Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Unlicensed Medicines Policy

This procedural document supersedes: PAT/MM 4 v.3 – Policy and Procedure for the Use of Unlicensed Medicines

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Name and title of author	John Bane – Deputy Chief Pharmacist
Date Revised	Mar 2016
Approved by (Committee/Group)	Drugs and Therapeutics Committee
Date of approval	12 April 2017
Date issued	9 May 2017
Review date	May 2020
Target audience:	All Clinical Staff

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Unlicensed Medicines Policy

Amendment Form

Please record brief details of the changes made alongside the next version number.

If the APD 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
4	9 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
3	12 August 2014	Updated references Format updated	R Hancocks
2	11/5/11	No changes	
2	11/06/2008	No changes	

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1 INTRODUCTION

In the UK no medicine for human use may be placed upon the market without first subjection market authorisation or being granted a Product License by the Licensing Authority (the Medicines and Healthcare Products Regulatory Agency). 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. 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 Liability

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.

3.2 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 standard 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 that 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.

3.3 Strict Product Liability (or liability without fault)

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.

3.4 Special Need Exemption

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

3.5 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.

3.5.1 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 (e.g. Sulpiride Mixture 200mg/5ml) 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 or Medicines for Children.
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.

3.5.2 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.

3.5.3 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 CONSENT

4.1 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 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.

4.3 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.

5 UNLICENSED USE OF LICENSED MEDICINES

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. Depending upon the circumstances unlicensed use could be assessed as low, medium, or high risk.

6 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 (RCPCH, 2003 xiii):

- Those who prescribe for a child should choose the medicine which offers the best prospect for that child, with due regard for cost.

- 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.

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 and the formulary *Medicines for Children* (RCPCH, 2003) are commended to prescribers as responsible and professional bodies of opinion to guide prescribing in this Trust.

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.

7 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.

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

8 PROCEDURE

8.1 Prescription

1. All new requests for unlicensed medicines will be risk assessed before purchasing 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.

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 juniors, or all 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.

8.2 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 administered 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.

9 TRAINING AND 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.

10 MONITORING AND COMPLIANCE

Care Group Management Teams are responsible for the monitoring of compliance against this policy.

11 ASSOCIATED PROCEDURAL DOCUMENTS

PAT/ MM 1 – Policy for the Safe and Secure Handling of Medicines.

12 REFERENCES

BNF for Children (2013-2014), Pharmaceutical Press
Guidance Note 14 MHRA 2014
RCPCH (1999) Medicines for Children, London, RCPCH Publications Ltd

APPENDIX 1 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Care Group/Executive Directorate and Department	Assessor(s)	New or Existing Service or Policy?	Date of Assessment
PAT MM4 – Unlicensed Medicines Policy	Pharmacy and Medicines Management	John Bane	Existing	24/4/17

1) Who is responsible for this policy? Pharmacy and Medicines Management

2) Describe the purpose of the service / function / policy / project/ strategy? To set out how the Trust manages the risk associated with unlicensed medicines

3) Are there any associated objectives? Compliance with the Human Medicines Regulation 2012; Compliance with CQC standard for medicines management

4) What factors contribute or detract from achieving intended outcomes? – Not following the 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? 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 in Appendix 4

Date for next review: May 2020

Checked by: John Bane Date: 24/4/17