Western Sussex Hospitals NHS
NHS Foundation Trust

Unlicensed Medicines Policy

Summary statement: How does the document support patient care?	This policy provides information on unlicensed medicines and medicines used outside of their license (off label). It outlines best practice on the use of unlicensed medicines and provides a method of risk assessment for practitioners prescribing and supplying unlicensed medicines to patients
Staff/stakeholders involved in development:	Head of Pharmacy Associate Head of Pharmacy
Division:	Core
Department:	Pharmacy
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For use by:	All staff involved in the prescribing, supplying and administration of medicines to patients within Western Sussex Hospitals NHS Foundation Trust.
Purpose:	This document provides information and instruction on the use of unlicensed and off label medicines. It describes the process by which these are categorised according to risk assessment in the Trust and outlines responsibilities.
This document supports: *Standards and legislation*	Statutory Instruments 2012. Number 1916. The human Medicines regulations 2012
Key related documents:	Medicines Management Policy
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1.0	Dec 2015	[redacted]		Replaced former WaSH policy 2009 prepared with stakeholder consultation
2.0	March 2019	[redacted]	live	Reviewed and updated in line with current legislation. Clearer definition of staff responsibilities. Simplified product risk assessment. Additional statement for PGD 'off label'. Separation of risk assessment of unlicensed products from 'off label' use.

Contents.

1. Background

Medicines Legislation, specifically The Medicines for Human Use Regulations 2012 (SI 2012/1916) requires that medicinal products are licensed before they are marketed in the UK. Medicines which meet standards of safety, quality and efficacy are granted marketing authorisation (MA) (previously known as product licence). This defines the clinical indications for which a licensed medicinal product can be marketed. It describes the form, dose, route of administration, contraindications, special warnings and precautions for use. It is in line with such use that the benefits of a medicine have been judged to outweigh the potential risks. Furthermore, a licensed medicine has been assessed for efficacy, safety and quality. It has been manufactured to appropriate standards and when placed on the market is accompanied by appropriate product information and labelling.

Hence licensed products would always be used in preference to unlicensed medicines for the majority of prescriptions.

In circumstances where patients have specific clinical requirements that cannot be met by licensed medicinal products the law allows manufacture and supply of unlicensed medicinal products (commonly known as 'specials' subject to certain conditions so that these requirements can be met).

Examples may include:

- Being unable to swallow tablets whole, and no equivalent licensed oral liquid preparation available.
- Allergy or other adverse reaction to products that hold a MA.
- No product available with a MA available for an indication.
- Majority of prescribing for paediatric and pregnant patients.

Additionally national guidance such as NICE may offer an unlicensed alternative in a pathway as a potential treatment option e.g: bevacizumab intravitreal injection for Age-related Macular Degeneration (AMD).

Type of unlicensed medicines use reviewed in this policy include:

- Products without a MA in the UK requiring the medicine to be imported.
- 'Off label' use of a licensed UK preparation. A product being used for anything outside that stated in the MA.
- Products prepared either under a 'specials' license or within a hospital pharmacy under sections 9,10 and 11 of The Medicines Act 1968.
- Products not classified as medicines but being used to treat rare conditions.
- A specific unlicensed product being advocated as part of an appropriate national recognised pathway.

The licensing status of a medicine is an important consideration for prescribers and pharmacists. If an untoward incident occurs with a licensed medicine as a result of a product defect or a problem arising from use outlined by the MA then any liability arising may in part or whole be transferred to the MA holders. Should a patient suffer harm as a result of effects of an unlicensed medicine or use outside of license, then the manufacturer is not liable (unless a defective product) and a claim against the prescriber or pharmacist is less easy to defend. The law allows appropriate prescribers to prescribe medicines without a license providing they are happy to assume full liability for the prescription.

2.0 Purpose and scope of the policy

This policy is directed at all Trust clinical staff who prescribe unlicensed medicines in the course of their duties. In addition to all pharmacists and other pharmacy staff involved in ordering, procuring and supplying unlicensed medicines.

The policy ensures that:

- The Trust acts in accordance with The Human Medicines regulations 2012(SI 2012/1916) regarding the use of unlicensed medicines and the MHRA guidance note 14.
- The request for, procurement of, prescribing and supply of all unlicensed medicines is managed safely and legally.
- All appropriate records are kept at each stage.
- The responsibilities of the Trust and its employees when dealing with unlicensed medicines.
- Patients are safeguarded against the risk of harm and minimises the likelihood of claim arising from the consequences of using unlicensed products.

The policy does not cover the following:

- Unlicensed products used in clinical trials – see Medicines Management Policy
- Repacked medicines (unlicensed status add minimal additional risk)
- Extemporaneously dispensed medicines- falls within section 10 of The Medicines Act and does not require a manufacturer’s specials license.
- EAMS: medicines made available through an Early Access Medicines Scheme (EAMS). EAMS enable Promising Innovative Medicines (PIMs) to be made available 12-18 months prior to marketing authorisation.

3. Categorisation of unlicensed medicines

Unlicensed medicines can be prescribed by doctors, dentists, non-medical prescribers, and independent nurse or pharmacist prescribers.

To assist in managing the risk from unlicensed medicine product use in Western Sussex Hospitals NHS Foundation Trust (WSHT) a system has been devised to highlight the level of risk and process to authorising the risk.

Hierarchy of risk on the basis of product origin has been provided by the **MHRA** as guidance. This is provided by them as guidance only and each individual case should be considered on its own merit.

1. An unlicensed medicine should not be used where a licensed product is available within the UK and could be used to meet the patient's requirements.

2. Whilst the MHRA does not recommend 'off label' use, if a UK licensed product can meet the clinical need it should be used in preference outside of the terms of its MA instead of using an unlicensed product that does not have a MA (See Section 6).

3. If a UK product cannot meet the special need , then an imported medicinal product which is licenced in its country of origin should be considered next

4. If none of these will suffice, then an unlicensed product may need to be used. For example a UK manufactured 'special'.

- The least acceptable products are unlicensed in their country of origin and are not classified as medicines in the country of origin. For example when classed as supplements as they may not be manufactured to expected standards of Good Manufacturing Practice (GMP). These should be avoided wherever possible.

This guidance forms the basis of risk rating products. They are divided into the following categories:

- Level 1: Low risk preparations
- Level 2: Intermediate risk preparations
- Level 3: Higher risk preparations
- Not approved preparations

Table 1: Categorisation, approval and governance process of unlicensed medicines

Category	Prescribing status	Patient consent	Approval/Governance
Level 1: low risk	**General usage:** A preparation licensed in the EEA, USA or country with a mutual recognition agreement or A preparation purchased from a manufacturer with a 'Specials' license, where there is good evidence to support its use and no serious safety concerns. **AND is one** of the following : - A preparation noted as unlicensed in BNF or BNFc - As an alternative to near patient aseptic manipulation e.g. pre made chemotherapy IV products. - An unlicensed topical preparation, and or preservative free ophthalmic products	No	1. Low risk. 2. Pharmacy will hold a record of purchasing, risk rating, copy of English PIL, QC sign off (if appropriate). 3. Dispensing will use internal pharmacy protocols/procedures. 4. Approval: HOP/AHOP. 5. Retrospective MOC notification for information.
Level 2: Intermediate Risk	**General use with some restrictions** A preparation licenced in the EEA, USA or country with a mutual recognition agreement or A preparation purchased from a manufacturer with a 'Specials' licence, where there is good evidence to support its use and no serious safety concerns.	Not usually required	1. Intermediate risk use. 2. Pharmacy will hold a record of purchasing ,risk rating, copy of English PIL, QC sign off (if appropriate) 3. Dispensing will use internal pharmacy procedures. 4. Approval: HOP/AHOP. 5. Retrospective MOC notification for information.

	However unlike level 1 they do not have the additional safeguards as listed above.		
Level 3 : Higher risk	**Specialist use only** Any preparation manufactured **outside** the EEA, USA or a country with a mutual recognition agreement. Any preparation that is manufactured in the EEA, USA or country with a mutual recognition agreement, but is **not licensed** in that country. Any other preparation where there maybe concerns over safety but the benefits are still judged to outweigh the risks. All radiopharmaceuticals	Yes	1. Higher level risk. 2. Prospective approvals only via MOC, but chairman's action maybe sort for urgently required items. 3. Pharmacy will hold a record of MOC approval via minutes, purchasing, Risk rating , copy of English PIL, QC sign off (if appropriate). 4. Dispensing will use internal pharmacy procedures.
Not approved	Not approved for use: risk outweighs benefit	N/A	1. Documentation via MOC minutes of any product refused approval.

Countries with a mutual recognition agreement :Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxemburg, Malta, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, USA

4 Responsibilities in relation to unlicensed medicines

4.1 Prescribers at WSHT

The General Medical Council issued the following guidance for the prescribing of unlicensed and 'off label' medicines and is applicable to **all prescribers**.

'You should usually prescribe licensed medicines in accordance with the terms of their license.

However, you may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient.

When prescribing an unlicensed medicine you must:

a. *be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy*
b. *take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so*
c. *make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.'*

All prescribers are professionally accountable for making this judgement and may be called to justify such action.

Prescribers are required to submit applications as detailed to obtain unlicensed medicines.

Prescribers have responsibility to give patients (or their parents or carers) sufficient information about the medicines you propose to prescribe to allow them to make an informed decision.

Some medicines are routinely used outside the terms of their license, for example in treating children, In emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the licence. In other cases, where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population.

You must always answer questions from patients (or their parents or carers) about medicines fully and honestly.

Details of any suspected or confirmed adverse reaction that a doctor is made aware of will be reported to the MHRA, using the yellow card reporting system www.yellowcard.gov.uk

4.2 GPs and primary care prescribers

The decision about who should take responsibility for prescribing of medicines after initial diagnosis should be based on the patient's best interest rather than healthcare professional convenience or cost. The legal responsibility for prescribing rests with the healthcare professional who signs the prescription.

Where a hospital doctor recommends the use of an unlicensed medicine or 'off label' use they are responsible for ensuring the GP is provided with sufficient

information to ensure safe and consistent supply of product for the patient, before transferring for prescribing of an unlicensed medicine.

For the level 2 category this could be in the form of an effective shared care guidance approved via MOC and APC. For level 3 category it is less likely that a GP would be requested to continue supply but each individual case should be taken on merit to ensure safe and effective treatment of the patient.

GPs and primary care prescribers should not be expected to **initiate** level 2 or 3 unlicensed medicines and transfer of prescribing responsibilities should only occur after an appropriate interval. This is usually after stabilisation has taken place. A minimum of one month's supply should be provided by the initiating specialist even if prescribing responsibility is transfer prior to this.

If a primary care prescriber feels unable to accept prescribing responsibility then clinical responsibility for prescribing should remain with the hospital clinician.

Should multiple use of a medicine in a level 2 or 3 category be intended for use in primary care that it will require approval at APC.

4.3 Pharmacy staff

The **Head of Pharmacy and Medicines Optimisation** has **overall responsibility** for the purchase and supply of unlicensed medicines within the Trust.

They are responsible for ensuring accurate and up to date unlicensed policies and procedures are in place for the Trust prescribers and pharmacy staff.

Pharmacists share with the prescriber accountability for supplying an unlicensed medicine. They must be able to demonstrate that they acted with due diligence in regards to patient safety and they have taken **reasonable steps** (when screening a prescription) to ensure the product:

- Has been procured from an appropriate source and of appropriate quality,
- meets the special clinical need of the patient,
- that relevant records and risk assessments have been made of product approval before releasing the product to the patient, and
- that the prescriber is fully aware of the unlicensed status of the product being prescribed.

Pharmacy procurement will ensure that unlicensed medicines:

- Prepared in the UK will only be purchased from a UK manufacturer holding an manufacturers 'specials' license, and if supplied with a

certificate of analysis or certificate of conformity, that this is retained for at least two years.

- Imported unlicensed medicines will only be purchased from agents who hold either a: wholesale dealers licence if imported from an EEA member state or a manufacturers specials licence if imported from a non- EEA country. Again these should be supplied with a certificate of analysis or certificate of conformity and retained for at least 2 years.

The Pharmacy Department will keep records of unlicensed medicines for a period of 5 years which must be available for inspection by the licencing authority (MHRA), including

- The source of the product,
- the person to whom and date on which the product was sold or supplied,
- the quantity supplied, and the
- batch number.

These will all be recorded electronically on the EPMA (JAC) dispensing and prescribing system and will be available for inspection.

Details of any suspected or confirmed adverse reaction that a pharmacist is made aware of will be reported to the MHRA, using the yellow card reporting system www.yellowcard.gov.uk

5.0 Requesting an unlicensed medicine.

Requests for new unlicensed products are made by the prescriber using the form in Appendix 1; 'Unlicensed medicine for individual patient use by an individual Consultant'.

The Pharmacist or Senior Technician receiving the request is responsible for determining the risk level as detailed in table 1 using the risk rating tool outlined in the internal pharmacy procedure before forwarding the request for approval:

- Level 1 HOP/AHOP signature of approval, retrospective MOC notification
- Level 2 HOP/AHOP signature of approval, retrospective MOC notification
- Level 3 Prospective MOC approval unless urgent, then chair's approval can be sort by the HOP/AHOP

6.0 'Off label' uses of medicines

Some medicines are routinely used outside of the terms of the MA, such as amitriptyline for neuropathic pain, gabapentin for post-operative analgesia and metformin for polycystic ovary syndrome. 'Off label' medicines are used widely in

critical care and emergency medicine, safe effective use having evolved in practice rather than from clinical trials.

Whilst healthcare professionals take the same responsibility and care when using medicines 'off label' it is often not apparent they are being used in this way especially for indications which have become routine nationally accepted practice over many years.

Many 'off label' indications are increasingly being noted within the BNF and the BNFc because of their accepted and wide use and need no further approval within the Trust. Whilst the MHRA does not recommend 'off label use, if a UK licensed product can meet the clinical need it should be used outside the terms of its MA instead of an unlicensed product.

Where a new or unusual indications for 'off label' use is made known or becomes apparent to a pharmacist, the professional opinion of the pharmacist allows them to refer for further advice to the HOP/AHOP who may seek approval from MOC (or chair's approval for urgent supply) before authorising/making that supply.

Licensed medicines can be used 'off label' under Patient Group Directions (PGDs) outside of the terms of their MA.

NICE MPG2 (2017) states: '*Ensure PGDs are consistent with the relevant summary of product characteristics, unless the medicine is being used off-label or relevant national guidance is being followed*'.

Additionally: *'Ensure that off-label use of a licensed medicine is included in a PGD only when clearly justified by best clinical practice. Clearly state that the medicine is being used outside the terms of the marketing authorisation on the PGD.'*

Therefore any PGD for the off-label use of a medication should clearly state when the product is being used outside the terms of its SPC and why this use is recommended with reference to the supporting evidence or guidance.

As practitioners should consider informing the patient or their carer when a medicine is being used off-label, it would be good practice for PGDs which cover off-label use to include a statement to this effect.

7.0 Other circumstances

7.1 Medicine shortages

If there are supply chain problems for products it may be necessary to procure a medicine that does not have a marketing authorisation. Pharmacy will endeavour

to identify a suitable alternative product and will discuss the choice(s) with the relevant clinical departments and agree an action plan.
.
Where substitution with an unlicensed medicine is necessary, pharmacists with the support of clinicians will disseminate / communicate the message to appropriate clinical areas so that all relevant prescribers are made aware of the change.

Pharmacy routinely manages short and long term shortages on a daily basis but has set up a shortages group to be responsive to any sudden or complex change in circumstances outside business as usual.

7.2 Manipulation of solid dose forms

This usually applies when patients have difficulty in taking solid oral forms of medicines, including administration via enteral feeding tubes. Although generally being referred to as crushing tablets, this also includes dispersion of tablets in water and emptying out the contents of capsules. These activities are regarded as ‘off-label’ use of a medicine.

Depending on the way that a tablet or capsule is formulated, crushing or opening it could result in an adverse effect. For example crushing a modified release preparation could cause immediate release of the medicine so causing toxicity. Another preparation may have a coating which is designed so that the active ingredient is not released until after the medicine has passed through the stomach and into the small intestine.

It is essential that medicines are not used in such a way without first checking whether they are suitable to be so. Advice should be sought from the ward pharmacist in the first instance to advise on potential licensed alternatives or ensure safe practice.

7.3 Unlicensed medicines use in paediatric practice

Prescribing in paediatric practice frequently requires the use of unlicensed preparations (most often as no licensed formulation for children exists) or the use of licensed preparations for outside of the terms of the MA (usually because the product is only licensed for adults). This has arisen because historically manufacturers have considered it not to be cost effective to undertake the necessary studies in children required for an MA to be granted for them.

In 2007, European (including UK) law introduced a requirement for pharmaceutical companies to undertake studies in children as part of the development plan for most new medicines. Over time, it is anticipated that the number of medicines licensed for use in children will increase.

In 2010 The Royal College of Paediatrics and Child Health jointly issued a statement with the Neonatal and Paediatric Pharmacists Group on the use of unlicensed medicines or licensed medicines for unlicensed application in paediatric practice, a further update to their original statement in 2000. The summary stated:

"Those who prescribe for a child should choose the medicine which offers the best prospect for that child, aware that such prescribing may be constrained by the availability of resources. Children should be able to receive medicines that are safe, effective, appropriate for their condition, palatable and available with minimal clinical risk.

The informed use of some unlicensed medicines or licensed medicines for unlicensed applications is necessary in paediatric practice.

Health professionals should have ready access to sound information on any medicine they prescribe, dispense or administer, and its availability.

In general, it is not necessary to take additional steps, beyond those taken when prescribing licensed medicines, to obtain the consent of parents, carers and child patients to prescribe or administer unlicensed medicines or licensed medicines for unlicensed applications.

NHS Trusts and Health Authorities should support therapeutic practices that are advocated by a respectable, responsible body of professional opinion."

The legal and professional aspects of prescribing unlicensed or off-label medicines for children are the same as for adults. However, as such practice is so common, there are several reference sources available for support. In particular the BNF for Children (www.medicinescomplete.com) indicates the licence status and indications of medicines. Additionally a leaflet explaining the use of unlicensed and off-label medicines, plus specific leaflets on individual commonly used medicines in children can be found on the Medicines for Children website www.medicinesforchildren.org.uk .

7.4 Unlicensed medicines use in obstetric patients

'Off label' prescribing is widespread practice in Obstetrics and is considered acceptable if there is no suitable alternative and the obstetricians are confident that they are using agents in accordance with the body of respected medical opinion. During pregnancy there are occasions when maternal health is the priority and the obstetrician will have no alternative other than to use medicines 'off-label'.

The use of all medications in pregnancy should follow a careful risk versus benefit assessment; drugs should be prescribed only where the expected benefit

to the mother is thought to be greater than the risk to the foetus. Medication with the best safety record over time should be chosen over a new medication, unless the safety of a new medication has been clearly established. In general, the use of medications in pregnancy should be avoided where possible, in the first trimester. However if a woman is on long-term medication for a pre-existing medical condition, it is important **not** to stop the medication on a positive pregnancy test without seeking advice from a maternal medicine specialist or senior obstetrician. This is because active disease may impact more on the developing foetus than the risks from the drug treatment. Expert advice can be sort on maternal exposure to medicines from www.uktis.org the UK national teratology service.

Each patient is entitled to know why she and her foetus would benefit from the treatment and whether any unnecessary risk is anticipated. The consent procedure should include discussing with the patient the reasons for using the medicine, possible alternative therapy and potential side effects. As the medicine is being used off-label, additional information about any uncertainties associated with such use should be given to the patient. Legible documentation of these discussions in the medical records is important.

8.0 Information for patients and carers

8.1 Information given by prescribers

As for all medicines, prescribers must give patients sufficient information about the proposed course of treatment including any known serious or common side effects or adverse reactions, in order to enable them to make an informed decision. Some medicines are routinely used outside the terms of their license; in emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the license. In other cases, where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population.

For level 2 and 3 unlicensed medicines, the prescriber must also inform the patient or carer of the license status of the medicine and why it has been chosen instead of a licensed medicine or medicine within its license. A Trust patient information leaflet (PIL) is available to support the verbal information, which can be found on the Trust Intranet and in Appendix 3. Alternatively, for paediatric patients, a nationally recognised leaflet designed specifically for children may be given instead of the Trust approved leaflet, link from Appendix 3

8.2 Information given by pharmacists

Pharmacists may only supply an unlicensed medicine with the full knowledge of the patient. To do this they (or a pharmacy technician under their supervision) should confirm that the patient or carer has been informed of the unlicensed status and that they are aware why the medicine has been prescribed instead of a licensed product. They should also give the unlicensed patient information leaflet if one has not already been given. Additionally where there is a locally developed PIL specific to the medicine, this should also be issued.

Provided that the pharmacist is aware a medicine has been prescribed 'off-label' he/she (or a pharmacy technician under his/her supervision) should confirm that the patient or carer has been informed of the 'off-label' status and that they are aware why the medicine has been prescribed instead of a licensed product within its licence. The pharmacist should also give them an unlicensed / off-label patient information leaflet if one has not already been given. Additionally where there is a locally developed PIL specific to the medicine, this should also be issued.
For children, a nationally recognised leaflet for children may be given instead of the Trust approved leaflet.

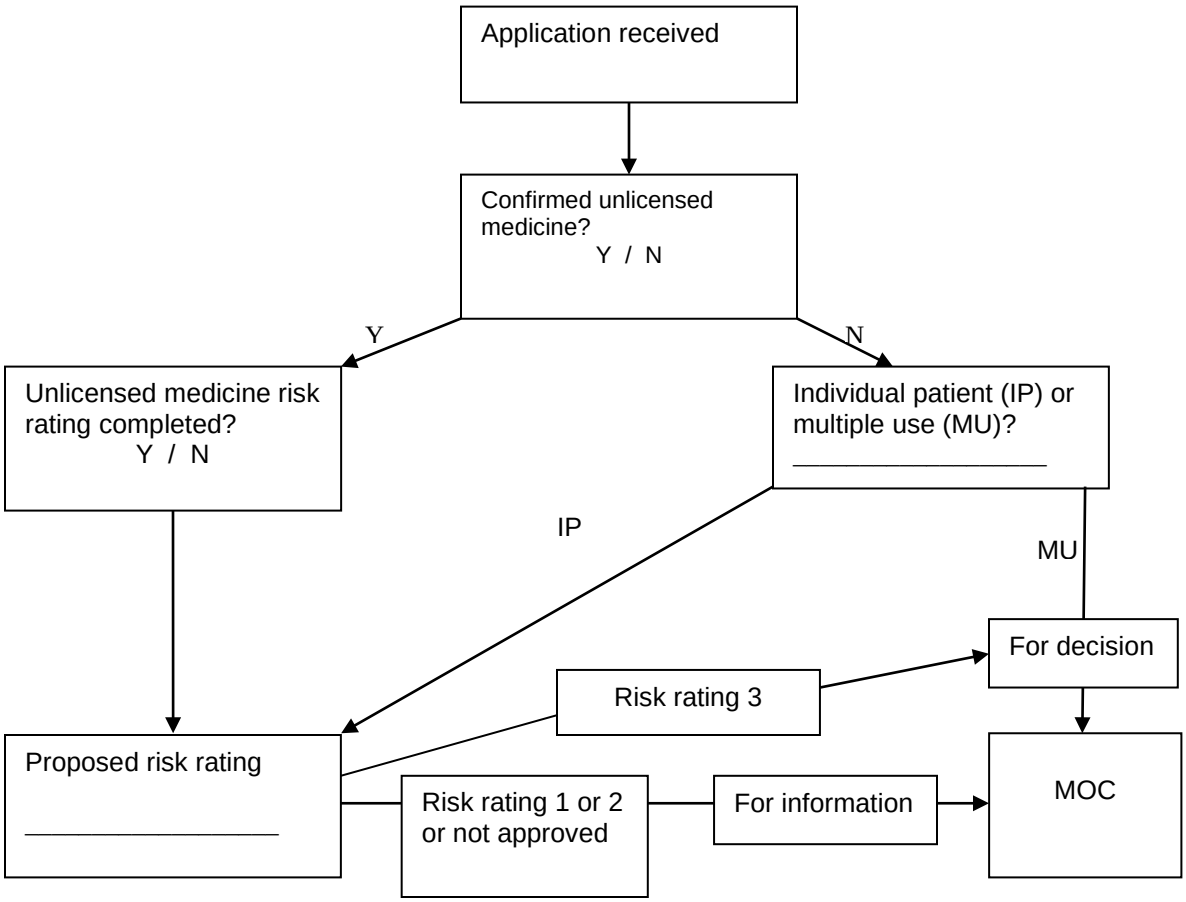
APPENDIX 1:

Request for unlicensed medicine for individual patient use by an individual consultant

Before completing this form, you must have read the Trust Unlicensed Medicines Policy and be aware of your responsibilities under this policy. It is not necessary to complete this for products described as unlicensed in either the BNF or the Children's BNF if the medicine is already on the Trust formulary.

Medicine details		
Generic Name:		
Strength and pharmaceutical form:		
Indication:		
Dose / frequency / route:		
If 'off-label' use, is it intended for one individual patient, or multiple patients?	Individual patient Multiple patients	
Are other centres using the medicine this way? If so, provide name(s):		Yes / No
Has this treatment been recommended by a specialist from another trust?	Yes / No If yes, please provide a copy of the letter	
Please explain why a licensed medicine being used within its licence is not suitable.		
Summarise below the supporting evidence, list references and attach copies of references where available.		
What side effects or toxic effects have been reported for the unlicensed product or when using it 'off-label'? Is any monitoring required? Please describe:		
Do you intend for patients' GP to be able to take on the prescribing of this medicine?		

Pharmacy Use Only



Additional Comments (include justification for risk rating)				
Pharmacist	Signature	Job Title	Print Name	Date
Medicine approved for use by	Signature (HOP/AHOP or MOC chair)	Job Title	Print Name	Date

APPENDIX 2: Definitions, references and abbreviations used

AHOP: Associate Head of Pharmacy

APC: Area Prescribing Committee

BNF: British National Formulary

BNFc: British National Formulary for children

EAMS: Early Access Medicines Scheme : This scheme allows promising Innovative medicines (**PIMS**) to be made available 12-18 months prior to Marketing authorisation, through joint work between NICE and MHRA

EEA: European Economic Area

GMP: Good manufacturing Practice: The recognised standard for pharmaceutical processing and manufacture to ensure medicinal products are consistently produced and controlled.

GP: General Practitioner

HOP: Head of Pharmacy

MA: Marketing Authorisation :The MHRA operates a system of licensing before marketing of medicines. Those medicines which meet the standards of safety , quality and efficacy are granted a marketing authorisation, (previously a product licence PL)

Manufacturers Special: products which are unlicensed and prescribed for an individual are known as 'specials'. Defined in law as a medicine made to satisfy an individual clinical need.

MCA / MHRA Guidance Note no. 14: The supply of unlicensed relevant medicinal products for individual patients – revised. January 2008

MHRA: Medicines and Healthcare Products Regulatory Agency. The UK government agency responsible for assuring medicines safety and licencing

MOC: Medicines Optimisation Committee

NICE: National Institute for Health and Care Excellence

Off-label: A licenced medicine used outside the terms of its licence , because it is judged to be in the best interest of the patient on the basis of available clinical evidence.

PIL: Patient Information Leaflet

PGDs: Patient Group Direction : is a written instruction for the sale, supply and/or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

QC: Quality Control

SPC: Summary of Product Characteristics

The Medicines for Human use Regulations 2012: (SI 2012/1916) consolidates all the law in the UK relating to medical products for human use. It came into force on 14th August 2012

APPENDIX 3:

Patient Information Leaflet

A national leaflet for Children is available via Medicines for Children, a partnership of three organisations that work in child health - Royal College of Paediatrics and Child Health (RCPCH), Neonatal and Paediatric Pharmacists Group (NPPG), and national child health charity WellChild.http://www.medicinesforchildren.org.uk/unlicensed-medicines

A Trust leaflet for Adults is on the following pages:

Western Sussex Hospitals NHS
NHS Foundation Trust

Use of Unlicensed and Off-Label Medicines: Information for Patients

Name of medicine

_____

What is this leaflet about?

You have been given this leaflet because a medicine you have been prescribed is either not licensed (unlicensed medicine) or is being used in a way that is not covered by the licence (off-label). This leaflet is intended to inform you that the most appropriate medicine has been chosen to treat your condition and to help answer any questions you may have.

Please ensure that you read this information before you start taking your medicine. Information given in the leaflet should be read with any patient information provided by the manufacturer.

Why are medicines licensed?

In the UK, most medicines go through strict checks to make sure that they are safe and effective. When the medicine passes all the required checks, a licence is granted which means that the medicine can be used in the treatment of specific medical conditions.

Pharmaceutical manufacturers must apply to the official government agency, the Medicines and Healthcare Products Regulatory Agency (MHRA), for a licence if they want to sell their medicines in the UK. The MHRA only grants this if it has been proven to work for the illnesses it was developed for, does not have too many side effects or risks and has been made to a high standard.

What is an unlicensed medicine or 'off-label' medicine?

Medicines are usually only licensed for conditions that have been investigated in clinical trials. However, some medicines may not have been studied in this way but are still required, for example a medicine for rare conditions, or where a patient is unable to take standard treatment. In these situations, doctors and pharmacists can use their medical experience and specialist knowledge to recommend the use of unlicensed or off-label medicines. They may choose to propose:

- A medicine that is being used 'off-label'. This is a licensed medicine for a purpose, dose or route that is not covered by the licence, or

- an unlicensed medicine, for example:

    - a medicine that is currently undergoing clinical trials but does not yet have a licence
    - a medicine that used to be licensed in the UK but is no longer available
    - a medicine that is only available from abroad and needs to be imported
    - a medicine that needs to be specially made because it is not readily available from a manufacturer

Why have I been given an unlicensed or 'off-label' medicine?
The doctor who is treating you has recommended an unlicensed or off-label medicine because no suitable licensed alternative is available to treat your condition.

This may be because:

- there is no suitable medicine in the UK e.g.
    - if you are allergic to the normal medicine or its preservatives
    - if you need a liquid form of a product that is 'licensed' in tablet form, or
    - for rare conditions
- the medicine is licensed in the UK but for a different condition or dose than you need it for

Should I be worried about taking unlicensed or 'off-label' medicines?
Doctors only prescribe these because they believe that the benefits of taking the medicines outweigh any risks of taking them.

To ensure that the quality of unlicensed medicines is of the highest possible standard, the pharmacy only obtains them from suppliers or importers who have been approved by the MHRA. We also run our own quality checks of the unlicensed medicines that we use.

Am I likely to have side-effects?
Like all medicines, the medicine you get may give side-effects. Your doctor or pharmacist will talk to you about these for the particular medicine you have been prescribed. If you do experience any side-effects you should report them to your doctor or pharmacist.

What else do I need to know?
Sometimes it will take longer for your local pharmacist to order in an unlicensed medicine. It is therefore best to allow one or two weeks for the pharmacist to obtain further supplies. You should bear this in mind if you need to get a repeat prescription from your doctor.

Any further questions

If you are unsure about any of this advice, please ask your doctor or pharmacist.
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We are committed to making our publications as accessible as possible. If you need this document in an alternative format - for example, large print, Braille or a language other than English - please contact the communications office by telephoning 01903 205111 ext 84038.

EQUALITY IMPACT ASSESSMENT

Name of Policy, Service, Function, Project or Proposal	**Unlicensed Medicines Policy**
Department	**Pharmacy**
Lead Officer for Assessment	**Associate Head of Pharmacy**
What is the main Purpose of the Policy/Service/Function/Project/Proposal?	This policy provides information on unlicensed medicines and medicines used outside their license (off label). It outlines best practice on the use of unlicensed medicines and provides a method of risk assessment for practitioners prescribing and supplying unlicensed medicines to patients
List the main activities of the policy or service re-design (e.g. Manual Handling would relate to health and safety of patients; health and safety of staff; compliance with NHS and Government legislation or standards etc)	This document provides information and instruction on use of unlicensed and off label medicines. It describes the process by which these are categorised according to risk assessment in the Trust and outlines responsibilities.
Is the policy or service relevant to: **Promoting Good Relations between different people?** **Eliminating discrimination?** **Promoting Equality of Opportunity?**	 **No** **No** **No**
Which groups of the population do you think may be affected by this proposal? **Minority Ethnic People** **Women and Men** **People in religious/faith groups** **Disabled people** **Older people** **Children and young people** **Lesbian, gay, bisexual and transgender people** **People of low income** **People with mental health problems** **Homeless people** **Staff** **Any other group (please detail)**	 **No** **No** **No** **No** **No** **No** **No** **No** **No** **No** **Yes**

Do you have any information that tells you of the current use of this service?
No (if yes please detail)

Is it broken down by ethnicity, gender, disability, age, religion and sexual orientation? Yes/No (please detail)

Does this information reflect the proportions from the 2001 Census?
Yes/No (If no, can you explain why)

If there is no information available or if this is patchy, specify the arrangements that will make this available

Using the information above, please complete the grids below:

How will the Policy etc affect Men and Women in different ways?

Gender	Positive Impact	Negative Impact	Neutral	Reason/Evidence	Don't know
Women			✓		
Men			✓		

How will the Policy etc affect Black and Minority ethnic people?

Race	Positive Impact	Negative Impact	Neutral	Reason/Evidence	Don't know
White			✓		
Mixed			✓		
Other Ethnic Group			✓		
Black/Black British			✓		
Asian/Asian British			✓		

How will the policy affect people with disabilities?

Disability	Positive Impact	Negative Impact	Neutral	Reason/Evidence	Don't know
Visually Impaired			✓		
Hearing			✓		

Impaired					
Physically Disabled			✓		
Learning Disability			✓		
Mental Health Related			✓		

How will the policy affect people of different ages?

Varying ages	Positive Impact	Negative Impact	Neutral	Reason/Evidence	Don't know
			✓		

How will the policy affect people of different sexual orientation?

Sexual Orientation	Positive Impact	Negative Impact	Neutral	Reason/Evidence	Don't know
			✓		

How will the policy affect Transgender or transsexual people?

	Positive Impact	Negative Impact	Neutral	Reason/Evidence	Don't know
Transgender			✓		
Transsexual			✓		

How will the policy affect people of varying religious beliefs?

Varying beliefs	Positive Impact	Negative Impact	Neutral	Reason/Evidence	Don't know
			✓		

How will the policy affect those with carer responsibilities or impact on basic human rights?

Carers / Human Rights	Positive Impact	Negative Impact	Neutral	Reason/Evidence	Don't know
			✓		

Considering your responses above, what are the areas that are have a positive and / or negative impact?

	Positive + /	Reason Given for Impact

	Negative -	
Gender		
Race		
Disability		
Age		
Sexual Orientation		
Religious Belief		

Has there been any consultation about this Policy etc? If there has, what were the key issues identified?

Consultation	Date	Summary of Key Issues to be addressed
Gender		
Race		
Disability		
Age		
Sexual Orientation		
Religious Belief		

If consultation is planned, when will it happen and what are the key themes for consultation?

How do you intend to consult staff?

What does Local / Regional / National research show with regards to these groups and the likely impact?

Group	Source	Key Issues
Gender		
Race		
Disability		
Age		
Sexual Orientation		
Religious Belief		

As a result of consultation / information gathering, what changes do you intend to make to the policy etc? If 'None', please state as relevant:

Gender

Issue	Action Required	Lead Officer	Timescale	Outcome Measure	Review Date

Race

Issue	Action Required	Lead Officer	Timescale	Outcome Measure	Review Date

Disability

Issue	Action Required	Lead Officer	Timescale	Outcome Measure	Review Date

Sexual Orientation

Issue	Action Required	Lead Officer	Timescale	Outcome Measure	Review Date

Religious Belief

Issue	Action Required	Lead Officer	Timescale	Outcome Measure	Review Date

Age

Issue	Action Required	Lead Officer	Timescale	Outcome Measure	Review Date