Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Unlicensed Medicines Policy

This procedural document supersedes: PAT/MM 4 v.4 Unlicensed Medicines Policy

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Executive Sponsor(s):	Dr Tim Noble – Medical Director
Author/reviewer: (this version)	Rachel Wilson – Deputy Chief Pharmacist
Date written/revised:	June 2021
Approved by:	Drug and Therapeutics Committee
Date of approval:	14 July 2021
Date issued:	5 November 2021
Next review date:	June 2024
Target audience:	All Clinical Staff

Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
Version 5	November 2021	• Format updated • References updated • Updated duties and responsibilities • Removed reference to "Medicines for Children" as information source • Added link to yellow card scheme • Inserted missing form in appendix 1	Rachel Wilson
Version 4	May 2017	Section 4: New section added on Special need Section 3.5.1: Added the scenario of buying in aseptically prepared preparation from a licensed unit	John Bane
Version 3	August 2014	Updated references Format updated	Roger Hancocks
Version 2	May 20211	No changes	Roger Hancocks

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1 INTRODUCTION

In the UK no medicine for human use may be placed upon the market without subjection to market authorisation (MA) or being granted a Product License (PL) by the Licensing Authority the Medicines and Healthcare Products Regulatory Agency (MHRA). In considering a licence application, the Licensing Authority gives particular consideration to the safety, efficacy, and quality of the product. This is put in place to protect the public, and ensures that the medicines on the market are of the appropriate quality. In the UK, Medicines that do not have a product licence issued by the MHRA are known as "unlicensed".

It is the policy of the Trust to use licensed medicines where these are available. However, an exemption exists to allow prescribers to use unlicensed medicines to meet the special clinical needs of a patient.

2 PURPOSE

The purpose of this policy is to describe the way the Trust manages the risks associated with the use of unlicensed medicines.

3 DUTIES AND RESPONSIBILITIES

3.1 Prescriber

Whilst prescribers will generally prescribe licensed products, the law allows them to prescribed unlicensed medicines, or use licensed products for an unlicensed indication for the special needs of their particular patient. However, in doing so, the prescriber, (and therefore the Trust), can place themselves at particular risk. This risk arises from two quarters. The first risk concerns the actions of the doctor in respect of what the patient can expect, the second concerns the quality of the product supplied.

a) Liability

The prescriber must ensure that the use of the Unlicensed Medicine is justified by the clinical condition of the patient and, where appropriate, the patient understands the implications of using an Unlicensed Medicine. Unlicensed Medicines must only be used where a special clinical need exists. Such use must be informed and guided by a respected and responsible body of professional opinion. The use of Unlicensed Medicines must be clearly justified and clinical benefits must be considered to outweigh the risks involved.

b) Negligence Liability

Doctors have a duty in common law to take reasonable care, and to act in a way consistent with the practice of a responsible body of their peers of a similar professional standing. Not to meet these standards lays them open to allegations of negligence liability.

In using an unlicensed medicine or a licensed medicine outside of its product licence, the doctor must act responsibly, and with reasonable care. It is important therefore that the doctor is aware of the licensing status of the medicine he is prescribing. It is also important that when obtaining consent for treatment the prescriber should, where possible, inform the patient of the medicine's licensed status, in terms they can understand, and that for an unlicensed medicine that its effects will be less understood than for those of a licensed medicine.

It is recognised that the prescriber may not know the licensed status of the drug to be supplied to the patient, and therefore the pharmacist has a role in identifying the status these products and bringing this to the attention of the prescriber.

c) Strict Product Liability

Strict product liability means that if a patient can demonstrate that he has suffered injury whilst undergoing a course of treatment and the medicine was defective, then he can bring an action for damages against the manufacturer of the product without needing to prove negligence. This applies to all medicinal products. In the case of a licensed product, the liability would rest with the product licence holder. However, because an unlicensed medicine cannot be offered for sale, but rather is procured or commissioned by a purchaser, the purchaser retains responsibility for the quality of the product; the manufacturer is considered to be acting as a subcontractor acting under directions.

d) Special Need Exception

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 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 therefore to the special **clinical** needs of the individual patient. It does not include reasons of cost, convenience or operational needs.

3.2 Drug and Therapeutics Committee

Drug and Therapeutics Committee are responsible for assessing all new product requests for both routine use of Unlicensed Medicines and use of Unlicensed Medicines for individual patients.

4 PROCEDURE

4.1 Risk Assessment

The degree of risk encountered will vary depending upon the circumstances in which a medicine is used. A medicine that has had its licensed revoked or suspended is likely to provide a greater risk than one that is unlicensed simply because a suitable formulation is not available. Therefore the policy provides for different degrees of control.

When a new product is requested that is unlicensed, a risk assessment will be undertaken by the Senior Clinical Pharmacist – Medicines Information (MI) before the product is purchased. Where a licensed product is knowingly used for an unlicensed indication this will also be risk assessed. It is the responsibility of person knowingly prescribing, authorising supply or administering a product in these circumstances to ask the MI pharmacist to undertake the risk assessment.

The medicine will be categorised into one of three categories detailed below. The examples described below are for guidance only. Individual assessments may place particular products in different categories, for example unlicensed use of a licensed medicine may be assessed as very low risk or conversely very high risk depending upon the circumstances.

4.1.1 Level One - Low Risk Preparations

Low risk preparations are always purchased from a trusted manufacturer or licensed within the EU or a country with a mutual recognition agreement.

1. A preparation obtained from a trusted Manufacturer with a MHRA 'Specials' license, where the licensed formulation is:
   a) Unsuitable for a particular patient or
   b) Requires reconstitution, mixing or manipulation before it is suitable for administration to a patient.
2. If the patient were able to take the licensed preparation, it would be for a licensed indication and at a licensed dose.
3. Topical dermatology preparations would normally be considered low risk.
4. A preparation commonly used in paediatric practice. Listed in the Children's BNF.
5. A preparation licensed in the EU (or a country with a mutual recognition agreement) to replace a licensed preparation temporarily unavailable in the UK.
6. A preparation where a UK license has been relinquished on commercial grounds or a low risk preparation where a license has never been sought.

4.1.2 Level Two – Medium Risk Preparations

1. Licensed preparations used outside of their licensed indications.
2. Preparation not licensed in the UK but licensed in the EU or country with a mutual recognition agreement.
3. A preparation where a UK license has never been sought.

4.1.3 Level Three - High Risk Preparations

1. Preparations which have been withdrawn from the UK market on safety grounds.
2. Preparation manufacturer outside of the EU or country with a mutual recognition agreement.

4.2 Consent

4.2.1 Level One Preparations

Low risk preparation where it is not considered necessary to take additional steps beyond those taken when prescribing licensed medicines.

4.2.2 Level Two Preparations

For these preparations the quality is assured and the side effect profiles are known. The prescriber must document in the notes the fact that the product is either being used outside of its license or has been imported. The verbal consent of the patient must be recorded in the notes. The patient should be asked to agree to notify the prescriber of any known or unknown side effects.

4.2.3 Level Three Preparations

The prescriber must obtain informed consent from the patient for whom he is prescribing these unlicensed medicines using the documentation specified in the Trust policy PAT/PA 2.

The prescriber will note the reasons for the use of the unlicensed medicine and specific risks and benefits of using the medicine.

The patient should be asked to agree to notify the prescriber immediately of any known or unknown side effects.

4.3 Prescription

1. All new requests for unlicensed medicines will be risk assessed before purchasing for the first time. And the prescriber (consultant) will be made aware of the assessment and recommended consent required.
2. A written record of this communication will be made using the form attached as Appendix 1.
3. Only a consultant may authorise the use of an unlicensed medicine.
4. A consultant may restrict the prescribing of the medicine to themselves or to specified members of the team.
5. A consultant may restrict the prescribing of an unlicensed medicine to specified patients or to all their patients.

6. The consultant is asked to consider carefully the use of the unlicensed medicine, and only use this form of therapy when the potential benefits outweigh the risks.

7. For products assessed as medium risk the prescriber must document in the patient's notes the fact that the product is being used and that the verbal consent of the patient has been given.
8. For products assessed as high risk the prescriber should inform their patients of the drug's license status, and that for an unlicensed medicine/indication its effects may be less well understood than those of a licensed product/indication. The prescriber must obtain informed consent and advise the patient to notify them if they experience any adverse effects.
9. If the prescriber wishes the unlicensed medicine to be continued by another colleague, e.g. a general practitioner, the prescriber must inform them of its licensed status and be prepared to continue prescribing if they do not wish to prescribe it themselves.

4.4 Supply and Administration

Both pharmacists and nurses have obligations under their respective codes of conduct to ensure the welfare of, and act in the best interest of their patients. This may mean in some circumstances the pharmacist, or nurse may refuse to supply, or administer the medicine prescribed.

The Drug and Therapeutics Committee will act to resolve any conflicts regarding the use of unlicensed medicines or medicines used outside of their licensed indications.

4.5 Paediatric Prescribing

Prescribing in paediatric practice often requires the use of unlicensed preparations, or the use of licensed preparations for unlicensed indications. It arises because drug manufacturers are unable to provide the licensing authority with sufficient data to support an application for licensed status. In these situations liability can be mitigated by the use being informed and guided by a respectable and responsible body of professional opinion.

The Standing Committee on Medicines, a joint committee of the Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacist Group has produced guidance on the use of unlicensed medicines in paediatric practice.
Its conclusions were as follows:

- Those who prescribe for a child should choose the medicine which offers the best prospect for that child, aware that such prescribing may be constrained by the availability of resources. Children should be able to receive medicines that are safe, effective, appropriate for their condition, palatable and available with minimal clinical risk.
- The informed use of some unlicensed medicines or licensed medicines for unlicensed applications is necessary in paediatric practice.
- Health professionals should have ready access to sound information on any medicine they prescribe, dispense or administer, and its availability.

- In general, it is not necessary to take additional steps, beyond those taken when prescribing licensed medicines, to obtain the consent of parents, carers, or child patients to prescribe or administer licensed medicines for unlicensed applications or unlicensed medicines.
- NHS Trusts and Health Authorities should support therapeutic practices that are advocated by a respectable, responsible body of professional opinion.
- Where available an appropriate licensed preparation should be prescribed and supplied in preference to an unlicensed preparation.

Therefore, in general, paediatricians are not expected to take addition steps, beyond those taken when prescribing a licensed medicine to obtain the consent for unlicensed use, and the British National Formulary for Children (BNF-C) provides reliable and up-to-date information and guidance on medicines for children.

The Royal College of Paediatrics and Child Health produce patient information leaflet explaining unlicensed medicine for child patients, parents and carers and these documents are recommended to be used when prescribing and dispensing.

4.6 Monitoring Adverse Effects

By their nature the adverse effect associated with unlicensed medicines may be less well known than for a medicine that has received licensing approval. Therefore it is important that prescribers, pharmacists, nurses, and patients are vigilant in monitoring any adverse effect of these medicines. Patients should be asked to report any adverse effects so that a dose may be reduced or stopped. Any serious adverse effects must be reported to the Medicines and Healthcare Products Regulatory Agency via the Yellow Card Scheme, https://yellowcard.mhra.gov.uk/

The Pharmacy Department will track the supply of each unlicensed medicine supplied.

PATIENTS LACKING CAPACITY

Sometimes it will be necessary to provide care and treatment to patients who lack the capacity to make decisions related to the content of this policy. In these instances staff must treat the patient in accordance with the Mental Capacity Act 2005 (MCA 2005).

- A person lacking capacity should not be treated in a manner which can be seen as discriminatory.
- Any act done for, or any decision made on behalf of a patient who lacks capacity must be done, or made, in the persons Best Interest.
- Further information can be found in the MCA policy, and the Code of Practice, both available on the intranet.

There is no single definition of Best Interest. Best Interest is *determined on an individual basis. All factors relevant to the decision must be taken into account, family*

and friends should be consulted, and the decision should be in the Best interest of the individual. Please see S5 of the MCA code of practice for further information.

5 TRAINING/SUPPORT

Prescribers and other staff requiring further information concerning unlicensed medicine or off label use should contact the Senior Clinical Pharmacist for their area. Alternatively advice may be sought from the Senior Clinical Pharmacist – Medicines Information.

Please note: The Standard Learning Needs Analysis (LNA) – The training requirements of staff will be identified through a learning needs analysis. Role specific education will be delivered by the service lead.

6 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Compliance with policy Routine monitoring of processes within the policy. - New product requests for unlicensed medicines - Unlicensed medicines supplied - Risk assessments completed	D&T, pharmacy procurement Pharmacy records Medicines information	Ongoing	Divisional management teams via Drug and Therapeutics or clinical governance.

7 DEFINITIONS

Unlicensed Medicines

Medicines that are manufactured by a recognised pharmaceutical manufacturer but are not available to purchase in the UK. Medicines may include;

- Medicines awaiting the granting of a licence to allow them to be sold in the UK.
- Medicines that are classified as licensed medicines in other countries, but are not licensed or available in the UK (manufactured for sale in another country).
- Medicines that have been withdrawn from sale in the UK.

Off-Label Use
Use of a licensed medicine for an indication other than what is specified in its licence.

8 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment for All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix 2)

9 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

Consent to Examination or Treatment Policy – Pat/PA 2
Mental Capacity Act 2005 Policy and Procedure, including Deprivation of Liberty Safeguards (DoLS) - PAT/PA 19
Privacy and Dignity Policy - PAT/PA 28
Safe and Secure Handling of Medicines Policy - PAT/MM 1 A

10 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) 2016).

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/uk-data-protection-legislation-eu-general-data-protection-regulation-gdpr/

11 REFERENCES

BNF for Children, https://bnfc.nice.org.uk/

Department of Constitutional Affairs
Mental Capacity Act (2005): Code of Practice, 2007 www.dca.gov.uk

General Medical Council: Good Practice in Prescribing and Managing Medicines and Devices; Prescribing Unlicensed Medicines, 103-109, 2021 www.gmc-uk.org

Human Medicines Regulations, 2012 (SI 2012/1916) www.legislation.gov.uk

Medicines and Healthcare products Regulatory Agency (MHRA): Yellow Card Scheme
https://yellowcard.mhra.gov.uk/

RCPCH: The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice, Royal College of Paediatrics and Child Health, 2013
https://www.rcpch.ac.uk/resources/use-unlicensed-medicines-or-licensed-medicines-unlicensed-applications-paediatric

APPENDIX 1 – UNLICENSED MEDICINE ADVICE LETTER

NHS
Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Directorate of Pharmacy and Medicines Optimisation

Advice of an Unlicensed Medicine[1]

Or a Licensed Product used in an Unlicensed Indication

Dear

I am writing to advise you the following product does not have a UK. Market Authorisation under the terms of the Medicines Act 1968.

Product:

Details concerning the implications of prescribing an unlicensed product can be found in policy Pat MM4

Please sign the attached form as an acknowledgement that you have been informed of the unlicensed nature of the product. You should inform the patient that its effect may be less well understood than those of a licensed product. You should ask the patient to report to you any known or unknown adverse effects in order that the dose may be altered. You must report any serious adverse effects to the Medicines and Healthcare products Regulatory Agency using the Yellow Card scheme

Assessment Level	
Consent Recommended:	
Other Comments	

If you are unhappy about signing this acknowledgement please contact the pharmacy department where we can advise you if there is a suitable licensed alternative available.

Yours sincerely,

Medicines Information Pharmacist

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[1] The term unlicensed medicine is taken to mean
1. **A medicine that does not hold UK Market Authorisation.**
2. **A licensed medicine used for an unlicensed indication.**

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NHS Foundation Trust

Directorate of Pharmacy and Medicines Optimisation

Unlicensed Medicine:

Assessment Level 3.2	
Consent Recommended	
Other Comments	

I acknowledge I have been advised that this product is unlicensed and of the consent recommended

I agree to prescribing for my patient in the following circumstances

Prescribers

This treatment to be restricted to my prescription only ( )+

This treatment may be prescribed by all my junior medical staff ( )+

I wish this treatment to be restricted to the prescription following members of my team ( )+ Please list below

Patients

This treatment may be prescribed for any of my patients ( )+

This treatment may be prescribed for the following patients only ( )+ Please list below

Signed (Consultant) Date.....

This advice will be renewed after 2 years

+Please tick as appropriate

Date Assessed:

For Reviewed:

Please return this acknowledgement to:
Medicines Information
Pharmacy Department
Doncaster Royal Infirmary

APPENDIX 2 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Division	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Unlicensed Medicines Policy	Trust Wide	Rachel Wilson	Existing	June 2021

1) Who is responsible for this policy? Drug and Therapeutics Committee

2) Describe the purpose of the service / function / policy / project/ strategy? To describe the way the Trust manages risks associated with the use of unlicensed medicines

3) Are there any associated objectives? Legislation, CQC standards, national best practice.

4) What factors contribute or detract from achieving intended outcomes? – non-compliance with policy

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation] –

6) Is there any scope for new measures which would promote equality? [any actions to be taken] N/A

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	No	
b) Disability	No	
c) Gender	No	
d) Gender Reassignment	No	
e) Marriage/Civil Partnership	No	
f) Maternity/Pregnancy	No	
g) Race	No	
h) Religion/Belief	No	
i) Sexual Orientation	No	

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form – see CORP/EMP 27.

Date for next review: June 2023

Checked by: Andrew Barker Date: June 2021