their care.

Carers have a responsibility to support the patient in fulfilling their roles and responsibilities as outlined above.

3.2 Prescribers

Includes non-medical prescribers.[9]

3.2.1 Unlicensed medicines should only be used where their use is clearly justified and their clinical and pharmaceutical benefits are considered to outweigh the risks involved. The prescriber is professionally accountable for this judgement in so doing, and may be called upon to justify their actions. Junior medical staff should not initiate unlicensed/off-label prescribing of medicines in the red and amber formulary categories without direct consultant instruction. This could include Lothian Joint Formulary instruction or via inclusion of the medicine in an approved treatment plan.

3.2.2 Provide patients (or their parents or carers) sufficient information, including information on side effects, about the medicines being prescribed to allow them to make an informed decision.[3,10]

3.2.3 If the intention is to prescribe unlicensed medicines where that is not routine or if there are suitably licensed alternatives available, this should be explained to the patient, including the reasons for doing so.[3]

3.2.4 Some medicines are routinely used outside the terms of their licence, for example in treating children. In emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the licence. In other cases, where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population. Questions from patients (or their patients or carers) about medicines must always be answered fully and honestly.[3,10]

3.2.5 Explain the reasons for prescribing a medicine off-label or prescribing an unlicensed medicine where there is little evidence to support its use, or where the use of a medicine is innovative.[10]

3.2.6 *Secondary care prescribers:* If the unlicensed medicine is not included in the formulary, and the product has previously been used within NHS Lothian for an off-label indication, the clinician must complete (jointly with the pharmacist) a non-formulary medicine request form for an individual patient. If the unlicensed medicine has not previously been used within NHS Lothian, the clinician must complete (jointly with the pharmacist) a request form to use an unlicensed medicine (Appendix 1) for the product, in addition to completing a non-formulary medicine request form for the specific patient before the medicine can be supplied. In urgent situations, the order may be placed or the supply made and the form completed retrospectively with required signatures.

3.3 Pharmacy Staff

3.3.1 Pharmacy staff should:

- Notify prescribers of licensed alternative products becoming available where appropriate
- Notify clinicians of any serious problems that they are alerted to with individual unlicensed medicines
- Report any defect in an unlicensed medicine through the relevant reporting routes
- Ensure that individual patients are given information regarding the availability of unlicensed medicines to pass on to the community pharmacist to ensure continuity of supply.

3.3.2 Pharmacists work closely with patients and other health professionals to reach a joint decision on which treatment option best suits an individual patient's needs. This is based on the risks and benefits of each option and supported by high quality information that includes the licensed status of the chosen treatment.[3]

3.3.3 Pharmacy staff will ensure, as far as is practicable, that the prescriber is aware that a medicine they have requested is only available on an unlicensed basis, and will provide advice on alternative licensed products.

3.3.4 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. Such cases will be referred to the relevant Drug and Therapeutics Committee for local review.

3.3.5 *Secondary care pharmacy staff:* If the unlicensed medicine is not included in the formulary, and the product has previously been used within NHS Lothian for an off-label indication, the clinician must complete (jointly with the pharmacist) a non-formulary medicine request form for an individual patient. If the unlicensed medicine has not previously been used within NHS Lothian, the clinician must complete (jointly with the pharmacist) a request form to use an unlicensed medicine (Appendix 1) for the product, in addition to completing a non-formulary medicine request form for the specific patient before the medicine can be supplied. In urgent situations, the order may be placed or the supply made and the form completed retrospectively with required signatures.

3.4 Medicines Governance

3.4.1 Prescribers

Includes non-medical prescribers.[9]

3.4.1.1 When an unlicensed medicine is to be recommended for use in a patient group, and it has not previously been used within NHS Lothian, the clinician must complete a request form to use an unlicensed medicine (Appendix 1) before the product can be supplied. If the medicine is a new off-label use for a licensed product in the UK, an unlicensed medicine request form is not required.

3.4.1.2 A Formulary Application Form (FAF3) should be completed by the responsible clinician, with the support of the appropriate clinical pharmacists in the following circumstances:

- New indication for an unlicensed medicine previously in use
- New off-label indication for a licensed medicine
- Medicine not previously used that requires to be imported from another country, except where for temporary supply resulting from unavailability in the UK of a licensed product
- If unlicensed medicine is to be prescribed in both primary and secondary care

The FAF3 should be submitted to the relevant Drug and Therapeutics Subcommittee for review prior to submission to the Formulary Committee.

3.4.1.3 Other clinical staff involved in the treatment of a patient with an unlicensed/off-label medicine should, where appropriate (and particularly for unlicensed medicines in the red category) be:

- Made aware of its unlicensed/off-label status
- Informed of any problems and risks involved and how to deal with them
- Given sufficient information to administer and use the product safely and correctly.

3.4.1.4 In clinical areas where there is a requirement for high levels of usage of such medicines (i.e. neonatal units, critical care, etc.) staff should be aware of the issues surrounding unlicensed drug usage and approach the use of medicines in their areas accordingly.

3.4.1.5 General practice recommendations – the consultant recommending the unlicensed medicine use is responsible for ensuring that the GP is given sufficient information about the product and its availability to allow safe and appropriate prescribing.

3.4.1.6 Whilst the decision to prescribe an unlicensed medicine ultimately rests with the individual prescriber, it is anticipated that, in general, GPs would be expected to prescribe medicines assigned to the green category. Medicines assigned to the amber category may require a shared care approach to prescribing. GPs are not expected to prescribe medicines assigned to the red category. See section 3.5.3, below.

3.4.1.7 Adverse drug reactions and medication incidents involving unlicensed medicines should be reported in the same manner as for licensed medicines via the Yellow Card Scheme www.yellowcard.gov.uk or YCC Scotland telephone 0131 242 2919 or via www.yccscotland.scot.nhs.uk

3.4.2 Pharmacy Staff

3.4.2.1 The Royal Pharmaceutical Society's professional standards for hospital pharmacy services states that governance arrangements should be consistent with the MHRA position on unlicensed medicines.[4]

3.4.2.2 A risk assessment is undertaken to assess the quality of the unlicensed medicine, before a clinical decision is made to recommend its use in a patient population. The pharmacist must complete a risk assessment for an unlicensed medicine (Appendix 2). This will enable documentation of actions to be taken to mitigate any risks, for example over labelling of foreign labelled packages and insertion of translated information. If deemed suitable for use then after procurement the medicine must be assessed before supply to ensure that it meets an acceptable standard in accordance with the relevant medicines policies and following any additional guidance from the NHS Pharmaceutical Quality Assurance Committee[10] and the MHRA[1].

3.4.2.3 A Formulary Application Form (FAF3) should be completed by the responsible clinician, with the support of the appropriate clinical pharmacists in the following circumstances:

- New indication for an unlicensed medicine previously in use
- New off-label indication for a licensed medicine
- Medicine not previously used that requires to be imported from another country, except where for temporary supply resulting from unavailability in the UK of a licensed product
- If unlicensed medicine is to be prescribed in both primary and secondary care

The FAF3 should be submitted to the relevant Drug and Therapeutics Subcommittee for review prior to submission to the Formulary Committee.

3.4.3 Medicines Governance Committees

Secondary care Drug and Therapeutics Committees will review submissions and where deemed appropriate will forward to the Formulary Committee, who will provisionally categorise it green, amber, red or black.

In general, only new medicines or new indications for existing medicines will be assigned to one of the three categories. However medicines in current use may be considered if a specific request is made or concerns are raised, for instance, if a GP practice is asked to prescribe an existing unlicensed medicine for the first time.

Category	Proposed Prescribing Status Within Lothian
Green	**Unrestricted general use** Used widely and in accordance with a respectable, responsible body of professional opinion.
Amber	**General use with restrictions** Use has been evaluated by a secondary care Drug and Therapeutics Committee, the Formulary Committee and the General Practice Prescribing Committee (GPPC), and its use has been authorised as being 'acceptable'. May require a shared care arrangement. Local use has peer group support.
Red	**Specialist use only** Limited evidence of efficacy available. Rarely used or may have serious potential side effects requiring close supervision. Medicines categorised as red will be placed on the approved medicines list for hospital specialist use only.
Black	**Not approved for use**

If appropriate (**green** or **amber**), the submission would be forwarded to the General Practice Prescribing Committee (GPPC) for consideration. GPPC would either endorse the proposed category or discuss the submission further with the Formulary Committee before agreeing the category. For some medicines categorised as **amber**, a request for a shared care arrangement may be made.

All medicines categorised **green**, **amber** or **red** are placed on an approved list of unlicensed medicines. A table of current Lothian Formulary recommendations is available on the Lothian Joint Formulary website.

The ADTC endorses this process and manages appeals from prescribers.

4.0 References

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10. Guidance for the purchase and supply of unlicensed medicinal products notes for prescribers and pharmacists. NHS Pharmaceutical Quality Assurance Committee. June 2004: Third edition.

5.0 List of Appendices

Appendix 1 Request Form to use an Unlicensed Medicine
Appendix 2 Risk Assessment Form for an Unlicensed Medicine
Appendix 3 Members of Short-Life Working Group
Appendix 4 Medicines Governance Committees involved in Consultation

Appendix 1

NHS Lothian – Hospital Pharmacy Services

Reference No.:

Request Form to use an Unlicensed Medicine

Form Owner / initiator	

Section 1: Clinical Assessment - This section is to be completed jointly by the requesting clinician/ pharmacist

Unlicensed Medicine Details

Consultant _____ Directorate _____

Site(s) _____ Ward(s)/users _____

Product Name _____ Strength / Form _____

Manufacturer _____ Dose _____

Indication _____ Frequency _____

Route _____ Duration of Treatment _____

- Approx. no. of patient per annum _____ Approx. total annual cost _____
- Where medicine is required for an individual patient, record CHI number _____

NHS Lothian ULM category (refer to Annex 1 of this form): Category 1 ☐ Category 2 ☐

Why is an unlicensed medicine being considered? (Indicate as appropriate)

Pharmaceutically Equivalent Licensed product temporarily unobtainable ☐
Equivalent UK Licensed unavailable / unsuitable ☐
Other (give details) ☐

Is the product completely new to NHS Lothian? Yes / No

Is the product for a clinical trial? Yes / No

Clinical Evidence

Is there any evidence to support its use for the proposed indication? Yes / No

- If not, is there evidence to support its use in other indications? Yes / No

Is there evidence to support its proposed administration schedule? Yes / No
Is the active drug currently in a UK licensed product for use via the same route? Yes / No
Is the product licensed for the specific indication in an EU member state? Yes / No / Unknown
Is the product licensed for the specific indication in a non-EU member state? Yes / No / Unknown
Has the prescribing consultant used this medicine before Yes / No
Are other centres using this medicine for the proposed indication? Yes / No / Unknown

- If so, name _____

Summarise the supporting evidence, list references and attach copies if available

Request Form to use an Unlicensed Medicine

Section 1: Clinical Assessment (continued)

What are the risks to the patient of NOT using this drug?

What side effects or toxic effects have been reported?

Are there any significant interactions?

Give details of contraindications and any other risks to the patient

Will there be any primary care implications e.g. shared-care scheme

Pharmaceutical Precautions / Precautions in Use

Stability information / Manipulation in pharmacy re: Health & Safety

Request Form to use an Unlicensed Medicine

Section 1: Clinical Assessment (continued)

Authority for prescribing for SpR Yes / No

Authority for prescribing by Junior Medical Staff Yes / No

I have read the NHS Lothian Policy on the prescribing, procurement and supply of unlicensed medicines, (available on NHS Lothian intranet) and accept full responsibility for its use.

Requesting Consultant (PRINT)_____

Signature: _____ Date:_____

In the case of a category 1 ULM (see Annex 1) for one off use for an individual patient or for the routine use for a patient group a "blanket" approval is made by the clinical director for the CMT.

Where the product is a category 2 ULM (see Annex 1) for use by an individual patient approval is made by the clinical director for the CMT.

In the above two cases once approval is given by the clinical director for the CMT then approval can be given by the Site Lead pharmacist to procure the medicine.

Where the product is a category 2 ULM (see Annex 1) for routine use for a patient group a "blanket" approval is made by the clinical director for the CMT and a FAF3 application must be made to the local hospital Drug and Therapeutics Committee then forwarded to Formulary Committee before approval to use can be granted.

Clinical Director Name (PRINT): _____

Signature: _____ Date:_____

Responsible Clinical Pharmacist Name (PRINT):_____

Signature: _____ Date:_____

For those ULMs requiring FAF3 approval:

FAF3 completed by (PRINT Name)**:** _____

Position:_____ Date submitted**:**_____

Until the FAF3 is approved by the Formulary Committee section one of this form must be completed for each patient who will be prescribed this medicine.

Request Form to use an Unlicensed Medicine

Section 2: Procurement & Quality Assurance Details – This section is to be completed jointly by stores and the requesting pharmacist. Advice can be sought from QAS.

Unlicensed Medicine Details

Product Name _____ Strength / Form _____

Manufacturer _____ UK Special / Import (delete as appropriate)

Quantity Required _____ Quoted Lead-Time _____

Procurement Details

Is the medicine to be obtained from (indicate as appropriate):

- An NHS "Specials" Manufacturer ☐
- A Licensed Importer ☐
- A commercial "Specials" Manufacturer ☐
- A company which already has licensed products of the same active ingredient ☐
- A licensed pharmaceutical wholesaler ☐
- A Registered Pharmacist ☐
- Other (provide details):

For UK "Specials":

Name of Supplier _____ ML Number _____

Is a Batch-Specific Certificate of Analysis available? Yes / No

Is a Product Specification available? (If yes, attach a copy) Yes / No

- If no, then a full product spec will need to be drawn up (contact QAS on ext 32341)

Is a Certificate of Conformity available Yes / No

Is GMP compliance available Yes / No

For Imported Products:

Name of Supplier _____ Manufacturer _____

Imported Medicine PL Number _____ Country of Licence _____

Is this country within the EU Yes / No

- If no, does this country have mutually recognised agreement with the UK for the manufacture of medicinal products Yes / No

Is a certificate of TSE compliance available? Yes / No

Is an English Translation of the SPC available? Yes / No

- Who will provide the translation _____

Is an English Translation of the Patient Information Leaflet available Yes / No

Are the Translations Certified? Yes / No

- If yes, by whom? _____

Is there a Technical Services / Medicines Information department Yes / No

Are there any problems associated with continuity of supply? Yes / No

If so describe;

Request Form to use an Unlicensed Medicine

Section 2: Procurement & Quality Assurance Details (continued)

Provide details of any additional information required by supplier / manufacturer e.g. consultant letter

What are the costs involved in obtaining this drug?

Provide details of any storage conditions or labelling issues

Are there any changes in the excipients compared to UK available alternative?

Clinical Pharmacist/Stores Signed Off by (PRINT Name)_____

Signature: _____ Date:_____

Section 3: Quality Assurance/Risk Assessment Details - For completion by ULM Officer, Medicines Information Pharmacist or QAS

Quality Control / Quality Assurance issues

Risk Level Assigned (LOW 0 - 5 : MED 6 - 14 : HIGH 15 - 36)

Reasons for Risk Level Assigned (and details of control mechanism, if required)

Signed Off by (Print name)_____ Signature _____ Date_____

Approval to procure

Approved / Not approved

Site Lead Pharmacist:_____

Signature: _____ Date: _____

A copy of the completed ULM request form should be sent to Formulary Implementation Pharmacist at Pharmacy Department, RIE.

Risk Assessment Form for an Unlicensed Medicine

Product Name _____ Manufacturer_____ Strength/Form_____

RISK LEVEL ASSIGNMENT: SCORING GUIDELINES		
Supplier		
MHRA licensed importer with full Pharmacovigilance in QMS (IDIS)	1	
Known NHS Unit with QA managed by qualified person or pharmacist	1	
Other NHS Specials Unit (not local)	2	
Commercial Specials Manufacturer (UK)	2	
Supplier **not** manufacturer (e.g. wholesalers)	3	
Registered Pharmacy (extemporaneous preparation)	4	
Origin		
UK manufacturers with Specials licence	0	
EU / USA / Canada / Australia / NZ and licensed in country of origin	1	
Elsewhere - licensed in country of origin	3	
EU / USA / Canada / Australia / NZ and **not** licensed in country of origin	3	
Elsewhere e.g. China, India and **not** licensed in country of origin	10	
UK Registered Pharmacy (extemporaneous preparation)	10	
Certification		
Full analytical report available	0	
Fully licensed product with EMEA / PL number (Imports)	1	
Certificate of Analysis and GMP compliance available (Specials)	1	
Certificate of Conformity available product analysed (Specials)	2	
Certificate of Conformity but **no** product analysis (Specials)	3	
No Certificate available / no analysis carried out (Specials / Section 10)	4	
Documentation		
Product TSE compliant with English-translated SPC	1	
Product TSE compliant with **no** English-translated SPC	2	
UK manuf. Special/ Section 10 – product TSE compliant with no product information	2	
No product TSE compliance certification	4	
Packaging & Labelling		
English	0	
Foreign language but easy to read critical data	5	
Foreign language and **not** easy to read critical data	10	
Specification		
BP / EP / USP monograph product	0	
Other Pharmacopoeial monograph	1	
Manufacturer's specification available	2	
No external specification available	3	
Route of Administration		
Topical to intact skin (non-sterile)	0	
Mucous membranes, broken skin, oral (non-sterile)	1	
Sterile all routes except intrathecal	2	
Sterile intrathecal	3	
Therapeutic Agent		
Established therapeutic agent - no special problems	0	
Recognised therapeutic agent - minor problems or little experience of use	2	
Novel therapeutic agent of unusual use	4	
Unrecognised therapeutic agent with some supporting information for use	6	
Unrecognised therapeutic agent with no information available	10	
Recognised therapeutic agent with known problems	10	
Products containing material of animal or human origin	10	
Total Score		
LOW	**0 to 5**	
MEDIUM	**6 to 14**	
HIGH	**15 to 44**	

Risk Level Assignment Signed Off by: _____ Position:_____

ANNEX 1

Category 1 unlicensed medicines include the following:

i.) A licensed medicine packaged into a pack size not otherwise available e.g. take home packs issued from clinics and Accident and Emergency departments or an overlabelled licensed medicine.
ii.) A licensed medicine formulated into a ready to use presentation to save time and reduce risk e.g. potassium chloride infusions, dose banded syringes of chemotherapy.
iii.) Different presentations of licensed medicines as long as the concentration or dose unit is within recommended limits, and the route of administration remains unchanged e.g. some preservative free eyedrops.
iv.) Ingredients for preparations dispensed in the pharmacy e.g. for total parental nutrition solutions.
v.) Equivalent unlicensed medicines preparations that must be sourced during situations of temporary supply problems with licensed medicines in the UK.
vi.) Previously licensed preparations, where the licence has been allowed to lapse because the product is not commercially viable.
vii.) An unlicensed medicine purchased as a result of unavailability of the licensed product in the UK.

Category 2 unlicensed medicines include the following:

All other unlicensed medicines including “named patient medicines”, compassionate use medicines, chemicals used for example to treat rare metabolic disorders.

Appendix 3
Members of Short-Life Working Group

Mr Ommar Ahmed	Specialist Clinical Pharmacist, Royal Edinburgh Hospital
Ms Melinda Cuthbert	Lead Pharmacist, Lothian Medicines Information Service and Yellow Card Centre Scotland
Ms Anne Gilchrist	Lead Pharmacist, Medicines Management Team
Dr Simon Hurding	Medicines Management Adviser, Medicines Management Team
Mr James McDade	Principal Pharmacist, Quality Risk and Governance Services
Ms Dawn Owen	Primary Care Pharmacist

Appendix 4
Medicines Governance Committees involved in Consultation

Committee	**Date discussed**
General Practice Prescribing Committee	11 Feb 2014
Formulary Committee	26 Feb 2014
Hospital and Specialist Services Medicines Committee	12 Mar 2014
Medicines Policies Subcommittee	20 Mar 2014
Cancer and Therapeutics Advisory Committee	24 Mar 2014
Paediatric and Neonatal Drug and Therapeutics Committee	27 Mar 2014
University Hospitals Division Drug and Therapeutics Committee	23 Apr 2014