Policy Document Control Sheet

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Table of Revisions

Date	Section	Revision	Author
October 2017		This policy replaces section 2 in the Trust Medicines Policy (POL/MM/0001)	

Contents

1. Introduction

Before a medicine can be widely used in the UK, it must obtain a product license (PL). This PL is also known as a marketing Authorisation (MA) issued by the Medicines & Healthcare products Regulatory Agency (MHRA) or European Agency for the Evaluation of Medicinal Products (EMEA).

Licensed medicines have a unique PL (or MA) number which is made up of a number prefix followed by numbers. This prefix will either be PL or MA for UK only licensed products or e.g. PL123454 or MA12345.

Medicines used in the UK can also be granted a license by the European Medicines Evaluation Agency (EMEA).

Licenses are only granted if high safety and quality standards are maintained during the manufacture of a medicine. The medicine must also be shown to be effective for the purpose it is used.

The presence of a license ensures that manufacture, storage and distribution conform to agreed international standards and that when used for the purpose for which marketing authorisation has been granted that clinical benefits outweigh any risks

When a medicine holds a MA issued by the MHRA and is used for the purpose covered by the MA, then both the medicine and the use of the medicine is “licenced”. In most cases medicines prescribed and used within the Trust will hold a MA or PL granted by the MHRA or EMEA).

In the UK, Medicines that do **not** have a MA or a PL issued by the MHRA are known as “unlicensed”. These products are usually identified by the absence of a unique PL or MA number.

The same assumptions of quality, safety and efficacy to that of licensed products cannot be made for unlicensed products.

When a medicine holds a MA issued by the MHRA but is used for a different purpose or indication to that covered by the MA, then the medicine is licensed but the use of the medicine is unlicensed. Use of a licensed medicine in a different way to that specified in the MA is often referred to as “off-label” use. “Off label” use of a licensed medicine can include administration by a different route, via crushing of medicine, use in a different patient group to that covered by the MA or use for a different purpose or indication to that listed in the MA.

For good clinical reasons it is often necessary to prescribe a medicine which does not hold a product licence (unlicensed use) or to prescribe a medicine outside the approved marketing authorisation (“off-label” use). It is accepted that such practice continues in order to provide the best care for patients. However, it is necessary that prescribers, pharmacists and nurses are aware of the increased risk and medico-legal implications associated with the use of Unlicensed Medicines. This policy describes how Unlicensed Medicines should be used within County Durham and Darlington NHS Foundation Trust (CDDFT) and sets out the responsibilities of all involved.

The NICE Medicines and Prescribing Centre provides advice and support for delivering safety, efficiency and effectiveness in the use of medicines. The Medicines and

Prescribing Centre is responsible for developing 'Evidence summaries: unlicensed and off-label medicines' (ESUOMs).

ESUOMs provide a summary of the published evidence for selected unlicensed or “off-label” medicines that are considered to be of significance to the NHS, usually when there is no licensed medicine for the condition requiring treatment or no licensed medicines are appropriate for a significant proportion of people requiring treatment. ESUOMs should not be considered to promote the use of unlicensed medicines solely for economic reasons.

2. Purpose

This policy provides a robust framework to ensure that Unlicensed Medicines are handled and used appropriately within CDDFT.

The purpose of this policy is to ensure that appropriate systems for the initial request, assessment, procurement, receipt, quarantine, quality control, release and storage of Unlicensed Medicines are in place in order to reduce the risk posed to patients, prescribers, nursing staff and pharmacists from their use.

3. Scope

This policy covers all aspects of the request, assessment, classification, procurement, receipt, quarantine, quality control, storage, supply, prescribing and administration of Unlicensed Medicines within CDDFT.

The document applies to all practitioners who are required to deal with Unlicensed Medicines, including Out-sourced Chemotherapy, as part of their role and they must read and understand this policy. In addition, all pharmacy staff who deal with Unlicensed Medicines must also have read and understand all associated Standard Operating Procedures (SOPs), specifically SOP/PROC/001 and SOP/ASEP/007. SOP/PROC/001 describes all processes relating to the management of all Unlicensed Medicines within the pharmacy department. The processes involving the management of out-sourced chemotherapy within the aseptics unit in the pharmacy department at Darlington Memorial Hospital (DMH) is covered by SOP/ASEP/007.

4. Medicines covered by this policy

Unlicensed Medicines are 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

4.1 This policy relates to the following medicinal products

- Medicines produced by a pharmaceutical manufacturer but not on sale in this country. Such products may be licensed and/or manufactured in other countries

and may be awaiting a product licence, may have never had a product licence or the product licence may have been abandoned, revoked or not renewed

- Products manufactured as “specials” from licensed medicines such as liquid formulations where only a solid dosage form holds a license. For example; low dose- formulations for children.
- Medicinal Products manufactured in NHS units holding a “specials” manufacturing license. This includes out-sourced chemotherapy and supplemented Total Parenteral Nutrition (TPN)
- Raw ingredients used in the manufacture of products for use in aseptic manufacture
- Compassionate Use Medicine, i.e. products required for compassionate use either where a patient is exiting a completed clinical trial or where a consultant has Clinical Standards & Therapeutics Committee (CSTC) approval to treat an individual patient or group of patients.

4.2 This policy does not relate to the following medicinal products

- Extemporaneously prepared products manufactured for a specific patient under the supervision of a pharmacist in accordance with section 10 of the Medicines Act 1968
- Products supplied as part of clinical trial. The use and supply of investigational Medicinal Products are covered by the Clinical Trials Policy (POL/MM/004).
- “Off-label” medicines.
- Products classified as Borderline substances by the Advisory Committee on Borderline Substances (ABCS), herbal or homeopathic medicines and medical devices.

5. New Requests for Unlicensed Medicines

This relates to Unlicensed Medicines that have never been procured by CDDFT or Unlicensed Medicines that were last procured more than 12 months ago

Requests can be either for products to be held as routine stock or products for an individual patient. The paper work required to be completed will differ depending on if the Unlicensed Medicine is for routine stock (appendix 1) or an individual patient (appendix 2).

5.1 Unlicensed Medicines for routine stock

A new request for the routine use of an Unlicensed Medicine must be requested by a consultant on behalf of a care group. Requests will not usually be accepted from individual consultants without the support of care group colleagues and approval at designated Care Group Governance Meeting, except in exceptional circumstances. These situations should be discussed with the Lead Pharmacist - Formulary & Procurement or designated other. Wherever possible, the request should be discussed at CSTC for evaluation and approval. The consultant must complete the section 1 of the application form (appendix 1) and forward to pharmacy, as detailed on the form.

If the request is for use of an Unlicensed Medicine that is **not currently** on formulary then a new product request form will also be required to be submitted to the Lead Pharmacist – Procurement & Formulary.

If this request is for a product that we have stocked as a licensed product which has either been discontinued or is no longer available in the UK, and then a new product request is not required in addition to this form, however the use of an alternative licenced product must have been considered and discussed within the care group. It would be expected that these discussions and outcomes would be documented within the minutes of the meeting it was discussed at. The request may also be discussed at the Formulary Steering Group (FSG) if relevant to use in other care setting e.g. primary care or mental health.

Section 2 of the application form will be completed by a member of the pharmacy team. Once sections 1 and 2 of the application form are completed the form must be submitted to the next CSTC for discussion.

The request should then be evaluated by members of CSTC with consideration given to the following:

- Is a similar licensed medicine already in use within CDDFT that would be acceptable?
- Is a similar unlicensed medicine available within the Trust which is appropriate for use?
- Do the CSTC members agree with the risk categorisation allocated by the Pharmacist who has carried out the risk assessment?
- Can the requested product be reasonably procured?
- What records need to be made and what quality control measures need to be taken?
- Should prescribing of the Unlicensed Medicine be restricted (e.g. to consultants and specialist registrars) or can the product to be prescribed by all registered prescribers (both medical and non-medical)?

A member of CSTC, usually a Pharmacist (but not restricted to a pharmacist) must complete section 3 of the application form and discuss outcome with requesting consultant outside of the meeting.

5.2 Request for a supply of an Unlicensed Medicine for use in an individual patient

A request for the use of an Unlicensed Medicine for an individual patient must be requested by the patients' consultant using the application form in appendix 2

Ideally this request should be discussed at CSTC; however if required urgently the request can be reviewed by the Lead Pharmacist – Formulary & Procurement, or designated other, before being approved via "chairs actions" by chair of CSTC. The request and approval for use will then be recorded within the minutes of the next CSTC meeting.

Note that if the Unlicensed Medicine is requested for use in more than THREE patients over a 12 month period (irrespective as whether this is the same consultant) then a new product request form will need to be completed along with the application form that can be found in appendix 1.

6. Duties and Responsibilities

This policy applies to all individuals within CDDFT who deal with requests, assessment, procurement, receipt, quarantine, quality control, storage, release, prescribing and supply of Unlicensed Medicines

This policy should be read in conjunction with the Trust Medicines Policy

6.1 The Trust Chief Pharmacist

The Trust Chief Pharmacist has overall responsibility for ensuring that

- Written procedures to cover all aspects of the procurement and supply of Unlicensed Medicines are in place to ensure the quality of Unlicensed Medicines.
- Arrangements are in place to make sure that Unlicensed Medicines are used only when an equivalent licensed product is unavailable.
- All new requests for Unlicensed products are submitted to the CSTC

6.2 Pharmacy staff

All pharmacy staff must have read and understood SOP/PROC/001, which describes the roles and responsibilities of all pharmacy staff involved with the management of Unlicensed Medicines. Pharmacy staff working in the aseptics unit must also have read and understood SOP/ASEP/007.

6.3 The prescriber

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.

Where the Unlicensed medicine is to be continued by another prescriber, e.g. GP, there must be communication regarding the unlicensed nature of the medicine,. If the GP has any concerns then they may wish to discuss the decision to prescribe the unlicensed medicine with the specialist. In the rare case that a GP may not agree to take on the prescribing of the unlicensed medication then the prescribing may need to stay with a CDDFT prescriber.

Similarly, prescribers who may be unfamiliar with the patient may be required to authorise or prescribe Unlicensed Medicines e.g. patients admitted to the Trust in an emergency. In these instances prescribers should be familiar with the Unlicensed status of the medicine. Wherever possible the Unlicensed Medicine should be continued and every effort should be made to gain a supply of the patients own from

home to avoid any delays in treatment as CDDFT may not routinely stock the Unlicensed Medicine. Prescribers must however be satisfied that the Unlicensed Medicine is suitable for the patient in their current clinical condition in the same way they would for licensed medicines.

Unlicensed medicines should only be used when no pharmaceutically equivalent licensed product or suitable alternative licensed product is available for use at the time the patient requires it.

The existence of a 'special need' relates to clinical criteria. It does not relate to reasons of cost, convenience or operational needs.

- Prescribers of unlicensed products are responsible and professionally accountable for their actions; in the case of adverse events they may be called upon to justify their prescribing.
- In exceptional circumstances, the prescribing of some unlicensed medicines may be restricted to consultant only prescribing, the decision will be made after discussion at Clinical Standards & therapeutics Committee (CSTC).

6.4 Clinical Standards & Therapeutics Committee

CSTC are responsible for assessing all new requests for both routine use of Unlicensed Medicines and use of Unlicensed Medicines for individual patients.

7. Initial assessment of Unlicensed Medicines

Before procuring an Unlicensed Medicine for the first time; the Unlicensed Medicine must be assessed for clinical and pharmaceutical appropriateness in accordance with locally approved protocols and procedures.

Every request for a newly procured Unlicensed product must be subject to a risk assessment by the pharmacy department; In addition, Unlicensed medicines procured from alternative suppliers must also undergo a risk assessment.

8. Procurement of Unlicensed Medicines

NHS Pharmaceutical Quality Assurance Committee 2016 states that the responsibility for ensuring the quality of any Unlicensed Medicine lies jointly with the prescriber and the supplying pharmacist. For this reason the Senior Pharmacy Technician - Procurement together with an appropriate Pharmacist must follow the processes described in SOP/PROC/001 to ensure all appropriate paperwork is completed prior to procuring an Unlicensed Medicine. This paperwork will include

- New Request for an unlicensed medicine to be routinely stocked in CDDFT (appendix 1)
- New Request for an unlicensed medicine for an individual patient (appendix 2)*
- Record of categorisation assessment

*Note that the patient details will be stored in a secure folder on the shared drive- the patient details will not be supplied to CSTC.

Several people are involved in the process and therefore multiple people are accountable. The authorised person signing the individual order and the Pharmacist who has been involved with the decision to procure the unlicensed medicine are both ultimately responsible for ensuring that the Unlicensed Medicine is appropriate to procure. This is auditable as pharmacy orders for Unlicensed medicines are retained for FIVE years and the signed Records of categorisations are stored electronically.

9. Quality Control and Quality Assurance before procuring Unlicensed Medicine

Procurement of Unlicensed Medicines must be carried out following locally approved procedures which have been developed in line with Regional Guidance and the hierarchy described in MHRA Guidance Note 14.

The country of origin must be determined. With regards imported medicines then medicines from within the European Union should be considered as first choice. Countries with mutual recognition should be considered secondly. These countries include Australia, Canada, Israel, New Zealand, Switzerland, Japan and the USA. As a last resort countries outside of the EU without a mutual recognition should be considered. If sourcing from a non-EU or non-mutually recognised country it is essential that imported Unlicensed Medicines are Transmissible Spongiform Encephalopathies (TSE) compliant.

It is vital that Unlicensed Medicines are accompanied by product information in English; this includes packaging, Summary of product characteristics (SPC) and patient information leaflets (PIL). Therefore, before procuring an Unlicensed Medicine the language used on the packaging must be determined along with details of who will supply the translation of the patient information leaflet and label

When procuring an imported Unlicensed Medicine an SPC and a PIL and in some cases a product summary sheet should be available. Wherever possible they should all be in English.

When procuring a batch manufactured special, a certificate of analysis should be available. This is a document that is issued by quality assurance that confirms that a regulated product meets its product specification.

When procuring a “one – off” bespoke manufactured special, a certificate of conformity should be available. This is a document that confirms that the final product conforms to the specification supplied for manufacture and should be supplied by a suitably authorised person.

An assessment of the supply chain should also be carried out, and the ease with which further supplies can be obtained. The cost of the drug and any special funding needs must be determined. Responsibility for continued supply must be identified.

10. Receipt and Quarantine of Unlicensed Medicines within the Pharmacy Department

Pharmacy Staff involved with the receipt of Unlicensed Medicines should refer to SOP/PROC/001 or SOP/ASEP/007 for details of the pharmacy process for receiving Unlicensed Medicines and which records are required to be kept. See section 13 for further details.

All supplies of Medicines from Unlicensed suppliers must be immediately quarantined in the designated quarantine area or brought to the attention of a phramcist for immediate inspection and release.

11. Storage and Release of Unlicensed Medicines from Quarantine within the Pharmacy Department

A pharmacist must assess the quality of all received Unlicensed Medicines categorised as “HIGH risk” before they can be released from quarantine. The Senior Pharmacy Technician – Procurement, or designated other is authorised to release Unlicensed Medicine categorised as “LOW risk” from quarantine. These processes are detailed in SOP/PROC/001.

Unlicensed Medicines should be segregated from Licensed Medicines and stored appropriately. In designated areas within the pharmacy department for the storage of Unlicensed Medicines. Any Unlicensed Medicines that have special storage requirements e.g. those requiring refrigeration or Controlled Drugs must also be segregated in trays labelled as “Unlicensed Medicines” within the Controlled Drugs cupboard or fridge.

12. Supply of Unlicensed medicines to wards and departments

The MHRA Guidance note 14 states that all Unlicensed Medicines should only be supplied to named patients. In practice CDDFT has taken a pragmatic approach to this advice and has split the classification of unlicensed into two categories as previously described. Unlicensed Medicines categorised as “HIGH risk” are subject to stringent record keeping as described in section 14 and SOP/PROC/001

When Unlicensed medicines are stocked on wards and departments the ward/department manager and prescribers must;

- Be made aware, by a member of the pharmacy team, of the Unlicensed nature of the medicine and implications this may have on use.
- Be aware of the category of unlicensed medicine and ensure they follow any records keeping required. (see section 14 of this policy)
- Be satisfied that there is no alternative licensed product available.

Wherever possible Unlicensed Medicine categorised as high risk will only be supplied to wards and departments for use by named patients. However some Unlicensed Medicines classified as “HIGH risk”, are required to be stocked on the wards or departments for routine use. In these instances records of every administration must be documented.

When these “HIGH risk” Unlicensed medicines are supplied to wards and departments they will be accompanied by an administration sheet for reach batch of the Unlicensed Medicine supplied from pharmacy. This administration sheet must be completed by the administering nurse or practitioner when administering each dose of the Unlicensed Medicine from the specific batch. The ward manager is responsible for ensuring this is completed and all completed forms should be sent to the pharmacy department at UHND who will retain for 5 years. A copy of the form should also be retained on the ward or department.

13. Record keeping

Records will be kept for all “HIGH risk” Unlicensed Medicines supplied to wards and departments or directly to patients as described above. Further details regarding what specific records are required for different categories of unlicensed medicines are covered in detail in SOP/PROC/001.

14. Communication with wards and departments regarding temporary shortages

On some occasions, supplies of licensed medicines may become unavailable. This may mean that we need to procure an Unlicensed version of a usually Licensed Medicine.

In these situations the ward/ department(s) who usually stock the Licensed Medicine should be made aware of the problem, and will be asked if they can use an alternative product, This will usually be coordinated by the Care group Lead Pharmacist or designated other. Should any ward or department who do not routinely stock the product, request the product whilst the Unlicensed version of the medicine is available then they must be made aware by either the Care group lead pharmacist or designated other, that the Licensed preparation is currently unavailable.

14.1 Temporary changes to the electronic Prescribing and Medicines administration (ePMA) system

If the newly sourced Unlicensed Medicine is exactly the same strength, form and dose units are the same size as the usual licensed product then a flag will be added to ePMA system to alert prescribers of the possibility that the usual licensed product is unavailable and that they may be prescribing an unlicensed product. The ePMA team will be made aware of the problem and the necessary changes required by the Lead Pharmacist – Formulary & Procurement.

If the product is of a different strength and the dose unit is not the same size as the usual licensed product then a **new product** will be added to ePMA. The usual licensed version of the medicine will be temporarily disabled to ensure the correct product is selected by the prescriber

The flag on the “new” Unlicensed product will state “This is an alternative to …….and is being sourced as an unlicensed product”, with the …….being the usual product

15. Monitoring

15.1 Compliance and Effectiveness Monitoring

Compliance with this policy will be monitored as outlined in the table below.

15.2 Compliance and Effectiveness Monitoring Table

Monitoring Criterion	Response
Who will perform the monitoring?	The Pharmacy team – co-ordinated by the Trust Chief pharmacist
What are you monitoring?	Adherence to the policy and upkeep of the list of unlicensed medicines and associated documentation
When will the monitoring be performed?	annually
How are you going to monitor?	Routine monitoring of the processes listed in this policy. Annual review of the list of unlicensed medicines and their categorisation
What will happen if any shortfalls are identified?	Discussed with the Trust Chief Pharmacist and improvements made to rectify
Where will the results of the monitoring be reported?	CSTC
How will the resulting action plan be progressed and monitored?	Monitored by spot checks when the processes are being undertaken
How will learning take place?	Regular update s of bew unlicensed medicines stocked within pharmacy

16. References

1. MHRA guidance on the supply of Unlicensed Medicines

   https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials

2. Recommendations for the Retention of Pharmacy Records (2015)

   psnc.org.uk

3. TSE requirements for imported unlicensed human medicines

17. Appendices

Appendix 1 - New Request for an unlicensed medicine to be routinely stocked in CDDFT

Appendix 2 - Request for a supply of an Unlicensed Medicine for use in an individual patient

18.1 Appendix 1: New Request for an unlicensed medicine to be routinely stocked in CDDFT

Please complete in black ink and scan, or email to beverley.walton2@nhs.net, copying in graeme.arthur@nhs.net and deborah.potts@nhs.net with a completed new product request form, where appropriate

Section 1 – TO BE COMPLETED BY CONSULTANT

Medicine (name, strength, formulation and route of administration)
Which speciality will this product be used in?
Is use of this unlicensed product supported by the care group?
Are there any licensed alternatives to this product? If so, please give details below:
Justification for use
Is there a treatment pathway that states where in therapy this medicinal product should be used, if so please detail.
Do you consider that this product is likely to be granted a product license in the future, if so please give an indication of the estimated timescale (if known)
How often do you consider this product to be used?
Do you think this product should be able to be prescribed by consultants only?
Is there any further staff training require to ensure approrpriate prescribing or administration of this policy (e.g. does a drug protocol need to be developed?)
I have read and taken note of the **POLICY ON THE USE OF UNLICENSED MEDICINES.** I understand that the medicine requested above does not have a UK marketing authorisation (product license). I agree to comply with the requirements set out in the Trust policy for the use

of unlicensed medicines Lead consultant…….. Signed ……. Date…… NB. Approval to use an unlicensed medicine, if granted, may be withdrawn following consultation with prescribers, should problems arise with safety, or should a suitable licensed alternative become available.

Section 2 – To be completed by Senior Pharmacy Technician - Procurement, Lead Pharmacist – Procurement & Formulary or designated other

Comments and details of any concerns regarding this product (relating to quality, safety, labelling, information on use etc.)
Is this product likely to classified as “high risk” or “low risk”
Are there any specific storage requirements?
Is the product a Controlled Drug?
Designation…….. Name …….. Signed ……

Section 3 – To be completed by representative of CSTC after discussion

Comments and discussions regarding use of this product
Is this Unlicensed Medicine approved for use by CSTC?
Is prescribing restricted to consultant only? If no who can prescribe,
Are there any exceptions where this product has not been approved by CSTC for use?
Date of CSTC meeting
Name …….. Designation…….. Signed …… Date……

18.2 Appendix 2: Request for a supply of an Unlicensed Medicine for use in an individual patient

Please complete in black ink and scan, or email to beverley.walton2@nhs.net, copying in graeme.arthur@nhs.net and deborah.potts@nhs.net with an individual patient request form

Note that prior to discussion at CSTC then patient identifiable information should be removed

Patients name	Patient - Date of Birth	Patient - Hospital number
Patient weight (if applicable)	Patient height (if applicable)	Patients Surface are (if applicable)
Is this an urgent request? (if not then the request should be discussed at CSTC prior to authorisation) If urgent then CSTC should be made aware of the use as the next CSTC meeting.		
Medicine (name, strength, formulation, dose and route of administration)		
Anticipated duration of therapy		
Indication		
Justification for use		
Are there any licensed alternatives to this product? Have any been tried in this patient? If not why not?		
I have read and taken note of the **POLICY ON THE USE OF UNLICENSED MEDICINES.** I understand that the medicine requested above does not have a UK marketing authorisation (product license). I agree to comply with the requirements set out in the Trust policy for the use of unlicensed medicines Consultant name……. Signed …….. Date…… NB. Approval to use an unlicensed medicine, if granted, may be withdrawn following consultation with prescribers, should problems arise with safety, or should a suitable licensed alternative become available		

The completed form should be saved in the folder requests for individual patients