MP 02
Unlicensed and Off-Label Medicines Policy

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Attachments

Attachment 1 – Unlicensed medicine request and risk assessment form.

1.0 Policy Statement

This policy covers the prescribing, supply and administration of all unlicensed medicines or medicines used outside their licensed indications in The Royal Wolverhampton NHS Trust.

Its purpose is to ensure safe and rational use of unlicensed medicines or licensed medicines used outside their licensed indications within the Trust, with due regard for the relevant legislation on medicines.

This policy is guided by legislation and relevant guidance produced by the Medicines Healthcare Regulatory Authority (MHRA), the General Pharmaceutical Council (GPhC), the General Medical Council (GMC) and the Royal Pharmaceutical Society (RPS)

2.0 Definitions

Marketing Authorisation and Summary of Product Characteristics

A marketing authorisation or product licence defines a medicine's terms of use; its summary of product characteristics outlines, among other things, the indication(s), recommended dose(s), contraindications, and special warnings and precautions for use on which the licence is based, and it is in line with such use that the benefits of the medicine have been judged to outweigh the potential risks.

The marketing authorisation of a licensed product assures the quality, safety and efficacy of the medicinal product and to a certain extent places liability on the marketing authorisation holder for adverse effects arising from the use of their product.

Licensed Medicines

The MHRA regulates medicinal products for human use in the UK. Licensed medicines are medicines with a UK marketing authorisation via the MHRA.

Unlicensed Medicine

There are four types of unlicensed medicinal products.

- Medicines unlicensed in the UK but licensed elsewhere.
- Medicines prepared for a patient in accordance with a prescriber's instructions. This includes any form of extemporaneous dispensing including total parenteral nutrition (TPN). Pharmacies are exempted from the need to hold a Manufacturing Licence if medicines are prepared under the supervision of a pharmacist in accordance with a practitioner's prescription.
- Unlicensed medicines prepared in a hospital or by a commercial supplier with a Specials Manufacturing Licence. These suppliers are regulated by the MHRA and follow Good Manufacturing Practice (GMP) as part of the conditions of their licence.
- Re-packed Medicines. The marketing authorisation for a medicine regulates not only its formulation at manufacture, but also the container in which it is sold. Therefore, when a medicine is removed from its original container and re-packed, either during the dispensing operation or for the assembly of small packs for use as ward stocks, it technically becomes an unlicensed product.

Since unlicensed medicines have not usually been subjected to the rigorous independent assessment of efficacy and safety applied to licensed products or to formal clinical trials, their use may carry a higher level of risk for patients.

Unlicensed medicines may also include the following.

- Medicines undergoing a clinical trial. This policy does not apply to clinical trials, see OP30 Research Governance policy.
- Medicines withdrawn from the UK market.
- Compassionate use medication i.e., products required for compassionate use either where a patient is exiting a completed clinical trial or where a consultant has a Medicines Management Group (MMG) approved agreement with the pharmaceutical company supplying the medication.

Off-label Use (UK licensed medicines being used outside the terms of the marketing authorisation)

'Off-label' medicines are medicines with a UK marketing authorisation which are prescribed for an unlicensed indication, at an unlicensed dose (e.g., high dose antipsychotic therapy), via an alternative route or site, or for a different patient group. Also included are those situations where the formulation is changed before administration e.g., mixing of medicines or crushed tablets.

If a patient is harmed by such use of a medicine, then the manufacturer is unlikely to be found liable unless the harm is directly attributable to a defect in the medicine rather than in the way in which it was prescribed.

Certain off-label use is well established in clinical practice and widely supported in the medical literature. Where there is a sufficient body of evidence for the Trust to endorse either the use of an unlicensed medicine or off-label use, it will be added to the unlicensed and off-label list and annotated accordingly.

Certificate of Analysis

A certificate of analysis is a certificate issued by the supplier of an unlicensed medicine to its recipient giving details of analytical testing which has been carried out on the unlicensed medicine and the results of this testing.

Certificate of Conformity

A certificate of conformity is granted to a product that meets a minimum set of regulatory, technical and safety requirements.

3.0 Accountabilities

3.1 Chief Executive

The Trust Chief Executive is responsible for ensuring that medicines management within the Trust conforms to best practice. This responsibility is delegated to the Clinical Director of Pharmacy, who is the medicines management lead for the Trust.

3.2 Medicines Management Group (MMG)

The MMG is responsible for critically evaluating the evidence, doing a risk assessment and making a decision regarding the approval of unlicensed or off-label medicines for use within the Trust.

In the case of urgent clinical need, the Clinical Director of Pharmacy or MMG Chairperson may authorise use of an unlicensed or off-label medicine.
The MMG also ensures appropriate audit systems are in place to monitor compliance with this policy and unlicensed medicines use within the Trust.

3.3 Clinical Director of Pharmacy

The Clinical Director of Pharmacy is professionally accountable for the safe and secure handling of unlicensed and off-label medicines within the Trust. They also have delegated responsibility for ensuring there is a policy and any necessary supporting procedures for the use of unlicensed and off-label medicines as part of safe and effective medicines management.

3.4 All Prescribers

All prescribers must accept professional, clinical and legal responsibility for unlicensed and "off-label" prescribing, and they must only undertake this in accordance with this policy, where it is accepted clinical practice and within the limits of their own knowledge and skill, competence and clinical expertise. Prescribing off-label should only be done where it is considered best practice.

3.5 Medical Prescribers

The General Medicine Council (GMC) provides guidance on prescribing unlicensed medicines in: *Good practice in prescribing and managing medicines and devices.*

3.6 Non-Medical Independent Prescribers (NMPs)

Non-medical independent prescribers can prescribe unlicensed medicines and off-label medicines for their patients on the same basis as doctors provided it is within their competency and scope of practice and they take responsibility for doing so.

Some regulatory bodies have placed restrictions on the prescribing of unlicensed and off-label medicines by some healthcare professions. Please refer to your regulatory body for current restrictions.

3.7 Supplementary Prescribers

A supplementary prescriber can prescribe any medicine, including an unlicensed medicine or an off-label medicine, for any condition within their competence. The scope of supplementary prescribing is an issue to be agreed in the patient's clinical management plan and will be for the clinical judgment of the independent medical prescriber.

3.8 Staff involved in the use of unlicensed or off-label medicines

It is the professional responsibility of all staff involved in the prescribing, supply and administration of medicines to be familiar with this policy.

3.9 Administrating Clinician

Any clinician who administers or supplies an unlicensed medicine or licensed medicine for off-label use is professionally and legally responsible for their actions and must ensure the medicine is clinically suitable, safe and approved for use. They have a responsibility to report any adverse events.

3.10 Supplying Pharmacist

The supplying pharmacist is both professionally responsible and legally accountable for the appropriate and safe use of an unlicensed or off-label medicine in accordance with the Human Medicines Regulations 2012. They have a responsibility to report any adverse events.

The pharmacist is responsible for any unlicensed or off-label medicine that they clinically check or approve for issue to a patient, ward or department.

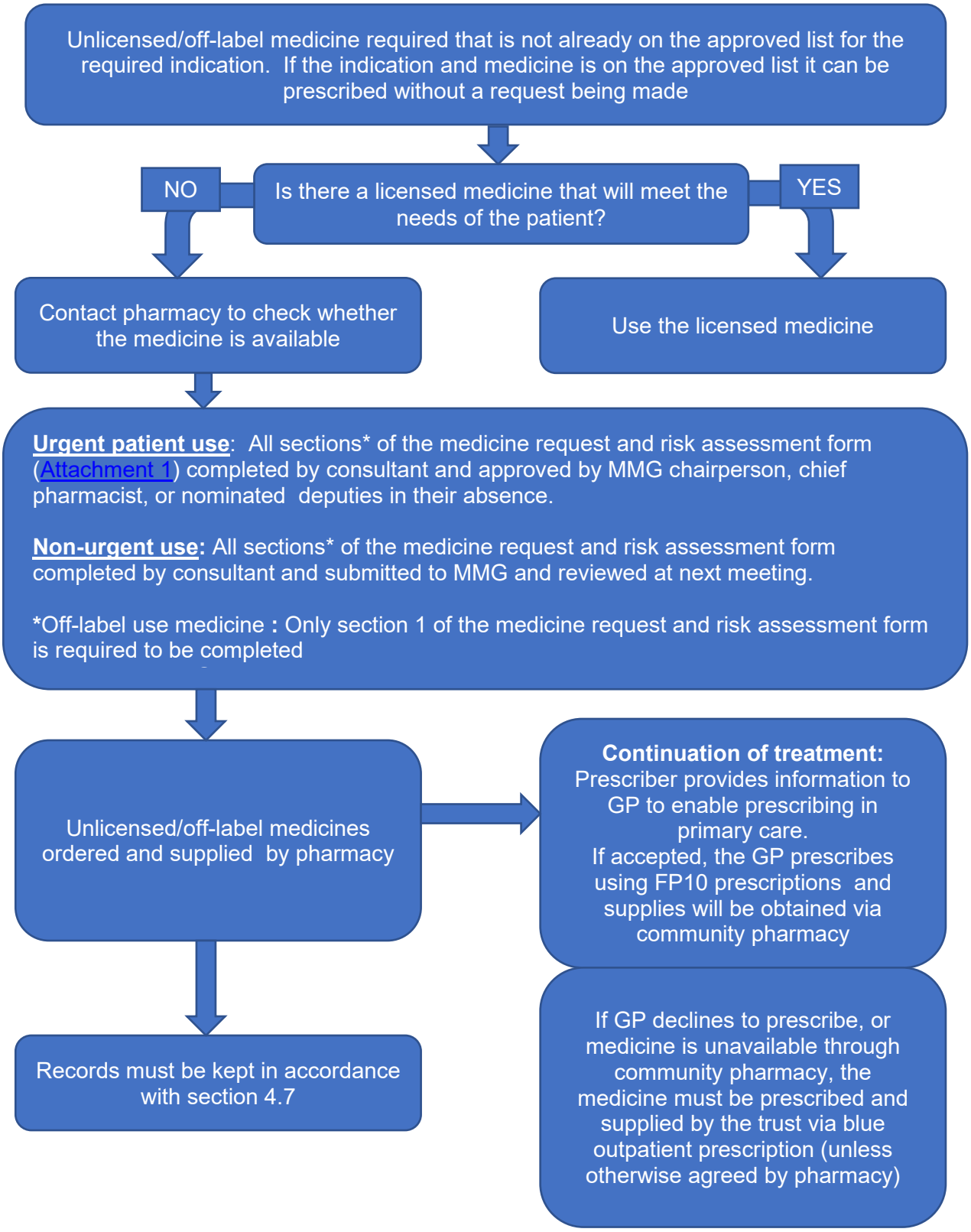
3.11 ARSAC Licence Holders

For the purpose of unlicensed and off-licence radiopharmaceuticals only, the Trust ARSAC licence holders will do the following.

- Ensure that appropriate procedures are in place within the Radiology Department and Medical Physics Department to cover all aspects of the procurement and supply of unlicensed and off-label radiopharmaceuticals.
- Authorise the purchase and use of all unlicensed and off-licence radiopharmaceuticals.
- Ensure that only authorised staff are able to order unlicensed radiopharmaceuticals and that they only do so from a Trust authorised supplier.
- Ensure that the unlicensed radiopharmaceutical has been approved before it is used.

4.0 Procedure

4.1 Process flow chart



4.2 Approval to use an unlicensed medicine

The Trust will, through the MMG, maintain a list of unlicensed medicines and established unlicensed indications where there is a sufficient body of evidence for the Trust to endorse their use. This list - 'List of Approved Unlicensed Medicines and Unlicensed Indications for Licensed Medicines' will be available to all prescribers on the pharmacy page of the Intranet and will be regularly updated. If a clinician wishes to prescribe a medicine that is already on the list then they can do so for the indications listed. A new request is not needed.

The MMG will review the current list of approved unlicensed medicines on an annual basis to ensure their use remains appropriate. If a medicine is recommended to be removed a notification will be sent to the original applicant prior to its removal. This will enable a re-submission to be made if it is necessary. All further requests for supplies will be declined at the time of removal from the list.

If a prescriber wishes to prescribe a medicine for an indication not on this list, they must apply to the Trust MMG for approval to use the medication and the medication must not be used until the decision has been made. This request must be supported by a thorough review of the literature, a summary of the current evidence base for the request, and a completed risk assessment for all unlicensed medicines. The unlicensed medicine request and risk assessment form is in attachment 1.

If the request is urgent then the unlicensed medicines request and risk assessment form must be completed and sent to the Chairperson of the MMG or the Clinical Director of Pharmacy for authorisation. Non-urgent requests must be completed and submitted to the Trust MMG for review at the next meeting.

When submitting the request and risk assessment form for an unlicensed medicine all sections must be completed. Off-label uses of a licensed medicine only need to have section 1 completed.

If a patient is admitted on an unlicensed or off-label medication that is already on the approved list, then a request and risk assessment form is not required; if the patient is admitted on an unlicensed or off-label medication that is not on the approved list, then a request and risk assessment form is required before a supply is made by Pharmacy. Consideration must be given to any potential adverse effects from withholding treatment whilst a request is made and clinical judgment applied.

4.3 Prescribing

Prescribing of unlicensed and off-label use medicines must be done within the competence, skill and expertise of the prescriber. NMPs must also comply with any restrictions placed upon them by their regulatory body, e.g. a regulatory body may restrict NMPs to only prescribe off-label use medicines.

When prescribing, the MHRA has a preferential sequence of use for unlicensed medicines which must be followed when prescribing any unlicensed medicine, as below.

Prescribers of unlicensed medicines carry their own responsibility and are professionally accountable for their judgement in so doing and in the case of adverse events may be called upon to justify their actions. It could be anticipated that such justification would be achieved if a body of peers would recognise the prescription as best practice.

The manufacturer carries no legal liability for unlicensed medicines or “off-label” use of medicines unless harm results from a defect in the product.

The prescriber’s and the Trust’s responsibility and potential liability are increased when prescribing unlicensed or off-label medicines. The ultimate responsibility for prescribing lies with the person who signs the prescription.

The prescribing of unlicensed medicines within the Trust may only be initiated by a consultant, unless the item is included in the Trust approved list of unlicensed medicines and is unrestricted. If a patient is to continue with treatment, any subsequent prescribing can be undertaken by any prescriber in accordance with this policy and within the limits of their knowledge, skills, competence and clinical expertise.

Prescribers must do the following.

- Ensure that the unlicensed or off-label use has been authorised by the Trust before prescribing. In urgent cases this can be expedited through the ward pharmacist.
- Satisfy themselves that the treatment is appropriate for the patient’s need and that there is enough evidence base to support the use of the medication for the indication.
- Satisfy themselves that an alternative, licensed medicine would not meet the patient’s needs.
- Record the details of the unlicensed or off-label use of a medicine in the patients’ notes, specifying the reasons for use & outline the monitoring plan.
- Ensure continuity of prescribing and overseeing the patient’s care, including monitoring and follow-up.

- Obtain patients' consent and record this in the notes prior to use. For patients, or those authorising treatment, who are unable to give consent, it would not be advisable to use an unlicensed or off-label medicine which is not included in the Trust's approved list.
- Give patients, or those authorising treatment on their behalf, enough information about the proposed treatment, including reasons for using this medicine, known serious or common adverse reactions, to enable them to make an informed decision.
- Record and report any medicine reactions to the MHRA via the yellow card scheme and the trust electronic incident reporting system (Datix).
- Where the responsibility for ongoing care is to be transferred to the patient's GP, the GP must be informed of the unlicensed status of the medicine and be willing to accept clinical and legal responsibility for prescribing. The Trust clinical team is responsible for continuing treatment if the GP will not accept responsibility for continuing care.

Prescribers should pay attention to the risks which may include:

- inappropriate or missing product information or labelling e.g. absence of information for some unlicensed medicines or information in a foreign language for unlicensed imports; and
- information in the patient information leaflet (PIL) is inconsistent with the off-label use, as well as the efficacy & safety for the proposed indication.

Where a patient is transferred to the care of another prescriber, it is the responsibility of the receiving prescriber to ensure an adequate risk assessment of the unlicensed or off-label use of the medicine has been undertaken before writing a prescription.

The prescriber must bring to the attention of the patient or those authorising treatment on their behalf, the fact that an unlicensed medicine does not have a marketing authorisation and its significance. As far as is possible, this must be done without undermining the patient's confidence in either the prescriber or the prescribed medicine.

The effects of an unlicensed medicine may be less well understood than those of a licensed product. A patient information leaflet is available on the intranet here . This must be given to the patient by the prescriber or pharmacist explaining the use of unlicensed medicines.

4.4 Prescribing for children and young adults

It is recognised that in neonatal and paediatric medicine, medicines are often used outside their licence limits because the cost and ethical considerations for clinical trials in children discourage manufacturers from applying for a licence for use in children. The Trust supports the policy statement on '*The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice*' produced by the Joint Standing Committee on Medicines, a joint committee of the Royal College of Paediatrics and Child Health (RCPCH) and the Neonatal and Paediatric Pharmacist Group (NPPG).

Many children require medicines not specifically licensed for neonatal and paediatric use,

and healthcare professionals involved in the care of children should be aware of the advice given in the BNF for Children with regards to prescribing unlicensed and off-licence medicines.

When a medicine is prescribed off-licence for a child or young adult, the prescriber will not normally be required to complete the unlicensed medicines request and risk assessment form . However, unlicensed medicines prescribed for children are subject to the same risk assessment process as for adults.

The RCPCH and NPPG have produced national PILs on the use of medicines for children. These PILs include information for patients and carers on unlicensed medicines. The PILs can be accessed via the medicines for children website Unlicensed medicines – Medicines For Children.

4.5 Ordering and supply

Pharmacy department

Before ordering an unlicensed medicine, the pharmacy procurement team must have a fully complete and approved unlicensed medicine request and risk assessment form.

Pharmacy stores must complete section 3 of the request and risk assessment form (Attachment 1) for all medicines ordered and held within the Trust. These must be reviewed annually to ensure they remain valid. They must also have a procedure in place to track the medicines within the Trust. See section 4.7 for administration, supply and record keeping

Pharmacy procurement will maintain an up-to-date list of Trust approved unlicensed medicines. This will be updated whenever there is an addition or deletion from the list and published on the intranet.

It is the responsibility of the pharmacy procurement team to assure the quality of the product. Pharmacy procurement must complete section 3 of the request and risk assessment form. If the product is high risk, then it should be referred back to the consultant and pharmacist for review prior to submission to the MMG or the ordering of the product.

When ordering the medicine, pharmacy procurement must create the item's product information within the pharmacy system. They must record the unlicensed status of the medicine in such a way that it is visible to the pharmacy teams in log view or on the ward stock list.

Where the supplier is a specials manufacturer or a specials importer, they must ensure that a " 'Certificate of Analysis' or 'Certificate of Conformity' is available, unless it is a Section 10 exemption (e.g., prepared by the hospital) in which case it is not necessary.

When ordering medicines which are imported from another country the MHRA list of currently approved countries for import must be followed. This is in accordance with Human Medicines Regulations 2012.

All imported unlicensed medicines must be quarantined until clinically approved as suitable.

All unlicensed medicines must be kept in a segregated designated area in the pharmacy store and the dispensary.

In accordance with MHRA guidance, pharmacy procurement must have a process in place to track all orders and supplies of unlicensed medicines.

Clinical pharmacist
They must ensure prescribers are aware if a medicine is unlicensed or being used off-label, and if the medicine is not on the Trust approved list of unlicensed or off-label medicines, then they must review and approve the completed request and risk assessment form (attachment 1) once completed by the consultant.

They must support pharmacy procurement by reviewing the product's suitability once it has been sourced, and if acceptable, approve its release from pharmacy. Any delay in obtaining the product should be communicated to the prescriber.

They must help obtain, where possible, an English specification of product characteristics and PIL. For licensed medicines used for off-label use, the PIL will be inappropriate for 'off-label' use and this must be communicated to the patient.

They must inform the patient of the unlicensed nature of the medicine or off-label use. This should be done without undermining the patient's confidence in either the prescriber or the prescribed medicine.

The prescriber may not know the licence status of the preparation dispensed for the patient since often this will be determined at the time of dispensing. It is the responsibility of the pharmacist to inform the prescriber that the medicine will be used in an unlicensed manner.

4.6 Consent
Patients' informed consent should be obtained for all medicine use in accordance with the Trust consent policy CP06.

In situations where the use of an unlicensed or off-label medicine is uncommon, novel, or believed to carry a substantial hazard, or where the evidence for its use is not overwhelming, it is appropriate to inform the patient to this effect. A record of the consent should be made in writing. The rationale for selecting this treatment must also be documented in the patient's notes.

The Trust MMG may deem that the use of certain unlicensed medicines requires mandatory written consent. There are also medicines which require this at the instigation of the Medicines and Healthcare Products Regulatory Agency (e.g., thalidomide).

A leaflet explaining unlicensed and off-label medicines is available on the intranet and may be given to the patient by the prescriber or pharmacist explaining briefly the issues

surrounding unlicensed medicines.

4.7 Administration, supply and record keeping

Each administration of an unlicensed medicine must be recorded within the patient's medicine administration record chart. The batch number and expiry date must be recorded at the point of every administration. It is a requirement that these records can be accessed for at least 5 years. It is the responsibility of the ward manager to ensure this process is followed.

When a medicine is supplied at discharge or as an outpatient, the pharmacy dispensary must have a procedure in place to record to whom the medicine was supplied and the batch number and expiry of the unlicensed medicine that was supplied

The Trust must retain records as follows.

Document	Duration of retention
Unlicensed medicine request and risk assessment	5 years after last use
Pharmacy stores unlicensed medicines tracking sheet	5 years from last issue
Unlicensed medicines record of administration or supply	5 years from last supply or administration

These records must be made available upon request by inspectors.

Should there be any incident with an unlicensed medicine this MUST be reported on the trust reporting system (Datix). This includes clinical incidents but also anything in relation to the product's quality or appearance.

4.8 Primary Care

Where initiation of treatment with an off-label or unlicensed medicine occurs in hospital, the consultant recommending the medicine is responsible for ensuring that appropriate information is provided to the GP and arrangements are made, in conjunction with pharmacy, for relevant information to be passed on to community pharmacists.

The consultant must ask pharmacy to confirm that the medicine is available through community pharmacy before considering asking the GP to continue prescribing. Some unlicensed products cannot be obtained via a community pharmacy. In this situation, the Trust will be responsible for supplying the whole course of treatment.

If the medicine can be supplied by community pharmacy, GPs may be asked to continue to prescribe unlicensed or off-label medicines e.g. hyoscine hydrobromide for hypersalivation. However, within the high and medium risk categories, unlicensed medicine prescribing is best done where there is a written protocol for use. These instances are best discussed with the GP on a case-by-case basis.

The consultant who has initiated treatment with the unlicensed or off-label medicine is responsible for ensuring that the relevant GP is given enough information about the product. The following information should be provided:

- name of medicine,
- dose and formulation,
- licensed status of the medicine,
- reason for prescribing,
- duration of treatment,
- common side effects, and
- monitoring requirements (if any) and when it is appropriate to refer the patient back to the consultant.

For some individuals it may be possible to transfer monitoring to primary care, but this requires the agreement of the patient's GP.

4.9 Unlicensed radiopharmaceuticals

All unlicensed radiopharmaceuticals used by the Radiology Department and Medical Physics Department will be used in accordance with local standard operating procedures and under supervision of the Trust ARSAC licence holders.

5.0 Equipment Required

None

6.0 Training

None

7.0 Financial Risk Assessment

1	Does the implementation of this document require any additional Capital resources	No
2	Does the implementation of this document require additional revenue resources	No
3	Does the implementation of this document require additional manpower	No
4	Does the implementation of this document release any manpower costs through a change in practice	No
5	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff.	No
	Other comments Using a licensed medicine rather than an unlicensed medicine may be more expensive. Importing an unlicensed medicine where there are supply problems with a licensed medicine may	

	also be more expensive. It is impossible to predict the overall financial impact to the Trust in advance of use of such products. Implementing this policy is unlikely to impact significantly on trust finances, but compliance with this policy does reduce the risk of corporate or individual litigation claims.	

8.0 Equality Impact Assessment

An initial equality analysis has been carried out and it indicates that there is no likely adverse impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010.

9.0 Maintenance

The Clinical Director of Pharmacy is responsible for keeping the policy up to date. Any revisions to the policy will be reviewed by the Trust's Medicines Management Group before being submitted through the Trust's policy approval procedure

10.0 Communication and Training

This policy will be published on the Trust Intranet. and will therefore be available to all staff. Managers will ensure that all relevant staff are briefed on its contents and on what it means for them.

The use of unlicensed medicines will be included in medical, nursing and pharmacy medicines management training and, or incorporated into local inductions.

11.0 Monitoring Process

Criterion	Lead	Monitoring method	Frequency	Evaluation
Completed unlicensed medicine request and risk assessment forms	Clinical Director of Pharmacy	Forms will be submitted to MMG for approval	Continually	Medicines Management Group (MMG)

Unlicensed medicines approved for use	Clinical Director of Pharmacy	A list of unlicensed medicines approved for use will be included in the MMG report to QSAG	Every 6 months	MMG

12.0 References

1. Section 10 of the Medicines act 1968 and Regulation 4 of the Human Medicines Regulations 2012
2. Good practice in prescribing and managing medicines and devices - ethical guidance summary - GMC (gmc-uk.org)
3. The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice, Joint Standing Committee on Medicines, updated 2020
   The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice | RCPCH
4. The Supply of Unlicensed Medicinal Products May 2014. MHRA Guidance Note No 14
   Supply unlicensed medicinal products (specials) - GOV.UK
5. Medicines for Children Unlicensed medicines – Medicines For Children
6. Royal Pharmaceutical Society, Professional Guidance for the Procurement and Supply of Specials, December 2015
   specials-professional-guidance.pdf (rpharms.com)
7. Royal Pharmaceutical Society, Guidance for the prescribers of Specials, April 2016
   professional-standards---prescribing-specials.pdf (rpharms.com)
8. Royal Pharmaceutical Society, A competency framework for all prescribers, September 2021
   A Competency Framework for all Prescribers | RPS (rpharms.com)

Part A - Document Control

Procedure/ Guidelines number and version	**MP 02 Unlicensed and Off-label Medicines Policy** **V4.0**	**Status:** FINAL		**Author:** Deputy Clinical Director of Pharmacy **For Trust-wide Procedures and Guidelines Chief Officer Sponsor:** Chief Medical Officer
Version / Amendment History	Version	Date	Author	Reason
	1.0	April 2009	Clinical Director of Pharmacy	Implementation of new policy
	2.0	August 2016	Clinical Director of Pharmacy	Review and renewal
	3.0	August 2019	Clinical Director of Pharmacy	Update
	3.1	December 2022	Clinical Director of Pharmacy	Extension
	4.0	December 2022	Deputy Clinical Director of Pharmacy	Full review of policy and update of request and risk assessment form
Intended Recipients: Consultants, Prescribers, Registered healthcare professionals				
Consultation Group / Role Titles and Date: Trust MMG				
Name and date of group where reviewed	Trust MMG Trust Policy Group – February 2023			
Name and date of final approval committee	Trust Management Committee – February 2023			

Date of Procedure/Guidelines issue	March 2023
Review Date and Frequency	February 2026
Training and Dissemination: Existing policy but reminder to be circulated within the consultants committee and to non-medical prescribers and pharmacists	
Publishing Requirements: Can this document be published on the Trust's public page: **Yes**	
To be read in conjunction with: MP 01 medicines policy; MP 04 Management of medication errors; MP05 Antimicrobial policy; MP06 Policy for shared care agreements	
Initial Equality Impact Assessment: Completed Yes / No Full Equality Impact assessment (as required): Completed Yes / No / NA If you require this document in an alternative format e.g., larger print please contact Policy Management Officer 85887 for Trust- wide documents or your line manager or Divisional Management office for Local documents.	
Contact for Review	Deputy Clinical Director of Pharmacy
Monitoring arrangements	Trust MMG
Document summary/key issues covered. The Policy and process for the approval and use of unlicensed and off-label medicines	
Key words for intranet searching purposes	Unlicensed medicine Off-label use

(Part B) Ratification Assurance Statement
Name of document: MP02 – Unlicensed and Off-label Medicines Policy

Name of author: Nicholas Carré Job Title: Deputy Clinical Director of Pharmacy

I, Nicholas Carré the above named author confirm that:

- The Policy (please delete) presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Management Officer for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author:

Date:

Name of Person Ratifying this document (Chief Officer or Nominee):
Job Title:
Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to:
The Policy Management Officer

IMPLEMENTATION PLAN
To be completed when submitted to the appropriate committee for consideration/approval

MP02	**Unlicensed and Off-label Medicines**	
Reviewing Group	Trust MMG	**Date reviewed: 06/12/2022**
Implementation lead: Print name and contact details		
Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.	n/a n/a	
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form	n/a	
Development of Forms, leaflets etc.; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed	Pt leaflet Held on intranet, managed separately to policy	Jan 2022
Procedure/Guidelines communication; Consider 1. Key communication messages from the policy / procedure, who to and how?	Comms to prescribers via email	Feb 2022 after TPG Approval
Financial cost implementation Consider Business case development	n/a	
Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation	n/a	

MP02 Attachment 1 Unlicensed Medicine Request and Risk Assessment Form

SECTION 1 - REQUEST

In the case of urgent clinical need an off-label use medicine may be authorised by a pharmacist, escalating as necessary. new unlicensed medicines must be approved by the MMG Chair or Clinical Director of Pharmacy (or designated deputies). The form must be completed at the time and submitted retrospectively to the MMG for ratification.

Generic Name Proprietary name (if know):	Pharmaceutical form
Strength	Indication for use
Dose (include range if applicable)	Frequency
Route	Duration of Treatment

Have the contraindications/precautions and side effect profile been reviewed?	Yes / No
Has a monitoring plan been developed that will be included in the medical notes?	Yes / No
I understand that the named product is an unlicensed medicine and the prescribing responsibilities/ implications of this	Yes / No
I accept responsibility for fully informing the patient or carer of the fact that the product is unlicensed and has no UK product licence. I will initiate each prescription for the patient and obtain their consent/carer's consent.	Yes / No
Providing the above has been undertaken and the medicine is approved for use, I understand that this prescription and its consequence will be covered for vicarious liability under terms of my contract with the Trust.	Yes / No
I understand that pharmacy will take all possible steps to ensure the quality and safety of an imported medicine but that it cannot be guaranteed.	Yes / No
Will there be any primary care implications e.g. transfer of care or need for a shared care agreement. If yes, please describe	Yes / No
The purpose of this policy is to provide an internal means of assessing the use of these products, safeguarding patients against the risk of injury and minimising risks of claims against the Trust. I acknowledge that all unlicensed medicines must be approved before use.	

Consultant Name:	Department/unit:
Signature:	Date:
Registration No.	email:

Declaration by Lead pharmacist:

An application form and risk assessment has been completed	Yes / No
The non-formulary form has been completed/medicines evaluation written (delete as appropriate)	Yes / No

Lead pharmacist name:	Department/unit:
Signature:	Date:
Registration No.	email:

To be completed by the Consultant

Patient Details:

Is this to be used for a single patient only?	Yes / No
If Yes NHS Number:	Ward/Clinic:

Multiple Patients Estimated number of patients a year:	

Clinical Details

Why is this unlicensed medicine being considered? (Please tick)

Pharmaceutically equivalent licensed product temporarily unavailable	
Equivalent UK Licensed product unavailable/unsuitable*	
Other*	

*Provide additional information

Clinical Evidence

Is there any evidence to support its use for the proposed indication?	Yes / No
Is there any evidence to support its use for other indications?	Yes / No
Is there any evidence to support its proposed administration schedule?	Yes / No
Is the active drug currently in a licensed product for use via the proposed route?	Yes / No
Is the product licensed in a country on the list of approved countries?	Yes / No
Is the product licensed in any country for the proposed indication? If yes, please state which ones	Yes / No
Are any other centres in the UK using this medicine? If so please state which	Yes / No / don't know Name:

Please summarise any published evidence to support the use of the drug for the indication proposed:
References
Authors: Title: Journal reference:
Authors: Title: Journal reference:
Please attach any more as necessary

Approval By:

Clinical Director of Pharmacy or Trust MMG Chairperson Name: Signature: Date:

To be completed by the Pharmacy Procurement Department

SECTION 2 - RISK ASSESSMENT

Product:		**Overall Risk Rating:**	
Proposed distribution	Named patient / ward stock	Specialty / Client group:	
Details of manufacturer and supplier (give both if different)			
Name of Importer*			
Importation Time*			
Quantity to be imported*			
Risk	Notes	Risk rating	Risk Score

Supplier			
Local unit with QA managed by regional QA lab		0	
Commercial specials manufacturer (UK)		0	
Other NHS Licensed specials unit (not local)		1	
Origin			
UK manufacturer with specials licence		0	
Country on UK list of approved countries		2	
Elsewhere licensed in country of origin		3	
Elsewhere – NOT licensed in country of origin but licensed elsewhere		4	
Supplier is not on the Trust approved list		6	
Elsewhere – NOT licensed in any country		15	
UK no specials licence		15	
Are special storage conditions required?		4	
Certification			
Full analytical report available		0	
Batch specific certificate of analysis available		0	
Batch specific certificate of conformity available		0	
No certificate available (licensed in country of origin)		3	
No certificate available		4	
Specification			
BP/EP/USP monograph product		0	
Other pharmacopoeia monograph		1	
Only a manufacturers specification available		2	
No external specification available		3	
Route of administration			
Topical to intact skin (non-sterile)		0	
Mucous membranes or broken skin		1	
Sterile all routes except intrathecal		2	
Sterile intrathecal		3	
Therapeutic agent			
Established therapeutic agent, no special problems		2	
Recognised therapeutic agent – minor problems or little experience of use		4	
Novel therapeutic agent or unusual use		6	

Unrecognised therapeutic agent with some supporting evidence for use		12	
Unrecognised therapeutic agent with no information available		15	
Recognised therapeutic agent with known problems		15	
Products containing material of animal or human origin		15	
Labelling			
Label conforms to UK standards		0	
Label does not contain all necessary information		6	
A PIL is available		0	
No PIL is available		4	
information been translated from another language and certified		4	
information been translated from another language but not certified		12	
non-English language packs are over-labelled in English language		2	
non-English language packs are not over-labelled in English		12	
TOTAL SCORE			

Products scoring 0 – 14 = Low risk rating
Products scoring 15 – 20 = medium risk and may require restrictions and additional monitoring put in place
Products scoring 21 or above = high risk rating and must have restrictions and additional monitoring put in place

Risk Rating (Please circle) **Low / Medium / High**

***if applicable**

Risk assessment carried out by: **Date:**

Risk assessment checked by: **Date:**

Outcome of Risk Assessment:

Risk assessment agreed by MMG: **Yes / No** **Date:**

Reasons if not approved:

Restrictions on prescribing:

Date of Review: **(Max 5 years)**	

Name of MMG member:	
Signature	
Date	

Date added to Trust approved unlicensed medicine list	
Added by:	

SECTION 3 - Pharmacy Product Summary Sheet

Product Details

Product Name	
Strength	
Form	
Pack Size	
Trade Name	
Storage Requirements	
Indication for use	

Supplier Details

Manufacturer	
Country of Origin	
Language on Packaging	
Certificate of Analysis	
Translation Leaflet	

Authorised Check by Pharmacist

Name	
Signature	
Date	

Check of Product released by Pharmacist

Name	
Signature	
Date	