1 Introduction

In the UK medicinal products can only be placed on the market after a Marketing Authorisation (MA), commonly known as a product licence (PL) in the UK, has been granted by the Medicines and Healthcare Products Regulatory Agency (MHRA) or the European Medicines Agency (EMA). However in order to meet the needs of some patients it is sometimes necessary that they receive treatment with a product that does not have a marketing authorisation in the UK (i.e. an unlicensed medicine) or to receive treatment with a medicinal product that is being used outside the terms of the marketing authorisation.

This policy covers all processes involved in the approval, procurement and use of unlicensed medicines.

2 Scope of the policy

The scope of this policy includes products that are:

a) Supplied from holders of a Manufacturing Authorisation (full manufacturing licence) either in the UK or abroad.

b) Manufactured by companies holding a ‘specials’ manufacturing licence to the specification of the doctor or pharmacist ordering them.

c) Manufactured in NHS units holding a specials manufacturing licence.

d) Unlicensed but corporately approved (based on quality assurance advice) for use when the licensed equivalent is unavailable.

e) Licensed but not for the intended route of administration.

f) Compassionate Use Medication i.e. products required for compassionate use either where a patient is exiting a completed clinical trial or where the consultant has a medicines management approved agreement with the pharmaceutical company supplying the medication for treatment of an individual patient or group of patients (see paragraph c below).

Excluded from this policy:

a) Medicines which are classified as “prepared”.(commonly known as ‘Extemps’) Although these are not technically licensed products they are prepared in accordance with a Standard Operating Procedure (SOP) for a specific patient under the supervision of a pharmacist (section 10 exemption from the Medicines Act 1968) and are outside
the scope of this policy. An example of this type of product would be preparation of a liquid formulation using a solid dosage form for a patient who cannot swallow.

b) Products required within a clinical trial which must be manufactured under a full Manufacturing and Importation Authorisation (MIA) - Investigational Medicinal Products - licence issued by the MHRA.

c) Governance and supply processes of compassionate use medication (procurement and quality assessment is included in the scope of this policy)

d) Use of a licensed medicine for an indication other than the indications(s) included in the MA but administered via a route which is included in the MA i.e. “off-label” use.

e) Repackaged Medicines
These are licensed medicines that have become de-licensed as a result of being repackaged e.g. from manufacturer’s original containers. Although these are technically unlicensed medicines they will not be considered further in the scope of this policy.

f) Borderline Substances, food supplements and medical devices.

3 Aims
To outline the processes involved in the approval, procurement and use of unlicensed medicines.

4 Classification of Unlicensed Medicines

MHRA guidance (MHRA Guidance Note 14) requires that unlicensed medicines are subject to a detailed level of record keeping. The usage of unlicensed medicines within Newcastle Upon Tyne Hospitals NHS Foundation Trust is extensive. A pragmatic approach has been developed to categorise unlicensed medicines which allows resources to be directed to the unlicensed medicines which have the potential to compromise patient safety. For that purpose the policy recognises two categories of unlicensed medicines.

The use of all unlicensed medicines must be approved according to the Access to Drugs Policy. In practice this means that approval has been granted either for use by an individual patient by the Medicines Management Committee chair, or has been granted full formulary approval by the North of Tyne Area Prescribing Committee. These approval processes include assessment of clinical suitability. As such the categories assigned below relate to pharmaceutical issues such safety in use, pharmaceutical quality and procurement risk.

4.1 Category 1

This category will include the following:
a) Medicines labelled in a foreign language.
b) Medicines licensed in the UK where the intended route of administration is different from that included in the licence unless the route is recognised clinically – see category 2c below.
c) Medicines imported from countries outside the UK, this includes countries of mutual recognition and within the EU for patient safety reasons as labelling and clinical information translation may be required.¹
d) “One-off” medicines procured from NHS units holding a Specials Manufacturing licence or other UK Specials licence holder, i.e. not batch produced.
e) Medicines licensed for use in animals.
f) Aseptically manufactured injectable medicines
g) Unlicensed medicines that do not fit the category 2 criteria.

¹ EEA member states, Switzerland, Canada, Australia, New Zealand and Japan

4.2 Category 2

This group of unlicensed medicines consists of a range of medicines that meet all of the following criteria:

a) Batch produced medicines procured from NHS units holding a Specials manufacturing licence, or other UK Specials licence holders.
b) Are considered to be of a suitable pharmaceutical quality.
c) Have a good clinical safety record, for example drugs that are included in the current British National Formulary (BNF) or BNF for children excluding medicines that are subsequently withdrawn on the grounds of safety.

5 Responsibilities and Governance

Unlicensed medicines should only be used where their use is clearly justified and their clinical/pharmaceutical benefits are considered to outweigh the risks involved.

New unlicensed medicines must 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.

Whenever an unlicensed medicine is prescribed, the prescriber is professionally accountable for his judgement in so doing, and may be called upon to justify their actions. As part of the request process for a new unlicensed medicine pharmacy must confirm that the prescriber has undertaken a suitable risk benefit assessment which must be documented. The only exception to this rule is when a formulary approved licensed medicine is unavailable and the Medical Director (or a nominated deputy) and the Director of Pharmacy (or a nominated deputy) have approved the use of an unlicensed equivalent following a QA assessment.

It must be ensured that before a new unlicensed medicine is introduced into use:
There is no suitable licensed alternative (unless approved by Medicines Management Committee) or that the patient may have either failed to respond or reacted adversely to the licensed alternative.

That the use is approved by the chair of the Trust’s Medicines Management Committee or the North Tyne Area Prescribing Committee, as appropriate.

The prescriber is aware that the medicine he/she has requested is an unlicensed medicine.

The Director of Pharmacy is responsible for ensuring that suitable processes are in place within pharmacy for the safe procurement and supply of unlicensed medicines. Prescribers requesting the purchase of a new unlicensed medicine will be requested to document the patient details, indication for use, justification for use, acknowledgement of the unlicensed status of the medicine and their responsibilities in terms of communications with patients and other prescribers before the product can be sourced.

Additionally subsequent to receipt in the Trust, a favourable pharmaceutical quality assessment is required before the product can be released for use in the treatment of a patient.

Inevitably, the procurement process for unlicensed medicines will take longer than that for licensed medicines and in some cases may be quite protracted. For example, where a non English language medicine is received which therefore requires the provision of an English overlabel and translation of information leaflets. Prescribers should be aware of this when making their clinical decisions.

For unlicensed medicines only, any healthcare professional involved in the prescribing, supply, administration and monitoring should be:

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

This information will be available on the web-BNF for unlicensed medicines classified as category 2. In addition to this for category 1 unlicensed medicines Consultants responsible for the patient’s care will be informed individually through the request and dispensing processes.

5.1 Specific Responsibilities

a) Referral to General Practitioners

It is the responsibility of the patient’s consultant to inform the patient’s General Practitioners (GP) that an unlicensed medicine has been initiated. GPs must not be asked to prescribe any unlicensed medicines containing drugs that are not licensed for any indication in the U.K. (unless they are included in the BNF, BNF for Children or North of Tyne Formulary). They may however be asked to prescribe other unlicensed products e.g. unlicensed oral liquid preparations for patients where licensed tablets
cannot be given, or unlicensed preservative free eye drops where the patient is allergic to the preservative, but this should only be with the agreement of the GP.

If a GP agrees to prescribe an unlicensed medicine he/she must be given sufficient information about the product and its availability.

b) Communication with Patients /Carers

Patients have the right to participate in the making of properly informed decisions on their healthcare. Due to the potential problems associated with the use of unlicensed medicines:

- Pharmacy will ensure that individual patients are given adequate information about any unlicensed medicines to ensure continuity of supply. Communication support will always be provided patients with communication needs such as Deaf patients and those with limited English.
- For category 1 unlicensed medicines NuTH requires that either documented informed consent is obtained, or if it is decided that it is more appropriate not to seek informed consent, the reason why is recorded in the patient’s notes.
- Clinicians should consider obtaining informed consent to the use of a category 2 unlicensed medicine.
- 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.

A patient information leaflet explaining why it may be necessary to prescribe unlicensed medicines will be issued; in a format appropriate to the patients communication needs, by pharmacy for each supply of a category 1 medicine made directly to the patient.

c) Administration to Patients

Healthcare professionals administering medicines to patients should:

- Be aware of the unlicensed status of any medicines they are using.
- Notify pharmacy staff and/or the doctor looking after the patient, as appropriate:
  - If the labelling/any instructions supplied with the medicines are unclear.
  - 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.
d) Records

Pharmacy staff must keep purchasing records of all unlicensed medicines for a period of at least 5 years.

In line with the pragmatic approach mentioned under Classification of Unlicensed Medicines (section 4) detailed patient specific supply records (including batch numbers issued) will be maintained by pharmacy for category 1 unlicensed medicines and retained for a period of at least 5 years.

For the purpose of record keeping, category 2 unlicensed medicines will be treated in the same way as licensed medicines and records will be kept for 2 years.

e) Monitoring

All staff involved in patient care have the responsibility to report any adverse reactions to the MHRA using the yellow card scheme. Additionally, any defects should be reported to the pharmacy department.

Pharmacy will:

- Monitor the usage of unlicensed medicines, confirming that continuing use remains as originally agreed. The more unlicensed medicines are used, the greater the risk that control of their use will be reduced.
- Notify clinicians of appropriate licensed alternative products becoming available
- Notify appropriate clinicians of any serious problems that they are alerted to with individual unlicensed medicines.
- Report any defects in unlicensed products to the regional quality assurance specialist.

f) Pharmaceutical Quality Assurance

During the procurement/supply process pharmacy staff should ensure that whenever possible:

- The manufacturer’s licence status is clearly understood and their licence covers the appropriate types of product e.g. sterile products.
- The product must:
  - Comply with an agreed/adopted specification.
  - Be manufactured in an appropriate environment.
  - Have a validated shelf life.
  - Be quarantined on receipt until it has been formally checked and cleared for use by a pharmacy quality assurance/quality control staff
  - Be labelled in English and where appropriate supplied with information in English to allow its use in a safe manner.
(Arrangements should be made for over-labelling and for translations to be prepared/obtained if necessary).

6 Policy

The use of unlicensed medicines within the Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) is supported in accordance with the principles outlined below and any associated guidelines:

6.1 Unlicensed medicines should only be used when there are no licensed products available. Exception to this must be approved by Medicines Management Committee.

6.2 Unlicensed medicines should only be used if their use can be clearly justified clinically and pharmaceutically to meet the special needs of individual patients. An unlicensed product should not be used purely on the grounds of lower cost unless approved by Medicines Management Committee.

6.3 Those involved in the prescribing or administration of an unlicensed medicine must be made aware of its unlicensed status and any known specific relevant risks associated with its use.

6.4 New unlicensed medicines must 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. Access to Drugs Policy

6.5 Adequate records to an appropriate level must be kept with regard to the approval, purchase and the supply of unlicensed medicines. (see Section 5d Records).

6.6 Pharmacy staff issuing unlicensed medicines should ensure that they are labelled clearly in English and that the users have adequate information in English to use them properly.

6.7 Consultants and other clinicians must not ask others to prescribe unlicensed medicines without ensuring that they are adequately informed about the medicine, how it is used and any risks involved.

6.8 Individual patients (and/or their parents/carers) should be given adequate information about any unlicensed medicines they are prescribed. This should include information regarding the unlicensed status of the medicine and continuity of supply.

6.9 For category 1 unlicensed medicines documented informed consent should be obtained, or if it is decided that it is more appropriate not to seek informed consent, the reason why must be recorded in the patient’s notes. Clinicians should consider obtaining informed consent to the use of a category 2 unlicensed medicine.
6.10 Problems associated with the use of an unlicensed medicine (e.g. product defects, problems with labelling/instructions) must be reported promptly to the hospital pharmacy. Adverse drug reactions should be reported to the MHRA using the yellow card scheme with a copy of the report being sent to the hospital pharmacy.

7  Training

Training for staff will be as outlined in the Mandatory Training Policy. Monitoring of staff training will be as detailed in the Mandatory Training Policy.

8  Equality and diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This document has been appropriately assessed.

9  Monitoring compliance

<table>
<thead>
<tr>
<th>Standard / process / issue</th>
<th>Monitoring and audit</th>
<th>Method</th>
<th>By</th>
<th>Committee</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring Trust approval for use prior to supply.</td>
<td>An audit will be undertaken of the 10 most recently dispensed unlicensed medicines at Freeman and at the RVI to establish if formal Trust approval for use has been documented.</td>
<td>Pharmacy Staff</td>
<td>Medicines Management Committee</td>
<td>Annually</td>
<td></td>
</tr>
</tbody>
</table>

10  Consultation and review

Medicines Management Committee (April 2012)
Medicines Management Committee and Senior Pharmacy Team (reviewed 2014, 2016).

11  Implementation (including raising awareness)

Changes to Policy highlighted in Trust Policy Update newsletter
Changes to Policy communicated to Pharmacy staff responsible for Policy implementation

12  References

- Medicines Act 1968
- MHRA guidance (MHRA Guidance Note 14).
13 Associated Documentation

- [Access to Drugs Policy](#)
The Newcastle upon Tyne Hospitals NHS Foundation Trust

Equality Analysis Form A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

PART 1

1. Assessment Date: 18.07.18

2. Name of policy / strategy / service:
   Unlicensed Medicines Policy

3. Name and designation of Author:
   Steven Brice, Assistant Director of Pharmacy

4. Names & designations of those involved in the impact analysis screening process:
   Steven Brice, Assistant Director of Pharmacy

5. Is this a: Policy x Strategy Service
   Is this: New x Revised Service
   Who is affected Employees x Service Users x Wider Community

6. What are the main aims, objectives of the policy, strategy, or service and the intended outcomes? (These can be cut and pasted from your policy)
   This policy covers all processes involved in the approval, procurement and use of unlicensed medicines.

7. Does this policy, strategy, or service have any equality implications? Yes x No
   If No, state reasons and the information used to make this decision, please refer to paragraph 2.3 of the Equality Analysis Guidance before providing reasons:
   This Policy states what is expected of all Trust staff involved in the approval, procurement and use of unlicensed medicines.
### 8. Summary of evidence related to protected characteristics

<table>
<thead>
<tr>
<th>Protected Characteristic</th>
<th>Evidence, i.e. What evidence do you have that the Trust is meeting the needs of people in various protected Groups</th>
<th>Does evidence/engagement highlight areas of direct or indirect discrimination? If yes describe steps to be taken to address (by whom, completion date and review date)</th>
<th>Does the evidence highlight any areas to advance opportunities or foster good relations. If yes what steps will be taken? (by whom, completion date and review date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race / Ethnic origin (including gypsies and travellers)</td>
<td>Staff are expected to comply with policy irrespective of their race / ethnic origin.</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Sex (male/ female)</td>
<td>Staff are expected to comply with policy irrespective of their sex.</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Religion and Belief</td>
<td>Staff are expected to comply with policy irrespective of their religion and belief.</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Sexual orientation including lesbian, gay and bisexual people</td>
<td>Staff are expected to comply with policy irrespective of their sexual orientation.</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Age</td>
<td>Staff are expected to comply with policy irrespective of their age.</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Disability – learning difficulties, physical disability, sensory impairment and mental health. Consider the needs of carers in this section</td>
<td>Staff with physical disabilities will be expected to comply with policy. Staff with learning difficulties, sensory impairment and mental health may be excluded from being involved in the approval and procurement of unlicensed medicines. This is appropriate from a safety and security perspective.</td>
<td>Staff with learning difficulties, sensory impairment and mental health may be excluded from the policy; this is on the grounds of safety.</td>
<td>No</td>
</tr>
<tr>
<td>Gender Re-assignment</td>
<td>Staff who have had gender re-assignment are expected to comply with policy.</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Marriage and Civil Partnership</td>
<td>Staff are expected to comply with policy whether they are married, in a civil partnership or single.</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Maternity / Pregnancy</td>
<td>Staff are expected to comply with policy when pregnant.</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

9. Are there any gaps in the evidence outlined above? If ‘yes’ how will these be rectified?

No

10. Engagement has taken place with people who have protected characteristics and will continue through the Equality Delivery System and the Equality Diversity and Human Rights Group. Please note you may require further engagement in respect of any
significant changes to policies, new developments and or changes to service delivery. In such circumstances please contact the Equality and Diversity Lead or the Involvement and Equalities Officer.

Do you require further engagement?  
Yes [ ] No [x]  

11. Could the policy, strategy or service have a negative impact on human rights? (E.g. the right to respect for private and family life, the right to a fair hearing and the right to education?)

No.

PART 2

Name:
Steven Brice

Date of completion:
18.07.18

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified, please refer to the Policy Author identified above, together with any suggestions for action required to avoid/reduce the impact.)