

UNLICENSED MEDICINES (ULM) POLICY

(For unlicensed medicines
and licensed medicines for unlicensed use)

Approved By:	Clinical Policy and Guideline Committee
Date of Original Approved :	8 November 2004
Trust Reference:	B29/2004
Version:	6
Supersedes:	Version 5 (September 2021)
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Name of Responsible Committee/Individual :	Medical Director Medicines Optimisation Committee
Most recent review:	February 2025
Review Date:	February 2030

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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

June 2024

- Minor changes to titles

KEY WORDS

Unlicensed medicines, ULM, off label

1 INTRODUCTION AND OVERVIEW

- 1.1 UK medicines legislation requires that medicinal products be licensed before they are marketed in the UK. Accordingly no medicinal product may be placed on the market unless a Marketing Authorisation (formerly known as a Product License) has been issued by the Medicines and Healthcare Products Regulatory Agency (MHRA).
- 1.2 The Marketing Authorisation provides assurance of the safety and efficacy of the drug in relation to a specified use, which has been reviewed and accepted by an official expert body. It also defines the legal status of the product and ensures its quality, specifying the clinical condition(s), dose(s) and routes of administration for the particular preparation, all of which are detailed in the Summary of Product Characteristics (SPC).
- 1.3 Licensed products on occasion are prescribed for unlicensed uses, and although situations vary it may be that there is a recognised body of evidence in support of such therapeutic use.
- 1.4 Effective from 1st January 2021 the MHRA introduced a national Conditional Marketing Authorisation (CMA) scheme for new medicinal products. The scheme is intended for new medicines for serious and life-threatening diseases where no satisfactory treatment methods are available or where the product offers a major therapeutic advantage. A CMA license may be granted where comprehensive clinical data is not yet complete but it is judged that such data will become available soon. An example of such authorisation was the Covid -19 vaccines. The CMA is only valid for 1 year and then renewed annually. A medicine with a CMA is not subjected to the same process as unlicensed medicines.
- 1.5 Unlicensed medicinal products (commonly known as “specials”) may be used for certain patients, where there is no clinically acceptable alternative licensed product, providing there is a bona fide unsolicited order, the product is formulated in accordance with the requirement of a doctor, dentist or non-medical prescriber registered in the UK, and the product is for use by individual patients on the clinicians direct personal responsibility.
- 1.6 As unlicensed products are not subject to stringent control by the Licensing Authority, neither prescribers nor pharmacists can make the same assumptions of quality, safety and efficacy as they do for licensed medicines.
- 1.7 For good clinical reasons the use of unlicensed medicines is widespread, particularly in teaching hospitals. Many liquids which are used for patients who cannot swallow are often unlicensed preparations. Epidural or patient controlled analgesia infusion bags, not used in community settings, are also unlicensed preparations.

This policy has been prepared taking into account information and guidance from sources including:

- *National and European legislation*
- *Medicines & Health Products Regulatory Authority (MHRA)*
- *NHS Pharmaceutical Quality Control Committee*
- *The Royal College of Paediatrics and Child Health*
- *The Pain Society and the Association for Palliative Medicine*
- *The University Hospitals of Leicester NHS Trust Therapeutic Advisory Service (TAS)*
- *Department of Health, particularly Guidance on the provision of patient information with dispensed medicines and Guidance on patient consent*
- *The Leicestershire Medicines Code.*

2 POLICY SCOPE –WHO THE POLICY APPLIES TO AND ANY SPECIFIC EXCLUSIONS

- 2.1 This policy applies to all members of staff within UHL who prescribe, administer dispense or advise on medicines.
- 2.2 This policy covers the use of unlicensed medicines and licensed medicines which are used for unlicensed indications often described as 'off label' use.
- 2.3 When tablets are crushed to aid administration it alters the status from a licensed product to an unlicensed product. Please refer to Policy for administration of medicines to adult patients who cannot swallow tablets or capsules Trust reference B31/2008
- 2.4 The policy does not cover the following:
- ❖ use of pre-packs which are overlabelled unlicensed medicines Please refer to the Policy and Procedures for Supply of Pre-Pack / Over Labelled Medication from Wards B25/2009.
 - ❖ Free of Charge (FOC) medicines. Please refer to the Free of Charge (FOC) Medicines schemes UHL Policy (B61/2019)

3 DEFINITIONS AND ABBREVIATIONS

3.1 Licensed Medicine

A medicinal product which has been issued with Marketing Authorisation (formerly known as a Product License) by the Medicines and Healthcare Products Regulatory Agency (MHRA).

3.2 Unlicensed Medicine

A medicinal product which has not been given a Marketing Authorisation but is available for clinical use. The preparation will not have the stringent controls and assessments which are in place for those products with a licence.

4 ROLES AND RESPONSIBILITIES

- 4.1 The executive director responsible for this policy is the Medical Director.
- 4.2 Clinical Management Group (CMG) Senior Team, Heads of Nursing and Clinical Directors are responsible for:**
- 4.2.1 Ensuring all new and existing staff are made aware of this policy through local induction.
- 4.2.2 Ensuring compliance with any associated audit of practice
- 4.2.3 Sign off of unlicensed medicines which can be kept as ward stock within their CMG.
- 4.3 Individual Prescribers**
- 4.3.1 Whenever an unlicensed medicine is prescribed, or a licensed medicine is prescribed for an unlicensed indication, the prescriber is professionally accountable for their own judgement in so doing, and may be called upon to justify their actions.

- 4.3.2 Please refer to the General Medical Guidance (GMC) 'Good practice in prescribing and managing medicines and devices' updated 5th April 2021, [statements 103-109](#) for prescribing Unlicensed Medicines
- 4.3.3 Patients have the right to participate in the making of properly informed decisions about their health care. Patients must be informed that the treatment being prescribed is an unlicensed product or a licensed product which is being used in an off label indication, and what that means so that they can make an informed decision.

The following website is useful for medicines in children. <https://www.medicinesforchildren.org.uk/> Clinicians must consider how they will obtain consent and this must be written for the use of a high risk unlicensed medicine particularly :-

- Where this involves a new or experimental treatment (ie a product being used outside a formal clinical trial protocol),

OR

- Where unlicensed medicines that carry a significant, or unknown risk of causing serious adverse reactions, including those that have been previously withdrawn from the market because of serious toxicity problems, are prescribed.

- 4.3.4 Inadequate provision of information may increase the clinician's or Trust's liability in the event of a mishap that results in a complaint and possible litigation.
- 4.3.5 The standard patient consent form must be used to document patient consent to treatment with an unlicensed medicine considered high risk.

[Consent to Examination or Treatment UHL Policy](#)

The statement from Royal College of Paediatrics and Child Health (RCPCH) provides details about consent and use of unlicensed medicines in Children:

<https://www.rcpch.ac.uk/resources/use-unlicensed-medicines-or-licensed-medicines-unlicensed-applications-paediatric#consent-of-parents-carers-and-patients>

- 4.3.6 The repeat prescribing of unlicensed products should be managed on an individual patient basis.
- 4.3.7 General practitioners (GP) may agree to prescribe unlicensed products e.g. unlicensed oral liquid preparations for a patient where licensed tablets cannot be given, or unlicensed preservative free eye drops where a patient is allergic to a preservative in a commercial product.
- 4.3.8 The initiating UHL prescriber should advise colleagues, e.g. GP's, of the need to continue the prescribing of an unlicensed medicine. The initiating clinician must gain their agreement to prescribe and ensure the primary care prescriber is adequately informed about the medicine, how it is used, the necessary monitoring arrangements and any risk involved.

4.4 Staff administering unlicensed products:

- 4.4.1 Staff administering unlicensed products must seek advice from pharmacy staff and/or the prescriber looking after the patient, as appropriate:
- If the labelling or any instructions supplied with the medicines are unclear.
 - If they are unsure about any aspects involved in the use/administration of the medicine, its quality, likely side effects or patient monitoring required.

- The patient experiences any serious or unexpected adverse reactions.
- The patient requests further medicine specific information they do not have readily available.

4.5 Pharmacy staff

4.5.1 General

- The Chief Pharmacist and Deputy Chief Pharmacist Medicines Optimisation are designated as having responsibility for controlling the procurement and supply of unlicensed medicines throughout the Trust.
- CMG Lead Pharmacists will monitor the usage of unlicensed medicines and licensed medicines for unlicensed use within their CMG and confirm that continuing use remains appropriate.
- All pharmacy staff are responsible for ensuring that they follow the Pharmacy standard operational procedures (SOPs) and the Pharmacy Purchasing for safety policy when dealing with unlicensed medicines.
- Pharmacy staff issuing unlicensed medicines will endeavour to ensure that they are labelled clearly in English and that the users have adequate information to use them properly.

4.5.2 New Requests

- *Pharmacy staff will ensure that, before an unlicensed medicine is ordered or dispensed:*
 - There is no suitable licensed medicinal product available to meet the clinical needs of the patient
 - There is no equivalent or more appropriate unlicensed alternative already available within the Trust
 - That the use is approved by the UHL Therapeutic Advisory Service as appropriate, according to current procedures
 - The prescriber is aware of the unlicensed status of the medicine use requested.
 - The prescriber is aware of the risk status of the unlicensed medicines and the need for formal written consent for high risk unlicensed medicines.
- The CMG Lead Pharmacist and Medicines Information will be involved in producing the unlicensed medicine review of a new product for the Therapeutic Advisory Service evaluation process.
- The Unlicensed Medicines Pharmacy Technician will draw up a specification for the unlicensed medicine, to meet the requirements of the prescriber, assisted by the CMG Lead Pharmacist.
- A risk assessment for the unlicensed medicines (see appendix 1) will be completed by the Unlicensed Medicines Pharmacy Technician and placed on the pharmacy unlicensed medicines risk spreadsheet.

- The specification and risk assessment will then be presented at the Pharmacy Quality and Safety Board for approval and allocated a risk level; low, medium or high

4.5.3 **Records**

- Adequate records must be kept by pharmacy staff with regard to the purchase, preparation and the supply of unlicensed medicines. These records will meet with current MHRA guidelines and legislation.
- Records made for purchasing and issue of all unlicensed medicines must be retained for a period of at least 5 years as per the Trust Records Management Policy B31/2005 and the Pharmacy Recording Keeping SOP 229

4.5.4 **Quality Assurance**

The Pharmacy Service will take responsibility for assuring, as far as possible, the pharmaceutical quality of unlicensed products.

This will include ensuring that the product

- *complies with the agreed specification*
- *manufacturer holds an appropriate licence*
- *is labelled in English and, where available supplied with information in English to allow it to be used safely*
- *is quarantined on receipt following pharmacy standard operating procedures*
- *is certified TSE free (supplier will hold TSE free certification) – TSE free means without any possibility of contaminants for transmissible spongiform encephalopathy*

4.5.5 **Supply from Community Pharmacies:**

Where agreement has been reached for a patient's GP to continue prescribing of an unlicensed medicine commenced in the Trust, the Pharmacy Department will make available to the community pharmacy information on the source of supply of the product, together with product specification, quality assurance and risk assessment documentation, as necessary.

This will also apply to the TrustMed Pharmacy based on sites. TrustMed will have their own specifications and processes but UHL provide advice and information on products used.

5. POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS –WHAT TO DO AND HOW TO DO IT

- 5.1 Where appropriate, those involved in the prescribing, supply or administration of an unlicensed medicine must be made aware of a products unlicensed status and any known relevant risks associated with its use. This information should be provided by the Pharmacy dept. or the prescriber, depending on the particular situation.

- 5.2 The use of unlicensed medicines or licensed medicines for unlicensed indications is only justified when the clinical needs of the patient cannot be met by the use of a licensed medicinal product.
- 5.3 Wherever possible a licensed product should be used if available and one which is licensed for the indication being treated.
- 5.4 New unlicensed medicines must not be used without appropriate clinical and pharmaceutical scrutiny. Their introduction should be subject to the same level of control and processes as that for licensed medicinal products with particular attention being paid to any additional risks associated with their use. A formal review of the request as appropriate will be undertaken by the UHL Therapeutic Advisory Service (TAS)
- 5.5 The Pharmacy department will take all reasonable steps to assure the pharmaceutical quality of all unlicensed medicines introduced into use. The assessment of the quality of a product will involve the assessment of the supplier, of the product specification and of production quality assurance processes.
- 5.6 The liability for harm caused by the use of unlicensed medicines will be accepted by the Trust, providing that this policy has been followed.
- 5.7 Unlicensed medicines will be risk assessed by the appropriate pharmacists and categorised according to their relative risk potential and managed accordingly, documented on the pharmacy unlicensed medicines risk spreadsheet. (See section appendix 1)
- 5.8 A check of the status of a product will be carried out annually by the Pharmacy Procurement Team. This check will include a search to see if a licensed alternative is now available which could be used instead if the product remains unlicensed.
- 5.9 Unlicensed products are generally not to be stored in wards or departments as stock, although in some circumstances this may be necessary. For example when a product is the only treatment option available in an emergency. Clinical Directors will be supplied annually with an up to date list of products used within their CMG and will be asked to authorise that these products can be kept as stock. (See appendix 2). This does not remove the required individual prescriber's responsibilities as stated in 4.3. Additional recording processes may be required for high risk products if kept as stock.
- 5.10 Individual patients (and/or their carers/parents) must be given adequate information about any unlicensed medicines they are prescribed. A generic unlicensed medicines information leaflet is available from the Pharmacy Dept. The leaflet explains why it is necessary to prescribe unlicensed medicines and should be widely available, to help to allay any concerns that patients and carers may have

The leaflet is available on the UHL yourhealth website

<https://yourhealth.leicestershospitals.nhs.uk/library/csi/pharmacy/1011-unlicensed-medicines/file>

Leaflet for childrens use is available from:

https://www.medicinesforchildren.org.uk/sites/default/files/content-type/leaflet/pdf/Unlicensed%20medicines_0.pdf

- 5.11 Where unlicensed medicines are used, patients must provide consent to their use, according to the relative risk potential. This consent must be recorded in the patient's notes particularly for the following:

- the product is being offered in an experimental nature, but not part of a clinical trial.
- the product has been assessed as “high risk” by pharmacy
- the risk of harm is significant or 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.

5.12 Consent should be obtained for licensed medicine used outside their current marketing authorisation and recorded in the patient’s notes where the prescriber feels that its use is beyond any recognised use and with an increased potential to cause harm ie no evidence is available from literature or experience.

5.13 It is recognised that UHL, as an acute teaching hospital and tertiary referral centre, will have occasion to provide emergency and innovative therapy in life-threatening situations. This may involve the use of unlicensed medicines, which may be categorised as high risk.

5.14 To minimise the risk to other patients, problems with the use of any unlicensed medicine (e.g. product defect, problems with labelling / instructions) must be reported promptly to the Chief Pharmacist / Deputy Chief Pharmacist Medicines Optimisation / Medication Safety Pharmacist.

5.15 All suspected adverse drug reactions that occur in patients treated with unlicensed medicines must be reported to the Committee on Safety of Medicines (CSM), via Medicines Information, in the same way as for licensed medicines, using the yellow card scheme. This is in addition to reporting untoward events on UHL incident reporting forms (Datix) as per the Trust’s Incident and Accident Reporting Policy A10/2002.

5.16 Licensed medicines for unlicensed indications

- The summary of product characteristics (SPC) for a licensed product states the approved indications, doses and precautions for which the approved drug is licensed and hence the manufacturer is liable.
- There are many situations where a licensed medication may be used for an unlicensed indication. This may be outside the terms of the licence eg in children, via different routes or where licensed indications do not reflect current knowledge, including well proven usage.
- It may not always be apparent that a medicine is being used for an unlicensed indication, but if in doubt, efforts should always be made to clarify the licensing status of the medication with reference to the SPC and wherever possible, a risk assessment should then be undertaken by the clinician and pharmacist.
- To be categorised as low risk, licensed products used for an unlicensed indication must be supported by evidence of peer support for the use/indication, often by inclusion in recognised texts e.g. Medicines for Children, The BNF, The Palliative Care Formulary. The large majority of these agents will be licensed products used for unlicensed purposes in paediatrics and palliative care.
- Written consent must be obtained when the product does not have the body of evidence from peers and is considered high risk following a risk assessment. The

CMG lead Pharmacist and Head of service must be involved prior to purchasing the product.

6 EDUCATION AND TRAINING REQUIREMENTS

It is expected that staff become familiar with the practices expected by reading this policy and require no additional training.

Any staff member who identifies a knowledge gap must discuss this with their line manager and take the necessary actions to address the gap.

7 PROCESS FOR MONITORING COMPLIANCE

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Incidents due to unlicensed medicines	Medication safety Pharmacist	Datix incident reporting system	6 weekly	Reported to Medicines Optimisation Committee
Review of usage of ULM	CMG Lead Pharmacists	Use of pharmacy stock computer system	Annual	To CMG

8 EQUALITY IMPACT ASSESSMENT

- 8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
- 8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

1. *EEC Directive 65/65.*
2. *Medicines Act Leaflet 81 (MAL81), The Medicines for Human Use (Marketing Authorisations Regulations 1994) S.I. 1994/3144.*
3. *MCA Guidance Note 14, The supply of Unlicensed Relevant Medicinal Products for Individual Patients, February 2000.*
4. *Guidance for the Purchase and Supply of Unlicensed Medicinal Products, Notes for Prescribers and Pharmacists, NHS Pharmaceutical Quality Control Subcommittee, June 2004*
5. Royal College of Paediatrics and Child Health Policy statement on the use of Unlicensed Medicines or Licensed Medicines for Unlicensed Applications in Paediatric Practice, 2000.
6. Leicestershire Medicines Code.
7. Policy for the administration of medicines to adult patients who cannot swallow tablets or capsules. (B31/2008)

8. Policy for Consent to Examination or Treatment (A16/2002)
9. Free of Charge (FOC) Medicines Schemes UHL Policy (B61/2019)
10. Human Medicines Regulations 2012, regulation 60, 'conditions of UK Marketing authorisation: exceptional circumstances'
11. General Medical Guidance (GMC) 'Good practice in prescribing and managing medicines and devices' updated 5th April 2021, statements 103-109

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

The updated version of the Policy will be reviewed every 3 years, uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system

Appendix 1 : RISK ASSESSMENT FORM FOR AN UNLICENSED MEDICINE

PRODUCT INFORMATION			
PRODUCT NAME, FORM, STRENGTH, PACK SIZE			
INTENDED THERAPEUTIC USE/ REASON REQUIRED			
FOR USE AS WARD STOCK	YES/NO	SPECIALTY	
PROCUREMENT DETAILS			
UK SPECIALS		IMPORTED PRODUCTS	
NAME OF SUPPLIER		NAME OF SUPPLIER	
MANUFACTURING LICENCE NUMBER		MANUFACTURER	
DOES LICENCE COVER PRODUCT TYPE	YES/NO	COUNTRY OF LICENCE	
IS GMP COMPLIANCE AVAILABLE	YES/NO	IMPORTED MEDICINE PL NUMBER	
METHOD OF MANUFACTURE (e.g. Aseptic preparation, batch production, terminal sterilisation)		Is this on the list as a country that has a mutually recognised agreement with the UK	YES/NO
QUALITY CONTROL DOCUMENTATION AVAILABLE	C of A <input type="checkbox"/> C of C <input type="checkbox"/> QUALITY STATEMENT <input type="checkbox"/>	IS A CERTIFICATE OF TSE COMPLIANCE AVAILABLE	YES/NO
IS STERILITY TESTING CARRIED OUT	YES / NO / NA	IS AN ENGLISH PIL/SPC AVAILABLE	PIL <input type="checkbox"/> SPC <input type="checkbox"/>
IS A CERTIFICATE OF TSE COMPLIANCE AVAILABLE		IS PRODUCT LABELLED IN ENGLISH	YES/NO
OTHER INFORMATION/COMMENTS:			
PRESCRIBING AND ADMINISTRATION INFORMATION			

Mutually recognised countries:

Australia, Canada, All European Union Countries (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden), Japan, New Zealand and Switzerland

USA – is acceptable by virtue of FDA approval

Japan – mutual recognition does NOT extend to injectable products

RISK ASSESSMENT SCORE		
SUPPLIER:		
MHRA licensed importer	0	
Licensed NHS unit with QA managed by qualified person or pharmacist	1	
Commercial Specials Manufacturer	1	
ORIGIN:		
UK manufacturer with specials license	1	
EU/USA/Canada/NZ and licensed in country of origin	0	
EU/USA/Canada/NZ and NOT licensed in country of origin	4	
Elsewhere – licensed in country of origin	3	
Elsewhere – NOT licensed in country of origin	HIGH RISK	
CERTIFICATION:		
Full analytical report available	0	
Batch specific Certificate of Analysis available	0	
No certificate available (fully licensed in country of origin)	1	
Batch specific Certificate of Conformity available	2	
No certificate available	4	
DOCUMENTATION:		
Product has an English-translated SPC	0	
Product has no English-translated SPC	1	
PACKAGING AND LABELLING:		
English	0	
Foreign language but easy to read critical data	2	
Foreign language but not easy to read critical data	4	
SPECIFICATION:		
BP/EP/USP monograph product	0	
Other Pharmacopeia 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	HIGH RISK	
Recognised therapeutic agent with known problems	HIGH RISK	
Products containing material of animal or human origin	HIGH RISK	
TOTAL SCORE:		
LOW	0-7	
MEDIUM	8-12	
HIGH	13 or above	

ASSESSMENT COMPLETED BY:

NAME:..... SIGNATURE:..... DATE:.....

Appendix 2

Re: Unlicensed Medicines held as Ward Stock

The Medicines Health and Regulatory Agency (MHRA) on behalf of the UK Licensing Authority (LA) regulate medicinal products for human use in accordance with the Medicines or Human Use regulations 1994 and Medicines Act 1968.

The MHRA has issued Guidance Note No: 14 “The supply of unlicensed relevant medicinal products for individual patients” and compliance is a statutory requirement. This guidance note requires an audit trail of named patients receiving an unlicensed medicine. For unlicensed medicines held as ward stock this audit trail is not feasible. The Trust, through the use of Unlicensed Medicines Policy, has been asked to acknowledge this situation and accept liability on behalf of its employees, provided the following authorisation has been received from each Clinical Director.

I have therefore, attached a list of unlicensed medicines kept as ward stocks in the wards to which your patients are admitted. Please would you sign and return the attached form to approve the use of these medicines held as ward stock within your CMG. Should you wish to remove any items from the list, please indicate this on the list and return to the Deputy Chief Pharmacist, Medicines Optimisation at the Leicester General Hospital. A new list will then be sent to you for authorisation.

Thank you for your help in this matter.
Yours sincerely

LIST OF UNLICENSED MEDICINES ON WARD

I hereby sign that I have approved the use of the attached list of unlicensed medicines used on wards indicated:

and that all medical personnel within the CMG are aware of the legal status of these medicines.

Name of Clinical Director:

Signature of Clinical Director:

Date:

Form to be returned to:

Deputy Chief Pharmacist, Medicines Optimisation
Pharmacy Department Leicester General Hospital.
Copy to be sent to CMG

Appendix 3 : Checklist of what should be documented in case notes

Good Practice prescribing - unlicensed medicines or licensed medicines for 'off label' indication

statements taken from guidance 5 April 2021 in italics

When prescribing an unlicensed medicine, you must:

- a. be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy*
- b. take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring and any follow up treatment, or make sure that arrangements are in place for another suitable doctor to do so*
- c. make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.*

Checklist of what should be documented in case notes:

- Record the medicines being prescribed and the reason for choosing this medicine – this is for unlicensed medicines and licensed medicines used outside their license.
- Document whether you have spoken to the patient / carer about the medicines which is to be prescribed and also if you have provided the patient / carer with any information on that medicine. This may not be appropriate for all situations: -
 - *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.*
 - *If you intend to prescribe unlicensed medicines where it's not routine or if there are suitably licensed alternatives available, you should explain this to the patient, and give your reasons for doing so.*
- Document whether the patient / carer has given verbal or written consent. Written consent is essential for all 'High risk' unlicensed medicines.
- Document how on going prescribing / treatment will be delivered – if this will be provided under the care of the GP (agreed to by the GP) or if it will remain within UHL.