Procurement and use of unlicensed medicines (i.e. medicines without a marketing authorisation) AND licensed medicines used outside their marketing authorisation (off-label) policy

POLICY

Reference	CPG-TW-MM-UMP
Approving Body	Drugs and Therapeutics Committee
Date Approved	v4.0, December 2020 v4.1, Minor Amends Agreed via Policy Sponsor
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Summary of Changes from Previous Version	v4.1 - P9 – link updated to DTC one-off process - Appendix A – form updated - Appendix for Risk Stratification Table removed/ included in Appendix A v4.0 - Sec 1 - Minor revision to Introduction section - Sec 3 – Re-structure of section to bring out further clarity between 'licensed', 'unlicensed' and 'off-label' medication - Sec 4.4 / 4.5 / 4.7 – Minor revision to offer further clarity around roles and responsibilities. - Sec 6.1 title – clarification that this an application for FIRST TIME use of an unlicensed medicine. - Sec 6.1 – revision of 'exceptions to the rule' in relation to when a clinician is required to fill in the unlicensed form. Most relevant adjustment is the clarification around an already approved indication for a medicine but now requiring the purchase of an alternative product/brand - Sec 6.1 – Clarification that MI may make initial informal inquiries with Procurement before a full submission is received - Sec 6.2 – removal of need of a poster on ward relating to unlicensed medicines (information overload) - Sec 6.2 – removal of mention of different categories of risk linked to levels of consent – now simplified - Sec 6.3 – Further clarity around the process for Medicines Information managing the application process. - Sec 6.4 – additional information relating to pre-application requests added - Sec 7 reconfigured into a table format as per new Policy guidelines - New approved version of an associated Patient Information Leaflet (linked to)
Supersedes	Replaces v4.0, Issued 31st December 2020 to Review Date December 2023
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Date of Environmental Impact Assessment (if applicable)	Not applicable
Legal and/or Accreditation Implications	To Be Confirmed

Target Audience	The policy applies to all medical, nursing and pharmacy staff employed within the Trust who are involved in the prescribing, procurement, supply or administration of unlicensed medicines.
Review Date	December 2023
Sponsor (Position)	Chief Pharmacist / Director of Medicines Optimisation
Author (Position & Name)	v4.0, Mohamed Rahman (Assistant Chief Pharmacist) v4.1, Sana Awan (Assistant Chief Pharmacist)
Lead Division/ Directorate	Clinical Support, Therapies and Outpatients
Lead Specialty/ Service/ Department	Medicines Management (Pharmacy)
Position of Person able to provide Further Guidance/Information	Sana Awan (Assistant Chief Pharmacist)

Associated Documents/ Information	**Date Associated Documents/ Information was reviewed**
1. 'Management of Unlicensed medicines SOP' - ST.08.14 (Sourcing, Ordering, Receipt, Supply)	*20th July, 2020*
2. 'Procedure for the generation, update and archiving of unlicensed medicines specifications' (QC.00.30 v3)	*October, 2022*
3. Pharmacy Procedure for Labelling and Dispensing of medicines	*January, 2021*
4. Unlicensed Medicines – Patient Information Leaflet	*March, 2020 (published to Trust's external website)*

CONTENTS

1.0 INTRODUCTION

1.1 In order to ensure that medicinal products are safe, effective and of appropriate quality for human use, their manufacture, sale and supply is controlled by national (UK) and European Union (EU) legislation. Accordingly, no medicinal product may be 'placed on the market' unless a marketing authorisation has been granted by the UK regulator - the Medicines and Healthcare products Regulatory Agency (MHRA). A marketing authorisation is only granted for a product which meets statutory standards of safety, quality and efficacy. It defines the clinical indications for which a licensed medicinal product can be marketed. It also relates to the form, dose, route of administration and the patient age group for whom the medicines can be used in and the container in which the product is supplied.

1.2 The legislation however does allow some exemptions from full control, in order to preserve prescribers' clinical freedom. Thus, medicinal products that are not licensed may be prescribed in order to fulfil special needs in individual patients on the **direct** responsibility of the prescribing clinician. For example, a clinician may:

- prescribe unlicensed medicines where an appropriate licensed alternative is not available (i.e. there is no equivalent licensed medicine that will meet the patient's needs);
- prescribe medicines for indications, doses or routes of administration outside the terms of their marketing authorisation (i.e. when the licenced medicine is not licensed for the specific indication that will meet the patient's needs); - this use of medicines outside their product licence is also referred to as 'off-label' use;
- over-ride the warnings and precautions given in the marketing authorisation.

In addition, the regulations permit these medicines, to be prescribed, dispensed and administered by healthcare professionals accordingly.

1.3 For good clinical reasons, the use of unlicensed medicines (and licensed medicines outside their marketing authorisation) is widespread both in primary and secondary care. The treatment of many patients would be impeded should this practice be curtailed. However, it is important that the Trust and all relevant health care professionals involved in the prescribing, supply and administration of unlicensed medicines are aware of the associated medico-legal implications.

1.4 Whilst licensed medicinal products are subject to stringent control by the Medicines and Healthcare Products Regulatory Agency (MHRA), the same assumptions cannot be made regarding the quality, safety and efficacy of unlicensed medicines.

1.5 Within this Trust, clinicians wishing to use unlicensed medicines (or licensed medicines outside the remit of the marketing authorisation) either in isolated cases or as part of established therapeutic guidelines for larger groups of patients, will be required to ensure appropriate risk assessments have been performed, with subsequent approval by the Trust Drugs and Therapeutics Committee (DTC).

1.6. The MHRA have also produced guidance on the hierarchy for the use of unlicensed medicines (MHRA Guidance Note 14):

a. An unlicensed product should not be used where a product available and licensed within the UK could be used to meet the patient's special need.

b. Although the MHRA does not recommend 'off-label' (outside of the licensed indications) use of products, if the UK licensed product can meet the clinical need, even 'off-label', it should be used instead of an unlicensed product. Licensed products available in the UK have been assessed for quality, safety and efficacy. If used 'off-label' some of this assessment may not apply, but much will still be valid. This is better than the use of an un-assessed, unlicensed product. The fact that the intended use is outside of the licensed indications is therefore not a reason to use an unlicensed product. It should be understood that the prescriber's responsibility and potential liability are increased when prescribing 'off-label'.

c. If a UK product cannot meet the need then another (imported) medicinal product should be considered, which is licensed in the country of origin.

d. If none of these options suffice then a completely unlicensed product may have to be used. For example, UK manufactured "specials" which are made in GMP inspected facilities, but which are otherwise unassessed.

e. The least acceptable products are those that are unlicensed in the country of origin, and which are not classed as medicines in the country of origin (but are in the UK). For example, the use of products from countries where they are classed as supplements, not pharmaceuticals, and may not be made to expected standards of pharmaceutical GMP. These should be avoided whenever possible.

2.0 POLICY STATEMENT

This document describes the Trust policy for the procurement, prescribing, supply and administration of unlicensed medicines (and licensed medicines outside their marketing authorisation i.e. 'off-label use').

The policy applies to all medical, nursing and pharmacy staff employed within the Trust who are involved in the prescribing, procurement, supply or administration of unlicensed medicines. Their responsibilities are outlined in this document.

3.0 DEFINITIONS/ ABBREVIATIONS

3.1 The **Trust** refers to the Sherwood Forest Hospitals NHS Foundation Trust (SFHT)

3.2 **'Medicine'** Article 1 of EU Directive 2001/83/EC defines a 'medicinal product' as:

- any substance or combination of substances presented as having properties for treating or preventing disease in human beings;
- any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Appliances, instruments and devices are not classed as medicines and are controlled by a European Devices Directive by the Devices section of the MHRA.

3.3 **Licensed medicines** are those that have been granted a marketing authorisation and are marketed in the UK for the treatment of medical conditions as defined in its marketing authorisation (i.e. the licensed indications). The Summary of Product Characteristics (SPC), also specifies the licensed indications (uses) of a medicinal product and how it is to be used (e.g. doses, frequency, route, form, reconstitution, dilution etc) and when it is not to be used (contra-indications) or used with caution (special precautions).

3.4 **Unlicensed medicines** are medicinal products which do not have a UK or EU marketing authorisation. They are manufactured by a licensed manufacturer but are not for sale in the UK. These may be:

- new medicines, post-clinical trial, awaiting a marketing authorisation. Such medicinal products can often be obtained from the manufacturer on a 'named patient / individual patient / compassionate supply basis.'
- medicines for which the marketing authorisation has been abandoned, suspended or revoked.
- medicines which have a marketing authorisation in another country, but not the UK and are imported. An unlicensed relevant medicinal product may only be imported into the UK in accordance with The Human Medicines Regulations 2012 (SI 2012/1916). An importer must hold the appropriate wholesale dealer's or manufacturer's licence that authorises import' (issued by the MHRA) and must comply with their licence conditions. Importers' licence conditions include the requirement that they must notify the MHRA on each occasion that they intend to import such a product. The MHRA may object and prevent importation because it has concerns about the safety or quality of the product, or because there is an equivalent licensed medicinal product available and it is not satisfied that there is a 'special need' for the supply to an individual patient.

Some patients may have clinical needs that cannot be met by licensed medicinal products. In order for these needs to be met, the law allows manufacture and supply of unlicensed medicinal products (commonly known as 'specials') subject to certain conditions. Regulation 167 of the Human Medicines Regulations 2012 provides an exemption from the need for a marketing authorisation for a medicinal product which is supplied;

- in response to an unsolicited order;
- manufactured and assembled in accordance with the specification of a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber registered in the UK;
- for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient; and meets the conditions specified in regulation 167(2)-(8).

If a 'special' is manufactured in the UK, the manufacturer must hold a manufacturer's (specials) licence issued by the MHRA. A 'special' may not be advertised and should not be supplied if an equivalent licensed product is available which could meet the patient's needs. Essential records must be kept and serious adverse drug reactions reported to the MHRA.

Some NHS pharmacy aseptic units and non-sterile manufacturing units are included in this group. They produce a medicinal product to the specification of an authorised purchaser, usually a pharmacist. As the products do not have a marketing authorisation, they do not have a specified indication for use, recommended dose or SPC.

3.5 **'Off-label' medicines** are medicinal products with a marketing authorisation, but used outside the terms and scope of clinical indications, doses, or routes of administration listed in their marketing authorisation. In neonatal or paediatric medicine, medicines are often used 'off-label' because the cost and ethical considerations for clinical trials in children discourage manufacturers from applying for the appropriate licence for use in these age groups. Up to 80% of neonatal drug use can be unlicensed or 'off-label'. Unlicensed drug use is also not uncommon in intensive care clinical practice.

3.6 **Exemptions:** Under Section 10 of the Medicines Act 1968, products made up in Pharmacy under the supervision of a pharmacist to the order of a doctor for an individual patient are exempt from marketing authorisation.
There are two activities within Pharmacy that can render a licensed product unlicensed:

- using a licensed drug as an ingredient in preparing a medicine for a specified patient in accordance with a prescriber's instructions. This activity (known as extemporaneous dispensing) includes parenteral nutrition compounding, preparation of intravenous additives, and cytotoxic drug reconstitution services. So long as best practice is used in the preparation process, and the plant, premises, processes and personnel are subject to audit and inspection, the risk involved in converting a licensed medicine to an unlicensed medicine in this way is small but justified if the clinical need cannot be met in another way.
- repackaging of a licensed medicinal product; eg preparing five packs of 20 tablets for use as patient packs in an emergency department from a manufacturer's pack of 100 tablets would 'de-licence' the medicinal product. Provided that the new packaging is appropriate to the product, the risk involved in converting a licensed pack to an unlicensed pack in this way is minimal and justified if the operational need cannot be met in another way. MHRA guidelines exist to limit this activity to a small scale.

3.7 **Certificate of Conformity or Analysis (COC/COA).** A certificate of conformity specifies that a pharmaceutical preparation has been manufactured to Good Manufacturing Practice standards. No analytical results will be given on this certificate and it is unlikely that it has been tested. A certificate of analysis will give detailed results of the chemical and physical testing of the product. It should also state the limits that apply to each test on the certificate. Both certificates should have an authorised signature, unless it is an electronic version not requiring one.

3.8 **Clinical Trials Medicines.** There are specific national provisions for regulating the use of medicines in clinical trials that are outside the scope of this document.

4.0 ROLES AND RESPONSIBILITES

4.1 The Trust

The Trust is responsible for ensuring that it has appropriate procedures in place for the procurement and use of unlicensed medicines and for the use of licensed medicines outside their marketing authorisation.

4.2. Drug and Therapeutics Committee (DTC)

The DTC is responsible for approving, monitoring and appraising all unlicensed medicines, and selected categories of licensed medicines being used outside their marketing authorisation. It 'risk assesses' that their use is justified (informed by the 'clinical information' provided by the requesting clinician and 'procurement' risk presented by the Quality Controller).

4.3. Prescriber

Prescribers (doctors, dentists, non-medical prescribers) who prescribe an unlicensed medicine or a licensed medicine outside the marketing authorisation are professionally accountable for their judgement and in so doing, may be called upon to justify their actions.

Prescribers should pay particular attention to the risks associated with unlicensed medicines or using licensed medicines outside their marketing authorisation. These risks may include adverse drug reactions; product quality; or discrepancy in product information or labelling. The prescriber takes **direct** responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or needs to ensure that arrangements are made for another suitable prescriber to do so.

The prescriber must;

- be satisfied that an alternative, licensed medicine would not meet the patient's needs before prescribing an unlicensed medicine or a licensed medicine outside its marketing authorisation;
- be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy;
- ensure that they adhere to the MHRA hierarchy for the use of unlicensed medicines (section 1.6);
- follow the appropriate channel for getting approval to use an unlicensed medicine or a licensed medicine outside its marketing authorisation - *see section 6.1 for more detail*;
- obtain consent from patient / parent / guardian as appropriate – *see section 6.2 for more detail*
- ensure that where treatment is to be continued in the community, there is discussion with the patient's GP around how further prescriptions are going to be issued.

Consultants are responsible for ensuring that junior doctors, who may initiate or continue treatment, are familiar with the status and prescribing requirements and that GPs are informed of the use of an unlicensed medicine or a licensed medicine outside of its marketing authorisation ('off-label' use).

Independent and supplementary prescribers are permitted to prescribe unlicensed medicines within their area of expertise and competence and in accordance with the Trust's non-medical prescribing requirements.

4.4. Medicines Information (MI)

A member of the MI team will verify relevant clinical information and forward onto procurement team or DTC as appropriate. The MI team will act as the conduit between the clinician requesting a product and the Procurement team in relation to any initial inquiries relating to product availability (prior to application) - *see section 6.3 for more detail*

4.5. Procurement staff

The assistant chief pharmacist / operations lead is responsible for ensuring that there is an up-to-date procedure for dealing with procurement of unlicensed medicines.

The procurement team will undertake relevant background work to present to the Quality Controller for assessment and order and supply the medication if required. The procurement team will also respond to any initial inquiries about product availability prior to a formal application - *see section 6.4 for more detail*

4.6. Quality controller

The Quality Controller will assign a quality risk rating to the potential product lines that could be purchased - *see section 6.5. for more detail*

4.7. Pharmacist screening prescriptions for unlicensed / off-label medicines

The pharmacist should only authorise supply if the unlicensed medicine (or licensed medicine outside its marketing authorisation) has been prescribed in accordance with this Trust policy (see Prescriber responsibilities).

The pharmacist will be able to verify previously authorised 'unlicensed' and 'licensed medicines outside its marketing authorisation', by accessing the Medicines Formulary (where records of approved unlicensed medicines are logged). Queries relating to specific particulars about previously procured products can be directed towards the Quality controller.

4.8. Pharmacy staff involved in the dispensing of unlicensed medicines

Pharmacy staff involved in the dispensing of unlicensed medicines should ensure that the prescribed medication is dispensed in accordance with the Pharmacy procedure for labelling and dispensing of medicines.

4.9. Nursing staff

Nursing staff should administer medicines in accordance with their code of professional practice, and general principles for 'all medicines' should be followed e.g. ensuring that if they are unfamiliar with a medicine, then they should verify with a doctor/pharmacist or the prescriber that it is an appropriate medicine for the patient - *see section 6.6 for more detail*

5.0 APPROVAL

Following consultation this policy has been approved by the Drugs and Therapeutics Committee.

6.0 DOCUMENT REQUIREMENTS (NARRATIVE)

6.1. Application for first time use of an unlicensed medicine or a licensed medicine outside its marketing authorisation (information for the prescriber)

The prescriber must complete parts 1–5 of the 'Unlicensed' or 'Off-label' use of Medication' application form **(**see **Appendix A** for representational copy**)** for requests relating to all unlicensed medicines and 'off-label' medicine use EXCEPT in the following circumstances;

a) where the medication already has a current Formulary approval but is unavailable and now an equivalent unlicensed product is being sourced *(note – a QC product evaluation is still required).*
b) Use of a licensed medicine outside its marketing authorisation (off-label) in the following circumstances;
    - use of a medicine by crushing / sprinkling contents when it is used in accordance with Formulary / Medicines Information department guidance
    - using liquid medicines where the equivalent medicine is licensed in other dosage forms e.g. tablet, capsule etc.
    - recognised alternative route e.g. use of parenterals sub-cutaneously in the palliative care setting
    - 'Dose/preparation endorsed by national guidance such as the 'BNF for Children'

On completion, the form should be passed onto the Medicines Information (MI) team for verification of information provided by the clinician. The MI team will maintain a log of all unlicensed medication requests.

A new submission (amendment only) is required if the medicine usage is to extend beyond that quoted in the original submission. For example, if the original submission was intended for a single patient, and now it is intended for multiple patients then a new submission is required with the relevant section highlighted.

In the case of an application for an unlicensed medicine, parts 1–5 will initially be reviewed by a member of the MI team who will ensure that all relevant sections have been completed and that the information provided within it is acceptable. If deemed appropriate, they will confirm this by signing part 6 of this form and then will forward it onto the Procurement team for further information gathering around the procurement options for the relevant product(s) with another sign-off by the Quality Controller (part 7) before it is passed onto DTC for ratification.

Where the request is for an off-label use of a licensed medicine outside of the agreed exemptions, the MI team will either accept or reject the application with or without further reference to DTC.

Urgent 'one-off' cases (for unlicensed as well as 'off-label' medication use) must be managed by the . DTC One-off process. If the DTC has rejected the application, further applications to the DTC may be made and the applicant may be asked to attend the DTC in

person. If these subsequent applications are rejected, or the DTC is unsure how to proceed in a specific case, the Medical Director, in conjunction with the Chief Pharmacist on behalf of the Trust, will be the final arbiters.

6.2. Patient consent (information for the prescriber)

Patients (or their parents or carers) should be provided with sufficient information about unlicensed / 'off-label' medicines by the prescriber, to allow them to make an informed choice about whether or not to receive that medication. This may include discussion around treatment alternatives, procedures, aims, efficacy and risks. A generic patient information leaflet for unlicensed medicines is available for issue to all patients (or their parents or carers) who are prescribed an unlicensed medicine or a licensed medicine outside its product licence. Where appropriate, written patient consent should be obtained, via the standard Trust consent procedure / form (and copy placed in the medical notes).

6.3. Medicines Information (MI)

A member of the MI team will ensure that all relevant sections of the form **(**see **Appendix A** for a representational copy**, Parts 1–5)**, have been completed and that the information provided within it is acceptable and then complete Part 6. They will then pass the form onto the Procurement team.

The MI team will be responsible for maintaining a register of 'unlicensed' and 'off-label' medicine requests that have been received via the application form (including split between 'approved' and 'rejected' applications). The MI team will also be responsible for ensuring that all approvals are annotated in the medicines Formulary.

The MI Lead pharmacist is responsible for tabling the relevant application at the DTC (after Part 7 has been completed by the Quality Controller).

In the case of requests for 'off-label' use, the MI team may make the decision to authorise (or reject) an application without the need to refer onto DTC ; or they may refer the decision to DTC if the request is deemed to be significantly outside the boundaries of the currently 'exempt' categories highlighted in this policy.

The MI team will relay the decision of the DTC to the requestor, including any adjustments to the details of the original submission.

On some occasions, the MI department will make some initial informal inquiries with the Procurement team around product options available before a full application is received.

6.4. Procurement team

The procurement team (on receipt of the 'Unlicensed' or 'Off-label' use of Medication application form' with Part 6 signed off) will then gather further information around the procurement options for the relevant product(s). They will then pass the form onto the Quality Controller.

The procurement team are responsible for purchasing the relevant product for patient use (but only after final authorisation by DTC – as denoted in Part 8). The purchase of a sample may be required to assess suitability.

The procurement team will also respond to any initial product inquiry requests from the MI department, prior to a formal application – this will allow the MI department to be aware of the existence of relevant products before a detailed explanation of requirement is requested from the clinician.

Detailed information relating to the above is described in the Pharmacy Stores Standard Operating Procedure 'Management of Unlicensed medicines' (ST.08.14)

6.5 Quality Controller

The Quality controller will undertake the associated product risk assessment and determine the level of risk for up to three products and then sign off the relevant section of the form **(**see **Appendix A – Part 7** for representational copy**).** They will then pass the form back to the Medicines Information team, for tabling at DTC.

Detailed information relating to the risk assessment process undertaken by the Quality Controller is described in the Pharmacy QC Standard Operating Procedure 'Procedure for the generation, update and archiving of unlicensed medicines specifications' (QC.00.30)

6.6. Nursing staff

In relation to unlicensed medicines, nursing staff should notify pharmacy staff and / or the prescriber as appropriate if;

- they are unsure about any aspects of the use / administration including its quality, possible side-effects or any requirement for patient monitoring;
- labelling or instructions for use are unclear;
- the patient experiences any adverse reaction.

Unlicensed medicines cannot be supplied or administered under a Patient Group Direction, however an 'off-label' medicine could be used under a Patient Group Direction when its use is considered 'best practice' and approved by the DTC.

7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
To ensure that there is an up-to-date policy	The Assistant Chief Pharmacist / Operations lead	Routine cyclical (every three years) process for review	Every three years	Drugs and Therapeutics Committee (DTC)
To report the number of unlicensed / off label medicine requests made (and provide the split between the number of 'approved' versus ' rejected' applications)	Medicines Information Department – Section Lead	Report to DTC	Every six months	Drugs and Therapeutics Committee (DTC)

8.0 TRAINING AND IMPLEMENTATION

8.1 All Trust staff will be informed of the existence of this Policy via the global email system.

8.2 All pharmacists and those staff in Pharmacy that handle or have responsibility for procurement of unlicensed medicines will have in-house training on the requirements outlined in the Policy.

8.3 Clinical staff requiring support can contact the Medicines Information team if they require any information relating to the use of unlicensed or off-label medicines use.

9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at Appendix B
- This document is not subject to an Environmental Impact Assessment

10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

Evidence Base:

- The supply of unlicensed medicinal products ('specials') – MHRA Guidance Note 14 (*Last accessed 9th March 2020 via MHRA website)*

Related SFHFT Documents:

- 'Management of Unlicensed medicines' - ST.08.14 (Sourcing, Ordering, Receipt, Supply)
- 'Procedure for the generation , update and archiving of unlicensed medicines specifications' (QC.00.30 v3)
- Pharmacy Procedure for Labelling and Dispensing of medicines

11.0 KEYWORDS

- 'off-label' ; 'specials'

11.0 APPENDICES

Appendix A: Unlicensed' or 'Off-label' use of Medication Application Form (*representational copy*)

Appendix B: Equality Impact Assessment

Appendix A

(*representational copy – not for printing/ use in practice – for live/ working copy please liaise with the Medicines Information Centre on sfh-tr.Medicines.Information@nhs.net or ext 3163*)

Unlicensed' or 'Off-label' Use Of Medication Application Form

As a requesting consultant wishing to initiate the use of an unlicensed medicine or a licensed medication outside its marketing authorisation, you must complete this form in conjunction with a senior pharmacist. Before doing so, you must be familiar with the Trust's 'Policy for the procurement and use of unlicensed medicines and licensed medicines used outside their marketing authorisation' [on intranet here] and understand your responsibilities as a prescriber under this policy.

Medicine details:

Medicine name:	
Brand name (if relevant):	
Medicine form (injection/tablet/liquids etc):	
This Product is:	○ Licensed in UK but to be used off-label ○ Licensed abroad and to be used for that indication ○ Unlicensed Medicine

Patient Details:

○ **Single patient only:**	Pt initials:	
○ **Multiple patients:**	Approx. number of patients per year:	

Clinical Details

Clinical indication for use:	
Dose range (including maximum dosage):	
Frequency:	
Route of administration:	
Duration of treatment:	
State reason(s) why an unlicensed medicine or 'off-label' use of a licensed medicine is being considered?	

Cost:

What is the cost per tablet/injection?	
What is the cost per treatment course (or per year)?	

Clinical Evidence:

Are other centres using this medicine? Who?	
Please summarise any published evidence to support the use of the unlicensed medicine and any previous clinical experience with the medicine, and state references (attach copies where these are available)	

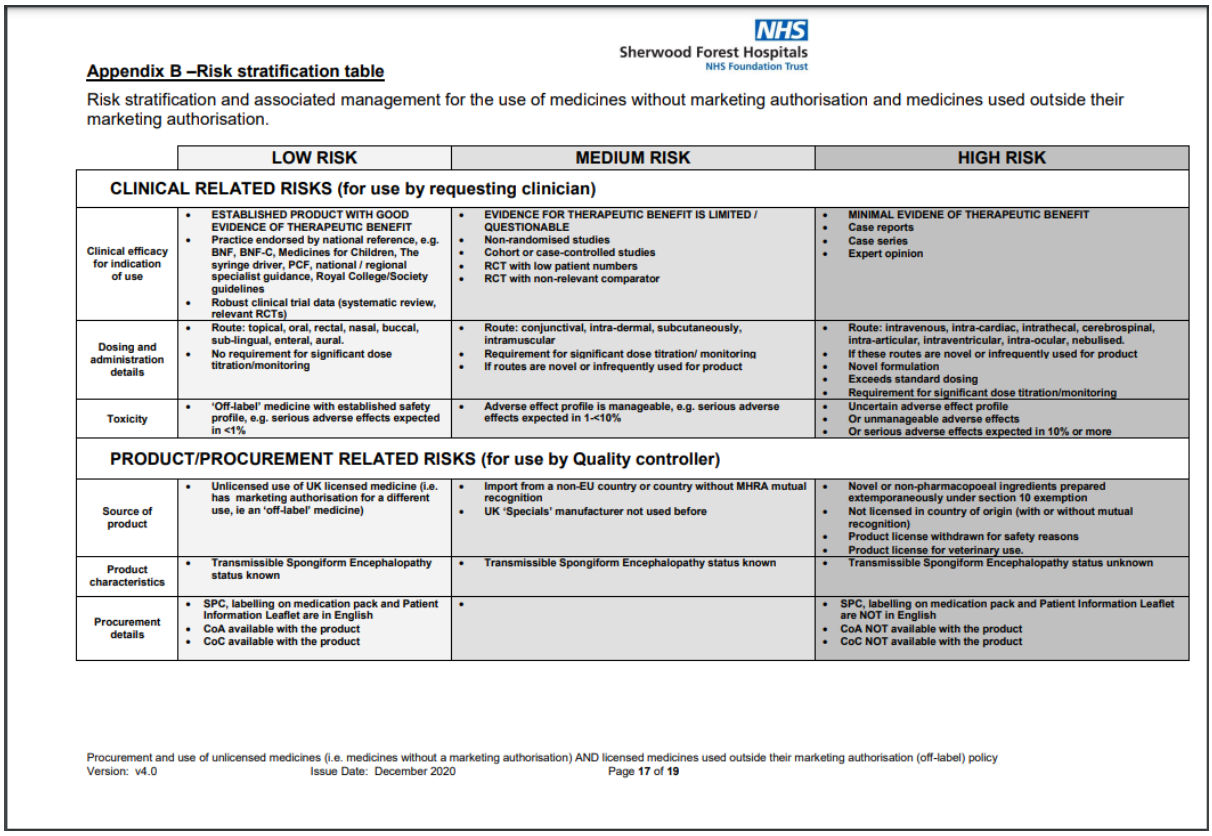
Current options:

What treatment (medicine or other) is currently used for this indication?	
What is the cost of this alternative?	

Risks:

What are the risks to the patient of NOT using this medicine?	
What are the side-effects of this treatment	
Describe any monitoring required:	
List any significant interactions:	
List any contraindications and any other risks to the patient:	
List any precautions, including precautions in use and pharmaceutical precautions:	
Is there a Patient Information Leaflet (PIL) appropriate for intended use?	

Using the table below, highlight the appropriate levels of risk for each category, Efficacy, Dosing & Toxicity:



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Appendix B –Risk stratification table

Risk stratification and associated management for the use of medicines without marketing authorisation and medicines used outside their marketing authorisation.

	LOW RISK	MEDIUM RISK	HIGH RISK
CLINICAL RELATED RISKS (for use by requesting clinician)			
Clinical efficacy for indication of use	• ESTABLISHED PRODUCT WITH GOOD EVIDENCE OF THERAPEUTIC BENEFIT • Practice endorsed by national reference, e.g. BNF, BNF-C, Medicines for Children, The syringe driver, PCF, national / regional specialist guidance, Royal College/Society guidelines • Robust clinical trial data (systematic review, relevant RCTs)	• EVIDENCE FOR THERAPEUTIC BENEFIT IS LIMITED / QUESTIONABLE • Non-randomised studies • Cohort or case-controlled studies • RCT with low patient numbers • RCT with non-relevant comparator	• MINIMAL EVIDENE OF THERAPEUTIC BENEFIT • Case reports • Case series • Expert opinion
Dosing and administration details	• Route: topical, oral, rectal, nasal, buccal, sub-lingual, enteral, aural. • No requirement for significant dose titration/monitoring	• Route: conjunctival, intra-dermal, subcutaneously, intramuscular • Requirement for significant dose titration/ monitoring • If routes are novel or infrequently used for product	• Route: intravenous, intra-cardiac, intrathecal, cerebrospinal, intra-articular, intraventricular, intra-ocular, nebulised. • If these routes are novel or infrequently used for product • Novel formulation • Exceeds standard dosing • Requirement for significant dose titration/monitoring
Toxicity	• 'Off-label' medicine with established safety profile, e.g. serious adverse effects expected in <1%	• Adverse effect profile is manageable, e.g. serious adverse effects expected in 1-<10%	• Uncertain adverse effect profile • Or unmanageable adverse effects • Or serious adverse effects expected in 10% or more
PRODUCT/PROCUREMENT RELATED RISKS (for use by Quality controller)			
Source of product	• Unlicensed use of UK licensed medicine (i.e. has marketing authorisation for a different use, ie an 'off-label' medicine)	• Import from a non-EU country or country without MHRA mutual recognition • UK 'Specials' manufacturer not used before	• Novel or non-pharmacopoeal ingredients prepared extemporaneously under section 10 exemption • Not licensed in country of origin (with or without mutual recognition) • Product license withdrawn for safety reasons • Product license for veterinary use.
Product characteristics	• Transmissible Spongiform Encephalopathy status known	• Transmissible Spongiform Encephalopathy status known	• Transmissible Spongiform Encephalopathy status unknown
Procurement details	• SPC, labelling on medication pack and Patient Information Leaflet are in English • CoA available with the product • CoC available with the product	•	• SPC, labelling on medication pack and Patient Information Leaflet are NOT in English • CoA NOT available with the product • CoC NOT available with the product

Procurement and use of unlicensed medicines (i.e. medicines without a marketing authorisation) AND licensed medicines used outside their marketing authorisation (off-label) policy
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Efficacy risk:	○ Low ○ Medium ○ High
Dosing risk:	○ Low ○ Medium ○ High
Toxicity risk:	○ Low ○ Medium ○ High

Prescribing:

○ Should be restricted to my signature only ○ May be prescribed by junior doctors involved in the treatment of patients under my care ○ May be prescribed by non-medical prescribers in accordance with agreed care
○ Yes ○ No. Will medicine be continued outside the hospital?
○ Hospital ○ GP. If yes, who will continue the prescription?
○ Yes ○ No. If GP is to continue prescriptions, is there a need for agreed shared care?

Details of person completing form

I have read the Trust Policy on the prescribing, use and supply of unlicensed medicines and, after considering the clinical benefits and associated risks in the prescribing of this unlicensed medicine, I accept full clinical responsibility for use of this medicine.

Consultant Name:			
Directorate / Speciality:			
Email address:			
Contact Number:		Date:	

Return the form to the Medicines Information Department: steven.haigh1@nhs.net

Medicines Information Department - Verification of information above

Name of Pharmacist:		Date:	

QC Risk assessment of product:

Based on the information provided by the Procurement team, I have assessed the risk of relevant product as below as assigned a product risk level;	○ Low risk ○ Medium risk ○ High Risk
Name of Quality controller:	
Date:	

Return the form to the Medicines Information Department: steven.haigh1@nhs.net

Final decision by DTC

Drugs and Therapeutics Committee approved?	Yes / No
Reasons if not approved:	
Restrictions on prescribing:	
Date of review (max 5 years):	
DTC chair:	
Date of meeting:	

APPENDIX B – EQUALITY IMPACT ASSESSMENT FORM (EQIA)

Name of service/policy/procedure being reviewed: Procurement and use of unlicensed medicines (ie medicines without a marketing authorisation) AND licensed medicines used outside their marketing authorisation (off label) policy			
New or existing service/policy/procedure: Existing			
Date of Assessment: March 2020			
For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)			
Protected Characteristic	**a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?**	**b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?**	**c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality**
The area of policy or its implementation being assessed:			
Race and Ethnicity	Patient education and consent for these highly complex issues may be more challenging for patients receiving information in a language other than their first language	An interpreter could be accessed to deliver key messages to a patient whose preference is another language	n/a
Gender	No impact identified	n/a	n/a
Age	Medicines are not always licensed for use within paediatric patients	Explanation is given to parents / guardians, and not directly to patients	Patient Information booklet to be utilised
Religion	No impact identified	n/a	n/a
Disability	No impact identified	n/a	n/a
Sexuality	No impact identified	n/a	n/a
Pregnancy and Maternity	Medicines are not always licensed for use within patients who are pregnant	Explanation is given to patients around the risk / benefit	Patient Information booklet to be utilised

Gender Reassignment	No impact identified	n/a	n/a
Marriage and Civil Partnership	No impact identified	n/a	n/a
Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation)	No impact identified	n/a	n/a

What consultation with protected characteristic groups including patient groups have you carried out?

- None

What data or information did you use in support of this EqIA?

- None

As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?

- No

Level of impact

From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (click here), please indicate the perceived level of impact:

High Level of Impact/ Medium Level of Impact/ **Low Level of Impact** *(Delete as appropriate)*

For high or medium levels of impact, please forward a copy of this form to the HR Secretaries for inclusion at the next Diversity and Inclusivity meeting.

Name of Responsible Person undertaking this assessment: **Mohamed Rahman**

Signature: **Mohamed Rahman**

Date: **March 2020**