Unlicensed Medication (use of) policy

Classification :	Policy
Authors Name:	Helen Chadwick
Authors Job Title:	Clinical Director of Pharmacy
Authors Division:	Core Clinical
Departments/Groups This Document Applies to: All clinical areas where unlicensed medicines are prescribed, procured and administered	
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Scope: staff who prescribe procure or administer unlicensed medication	**Document for Public Display:** No	

To be read in conjunction with the following documents:
Milton Keynes Trust Medicines Management Policy

Terms of Reference Milton Keynes Prescribing Advisory Group

The Medical, Nursing and Pharmaceutical professional bodies each provide guidance for their members on the use of unlicensed medicines and registered health professionals should ensure they are compliant with this guidance.

Required CQC evidence? Regulation 12 Safe care and Treatment & 17 Good Governance; Health and Social Care Act 2008 (Regulated Activities) Regulations 2014	**Key CQC Question:** Safe Well-led

Disclaimer

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.

The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with** the prescriber.

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Policy Statement

This policy will provide information on the range of unlicensed medication available and promotes compliance with national guidance relating to the medico legal issues associated with the issue of unlicensed medicines.
The policy aims to support the prescriber in the use of these medicines within a clinical governance framework designed to provide a structured evaluation of the risks and benefits.
Through this policy the Trust will ensure that appropriate systems are established and maintained in order to reduce the risk posed to patients, prescribers and pharmacists by unlicensed medicines.
Where such systems have been applied in accordance with this policy, the Trust will accept liability for the use of medicines that do not have UK marketing authorizations granted by the Medicines and Healthcare products Regulatory Agency (MHRA) or European Agency for the Evaluation of Medicinal Products (EMEA). In all other situations, where unlicensed medications are used without express approval of the Trust as set out in this policy, liability for harm will rest with the individual prescriber and pharmacist involved.

Executive Summary

This policy is applicable to all healthcare professionals involved with the prescription, administration, storage and supply of unlicensed medicines. This policy does not relate to licensed medicinal products which have MHRA or EMEA marketing authorisation for use in the UK even when used for treatment outside the stated licensed indications (off-label use). In this case refer to separate policy statement.

Flow chart for Requesting Unlicensed Medicines

Consultant identifies a need for an unlicensed medicine to be available for use within the Trust

↓

Conducts risk assessment and establishes benefits over licensed medicines available. Discusses with colleagues within specialty including specialty pharmacist to identify:

- where the medicine has benefits over established treatments and a possible place in therapy including criteria for consideration before selecting for a specific patient
- Possible source and the quality of the manufacture process
- The financial impact for the division should the medicine be procured

↓

Request form (Appendix3) and supplementary information regarding evidence for use, risks and procurement risk assessment sent to Joint Milton Keynes Prescribing Advisory Group (MKPAG) for consideration and risk category assigned.

↓

Unlicensed Medicine Categorised:

Low risk: Medicine procured, held in pharmacy and dispensed when criteria met

High risk: Medicine considered as having significant risks and restricted to consideration only on an individual patient basis.

Medicine not categorised and not supplied due to

- Insufficient information or evidence and need not proven
- Licensed alternative available and need not proven.

Normal methods for appeal via MKPAG to be used where necessary.

1.0 Roles and 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 responsible for the quality of the medicine.
Wherever an unlicensed medicine is prescribed, the prescriber is **professionally accountable** for this decision and must be able to justify this decision.
The Chief Pharmacist is responsible for ensuring there are processes in place to identify unlicensed medicines and that there is a framework for risk assessment. The Chief Pharmacist is also responsible for ensuring there is a process for risk assessment of suppliers of unlicensed medicines. The procurement role also includes reviewing costs and determining if they represent a financial risk to the Trust.

The pharmacist providing a clinical review of the prescription should highlight to the prescriber and the nurse the nature of the license if not already aware to ensure that all involved are aware of the unlicensed status of a medicine

If a patient is harmed by a defective medicine, whether licensed or unlicensed, then the supplier of that medicine is liable for the harm. If the supplier can identify the manufacturer of the medicine, then liability passes to the manufacturer.
If the medicine has been prepared by or under the supervision of a pharmacist, then that pharmacist is liable for the harm, as the manufacturer of the medicine. In the case of MKHFT pharmacy accountability rests with the Chief Pharmacist.

Furthermore, if the medicine has been procured from a 'Specials' manufacturer, then the pharmacy that placed the order is considered IN LAW to be the manufacturer and is liable as such.

2.0 Background

The term 'unlicensed medicine' is normally applied to those medicines which do not have a UK Marketing Authorisation (MA), formerly a Product Licence (PL), granted by the MHRA or EMEA.

The vast majority of medicinal products used within the Trust do have the appropriate Marketing

Authorisation and wherever possible licensed products will be the preferred choice.
There are, however many occasions where the use of an unlicensed medicinal product is clinically appropriate or essential and in the patients' best interests and for these reasons the use of unlicensed medicines is widespread in hospitals. It is important that such use continues, since if this practice were to be curtailed, the treatment of many patients would be impeded. It is essential however that all prescribers and pharmacists should be aware of the associated medico-legal implications of such practice.

Unlicensed medicines are not illegal. However, the use of unlicensed medicines poses risks to patients, prescribers and pharmacists involved which need to be identified and evaluated. Whilst a licensed product is subject to stringent controls by the MHRA or EMEA, neither the prescriber nor pharmacist can make the same assumptions of quality, safety and efficacy about unlicensed products.

It is not always possible to know why a product has not been licensed, it may be with regard to undisclosed animal toxicology but equally if may be for a variety of other reasons.

Unlicensed medicines fall into a number of different categories. These are described below in order to provide a full background. It is key that the category in which a selected medication is placed is recognised as each category carries with it a different degree or clinical and organisational risk.

2.1 Types of Unlicensed medicines
Unlicensed Medicines are divided into two sections

Section 1
2.1.1 Medicines prepared by a UK manufacturer but not on sale in this country.
Such medicines may be manufactured for export or may have been withdrawn from the UK market for commercial reasons.
It is usually possible to obtain supplies of these medicines from the manufacturer or through a specialist importer.

2.1.2 Imported medicines
These medicines may have a full product licence in an EU or non-EU country but do not have a licence in the UK. They are often imported directly from the manufacturer or through a specialist importer.

2.1.3 Orphan Products
Orphan medicinal products are for diagnosing, preventing or treating rare life-threatening or very serious conditions that do not affect more than 5 in 10,000 persons in the European Union. Pharmaceutical companies unwilling to develop such products under normal market conditions are able to apply for marketing authorization for orphan designation; hence the product does not have a full product licence.

2.1.4 Compassionate Use Medication
This may be a product used in a clinical trial or awaiting the grant of a licence or through an early access scheme.

Section 2
2.2.1 Medicines prepared for a patient in accordance with a prescriber's instructions.
This broadly includes any form of extemporaneous preparation and dispensing including: preparation of liquids, Total Parenteral Nutrition (TPN) compounding, intravenous additive and cytotoxic reconstitution services. Pharmacy departments are exempt from the need to hold a Manufacturing Licence as long as certain criteria are adhered to.

2.2.2 Unlicensed Medicines obtained from a hospital or commercial supplier with a Specials Manufacturing Licence.
These medicines are widely known as 'Specials'. They can be supplied against an order or prescription by a hospital manufacturing unit or commercial manufacturer holding a 'Specials' Manufacturing Licence. Such units would be subject to inspection by MHRA.

2.2.3 Re-packed Medicines.
The Product Licence for a medicine regulates not only its formulation and manufacture but also the container in which it is sold. When a medicine is removed from its original container and re-

packed, either during a dispensing operation or for the assembly of small packs for use as ward stocks, it technically becomes an unlicensed product (the term de-licensed is often used). Such operations can be performed 'in-house' on a small scale or can be commissioned from a unit holding a 'Specials' Manufacturing (Assembly) Licence.

2.2.4 Non-medicinal classification.
Items not classed as medicines by the MHRA do not hold a product licence and will be classified as lower risk medicines e.g. white soft paraffin/liquid paraffin equal parts. Homeopathic or unlicensed herbal remedies brought into the hospital by patients are not addressed by this policy and the Trust medicines management policy should be followed in this situation.

The degree of risk encountered will vary depending upon the circumstances in which a medicine is used. A medicine that has had its license revoked or suspended is likely to provide a greater risk than one that is unlicensed simply because of commercial reasons.
Wherever possible licensed medicines are the preferred choice as unlicensed products are not intended for routine ongoing use. Where a licensed alternative exits it should always be considered in preference to the unlicensed product.
As described above for the range of unlicensed medications available it is possible to conclude that not all unlicensed medicines confer the same level of risk. The process for the use of unlicensed medication within the Trust is specifically intended to identify and manage high risk use and also provide the necessary level of documentation for all categories.

Clinical Trial medication although unlicensed will be covered by a separate policy and procedure

2.3 Supporting Information and Guidance

In a number of cases the unlicensed medicine may be for part of an established treatment strategy and dose information is included in the British National Formulary. When this is the case the medicine is annotated as unlicensed.

The National Institute for Health and Care Excellence (NICE) acknowledges that unlicensed and off-label medicines have a valuable role in the care of certain patients when there are no suitable licensed medicines available which meet their needs but that information for healthcare professionals and patients to decide whether these medicines are safe and effective, and when they are most likely to yield good patient outcomes, can be difficult to find. NICE produces 'Evidence summaries: unlicensed and off-label medicines' (ESUOMs) which are developed to provide information for clinicians and patients to inform their decision-making and support the construction and updating of local formularies. The strengths and weaknesses of the relevant evidence are critically reviewed within each ESUOM. Importantly, **an ESUOM does not constitute formal NICE guidance** and this is clearly stated on each publication.

The Medical, Nursing and Pharmaceutical professional bodies each provide guidance for their members on the use of unlicensed medicines and registered health professionals should ensure they are compliant with this guidance.

3.0 Implementation and dissemination of document

This document is to guide nurses, midwives and medical staff within the ward areas in line within national and Trust guidance and policies

This document will be published on the Trust intranet following ratification. The information will be cascaded through clinical forum and ward/department meetings.

An e-mail with link to the Policy location will be circulated to all acute user groups within the Trust.

All healthcare staff will be made aware of the document on induction, either through the mandatory Medicines Management training (doctors, most registered nurses/midwives and pharmacy staff) or through their line managers if medicines use is to form any part of their work for the Trust.

4.0 Processes and procedures

A list of unlicensed medications currently in use within the Trust together with a risk assessment based on safety, quality and clinical efficiency will be held within the Pharmacy Department. This list will be reviewed on an annual basis through the procurement process to check whether a licensed alternative is now available. Should a licensed alternative become available outside the audit period, prescribers will be alerted so that a review of current prescribing practice can be undertaken. Routine statistics will be provided to the Medicines Safety Group on quantities of unlicensed medicines used, in order to highlight any unusual variances.

4.1 New Requests

New unlicensed medicines from section 1 should only be introduced following a clinical risk assessment and approval through the MK Prescribing Advisory Group (MKPAG).

The Consultant requesting the medicine should complete the risk assessment form Appendix . The procurement of a new unlicensed medicine will take longer than a standard medicine and the level of urgency for the medicine should be communicated to the pharmacy department at the time of the request.

Where the unlicensed medicine is requested for consideration for a group of patients rather than a single patient then a protocol or treatment pathway should be included with the request form. Given that the prescribing of unlicensed medication confers extra responsibilities, the request form and risk assessment should provide justification that the use is in accordance with a sufficient body of medical opinion and that the decision to prescribe can withstand logical analysis. Evidence may come from peer review literature or specialist centres or NICE.

As an aid to completing the request and risk assessment form the following risk matrix is provided

Clinical Risk Matrix

Criteria	Low	Medium	High
Rationale for selection	Established practice e.g. BNF, BNF-C	Established use in specialty e.g. specialty published guidelines	Case reports, theoretical assumptions.
Therapeutic agent	Recognised therapeutic agent - minor problems and some experience of use	Novel therapeutic agent or unusual use Recognised therapeutic agent with known problems	Unrecognised therapeutic agent with some or little supporting information for use
Side effect profile	Few side-effects	Known significant side-effect profile	Product teratogenic,carcinogenic, cytotoxic or biological
Route of administration	Topical to intact skin Mucous membranes, broken skin, oral (non-sterile)	Intravenous, installation in cavity or bone, subcutaneous	Intrathaecal, epidural
COSSH data	Non specific	Specific COSHH requirements for handling	Hazardous products
Origin	UK manufacturer with specials licence, manufacture in EU/USA/Canada/Australia/ NZ and licensed in country of origin	EU/USA/Canada/Australia/ NZ and NOT licensed in country of origin Elsewhere - licensed in country of origin	NOT licensed in country of origin, UK - no specials licence
Specification	BP/EP/USP monograph product	Other Pharmacopoeia monograph, manufacturer's specification available	No external specification available
Certification	Full Analytical report available or batch specific Certificate of Analysis available	Batch specific Certificate of Conformity available	No certificate available
Supporting SPC and Patient Information	Easily available	Requirement for translation	Non available

The list is not exhaustive and an element of subjectivity is needed. Discussions are encouraged with clinical peers, Medicines Information and clinical pharmacist for the specialty.
It is recommended that discussion with the patient is delayed until after MKPAG approval and the likely time lag in supply is understood.

The risk assessment form is sent to pharmacy for processing.
At this stage a procurement risk assessment will be completed to provide information on the source and quality of the unlicensed medicines.

Further information may be sought from the requesting Consultant to aid discussions at MKPAG.

The risk assessment form will be reviewed by the Milton Keynes Prescribing Advisory Group and a risk rating of either low or high agreed.

For High risk unlicensed medicines an application/request form will be needed before each individual patient is prescribed the unlicensed medication.

Low risk no further action required the protocol treatment pathway is sufficient evidence and a new request form is only needed if the circumstances of use change, the prescription should be endorsed prior to dispensing or administration.

4.2 Procurement/Supply

The medicines in section 1 above tend to have a higher propensity for risk than those found in section 2. Although a clinical risk assessment is not required for section 2 medicines, the pharmacy procurement manager will ensure that the procurement process includes a risk assessment of the quality of the source supplier and that the pharmacy procedure for this is followed.

Medicines in section 1 will require a procurement risk assessment Appendix 4 to be completed before purchasing the medicine.
A written English translation of product information and SPC for imported products will be sourced by pharmacy.
If at any stage the supplier or source changes then a new procurement risk assessment form will be required prior to purchase.

A record of all issues must be kept in the dispensary. This will be done electronically using the pharmacy JAC stock management system. This is legally required to be kept for 5 years.
The following details must be noted;

a) Date of issue
b) Patient's name
c) Consultant's name
d) Ward or Clinic
e) Quantity supplied
f) Batch number(s)
g) Expiry date

Stored in Medicines Information

h) Information on any reported side effects/adverse effects that the individual patient has experienced

4.3 Consent of Patients, Carers and Parents

Active participation by the patient is discussions and decision making regarding the plan for their ongoing treatment should always be encouraged although it is recognised that in emergency situations this is not always possible. As part of the decision making process sufficient information should be included with regard to the nature and status of the medications considered, particularly for medicines where the use is not routine or if there are suitably licensed alternatives available giving your reasons for offering the alternative.

You must always answer questions from patients (or their parents or carers) about medicines fully and honestly.

Although no additional steps beyond those taken when prescribing licensed medicines, are required in terms of written consent of patients and parents/carers for the use of unlicensed medicines of lower risk it is advised that for high risk medicines that consent is recorded in the patient's notes, particularly for the following circumstances:

- The product is being offered in an experimental nature, but not part of an ethics-committee approved clinical trial.
- The risk of harm is significant or is unknown.
- The evidence in support of the product use is poor.
- The product has previously been withdrawn from the market because of serious toxicity problems

4.4 Unlicensed Medicines for longer term treatment

In some instances the unlicensed medicine may be considered for long term use for the patient and collaboration with patient's General Practitioner should be sought.

- If this situation is likely to be the case then early communication with the GP is needed.
- The initiating Consultant should provide full information regarding the clinical need, dosage, adverse effects, monitoring requirements and supply mechanism.
- The information should also include appropriate arrangements for ongoing review.

The GP may agree to prescribe the medication, but is not obliged to prescribe an unlicensed medicine and is entitled to refuse if they feel that he/she has insufficient information and knowledge of the medication.

Arrangements should also be put in place with the patient's Community Pharmacist to ensure continuity of supply post discharge. However, please note that it is not possible for Community Pharmacists to purchase unlicensed medicines directly from the Trust pharmacy and arrangements need to be in place to prevent gaps in treatment either through the lack of a prescription or the ability to fulfil a GP prescription.

4.5 Prescribing, Dispensing and Administration

The prescriber should in all circumstances work within their level of competence. Nurse/Pharmacist Independent prescribers can prescribe unlicensed medicines within their area of expertise and competence. Nurse/Pharmacist Supplementary prescribers are only allowed to prescribe unlicensed medicines under a clinical management plan.
Given that the healthcare professionals involved in the dispensing and administration process also have a duty of care to the patient it is advisable to annotate the prescription in such a way so that it is clear that the status of the prescription is recognised by the prescriber.

When dispensing a prescription for an unlicensed medicine the pharmacist should wherever possible provide a summary of product characteristics or equivalent information and a patient information leaflet.

Healthcare professional's administering unlicensed medicines should be satisfied they have sufficient information to administer the medicine safely and that there is acceptable evidence for the use of the medicine for the intended indication. This does not mean withholding treatment. It means actively seeking information from the prescriber and other appropriate sources.

5.0 Statement of evidence/references

General Medical Council Guidance Prescribing, Prescribing Unlicensed medicines

Royal Pharmaceutical Society. Medicines, Ethics and Practice 37, July 2013

Nursing and Midwifery Council (NMC) Standards for Medicines Management 2008

NMC Code of Conduct Professional Standards for Nurses and Midwives

Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, as amended and the Medicines for Human Use (manufacturing, wholesale dealing and miscellaneous amendments) Regulations 2005.

Drug Safety Update. Off label use or unlicensed medicines: prescribers' responsibilities. MHRA 2009; 2 (9): 6

MHRA Guidance Note 14 The supply of unlicensed medicinal products ("specials") Crown Copyright 2014
http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON413521 last accessed 27th July 2014

MHRA Consultation on unlicensed specials
http://www.mhra.gov.uk/Howweregulate/Medicines/Reviewofunlicensedmedicines/

6.0 Governance

6.1 Record of changes to document

Version number: 1		**Date:** September 2009		
Section Number	**Amendment**	**Deletion**	**Addition**	**Reason**
Folake Kufeji	New Policy for Unlicensed Medicines and Off Label use of Medicines			
Version number: 2		**Date:** September 2011		
Section Number	**Amendment**	**Deletion**	**Addition**	**Reason**
Folake Kufeji	Update			
Version number: 3		**Date:** November 2012		
Section Number	**Amendment**	**Deletion**	**Addition**	**Reason**
Folake Kufeji	Update			
Version number: 4		**Date:** January 2014		
Section Number	**Amendment**	**Deletion**	**Addition**	**Reason**
Sue Ashwell & Susan Manktelow	Separate policy for unlicensed medicines Reviewed to take account of latest MHRA guidance on unlicensed medicines use			
Version number: 5		**Date:** May 2015		
Section Number	**Amendment**	**Deletion**	**Addition**	**Reason**
Whole document, Appendix		Policy for unlicensed medicines	Appendix 3: Flowchart	New Separate Policy for Unlicensed

3		separated from policy for licensed off label medicines		Medicines and Off Label use of Medicines

6.2 Consultation History

Stakeholders Name/Board	Area of Expertise	Date Sent	Date Received	Comments	Endorsed Yes/No
Pharmacy CIG	Pharmacist and technicians	September 2010	September 2010	Jill McDonald amendments	Yes
Pharmacy CIG	Pharmacist and technicians	September 2012	September 2012	No comments	Review of policy and update to Trust template
Helen Chadwick	Clinical Director of Pharmacy	May 2015	May 2015	No comments	Review of Policy – no change
Jill McDonald	Deputy Chief Pharmacist	May 2015	May 2015	No comments	Review of Policy – no change
Olatokunbo Ogunbanjo	Deputy Chief Pharmacist	May 2015	May 2015	No comments	Review of Policy – no change
Nick Beason	Chief Technician	May 2015	May 2015	No comments	Review of Policy – no change
Alan Dutta-Plummer	Pharmacy Procurement Services Manager	May 2015	May 2015	No comments	Review of Policy – no change
Lisa Green	Dispensary Manager	May 2015	May 2015	No comments	Review of Policy – no change
Quynh Nguyen	Principal Pharmacist -Medicine	May 2015	May 2015	No comments	Review of Policy – no change
Josephine Adjepong	Principal Pharmacist -Surgery	May 2015	May 2015	No comments	Review of Policy – no change
Stephanie Brown	Principal Pharmacist – Women and Children	May 2015	May 2015	No comments	Review of Policy – no change
Dona Wingfield	Pharmacy Manager – Cancer & Aseptics	May 2015	May 2015	No comments	Review of Policy – no change
Pharmacy CIG	Pharmacist and technicians	June 2015	June 2015	Review of Policy – no change	Yes
Clinical Board		June 2015	June 2015	Review of Policy – no change	Yes

6.3 Audit and monitoring

This Policy outlines the process for document development will be monitored on an ongoing basis. The centralisation of the process for development of documents will enable the Trust to audit more effectively. The centralisation in recording documents onto a Quality Management database will ensure the process is robust.

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board
How unlicensed medicines are prescribed and identified	Prescription review	Principal Pharmacists	annually	Pharmacy CIG

6.4 Equality Impact Assessment

This document has been assessed using the Trust's Equality Impact Assessment Screening Tool. No detailed action plan is required. Any ad-hoc incident which highlights a potential problem will be addressed by the monitoring committee.

Impact	Age	Disability	Race	Gender	Religion or Belief	Sexual Orientation
Do different groups have different needs, experiences, issues and priorities in relation to the proposed policy?	No	No	No	No	No	No
Is there potential for or evidence that the proposed policy will not promote equality of opportunity for all and promote good relations between different groups?	No	No	No	No	No	No
Is there potential for or evidence that the proposed policy will affect different population groups differently (including possibly discriminating against certain groups)?	No	No	No	No	No	No
Is there public concern (including media, academic, voluntary or sector specific interest) in potential discrimination against a particular population group or groups?	No	No	No	No	No	No

Appendix 1: Request and Clinical Risk Assessment Form for an Unlicensed Medicine

Before completing this form, please consider the risk matrix in the policy and provide as much information as possible.

Please complete electronically and email to the pharmacy medicines.information@mkhospital.nhs.uk

Patient Details or Patient Group

Hospital No

Medicine Details

Generic name	
Form & Strength	
Dose/frequency/route	
Duration of treatment	

Clinical Risk Assessment

Rational for use and consequences of not using this treatment

-

Side effect profile and risks to patient

-

Please attach evidence and indicate level of urgency.

-

Clinical Risk assessment		**Categorisation of risk (Tick appropriate risk)**					
HARM TO PATIENT	Harm due to permanent or long-lasting side effects *	**5**					
	Some harm * Side effects are significant * Significant contra-indications for use *	**4**					
	No permanent harm. Some contra-indications for use.	**3**					
	No permanent harm. Side effects are transient and/or readily manageable. Some contra-indications for use.	**2**					
	None. No obvious harm likely to be caused. No obvious contra-indications for use.	**1**					
	LIKELIHOOD OF OCCURENCE		**1**	**2**	**3**	**4**	**5**
			very common (≥ 1/10)	common (≥ 1/100, <1/10)	uncommon (≥ 1/1,000, <1/100)	rare (≥ 1/10,000, <1/1,000)	very rare (<1/10,000)

I have read the Trust policy for the use of unlicensed medicines and consider the clinical benefits outweigh the risks. I understand my responsibilities in use.

Name _____

Directorate/specialty _____

Signature of consultant _____ Date _____

Appendix 2 Procurement Risk Assessment

Pharmacy to complete

Procurement details

1. Name the supplier of the unlicensed medicine

   _____

2. Where will the medicine be obtained from?
3. Is a certificate of analysis available with the product? Yes/No
4. Is a certificate of TSE compliance available with the product? Yes/No
5. Is a product specification available with the product? Yes/No
6. Is the manufacturer in the UK? Yes/No

   If No

State country	
Is this an EU country	
If no, does this country have a mutual recognition agreement with the UK for the manufacture of medicinal products?	
Does the importer have a Wholesale Dealer Import Licence?	
What is the quoted importation time?	
What quantity is to be imported?	
What language is used on the label?	
If not in English, is a translation available?	
Who will provide the translation?	
Is an English translation of the PIL available?	
Who will provide/has provided the translation?	
Are the English translations certified? By whom?	

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

   If Yes, describe

   _____

   _____

   _____

8. Any additional information required by supplier/manufacturer? Yes/No

   e.g. consultants letter

   _____

   _____

   _____

9. What are the costs involved in obtaining this drug?

   _____

   _____

   _____

10. Quality control/ quality assurance issues?

    _____

Procurement risk assessment *	Categorisation of risk	Tick as appropriate
Product obtained from a "Special's" manufacturer.	**Low**	
Preparation licensed in the EU or country with mutual recognition agreement.	**Medium**	
Preparation previously withdrawn from the UK market on safety grounds. Preparation licensed outside the EU or country with mutual recognition agreement.	**High**	

* This must be completed by a pharmacist

Details of person(s) completing the form

Procurement _____

Procurement signature _____ Date _____

Pharmacists name _____

Pharmacists signature _____ Date _____

Appendix 3 Flowchart Guidance for Pharmacy Staff

Unlicensed

Step 1
Identify the prescriber and the indication for use the check if the medicine has prior approval for use within the directorate (CSU) for this indication.

If Yes:
Endorse prescription to indicate an unlicensed medicine has been prescribed then follow standard dispensing procedure ensuring that all necessary records for unlicensed medications are maintained.

If No: Step 2
Contact senior pharmacist for the specialty or prescriber and establish

- Urgency of request
- Rationale for choice
- The reasons why a licensed alternative is unsuitable
- Evidence supporting choice
- Possible source for purchase, quantity required and provisional length of treatment

Step 3 Ensure:
Consultant has been provided with an unlicensed medicine request form

Pharmacy procurement manager is aware of timescales and is completing a risk assessment form.

Senior pharmacist has been made aware and can prioritise request for discussion at Milton Keynes Prescribing Advisory Group with, if necessary, Chairman's Action for urgently required treatments.

A senior pharmacist is coordinating the risk assessment; approval and procurement to ensure timescales are met.