University Hospitals of North Midlands NHS Trust

Policy No. MM04
Trust Policy for the Prescribing, Supply and Use of Unlicensed and Off-Licence Medicines

The following personnel have direct roles and responsibilities in the implementation of this policy:

- **Medical Director**
- **Divisional Chairpersons and Clinical Directors**
- **Divisional Clinical Governance Managers**
- **All Medical Staff**
- **All Nursing Staff**
- **All Pharmacy Staff**
- **All Allied Healthcare Professionals**

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Executive Lead:	**Medical Director**

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2	Dec 2011	Policy reviewed and updated.
3	August 2015	

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University Hospitals of North Midlands NHS
NHS Trust

Statement on Trust Policies to be included in all policies

Staff Side and Trade Unions
The University Hospitals of North Midlands NHS Trust is committed to ensuring that, as far as is reasonably practicable, the way in which we provide services to the public and the way in which we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds.

Equality and Diversity
The University Hospitals of North Midlands aims to promote equality and diversity and value the benefits this brings. It is our aim to ensure that all staff feel valued and have a fair and equitable quality of working life.

Equality Impact Assessment
The organisation aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. The Equality Impact Assessment tool is designed to help you consider the needs and assess the impact of your policy.

Information Governance
Any Trust policy which impacts on or involves the use and disclosure of personal information (patient or employee) must make reference to and ensure that the content of the policy is comparable with the relevant statutory or legal requirement and ethical standards

Data Protection Bill, General Data Protection Regulations (GDPR) and the NHS Code of Confidentiality
GDPR replaces the EU Data Protection Directive of 1995 and supersedes the law of member states that were developed in compliance with the Data Protection Directive 95/45/EC. Its purpose is to protect the "right and freedom" of natural persons (i.e. livening individuals) and to ensure that personal data is not processed without their knowledge, and, wherever possible, that it is processed with their consent.

Processing includes holding, obtaining, recording, using and disclosing of information and applies to all forms of media, including paper and images. It applies to confidential patient information but is far wider in its scope, e.g. it also covers personal records

Whiles GDPR applies to both patient and employee information, the Confidentiality Code of Practice (COP) applies only to patient information. The COP incorporates, the requirements of GDPR and other relevant legislations together with the recommendations of the Caldicott report and medical ethics considerations, in some cases extending statutory requirements and provides detailed specific guidance.

Freedom of Information Act 2000
The Freedom of Information Act 2000 (FOIA) is an Act which makes legal provision and creates a legal gateway and timetable for the disclosure, to the public, of the **majority** of corporate information held (but not necessarily created) by this Trust. The Trust has a legal responsibility to proactively provide a large amount of information to the public and to pro-actively respond to specific requests for information. Information will not be disclosed when the Trust can claim legal exemption. Any non-disclosure must be conveyed in writing; quoting the relevant exemption together with signposting to internal and external methods of compliant. Locally, guidance on the DPA, FOIA and COP can be obtained from the Information Governance Manager or the Caldicott Guardian.

Mental Capacity Act

Any Trust policy which may affect a person who may lack capacity should comply with the requirements of the Mental Capacity Act 2005 (MCA)

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The MCA and its associated Code of Practice provides the framework for making decisions on behalf of individuals who lack the mental capacity to do these acts or make these decisions for themselves. Everyone working with and/or caring for adults who lack capacity, whether they are dealing with everyday matters or life-changing events in the lives of people who lack capacity must comply with the Act.

In a day to day context mental capacity includes making decisions or taking actions affecting daily life – when to get up, what to wear, what to eat etc. In a legal context it refers to a person's ability to do something, including making a decision, which may have legal consequences for the person lacking capacity, or for other people.

The Code provides guidance to all those working with and/or caring for adults who lack capacity, including family members, professionals and carers. It describes their responsibilities when acting or making decisions with, or on behalf of, individuals who lack the capacity to do this for themselves. In particular, it focuses on those who will have a duty of care to a person lacking capacity and explains how the legal rules set out in the Act will work in practice.

The Health Act: Code of Practice for the Prevention and Control of Health Care Associated Infections
The purpose of the Code is to help NHS bodies plan and implement how they can prevent and control HCAI. It sets out criteria by which managers of NHS organisations are to ensure that patients are cared for in a clean, safe environment, where the risk of HCAI is kept as low as possible. Failure to observe the Code may either result in an Improvement Notice being issued by the Care Quality Commission, or in the Trust being reported for significant failings and placed on 'Special Measures'.

The Code relates to healthcare provided by all NHS bodies. Each NHS body is expected to have systems in place sufficient to comply with the relevant provisions of the Code, so as to minimise the risk of HCAI to patients, staff and visitors.
The Trust Board must have an agreement outlining its collective responsibility for minimising the risks of infection and the general means by which it prevents and controls such risks.

Effective prevention and control of HCAI must be embedded into everyday practice and applied consistently by all staff.

Human Rights
The Trust is committed to the principles contained in the Human Rights Act. We aim to ensure that our employment policies protect the rights and interests of our staff and ensure that they are treated in a fair, dignified and equitable way when employed at the Trust.

Sustainable Development
The University Hospitals of North Midlands NHS Trust (UHNM) is committed to demonstrating leadership in sustainability and has a Trust Board approved Sustainable Development Management Plan (SDMP): Our 2020 Vision: Our Sustainable Future which sets out the route to developing a world-class healthcare system that is financially, socially and environmentally sustainable.

There are three 'Key Priorities' to aim for by 2020. With the help of employees, key partners and other stakeholders the trust will embed opportunities to:

1. Reduce our environmental impact, associated carbon emissions and benefit from a healthier environment;
2. Improve the resilience of our services and built environment as a result of severe environmental and climatic changes;
3. Embed sustainable models of care and support our local community to be well-connected, healthy, resilient, independent and managing their lives in a positive way.

The SWITCH campaign is designed to achieve these priorities. It is relevant to all departments and all members of staff. The focus is on using resources sustainably in order to provide better patient care, improve health and our working environment.

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1. INTRODUCTION

The purpose of this policy is to ensure that the Trust uses unlicensed medicines and licensed medicines for unlicensed indications (off-licence use) in a safe manner and any risks associated with the use of unlicensed medicines and off-licence medicines are identified and managed.

The Health and Social Care Act 2008 requires NHS Trusts to protect service users against the risks associated with the unsafe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines. This policy supports the Trust in complying with the regulations within the Act and with achieving compliance with the Care Quality Commission Outcome 9 on Management of Medicines.

This policy also supports delivery of the Trust Medicines Optimisation Strategy which is informed by tools such as the NTDA Medicines Optimisation Framework, the later which includes safe use of unlicensed medicines and off-licence medicines in domain 2 'Safe Use of Medicines' .

In order to ensure that medicines are safe, effective and of appropriate quality, their manufacture and sale or supply is controlled by national and EU legislation. Accordingly, no medicinal product may be placed on the market unless a Product Licence (PL) (also known as marketing authorisation (MA)) has been granted. However, in order to preserve prescribers clinical freedom the legislation gives some exemptions from full control. Thus medicinal products that do not have a PL may be prescribed in order to fulfil special needs in individual patients on the direct personal responsibility of the prescriber. For good clinical reason the use of unlicensed medicines and off-licence medicines is widespread and were this practice to be curtailed the treatment of many patients would be impeded.

Licensed medicines in the UK are subject to rigorous independent assessment by the Medicines and Healthcare Products Regulatory Authority (MHRA), however the same assumptions of quality, safety and efficacy cannot be made for unlicensed medicines. As a result of this unlicensed medicines may potentially carry a higher level of risk to our patients. Hence, safeguards and locally agreed policies and procedures need to be in place for the use of unlicensed medicines.

A fatal incident that occurred at Heartlands Hospital in 2009 highlights the importance of having adequate systems in place to manage unlicensed medicines. A 64 year old lady died of multiple organ failure 10 days following administration of an unlicensed phosphate solution during a routine bronchoscopy procedure. The investigation that followed revealed that the patients received a solution which was 10 times more concentrated that the solution normally used. No quality checks were carried out in Pharmacy, the product contained no information regarding the concentration and both the Doctor and Nurse assumed the new solution was the same as that used previously. The inquest ruled that 'neglect and failure led to the woman's death'.

All staff involved with the use of unlicensed medicines and off-licence medicines should be familiar with other relevant Trust policies and associated standard operating procedures. These include:

MM03 Policy for the Storage, Prescription, Supply and Administration of Medicines

An "Equality Impact Assessment" has been undertaken and no actual or potential discriminatory impact has been identified relating to this document.

2. POLICY STATEMENT

The Trust will use UK licensed medicines within the limits of their licence wherever possible. Unlicensed medicines and off-licence medicines will only be used when no pharmaceutically equivalent licensed product or suitable alternative licensed product is available for use at the time the patient requires it. All unlicensed medicines and off-licence medicines used within the Trust will only be used in accordance with this Policy, including the guidance provided in Appendix A and the procedure outline in Appendix B.

3. SCOPE

This policy and associated guidance (Appendix A) and procedure (Appendix B) applies to all Trust staff and any external contractors, agency or locum staff involved in any aspect of the procurement, prescribing, supply and administration of unlicensed medicines or off-licence medicines. The policy, guidance and standard operating procedure must be followed at all times.

This policy also applies to the prescribing, supply and use of unlicensed radiopharmaceuticals.

The policy does not cover:

- Investigational medicinal products (clinical trials material)
- Non-medicines
- Medical Devices

4. DEFINITIONS

A UK **licensed medicine** is one that has been granted a Product Licence (PL) and can be marketed in the UK for the treatment of medical conditions as defined in its PL i.e. its licensed indications. The Summary of Product Characteristics (SPC) specifies the licensed indications of a medicine and how it is to be used (e.g. doses, frequency, reconstitution, dilution etc) and when it is not to be used (contra-indications) or used with caution (special precautions).

Sometimes medicines are used for a clinical indication or in a way that is not covered by the PL. This would constitute the unlicensed use of a licensed medicine which is often referred to as **off-licence** or **off-label** use.

A UK **unlicensed medicine** is one that does not have a UK PL. There are 3 reasons for a product being unlicensed: No UK PL has been granted; Licensed in a county other that the UK; UK manufactured 'special'. Further explanation of these reasons is given in Appendix A.

Activities within Pharmacy can also render a licensed product unlicensed and further information on these activities is given in Appendix A.

Products are considered **pharmaceutically equivalent** if they contain the same amount (or concentration) of the same active substances in the same dosage form, and meet the same or comparable standards considered in the light of the clinical needs of the patient at the time of its use.

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Prescriber applies to any practitioner legally authorised to prescribe under the Medicines Act 1968 or any subsequent amendments. Thus, this policy applies equally to both medical and non-medical practitioner prescribing. Authorised prescribers must be approved by the Trust and include registered medical staff and accredited nurse, pharmacist or other non-medical prescribers**.** Registered non-medical prescribers are authorised by the Deputy Chief Nurse and may prescribe as independent or supplementary prescribers according to their annotation on the register.

5. ROLES AND RESPONSIBILITIES

5.1 Medical Director

The Medical Director has overall responsibility for Medicines Optimisation within the Trust and is supported in the role by the Clinical Director of Pharmacy and the Chief Nurse. The Medical Director will:

- Ensure through membership of the Executive Team that corporate performance management arrangements are in place regarding Divisional implementation of the Trust Medicines Optimisation Strategy, which includes implementation of this policy.
- If appropriate authorise the use of unlicensed medicines and off-licence medicines according to the procedure outlined in Appendix B.
- Appoint a designated deputy or deputies to authorise the use of unlicensed medicines and off-licence medicines according to the procedure outlined in Appendix B, in his/her absence.

5.2 Clinical Director of Pharmacy and Medicines Optimisation

The Clinical Director of Pharmacy will:

- Ensure that this policy is reviewed and updated in line with the review date specified.
- Ensure that appropriate procedures are in place within the Pharmacy Directorate to cover all aspects of the procurement and supply of unlicensed medicines and off-licence medicines.

5.3 ARSAC licence holders

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

- Ensure that appropriate procedures are in place within the Imaging Department and Medical Physics Department to cover all aspects of the procurement and supply of unlicensed and off-label radiopharmaceuticals.
- Will authorise the purchase and use of all unlicensed and off-licence radiopharmaceuticals according to the procedure outlined in Appendix B.
- Will ensure that only authorised staff are able to order unlicensed radiopharmaceuticals and that they only do so from a Trust authorised supplier.
- Will ensure that the unlicensed radiopharmaceutical has been approved by the Pharmacy Quality Team before it is used.

5.4 Prescribers

A prescriber who prescribes an unlicensed medicine or an off licence medicine is professionally accountable for his/her judgement in doing so, and in the case of adverse events may be called upon to justify his/her actions. However, it could be

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anticipated that such justification would be achieved if a body of peers would recognise the prescription as best practice.

Prescribers will:

- Ensure the use of the unlicensed medicine or off-license medicine is justified by the clinical condition of the patient and be satisfied that an alternative licensed medicine would not meet the patient's needs.
- Be satisfied that there is sufficient evidence base and experience of using the medicine to demonstrate its safety and efficacy.
- Before prescribing an unlicensed medicine for the first time ensure that it has been approved by the Trust for the intended use, and if not, follow the procedure outlined in Appendix B, remembering to allow Pharmacy adequate time to source and obtain the medicine.
- Ensure that the Trust policy relating to obtaining patient consent is complied with.
- Record the medicine prescribed and, where this does not follow common practice, document clear reasons for choosing the medicine in the patient's notes.
- Where appropriate provide information for the patient about the unlicensed / off-licence medicine and provide the patient with a copy of the Patient Information Leaflet (Appendix C).
- Ensure that incidents of patient adverse reactions are recorded and reported to the MHRA via the yellow card scheme and to the Trusts Adverse Incident Reporting Scheme (Datix®).
- Ensure that before on-going care is transferred to the patients General Practitioner (GP) the patients GP has been informed of the unlicensed / off-licence status of the medicine, including the reason for prescribing it, and he/she is willing to accept responsibility for its on-going prescription.

5.5 Pharmacists

Every pharmacist assumes a duty of care to the patient when he/she supplies medication to the patient. When supplying a product without a PL or outside of the PL the pharmacist who clinically checks the initial prescription and the pharmacist who authorises the purchase of the product may share liability, with the prescriber, should the patient suffer an adverse event. This particularly applies where the pharmacist is involved in specifying the product to be purchased, or if their actions or omissions have contributed to the harm.

The pharmacist who clinically checks the prescription will:

- Ensure that a medicine with a PL is supplied where such a product exists in a suitable formulation and when the patient requires it.
- Only authorise supply of unlicensed medicines and off-licence medicines in accordance with this policy and the procedure outlined in Appendix B.
- Ensure, wherever possible, that the prescriber is aware that the medicine they have prescribed is unlicensed or off-licence.
- Be satisfied that the use of an unlicensed medicine or an off-licence medicine is justified by the clinical circumstances and there is published evidence, relevant experience and/or sound therapeutic argument to support its use.
- Where appropriate, counsel the patient on the use of the unlicensed / off-licence medicine and provide them with the Patient Information Leaflet (Appendix C).

The pharmacist responsible for the procurement of unlicensed medicines will:

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- Ensure that before an unlicensed medicine is purchased for the first time the procurement risk assessment is completed and authorised by a Senior Pharmacist.
- Ensure procedures are in place to: enable identification and quarantine of unlicensed medicines on receipt into Pharmacy; inspection and release by the Pharmacy Quality Team of all unlicensed medicines; over-labelling of all medicines requiring translation of product information into English; enable tracing of an unlicensed medicine to patient level, as far as reasonably possible, in the event of a product recall.
- Maintain a register of all unlicensed medicines approved for use in the Trust, including the relevant risk assessments.
- Provide the Trust Safe Medicines Group and Divisional Safe Medicines Groups with quarterly reports of unlicensed medicines use, including any outstanding risk assessments.

The Pharmacy Quality Team will:

- Check that the unlicensed medicine is correct against the original order and the specification in the unlicensed medicine risk assessment.
- Undertake a visual inspection of the product including the labelling and packaging.
- Retain a record of the products inspected including batch number, expiry date and any accompanying certificates.
- Ensure that products requiring translation of product information into English are over-labelled.
- Ensure that where necessary appropriate change controls are undertaken to cover all aspects of the use of new unlicensed medicine.
- Authorise release of the unlicensed medicine only if satisfied that the product is correct against the order and specification and is of suitable quality. Any concerns will be immediately brought to the attention of the Procurement Pharmacist or Clinical Director of Pharmacy.
- Authorise the release of unlicensed radiopharmaceuticals based on satisfactory review of the individual product certificate of assurance. Any concerns will be immediately brought to the attention of the ARSAC licence holder.

5.6 Nursing staff and healthcare professionals involved in the administration of medicines

In October 2007 the Nursing and Midwifery Council issued standards regarding medicines management, these were updated in April 2010. These standards state that a registrant may administer an unlicensed medicine with the patient's informed consent against a patient-specific direction. There is additional guidance relating to administration of medicines being used off-licence.

All healthcare professionals who administer medicines are responsible for:

- Ensuring that the unlicensed or off-licence medicine is only administered against a patient specific prescription and with the patient's informed consent.
- Ensuring that they have sufficient information to administer the medicine safely and, wherever possible, that they are satisfied that there is acceptable evidence for the use of that product for the intended indication and in the intended manner.
- Where appropriate, provide information to the patient on the medicine and provide them with the Patient Information Leaflet (Appendix C).

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5.7 Divisional Chairperson and Clinical Directors

Divisional Chairs and Clinical Directors will:

- Ensure that systems are in place to ensure that prescribers working within their Division and Directorate respectively are aware of this policy and their responsibilities in relation to the prescribing and use of unlicensed medicines and off-licence medicines.
- Provide leadership and advice, and support decision making, in the prescribing and use of unlicensed and off-licence medicines in relation to their Divisions and Directorates respectively.
- Support the Pharmacy Team and Divisional Safe Medicines Group with ensuring compliance with this policy and addressing areas with outstanding clinical risk assessments.
- If appropriate authorise the use of unlicensed medicines and off-licence medicines according to the procedure outlined in Appendix B.

5.8 Divisional Safe Medicines Groups

Each Division should have a Safe Medicines Group who will:

- Actively support implementation of this policy within their Division through review and approval of quarterly unlicensed medicines usage reports from Pharmacy.
- Work with the Divisional Pharmacist, Divisional Chairperson and Clinical Directors to address areas of non-compliance including completion of outstanding clinical risk assessments.
- Review, and if appropriate approve, the use of unlicensed and off-licence medicines according to the procedure outlined in Appendix B.

5.9 Trust Safe Medicines Groups

The Trust Safe Medicines Group is responsible for:

- Overseeing and supporting the Divisional Safe Medicines Groups with implementation of this Policy through review and approval of Divisional action plans and usage reports provided by Pharmacy.
- Review, and if appropriate approve, the use of unlicensed and off-licence medicines according to the procedure outlined in Appendix B.

6. Education, Training and Plan of Implementation

Individual registered practitioners are responsible for ensuring that they have appropriate knowledge and experience to prescribe, supply or administer medicines competently in their area of practice, this includes knowledge of the licensed status of any medicines that they prescribe. They need to comply with the registration requirements of their registering body and ensure that they keep their professional and clinical knowledge up-to-date. This should form part of their personal development plan and be reviewed at their annual appraisal.

Consultants are responsible for ensuring that all medical officers in their teams are trained to be competent in all aspects of the prescribing of medicines, including unlicensed and off-licence medicines. Nursing and departmental managers are responsible for ensuring that any non-medical prescribers working for them are similarly competent.

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Matrons and Ward Managers are responsible for ensuring that all nurses administering medicines are aware of this policy and the procedure for obtaining and administering unlicensed medicines.

Divisional and departmental managers have a responsibility to ensure that copies of this policy and associated guidance and standard operating procedure is available to their staff, and they must ensure that their staff are fully aware of all relevant procedures applicable to their Ward / Clinical Area.

The Pharmacy Directorate provides an overview of medicines optimisation arrangements within the Trust on the corporate induction programme and through medicines optimisation mandatory training. In addition the Pharmacy Directorate can support Divisions and Directorates in delivering educational sessions for specific staff groups. Specific medicines optimisation training is routinely given to Foundation Year 1 doctors and perceptorship nurses.

It is essential that the Trust and Divisions are able to demonstrate compliance with this policy to support compliance with CQC Outcome 9. The Trust Safe Medicines Group and Divisional Safe Medicines Groups will oversee the implementation of this policy and as far as possible ensure compliance with it. The Pharmacy Directorate will provide information on the use of unlicensed medicines within the Trust including completed risk assessments to support these groups with this.

7. Monitoring and Review Arrangements

Implementation of this policy will be audited on an on-going basis through review of quarterly information reports sent to Divisional Safe Medicines Groups and the Trust Safe Medicines Group. The information reports will be provided by Pharmacy and will include newly approved unlicensed medicines, medicines requiring Divisional or Trust approval and any outstanding risk assessments. Divisional Safe Medicines Groups will be responsible for addressing any concerns/areas of non-compliance identified. See monitoring table below for full details.

The Pharmacy Directorate will maintain records of all unlicensed medicines used within the Trust and will publish and maintain an up-to-date register of Trust approved unlicensed medicines which is accessible via the Trust intranet. The Pharmacy Directorate will review the register annually and remove any unlicensed medicines that are no longer in use. The Pharmacy Directorate will keep all completed clinical and procurement risk assessment forms for a minimum of 5 years.

Review

This policy will be reviewed at least every 3 years by Clinical Director of Pharmacy or earlier if major change is required due to change in legislation or national initiatives relating to unlicensed medicines.

Monitoring Table

MM04 Policy for the Prescribing, Supply and Use of Unlicensed and Off-Licence Medicines Monitoring Table					
Aspect of compliance or effectiveness being monitored	Monitoring method	Individual or department responsible for the monitoring	Frequency of the monitoring activity	Group/committee/ forum which will receive the findings/monitoring report	Committee/ individual responsible for ensuring that the actions are completed
Newly approved unlicensed medicines	The Pharmacy Directorate will provide a report of all newly approved unlicensed	Pharmacy Directorate Clinical	Quarterly	Divisional Safe Medicines Group	Divisional Safe Medicines Group

	medicines to Directorate level. Pharmacy will maintain a register on the Trust intranet of all approved unlicensed medicines.	Information Service			Trust Safe Medicines Group
Unlicensed medicine requests requiring Divisional or Trust approval	The Pharmacy Directorate will provide a list of unlicensed medicines requiring Divisional or Trust approval including copies of the completed risk assessment forms.	Pharmacy Directorate Clinical Information Service	Quarterly (this may be more frequently if urgent approval is required)	Divisional Safe Medicines Group	Divisional Safe Medicines Group Trust Safe Medicines Group
Outstanding risk assessments	Pharmacy will provide a list of all unlicensed medicines in use which do not have up to date risk assessments	Pharmacy Directorate Clinical Information Service	Quarterly	Divisional Safe Medicines Group	Divisional Safe Medicines Group Trust Safe Medicines Group

8. REFERENCES AND FURTHER READING

MHRA Guideline Note 14: The supply of unlicensed medicinal products 'specials'. Medicines and Healthcare products Regulatory Agency, 2014.

Guidance for the Purchase and Supply of Unlicensed Medicinal Products - Notes for prescribers and pharmacists. NHS Pharmaceutical Quality Control Committee, 3rd edition, June 2004.

Legal and Ethical Advisory Service Fact Sheet 5: The Use of Unlicensed Medicines in Pharmacy. The Royal Pharmaceutical Society of Great Britain, September 2007.

Medicines, Ethics and Practice. The Royal Pharmaceutical Society of Great Britain, August 2015.

Rules and Guidance for Pharmaceutical Manufacturers and Distributors. Medicines and Healthcare products Regulatory Agency, 2015.

The Purchase and Use of Unlicensed Medicines in Hospital. Policy Statement No 006. Guild of Healthcare Pharmacists, January 1997.

G Matthews. Report for Importation of Unlicensed Medicines; January – March 2011. Medicines and Healthcare Regulatory Authority. October 2011. Available from www.mhra.gov.uk

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Standing Committee on Medicines of the Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacist Group (2010). The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice. Available from www.nppg.scot.nhs.uk

Good Medical Practice. The General Medical Council 2013. Available from http://www.gmc-uk.org

Nursing and Midwifery Council. Standards for Medicines Management. 2010. Available from www.nmc-uk.org

The Paediatric Formulary Committee. BNF for Children. BMJ Publishing Group Ltd, RPS Publishing and RCPCH Publishing. London. 2015. Available at www.bnfc.org

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Appendix A

UNLICENSED MEDICINES AND OFF-LICENCE MEDICINES GUIDING PRINCIPLES

1. Trust Policy

The Trust Policy on unlicensed and off-licence medicines is that the Trust will use UK licensed medicines within the limits of their licence wherever possible. Unlicensed medicines and off-licence medicines will only be used when no pharmaceutically equivalent licensed product or suitable alternative licensed product is available for use at the time the patient requires it.

All unlicensed medicines and off-licence medicines used within the Trust will only be used in accordance with the Trust Policy, including this guidance and the procedure outlined in Appendix B.

It is recognised that compliance with this policy and guidance may have additional financial implications for the Trust, however cost should not be a factor in the risk assessment of unlicensed medicines. Any potential cost pressures will be highlighted to the appropriate Division(s) and Directorate(s) by the Pharmacy Directorate.

2. Unlicensed Medicines

A UK unlicensed medicine is one that does not have a UK Product Licence (PL). There are 3 reasons for a product being unlicensed: No UK PL has been granted; Licensed in a county other that the UK; UK manufactured 'special'.

No UK PL may have been issued because the product is waiting the granting of a licence in the UK, or it is undergoing clinical trials, or is only manufactured for export, or has been withdrawn from the UK market. Such medicinal products can often be obtained from the manufacturer on a named patient / individual patient / compassionate supply basis.

Medicines available and licensed in a country other than the UK may be imported through specialist importers, and their UK use would be unlicensed.

Some manufacturers specialise in the preparation of products for which demand does not justify commercial production and licensing. 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. Such products are often known as 'specials', and as the products do not have a PL they do not have a specified indication for use, recommended dose or SPC (Summary of Product Characteristics). The Trust holds a MHRA specials manufacturing licence for the pharmacy manufacturing unit at the Royal Stoke Hospital and the radiopharmacy laboratory within the Department of Nuclear Medicine.

In addition to the above two activities within Pharmacy can also render a licensed product unlicensed. These are:

The use of a licensed medicine 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 total 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 medicine e.g. preparing 5 packs of 20 tablets for use as take home patient packs in an A & E department from a manufacturer's pack of 100 tablets, would 'de-licence' the medicine. So long as 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 extent.

3. Level of Risk

The hierarchy of risk for medicines for a patient's requirement proposed by the MHRA is as follows (lowest risk first):

1. Use of a licensed medicine for a licensed indication.
2. A licensed medicine used outside of its PL.
3. Use of an imported medicine licensed in its country of origin.
4. If none of the above can be met: a completely unlicensed product, for example a UK manufactured 'special' made in GMP (good manufacturing practice) inspected facilities.
5. Products not classified as a medicine in the country of origin, but which are classified as a medicine in the UK.

The medicine which carries the lowest risk according to the above hierarchy should always be selected, however it is recognised that in practice preference may occasionally be given to a lower graded category if the net risk/benefit is in favour of the lower graded medicine based on professional judgement. For example, an imported licensed medicine may:

- Be in a presentation unfamiliar to UK practice; or
- Involve complex manipulation to prepare or administer; or
- Have labelling, packaging and/or supporting information that are not to UK standards or not in English.

4. Liability

Liability for an unlicensed medicine and any adverse reactions associated with its use lies with the prescriber and pharmacist responsible for the procurement and supply of the medicine.

If a patient is harmed by a licensed medicine used for an unlicensed indication or in an unlicensed way, and not because of any defect in the product itself, then the prescriber is liable for the harm, in the same way that they would be liable when a licensed medicine is used according to its licence.

If a patient is harmed by a defective medicine, whether licensed or unlicensed, then the supplier of that medicine (normally a pharmacist) is liable for the harm. If the supplier can identify the manufacturer of the medicine the liability passes to the manufacturer. If the manufacturer can prove that the specification of the medicine, as provided by the pharmacist ordering the medicine, contributed to it being defective, the liability passes back to the pharmacist.

If the patient is harmed be a defective medicine which has been prepared by or under the supervision of a pharmacist, the pharmacist is liable for the harm as the manufacturer of the

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medicine. If the medicine has been procured from a 'specials' manufacturer then the pharmacist who placed the order is considered by law to be the manufacturer and is therefore liable.

The Trust recognises its vicarious liability for the actions if its employees.

5. Supply of Unlicensed Medicines

All unlicensed and off-licence medicines used by the Trust will be supplied by the Pharmacy Department and only in accordance with this policy and standard operating procedure (Appendix B). All unlicensed medicines used by the Trust will be subject to authorisation and risk assessment following the procedure outlined in Appendix B.

As prescribing of unlicensed medicines is expected to be exceptional as oppose to routine and to keep paperwork to a minimum, non-formulary forms are not routinely required for unlicensed medicines. Unlicensed medicines will not normally be included in the North Staffordshire Joint Formulary.

6. Patient Consent

Health professionals must respect the right of patients, carers and parents to participate in discussions regarding the health care of the patient and to seek to ensure that decisions are properly informed. There is no statutory requirement to obtain more specific consent from a patient or carer in order to prescribe and supply an unlicensed medicine or to prescribe an unlicensed medicine in an unlicensed way. However, this would represent good professional practice and all patients, or their representatives, should be given sufficient information by the prescriber, whenever possible, for them to be aware that they are being prescribed an unlicensed medicine, and for them to make an informed choice to consent. Prescribers must comply with the Trust Policy for obtaining consent. A suitable patient information leaflet (Appendix C) is available on the Trust intranet under Home/Clinicians/Support Services/Pharmacy/Unlicensed Medicines.

It is accepted that this practice may not be practical in paediatric or neonatal care due to the large number of off-licence medicines used, or in circumstances where involving patients in decisions is inappropriate or impractical e.g. clinical emergencies, unconscious patients.

7. Paediatrics

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 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.

FOI ref 4443-1920

The policy statement produced by joint RCPCH / NPPG Standing Committee on Medicines aims to inform and guide health professionals, health service managers, parents and carers who prescribe, dispense, administer or have a responsibility for medicines for children.

The key recommendations of the Committee are that

- Those who prescribe for a child should choose the medicine which offers the best prospect of benefit 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 RCPCH / NPPG have produced national patient information leaflets, one for parents and carers and the other for older children, on the use of medicines for children. The PILs include information on medicines that do not have a product license for neonatal and paediatric use. The PILs can be accessed via the NPPG website (www.nppg.scot.nhs.uk) under patient information leaflets.

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

8. Reporting of Adverse Drug Reactions and Defective Products

Adverse drug reactions and defective products are handled in the same way as licensed medicines. Serious adverse reactions should be reported to the MHRA via the yellow card scheme and to the Trust's Adverse Incident Reporting Scheme (Datix®).

Suspected defects in unlicensed medicines should be reported immediately to the Pharmacy Quality Team.

9. Records of Dispensing

Pharmacy will not keep records of dispensing of medicines which are to be used off-licence.

Pharmacy will not keep records of dispensing of unlicensed medicines which are kept as stock on wards or other clinical areas. Unlicensed medicines will only be kept as stock items on wards or in clinical areas where this is clinically justified and agreed by the Specialist Pharmacist responsible for that area. The name of the unlicensed medicine administered, batch number and expiry date should be recorded in the patient's medical notes.

FOI ref 2423-1920

Pharmacy will keep dispensing records for all other unlicensed medicines via the Ascribe® system.

10. Transferring Prescribing to Primary Care

Any Secondary Care Consultant who asks a General Practitioner (GP) to prescribe a medicine that is unlicensed or off-licence should clearly state the licence status of the medicine. The Consultant must explain the reasons for using this medicine and justify its use in preference to licensed alternatives. The evidence base behind the recommendation must be given and it should be made clear whether or not treatment recommended is a peer-supported option. Prescribing responsibilities between the Consultant and the GP must be clearly documented and state the specific responsibilities of each party. It should not be assumed that GPs will take on responsibility for prescribing unlicensed or off-licence medication and the Consultant initiating treatment is responsible for continuing treatment if the GP will not accept responsibility for continuing care. If there is financial concern in terms of the impact on Secondary Care or Primary Care drug budgets then this needs to be clarified before treatment is initiated. The patient should be informed of arrangements for how further supplies of their unlicensed medicine will be obtained i.e. either via prescription from their GP and dispensed by a community pharmacy or via a hospital prescription from their Consultant and dispensed by the hospital out-patient pharmacy.

11. Commissioning of Unlicensed Medicines

If the Commissioners commission the Trust to provide a clinical service using an unlicensed medicine then the Trust will require the Commissioners to undertake a risk assessment of the unlicensed medicine as part of the commissioning process. A copy of the risk assessment must be provided to the Trust before the service is initiated.

The prescription of unlicensed medicines cannot be enforced on prescribers as they carry their own responsibility and are professionally accountable for their judgement in so doing. Commissioners must recognise and acknowledge this fact.

FOI ref 2435/16

Appendix B

Everyone Improving Quality

University Hospital of North Staffordshire NHS Trust

STANDARD OPERATING PROCEDURE			
Title	Trust procedure for the supply of unlicensed and off-licence medicines		
Author	**Angela Davis, Deputy Clinical Director of Pharmacy**		
Ratified by	**Trust Safe Medicines Group**		
Date of ratification	**April 2015**	**Review date:**	**April 2017**
Purpose	To outline the process for the supply of unlicensed and off-licence medicines to ensure compliance with the Trust Policy for the Prescribing, Supply and Use of Unlicensed and Off-Licence Medicines.		
Scope	This procedure applies to all Trust staff and any external contractors, agency or locum staff involved in any aspect of the prescribing, supply and administration of unlicensed medicines or off-licence medicines. The procedure must be followed at all times. This procedure also applies to the supply of unlicensed radiopharmaceuticals. The procedure does not apply to: • Investigational medicinal products (clinical trials material) • Non-medicines • Medical Devices		
Background	This procedure was developed to support Trust Policy MM04; Policy for the Prescribing, Supply and Use of Unlicensed and Off-Licence Medicines. Policy MM04 was developed to ensure that the Trust uses unlicensed medicines and licensed medicines for unlicensed indications (off-licence use) in a safe manner and any risks associated with the use of unlicensed medicines and off-licence medicines are identified and managed. Licensed medicines in the UK are subject to rigorous independent assessment by the Medicines and Healthcare Products Regulatory Authority (MHRA), however the same assumptions of quality, safety and efficacy cannot be made for unlicensed medicines. As a result of this unlicensed medicines may potentially carry a higher level of risk to our patients. Hence, safeguards and locally agreed procedures need to be in place for the use of unlicensed medicines.		
Related documents	**Trust Policies:** • **MM03:** Policy for the Storage, Prescription, Supply and Administration of Medicines.		

<table>
<tr><th colspan="2">Instruction</th></tr>
<tr><th colspan="2">Unlicensed Medicines</th></tr>
<tr><td>1.</td><td>The prescriber ensures the use of the unlicensed medicine is justified by the clinical condition of the patient and is satisfied that an alternative licensed medicine would not meet the patient's needs. The prescriber is satisfied that there is sufficient evidence base and experience of using the medicine to demonstrate its safety and efficacy.</td></tr>
<tr><td>2.</td><td>The prescriber checks whether the unlicensed medicine has been approved by the Trust for the intended use. Approved medicines and indications are listed on the Trust unlicensed medicines register found on the Trust intranet under Home/Clinicians/Support Services/Pharmacy/Unlicensed Medicines, or alternatively the prescriber should contact the ward pharmacist or Pharmacy Medicines Information for advice.

Unlicensed liquid formulations of licensed medicines where the licensed formulation is not suitable to meet the patient's needs (e.g. the patient has an enteral tube) will normally receive automatic approval for use, the prescriber should contact the ward pharmacist or Pharmacy Medicines Information for advice.</td></tr>
<tr><td colspan="2">Unlicensed medicine approved for intended use / listed on register</td></tr>
<tr><td>3.</td><td>Pharmacy will supply the unlicensed medicine against the patient's prescription. The prescriber is to ensure that the treatment and justification for use are documented in the patients notes, the patient has been provided with sufficient information (including patient information leaflet if appropriate) and has consented to treatment (see Trust Policy MM04 for further guidance).</td></tr>
<tr><td colspan="2">Unlicensed medicine not approved for intended use / not listed on register</td></tr>
<tr><td>4.</td><td>The prescriber completes the clinical risk assessment for the intended indication. The clinical risk assessment form can be found on the Trust intranet under Home/Clinicians/Support Services/Pharmacy/Unlicensed Medicines. The prescriber seeks approval for use of the unlicensed medicine according to the category in the table below:

<table>
<tr><th>Category</th><th>Criteria</th><th>Approval required</th></tr>
<tr><td>1</td><td>• Use of the unlicensed medicine recommended in BNF, cBNF or recognised UK guidelines, OR
• Established pharmaceutically equivalent licensed medicine temporarily unavailable.</td><td>Consultant to sign clinical risk assessment.

Specialist/Directorate Pharmacist to be informed.</td></tr>
<tr><td>2</td><td>• Use of the unlicensed medicine <u>not</u> recommended in recognised UK guidelines but prescriber satisfied that sufficient evidence base and experience to support use, OR
• Established pharmaceutically equivalent licensed medicine discontinued or unavailable for undetermined timeframe.</td><td>Consultant and Clinical Director to sign clinical risk assessment.

Specialist/Directorate Pharmacist to be informed.</td></tr>
<tr><td>3</td><td>• All unlicensed medicines assessed as being high or extreme risk (risk score <u>≥</u>8), after risk reduction strategies applied, OR
• Use of all unlicensed medicines which falls outside of Trust policy e.g. insufficient evidence base and/or experience, licensed alternative available but not funded.</td><td>Consultant and Clinical Director to sign clinical risk assessment.

Divisional Pharmacist to be informed.

Divisional Safe Medicines</td></tr>
</table>
</td></tr>
</table>

			Group and Trust Safe Medicines Group (or Medical Director if required urgently) to authorise use.

5.	The prescriber gets the required approval to use the unlicensed medicine and sends completed clinical risk assessment form to Pharmacy. The prescriber ensures Pharmacy has adequate time to source and obtain the unlicensed medicine.
6.	Upon receipt of the approved clinical risk assessment form Pharmacy Procurement will complete a procurement risk assessment of the product that they intend to purchase to meet the requirements of the prescriber. The front page of the procurement risk assessment will be the product 'specification'. The prescriber will be contacted if the medicine to be purchased is assessed by Pharmacy Procurement as being high or extreme risk. Medicines assessed as high or extreme risk will not be purchased without approval of the Clinical Director of Pharmacy, the relevant Divisional Safe Medicines Group and the Trust Safe Medicines Group (or the Medical Director if the request is urgent).
7.	Pharmacy will enter the approved unlicensed medicine onto the Trusts unlicensed medicines register for use for the intended indication. Any restrictions to use will also be added e.g. 'Consultant prescription only', 'single patient use only - non-formulary forms required'.
8.	Pharmacy will purchase the unlicensed medicine.
9.	When received into Pharmacy the unlicensed medicine will be quarantined. Only the Pharmacy Quality Team can release the unlicensed medicine from quarantine. The Pharmacy Quality Team will check that the unlicensed medicine is correct against the original order and the specification on the front page of the unlicensed medicine risk assessment. They will also undertake a visual inspection of the product including the labelling and packaging. The Pharmacy Quality Team maintains records of the products inspected including batch number, expiry date and any accompanying certificates. All products requiring translation of product information into English are sent to the Pharmacy Manufacturing Unit to be over-labelled. The Pharmacy Quality Team will release the medicine if they are satisfied that the product is correct against the order and specification and is of suitable quality
10.	Pharmacy will supply the unlicensed medicine when in receipt of a legally valid prescription.
11.	The prescriber must ensure that the treatment and justification for use are documented in the patients notes, the patient has been provided with sufficient information (including patient information leaflet if appropriate) and has consented to treatment (see Trust Policy MM04 for further guidance).
12.	Pharmacy will issue quarterly reports to the Divisional Safe Medicines Groups detailing newly approved unlicensed medicines and any outstanding risk assessments. Pharmacy will keep all risk assessments for a minimum of 5 years.

Off-licence Medicines	
9.	If a licensed medicine is to be used outside of it product license the prescriber will ensure that the use of the medicine is justified by the clinical condition of the patient and will be satisfied that an alternative licensed medicine used according to its product licence would not meet the patient's needs. The prescriber will be satisfied that there is sufficient evidence base and experience of using the medicine for the intended indication, or in the intended manner, to demonstrate its safety and efficacy.
10.	No clinical risk assessment or approval is required for off-licence medicines. For adult patients the prescriber should complete the off-licence medicines disclaimer form. This form need not be completed when prescribing an off-licence medicine for a child. The completed form should be sent to Pharmacy with the patient's prescription and will be retained in Pharmacy for a minimum of 5 years.
11.	The prescriber must ensure that the treatment and justification for use are documented in the patients notes, the patient has been provided with sufficient information (including patient information leaflet if appropriate) and has consented to treatment (see Trust Policy MM04 for further guidance).
Unlicensed Radiopharmaceuticals	
12.	All unlicensed radiopharmaceuticals used by the Imaging Department and Medical Physics Department will be used in accordance to local standard operating procedures and under supervisor of the Trust ARSAC licence holders.

FOI ref 2483-1920

Appendix C

Where do I obtain further supplies?

Your GP may or may not be prepared to continue to the supply of an unlicensed medicine. They are not obliged to do so. In the event of the latter, further supplies may be obtained by contacting your hospital prescriber to provide another prescription to be dispensed by the out-patient hospital pharmacy.

Sometimes it will take longer for the pharmacist to order in an unlicensed medicine. It may need to be made up specially. It is therefore best to allow one or two weeks for the pharmacist to obtain further supplies. You should bare this in mind if you need to get a repeat prescription from your GP or doctor.

Where can I get more information about this medicine?

In some cases your doctor or pharmacist may give you some separate information about the medicine. If this is written information, please read it carefully and follow any instructions you are given.

You may notice that the manufacturer's information leaflet supplied with the medicine is not personalised. For example, it may not include information about the condition for which you are being treated, or about the use of the medicine in children or old people.

Often there are support groups for patients with particular illnesses or conditions. If you are a member you could talk to someone from the group. If you are not a member, or don't know if there is a group, ask your doctor, pharmacist or nurse for more information.

Further Information

If you are unsure about any of this advice, please ask your doctor or pharmacist. Alternatively:

Access NHS Choices: Medicines Information - Licensing (www.nhs.uk/Conditions/Medicinesinfo/Pages/Safetyissues.aspx)
Access Medicines for Children (www.medicinesforchildren.org.uk) for national information leaflet for parents and carers on unlicensed medicines.

Contact UHNM Medicines Helpline

[redacted]

If you have any concerns or questions about the medications given to you after your recent hospital visit, please contact our pharmacists for further support. Monday to Friday: 10am to 1pm and 2pm to 4pm

Contact the Patient Advice and Liaison Service would be pleased to offer confidential advice and support if you have any concerns. PALS can be contacted on 01782 552814 or

Email patient.advice@uhns.nhs.uk

University Hospitals of North Midlands NHS Trust
Royal Stoke University Hospital
Newcastle Road
Stoke-on-Trent
ST4 6QG
County Hospital
Weston Road
Stafford
ST16 3SA

University Hospitals of North Midlands NHS
NHS Trust

Unlicensed and Off-Label Medicines - Your Guide

Patient Information Leaflet

What is this leaflet about?

Most medicines prescribed in the UK are approved or licensed for use by the Government's Medicines and Healthcare Products Regulatory Agency (MHRA).

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

Why are medicines licensed?

Most medicines go through an approval process to make sure they are safe and effective. When the medicine passes all these checks, a product licence is granted which means that the medicine can be used in the treatment of a specific medical condition(s).

Pharmaceutical manufacturers must apply to the MHRA for a product licence if they want to sell their medicines in the UK. The MHRA only agrees a product licence if it has been proven to work for the illness(es) it was developed for, does not cause too many side effects and has been manufactured 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 and / or illnesses (e.g. rare conditions) may not have been studied in this way.

Many medicines used in children are unlicensed or 'off-label' as clinical trials are almost always done in adults first.

In order to provide the best or most suitable treatment, doctors may need to prescribe medicines that have not gone through this approval process. In these situations, both doctors and pharmacists will consider the evidence available and use their medical experience and specialist knowledge to recommend the use of unlicensed or off-label medicines. They may choose to use:

- A licensed medicine for a purpose, dose or route that is not covered by the licence – 'off-label' use.
- A medicine that is currently undergoing clinical trials but does not yet have a product 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 i.e. not licenced in UK.
- A medicine that needs to be specially made (e.g. liquid) because it is not readily available from a manufacturer.

Why have I been given an unlicensed 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:

- You are allergic to the normal medicine or its preservatives.
- The medicine you require is not available in the UK.
- You need a liquid form of a product that is only 'licensed' in tablet form.

Should I be worried about taking unlicensed or off-label medicines?

Doctors only prescribe these medicines because they believe that the benefits of taking the medicine(s) outweigh any risks of taking them. If you are still worried after reading this leaflet, please talk to your doctor or pharmacist.

Am I likely to have side-effects?

Like all medicines, the medicine you are given may cause side-effects. Your doctor or pharmacist will talk to you about these for the particular medicine you have been prescribed. It is important that you take the medicine as directed. If you do experience any side-effects you should report them to your doctor or pharmacist.

FOI ref 2243-1920