Trust Policy

Policy for the Procurement, Prescribing, Supply and Administration of Unlicensed Medicines

Issue Date	Review Date	Version
October 2021	October 2026	4

Purpose

The manufacture and sale/supply of medicinal products was brought under legal control by The Medicines Act 1968. In order to ensure that medicines are safe, effective and of an appropriate quality, their manufacture and sale/supply is controlled by national legislation. No medicinal product may be placed on the market unless a Marketing Authorisation (MA) (formerly known as a Product Licence) is granted by the MHRA after consideration of data relating to a specified use of the product.

- Ensure the Trust acts in accordance with The Human Medicines Regulations 2012 (SI 2012/1916) regarding the use of unlicensed medicines.
- Ensure that the procurement, prescribing and supply of all unlicensed medicines is managed safely and legally.
- Ensure that all appropriate records are kept at each stage.
- Make clear the responsibilities of the trust and its employees, when dealing with unlicensed medicines.
- Safeguard patients against the risk of harm and minimise the likelihood of claims resulting from the consequences of using unlicensed products

Who should read this document?

- Doctors, dentists, non-medical prescribers, supplementary prescribers as part of a clinical management plan who prescribe unlicensed medicines in the course of their duties
- Pharmacists and pharmacy staff involved in the ordering, procurement, and supply of unlicensed medicines.

Key Messages

This policy has been developed to set the standards for the correct management of unlicensed medicines i.e. prescribing, risk assessment, procurement, ordering, administration and storage

Ensuring that patients are safeguarded against the risk of harm and to minimise the likelihood of litigation resulting from the consequences of using unlicensed products and the responsibilities of the Trust and its employees are clear when dealing with unlicensed medicines.

There are sections within policy that facilitate appropriate audit of unlicensed medicines.

Core accountabilities	
Owner	Chief Pharmacist and Clinical Director Medicines Optimisation
Review	Drugs and Therapeutics Committee
Ratification	Dr Paul Mcardle, Deputy Medical Director
Dissemination (Raising Awareness)	Drugs and Therapeutics Committee
Compliance	Chief Pharmacist and Clinical Director Medicines Optimisation / Drugs and Therapeutics Committee

Links to other policies and procedures
Medicines Management Policy and Standard Procedures: v10.5 Non-Medical Prescribing Policy v8

Version History		
2	February 2012	Risk classification is simplified to low and high risk (medium risk combined with low risk) Patient consent section updated Policy reformatted Annex's 4 & 5 updated
3	February 2012	Approved Dr Alex Maynor, Medical Director
3	November 2018	Agreed at Medicines Utilisation and Assurance Committee to extend the Review date extended policy expired 2019
4	October 2021	Wholesale Changes to Policy to reflect current legislation and EU exit. Policy refreshed and reformatted in line with best practice with updates to Flow diagrams, risk assessment for low and high risk products and patient consent

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Contents

Note for Document Authors

Red text – Indicates assistance with content of the section.

Black text – Standard text that relates to all formal documents and can be left in situ.

1 Introduction

1. Introduction

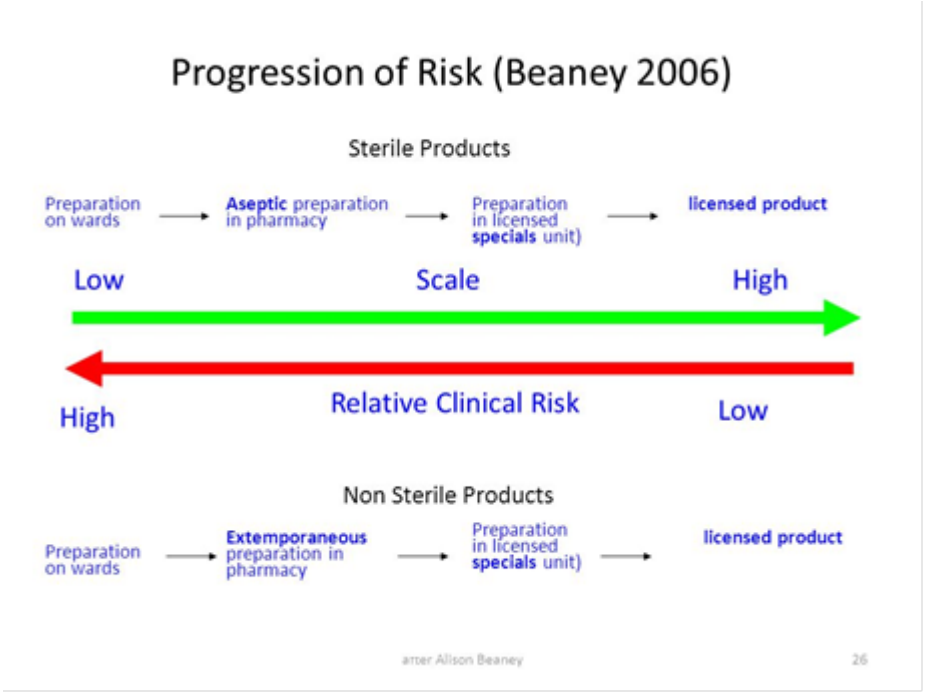
1.1. Medicines legislation (specifically The Human Medicines Regulations 2012 (SI 2012/1916)) requires that medicinal products are licensed before they are marketed in Great Britain (GB). Following a rigorous assessment process every marketed medicinal product in the GB is issued a Marketing Authorisation (MA) number by the regulatory authority the Medicines and Healthcare products Regulatory Agency (MHRA). The MA number previously known as a Product Licence (PL) number must be displayed on the pack and provides assurance of the assessment process for safety, quality and efficacy. Some products available within GB may have the European Medicines Agency EU number on their packaging but these do still have MHRA approval for marketing in GB

1.2. Some patients may have a special clinical need that cannot be met by available licensed medicinal products. So that this special need may be met, the law allows manufacture and supply of unlicensed medicinal products (commonly known as 'specials') subject to certain conditions.

1.3. A pharmaceutical special (often abbreviated to 'special') is defined by law as an unlicensed medicine and is made to satisfy an individual patient need. The law allows appropriate prescribers to prescribe medicines without a licence providing they are happy to assume full liability for the prescription.

1.4. Other types of unlicensed medicines are imported medicines that will have a marketing authorisation in an EU country or a non-EU country with a Mutual Recognition Agreement (MRA) (e.g. Australia, USA, Canada, Japan) and are obtained through a specialist importer (e.g. Clinigen, Durbin) or those medicines imported from countries without MRA (e.g. India, China, Mexico or Brazil).

1.5. Wherever possible licensed products will be used in preference to unlicensed medicines.



2 Purpose

2. Purpose

2.1. The manufacture and sale/supply of medicinal products was brought under legal control by The Medicines Act 1968. In order to ensure that medicines are safe, effective and of an appropriate quality, their manufacture and sale/supply is controlled by national legislation. No medicinal product may be placed on the market unless a Marketing Authorisation (MA) (formerly known as a Product Licence) is granted by the MHRA after consideration of data relating to a specified use of the product. This policy controls all medicines that are not licensed medicines.

2.2. The purposes of this policy are to:

- Ensure the Trust acts in accordance with The Human Medicines Regulations 2012 (SI 2012/1916) regarding the use of unlicensed medicines.
- Ensure that the procurement, prescribing and supply of all unlicensed medicines is managed safely and legally.
- Ensure that all appropriate records are kept at each stage.
- Make clear the responsibilities of the trust and its employees, when dealing with unlicensed medicines.
- Safeguard patients against the risk of harm and minimise the likelihood of claims resulting from the consequences of using unlicensed products.

2.3. This policy applies to:

- Doctors, dentists, non-medical prescribers, supplementary prescribers as part of a clinical management plan who prescribe unlicensed medicines in the course of their duties
- Pharmacists and pharmacy staff involved in the ordering, procurement, and supply of unlicensed medicines.

2.4. This policy does **not** relate to:

- Unlicensed medicines used in approved clinical trials (Investigational Medicinal Products (IMPs)).
- Products extemporaneously dispensed/ within UHP in response to a prescription.
- Non-medicines or medical devices
- Repackaged licensed products including pre-packs and overlabelled licensed products.
- Licensed medicines which become unlicensed when administered (i.e. the formulation of the medicine is altered e.g. by crushing tablets or opening capsules to aid administration to patients with swallowing difficulties).
- EAMS - Medicines made available through an Early Access Medicines Scheme (EAMS). EAMS enable promising innovative medicines (PIMs) to be made available 12-18months prior to marketing authorisation. These schemes are approved and authorised by joint work between NICE and the MHRA and often involve the gathering of data to support future marketing authorisation and governance of such medicines introduction to UK practice. As these medicines are manufactured and part of a recognized approval pathway to practice governance can differ from that applied to unlicensed medicines.

- Medicines that are sourced as a parallel import from the European Economic Area (EEA) – these medicines are licensed.

3 Definitions

3. Definitions

3.1. **Unlicensed medicine** - within the scope of this policy the term "unlicensed medicine" includes products that are:

3.1.1. Supplied from holders of a Manufacturing Authorisation from outside of GB.

3.1.2. Manufactured by companies holding a UK 'specials' manufacturing licence (either commercial or NHS) to the specification of the doctor or pharmacist ordering them.

3.1.3. Compassionate use medication i.e. products required for compassionate use either where a patient is exiting a completed clinical trial or where the consultant has a Trust-approved agreement with the pharmaceutical company supplying the medication for treatment of an individual patient or group of patients

3.2. **Drug and Therapeutic Committee (DTC) (or equivalent) –** The Trust body that where necessary approves the use of unlicensed medicines and reviews and monitors their ongoing use. The DTC will provide assurance to the organisation regarding the use of these medicines and will report to the appropriate governance committee

3.3. **Special** - Human Medicines Regulations 2012 provide exemptions from the requirement to hold a Marketing Authorisation in certain circumstances. A Special is an unlicensed medicine that does not hold marketing authorisation status in Great Britain and is manufactured, imported or supplied to meet the special clinical needs of an individual patient.

3.4. **UHP –** University Hospitals Plymouth NHS Trust (also referred to as "the Trust")

3.5. **Prescriber** – includes medical and qualified and registered non-medical prescribers

3.6. **ADR -**Adverse Drug Reaction. A harmful and unintended reaction that occurs at a dose normally used for the prophylaxis, diagnosis or treatment of disease or the modification of physiological function.

3.7. **CIVAs -** Centralised Intravenous Additive Service. An aseptics service preparing injections centrally within the pharmacy department

3.8. **EAMS -** Medicines made available through an Early Access Medicines Scheme. EAMS enable promising innovative medicines to be made available 12-18 months prior to marketing authorisation through joint work between NICE and the MHRA.

3.9. **EMA** -European Medicines Agency. This is a decentralised body of the European Union. It is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union (including Northern Ireland).

3.10. **EU marketing authorisation** - A marketing authorisation granted or renewed by the European Commission under Regulation (EC) No 726/2004.

3.11. **Marketing Authorisation (MA)** - The MHRA operates a system of licensing before the marketing of medicines. Medicines which meet the standards of safety, quality and efficacy are granted a marketing authorisation (MA) (previously a product licence, PL), which is normally necessary before they can be prescribed or sold. This authorisation covers all the main activities associated with the marketing of a medicinal product.

3.12. **Manufacturer's Licence (ML)** - Medicinal products manufactured for the GB market must be produced on a site that holds an appropriate manufacturer's licence.

3.13. **Medicines and Healthcare products Regulatory Agency (MHRA) -** The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency which is responsible for ensuring that medicines and medical devices work and are safe. They also hold responsibility for licensing medicines for use in GB and in NI.

3.14. **Off-label -** A licensed 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.

3.15. **Pharmacovigilance -** A technical term used for identifying and responding to risk/benefit issues emerging for authorised medicines as used in clinical practice, and including the effective dissemination of such information to optimise the safe and effective use of medicines.

3.16. **Product Licence (PL) -** Now superseded by Marketing Authorisation (MA) however there are still products in circulation which will be labelled with PL rather than MA.

3.17. **Unlicensed Import -** A pharmaceutical product, licensed in a foreign country, whose importation by a company has been approved by the MHRA. Once in the UK, its technical status is that of an unlicensed product.

3.18. **Parallel Import (PI) –** The United Kingdom has a scheme regulated by the MHRA to allow a medicine authorised in European Economic Area (EEA) Member State be marketed in the UK, as long as the imported product has no therapeutic difference from the cross-referenced UK product. Products in this category require registration as a PI with the MHRA and will have a unique Product Licence number prefaced with PLPI.

3.19. **Peninsula Purchasing and Supplies Alliance (PPSA) –** An NHS funded body with UHP as a member that brokers local contracts for the region which include the procurement of medicines

3.20. **GN14** – Guidance note 14 is a publication from the MHRA that sets out requirements and rules for the supply and use of Unlicensed Medicines (Specials) in the UK.

4 Duties

4. Duties

4.1. Drugs and Therapeutic Committee (or equivalent)

4.1.1. The DTC is responsible for the ratification of new requests for the use of unlicensed medicines in the Trust.

4.1.2. The Committee is additionally responsible for monitoring and reappraising the use within the Trust of all unlicensed medicines.

4.1.3. The Committee will ensure appropriate audit systems are in place to monitor compliance with this policy.

4.2. Prescribers

4.2.1. A prescriber is permitted to prescribe an unlicensed medicine only if there are valid clinical reasons to justify its use in preference to a licensed alternative and that that there is sufficient evidence and/or experience to demonstrate its safety and efficacy. The rationale for this decision must be documented in the patient record.

4.2.2. The prescriber must give the patient sufficient information about the medicine to make an informed decision about its use in accordance with guidance on informed consent. The prescriber has undertaken a suitable risk benefit assessment which must be documented. The only exception to this rule is when a formulary approved licensed medicine is unavailable and the Medical Director (or a nominated deputy) and the Chief Pharmacist and Clinical Director Medicines Optimisation (or a nominated deputy) have approved the use of an unlicensed equivalent following a QA and clinical assessment.

4.2.3. Patients have the right to participate in the making of properly informed decisions about their health care. With the exception of emergency use or where unnecessary distress may be caused, patients must be informed that the treatment being prescribed is an unlicensed product and what that means so that they can make an informed decision. Clinicians must consider how they will obtain consent and this must be in written format for the use of a high risk unlicensed medicine.

4.2.4. Inadequate provision of information may increase the clinician's or Trust's liability in the event of a mishap that results in a complaint and possible litigation.

4.2.5. The prescriber must ensure that all incidents of patient adverse drug reactions are recorded and reported to the MHRA via the yellow card scheme and through the Trust's incident reporting scheme.

4.2.6. The prescriber must ensure that the patient's general practitioner is informed of the unlicensed status of the medicine and confirm that he or she is willing to accept clinical and legal responsibility for prescribing before transferring responsibility for ongoing care. Where this is not accepted, the Chief Pharmacist and Clinical Director of Medicines Optimisation (or nominated Deputy) will engage with the appropriate commissioner to reach a satisfactory resolution. Until a decision is reached the prescriber must ensure continuing treatment is provided and accepted by UHP.

4.2.7. The prescriber must ensure that any healthcare professional involved in the prescribing, supply, administration and monitoring is:

4.2.7.1. made aware of its unlicensed status

4.2.7.2. informed of any problems/risks involved and how to deal with them

4.2.7.3. given sufficient information to administer/use the product safely and correctly

4.2.7.4. The prescriber is professionally accountable and liable for any harm caused by the use of unlicensed medicines and may be called upon to justify their actions.

4.3. Pharmacy Staff

4.3.1. The Chief Pharmacist and Clinical Director Medicines Optimisation is responsible for ensuring that suitable processes are in place within pharmacy for the safe procurement and supply of unlicensed medicines. They are also responsible for approval (or delegating approval) of the unlicensed request forms & risk assessments.

4.3.2. The Pharmacoeconomics Specialist Pharmacist (or nominated deputy(s): Assistant Director Pharmacy / Formulary Pharmacist / Chief Procurement Technician) is responsible for:

4.3.2.1. ensuring that a risk assessment has been completed for all new unlicensed medicine requests, as outlined in Appendix 3

4.3.2.2. the monitoring of usage of unlicensed medicines and confirmation that continuing use remains appropriate

4.3.3. All pharmacy staff are responsible for ensuring that they follow the appropriate Pharmacy standard operational procedures (SOPs) when dealing with unlicensed medicines and maintain all required records.

4.3.4. Pharmacy staff issuing unlicensed medicines will ensure that they are labelled clearly in English and that the users have adequate information to use them properly.

4.3.5. Pharmacists who procure, manufacture or prepare unlicensed medicines are professionally accountable for the quality of the product that they supply.

4.3.6. Pharmacy staff will ensure that individual patients are given adequate information about any unlicensed medicines to ensure continuity of supply.

4.4. Nursing Staff

4.4.1. Nurses remain accountable for their actions and should acquire sufficient information to ensure the safe administration of the medicine.
4.4.2. In addition, wherever possible, nursing staff must be satisfied that there is acceptable evidence for the use of that product for the intended indication.

5 Detail

5. Policy Details

5.1. Prescribing

5.1.1. In routine practice prescribers should usually prescribe licensed medicines in accordance with the terms of the marketing authorisation. No unlicensed medicine is to be prescribed where an appropriate licensed product is available. If a suitable licensed product is available, any request for use of an unlicensed medicine will automatically be treated as high risk and require approval by the UHP Drugs and Therapeutic Committee (DTC).

5.1.2. Unlicensed medicines will only be prescribed after assessing that the product is necessary to meet the special clinical needs of the patient, and not for reasons of cost, convenience or operational needs as per the requirements of section 2 of the MHRA GN14 publication.

5.1.3. Prescribing unlicensed or off-label medicines may be necessary where:

5.1.3.1. There is no UK licensed medicine available to meet the specific clinical need of the patient

5.1.3.2. Available UK licensed medicines are not suitable to meet the needs of the patient because

- the licence does not apply to the patient in question (often this is because the medicine is licensed for a specific age group or for males or females only)

- the medicine is intended to treat a condition not covered by the licence (unlicensed indication)
- the formulation of the product is not suitable for the patient in question (commonly applies in paediatrics or if patients have swallowing difficulties or allergies/sensitivities)
- the licenced dose of the medicine is not suitable to meet the needs of the patient (commonly applies in paediatrics)
- A suitable licensed medicine that would meet the patient's need is not currently available (e.g. where there is a temporary shortage in supply).

5.1.4. When prescribing an unlicensed medicine the prescriber must:

- Be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy for the intended purpose and that there is not an available licensed medicine to cover the required clinical need.

- 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 prescriber to do so.

- Make a clear, accurate and legible record in the medical notes of all unlicensed medicines prescribed and, where the prescriber is not following common practice, the reason for prescribing an unlicensed medicine.

5.1.5. The prescriber must give patients (or their parents or carers) sufficient information about the proposed unlicensed medicines to allow them to make an informed decision. The prescriber must always answer questions from patients (or their parents or carers) about medicines fully and honestly.

5.1.6. The prescriber should obtain and record the patient's consent before prescribing the unlicensed medicines. In emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be appropriate to draw attention to the fact that the medicine is unlicensed. 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. When prescribing medicines which are licensed and manipulated to be provided in a ready to administer form such as CIVAs, it may be sufficient to explain in general terms that the product used has been prepared as such rather than refer to licensed status.

5.1.7. Healthcare professionals have a responsibility to help monitor the safety of medicines in clinical use through the submission of suspected adverse drug reactions to the MHRA and CHM via the Yellow Card Scheme (https://yellowcard.mhra.gov.uk/). Such reporting is equally important for unlicensed medicines or those used off-label as for those that are licensed.

5.1.8. Prescribers must seek the input of a senior clinical pharmacist or care group lead pharmacist, ideally with responsibility for the relevant clinical specialty, when requesting an unlicensed medicine:

5.1.8.1. Not currently stocked at UHP

5.1.8.2. For an indication not yet approved by DTC

5.1.8.3. For use by a clinical team which is not yet covered by the medicine's approval from the DTC

5.2. Authorisation for Use

5.2.1. The general process for authorisation to use unlicensed medicines within UHP is described in Appendix 3.

5.2.2. Only named prescribers listed on the Request and Declaration of Responsibility Form will be authorised to prescribe the unlicensed product. The first course of treatment should be initiated by a consultant or registrar. In the case of "high risk" medicines, initiation should be via a consultant only. (Appendix 4).

5.2.3. The prescriber is responsible for obtaining approval for the use of the unlicensed medicine and should liaise with the relevant clinical pharmacist to complete a Request and Declaration Form (Appendix 4).The Request and Declaration of Responsibility Form includes the information on the agreed use, dosage regimens, the relevant references evidence supporting its use.

5.2.4. The specialist clinical pharmacist for the relevant clinical area or care group lead pharmacist will then carry out the risk assessment of the specific unlicensed product in conjunction with Quality Control / Accountable Pharmacist or nominated deputy(s) and the Pharmacoeconomics Specialist Pharmacist or nominated deputy(s) (Assistant Director Pharmacy / Formulary Pharmacist / Chief Procurement Technician) (Appendix 5). Where the unlicensed medicine is sourced under a procurement agreement by the Peninsula Purchasing and Supplies Alliance (PPSA) and regional QA has undertaken an assessment of this medicine from a quality perspective, this assessment can be used to support the local risk assessment.

5.2.5. The Chief Pharmacist and Clinical Director Medicines Optimisation or nominated deputy(s) (Pharmacoeconomics Specialist Pharmacist / Assistant Director Pharmacy / Formulary Pharmacist / Chief Procurement Technician) will approve the Request and Declaration of Responsibility and the risk assessment prior to the procurement of the product (Appendix 5).

5.2.6. Records of all approved unlicensed medicines will be kept by the formulary pharmacist and notified to the DTC at the next routine meeting and will be forwarded for inclusion on the Devon Formulary if appropriate.

5.2.7. The Trust will accept liability for the use of unlicensed products assessed as essential and posing relatively **LOW RISK**, providing they are used in accordance with widely accepted clinical practice. An unlicensed medicines patient information leaflet (Appendix 7) must be given to all patients at the point

of dispensing (as appropriate). It will be the responsibility of the dispensing pharmacy to ensure this is done.

5.2.8. Prescribers are reminded that University Hospitals Plymouth NHS Trust will **NOT** automatically accept liability for the use of unlicensed products assessed as **HIGH RISK**. Liability will only be accepted where the following provisions have been adhered to:

5.2.8.1. Medical staff up to and including registrar are **NOT** permitted to initiate the prescribing of a high risk unlicensed medicine that has **NOT** received approval from DTC.

5.2.8.2. A written treatment protocol is in place

5.2.8.3. Written informed patient consent is sought and obtained (see Appendix 6). A copy of this consent form MUST accompany the first prescription to Pharmacy (or if an emergency within 72 hours).

5.2.8.4. The use of the high risk product is clinically and operationally risk assessed by the relevant Service Line along with appropriate clinical pharmacist or care group lead pharmacist and entered into their risk register and that of the Trust together with robust controls for managing the risk.

5.2.8.5. An unlicensed medicines patient information leaflet (Appendix 7) must be given to all patients on dispensing as appropriate and it will be the responsibility of the dispensing pharmacy to ensure this is done.

5.3. Procurement of Unlicensed Medicines

5.3.1. Pharmacy procurement is responsible for ensuring that unlicensed medicines are procured from approved suppliers. Any new supplier goes through a supplier validation process by Quality Control before an order is raised.

5.3.2. All unlicensed medicines purchased by the Trust should ideally be licensed in the country of origin or be from a licensed specials manufacturer in the UK (exceptions will include those products with international packaging). A certificate of analysis or conformance should be requested for each unlicensed product ordered unless imported from the EEA or MRA countries.

5.3.3. Some manufacturers, importers or distributors of unlicensed medicines may require a letter from the prescriber documenting evidence of the specific need for the particular unlicensed medicine. Patient identifiable details must not be supplied.

5.3.4. Orders must only be placed after the completion of the Request and Declaration of Responsibility Form (Appendix 4) and Risk Assessment (Appendix 5).

5.4. Dispensing Unlicensed Medicines

5.4.1. All unlicensed medicines administered or supplied to patients under the care of UHP must be ordered and supplied through the UHP Pharmacy Department.

5.4.2. Unlicensed medicines are stored separately from licensed stock in the dispensary.

5.4.3. All unlicensed medicines will only be supplied against a prescription written on UHP approved paperwork or using UHP approved systems e.g. EPMA.

5.4.4. If a prescription is received in the dispensary for an unlicensed medicine, the pharmacist will check if the prescriber has been authorised by a completed Request and Declaration Form. Where records show that this is the first issue for the prescriber, the screening pharmacist will inform them of the unlicensed status of the medicine and ask them to liaise with the relevant clinical pharmacist to complete a Request and Declaration Form (Appendix 4) and to take via the u\hp formulary process if appropriate.

5.4.5. The Pharmacy Department must keep the records of supply listed below for at least 5 years:

Records required	Where data is recorded
The date of and source of obtaining the unlicensed medicine.	Recorded via Ascribe Pharmacy System
Patient details	Ascribe pharmacy records and the relevant *Unlicensed Medicines: Record of Supplies* form when dispensed.
Date of supply	
Quantity supplied	
Batch number supplied	

5.5. CIVAS

5.5.1. CIVAs and prefilled syringes purchased from previously approved NHS or commercially licensed 'specials' manufacturers are automatically classified as low risk and do not require a Request and Declaration Form to be completed. However, approval should be sought from the Chief Pharmacist and clinical director of medicines optimisation (or nominated deputy) prior to purchase of new lines.

5.5.2. Prior to supplying a CIVAs manufactured product a *Finished Product Specification* which outlines the details of the product should be obtained and kept on record. The specialist pharmacist for the clinical area in conjunction with the Pharmacoeconomics Pharmacist, Accountable Pharmacist (and nominated deputies alongside Quality Control are responsible for checking that the details, requirements and label are correct. By signing this approval, the clinical pharmacist is assuming the responsibility for the product. Finished product specifications should be in-line with published national specifications and comply with BP unlicensed monographs where either or both are available.

5.6. Administration

5.6.1. To enable treatment with an unlicensed medicine to be given quickly or out of normal working hours, it may be necessary for the Chief Pharmacist and Clinical Director Medicines Optimisation or nominated deputy(s) to consider approval for a clinical area to keep an unlicensed medicine with a high risk rating as ward stock.

5.6.2. Any patient's own medicines (PODs) brought into hospital which are unlicensed medicines should be assessed in accordance with the UHP Medicines Reconciliation Policy before being administered to the patient. If a resupply is required then the clinical responsibility lays with the consultant responsible for the patient and the process in Appendix 3 should be followed.

6 Overall Responsibility for the Document

This document will be reviewed by the Drugs and Therapeutics Committee / Chief Pharmacist and Clinical Director Medicines Optimisation (or appointed Deputy) and ratified by the chair.

7 Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Drugs and Therapeutics Committee / Chief Pharmacist and Clinical Director Medicines Optimisation (or appointed Deputy) and ratified by the chair.

Non-significant amendments to this document may be made, under delegated authority from the Chair, by the nominated author. These must be ratified by the Chair and should be reported, retrospectively, to the Drugs and Therapeutics Committee.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

8 Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document owner will be responsible for agreeing the training requirements associated with the newly ratified document with the Chief Pharmacist and Clinical Director Medicines Optimisation and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

9 Monitoring Compliance and Effectiveness

Minimum requirement to be monitored	Lead(s)	Tool	Frequency of Report of Compliance	Reporting arrangements	Lead(s) for acting on Recommendations
Unlicensed medicines usage within UHP will be reviewed annually at the DTC	Formulary Pharmacist	Ascribe / EPMA	Annually	Audit reported to DTC	Formulary Pharmacist / Care Group Lead Pharmacists
Audit Risk agreed sample Assessment	Formulary	Record /	Annually	Audit reported to	Formulary Pharmacist / Accountable

Forms for accuracy against products used	Pharmacist	Audit		DTC	Pharmacist / Senior Pharmacy Team
Audit of records for stock unlicensed medicines	Formulary Pharmacist / Chief Procurement Technician	Ascribe / EPMA	Annually	Audit reported to DTC / Care Group Lead pharmacists / Supply Services Manager	Formulary Pharmacist / Senior Pharmacy Team

10 References and Associated Documentation

- The Supply of Unlicensed Medicinal Products ("specials"), Guidance Note No. 14: MHRA,May 2014. www.mhra.gov.uk
- Health and Social Care Act 2012. London. The Stationery Office. Available at: www.legislation.gov.uk
- The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994
- Good practice in prescribing and managing medicines and devices: GMC, Feb. 2013. www.gmc-uk.org
- Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2014: MHRA, 2014.

Dissemination Plan and Review Checklist | Appendix 1

Dissemination Plan	
Document Title	Policy for the Procurement, Prescribing, Supplying and Administration of Unlicensed Medicines
Date Finalised	October 2021
Previous Documents	
Action to retrieve old copies	Nil – all electronic

Dissemination Plan

Recipient(s)	When	How	Responsibility
All Nursing Staff	February 2013	Vital signs and Trust-wide e-mail	Andrew Prowse
All doctors	February 2013	Vital signs and Trust wide e-mail	Andrew Prowse
All Pharmacists and Pharmacy technicians	February 2013	Vital signs and Trust wide e-mail	Andrew Prowse
All Trust staff		Information Governance StaffNet Page	Information Governance Team

Review Checklist		
Title	Is the title clear and unambiguous?	Y
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Y
	Does the style & format comply?	Y
Rationale	Are reasons for development of the document stated?	Y
Development Process	Is the method described in brief?	Y
	Are people involved in the development identified?	Y
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Y
	Is there evidence of consultation with stakeholders and users?	Y
Content	Is the objective of the document clear?	Y
	Is the target population clear and unambiguous?	Y
	Are the intended outcomes described?	Y
	Are the statements clear and unambiguous?	Y
Evidence Base	Is the type of evidence to support the document identified explicitly?	Y
	Are key references cited and in full?	Y
	Are supporting documents referenced?	Y
Approval	Does the document identify which committee/group will review it?	Y
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A
	Does the document identify which Executive Director will ratify it?	Y
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Y
	Does the plan include the necessary training/support to ensure compliance?	Y
Document Control	Does the document identify where it will be held?	Y

	Have archiving arrangements for superseded documents been addressed?	Y
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Y
	Is there a plan to review or audit compliance with the document?	Y
Review Date	Is the review date identified?	Y
	Is the frequency of review identified? If so is it acceptable?	Y
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Y

Equalities and Human Rights Impact Assessment | Appendix 2

Core Information	
Date	October 2021
Title	Policy for the Procurement, Prescribing, Supplying and Administration of Unlicensed Medicines
What are the aims, objectives & projected outcomes?	The Trust will ensure, through the Director of Pharmacy, that appropriate systems are established and maintained in order to reduce the risk posed to patients, prescribers and pharmacists by the use of unlicensed medicines. Where such systems have been applied in accordance with this policy, Plymouth Hospitals NHS Trust (PHNT) will accept liability for the use of medicines that do not have UK marketing authorisations granted by the MHRA or EMA. In all other situations, where unlicensed medications are used without express approval of the Trust as set out in this policy, liability for harm will rest with the individual prescriber and pharmacist involved. This framework is based on national guidance from the Royal Pharmaceutical Society of Great Britain and the Medicines Healthcare Products Regulatory agency (MHRA)
Scope of the assessment	
See names and contributors on page one of the policy	
Collecting data	
Race	Consideration will be made if information provided to patients is required in a different language. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Religion	There is no evidence to suggest that there is an impact on religion or belief and non-belief regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Disability	Consideration will be made if information about unlicensed medicines is required in different formats for people with disabilities/learning disabilities Data collected from Datix incident reporting and complaints will ensure this is monitored.
Sex	There is no evidence to suggest that there is an impact on sex regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Gender Identity	There is no evidence to suggest that there is an impact on gender identity regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.

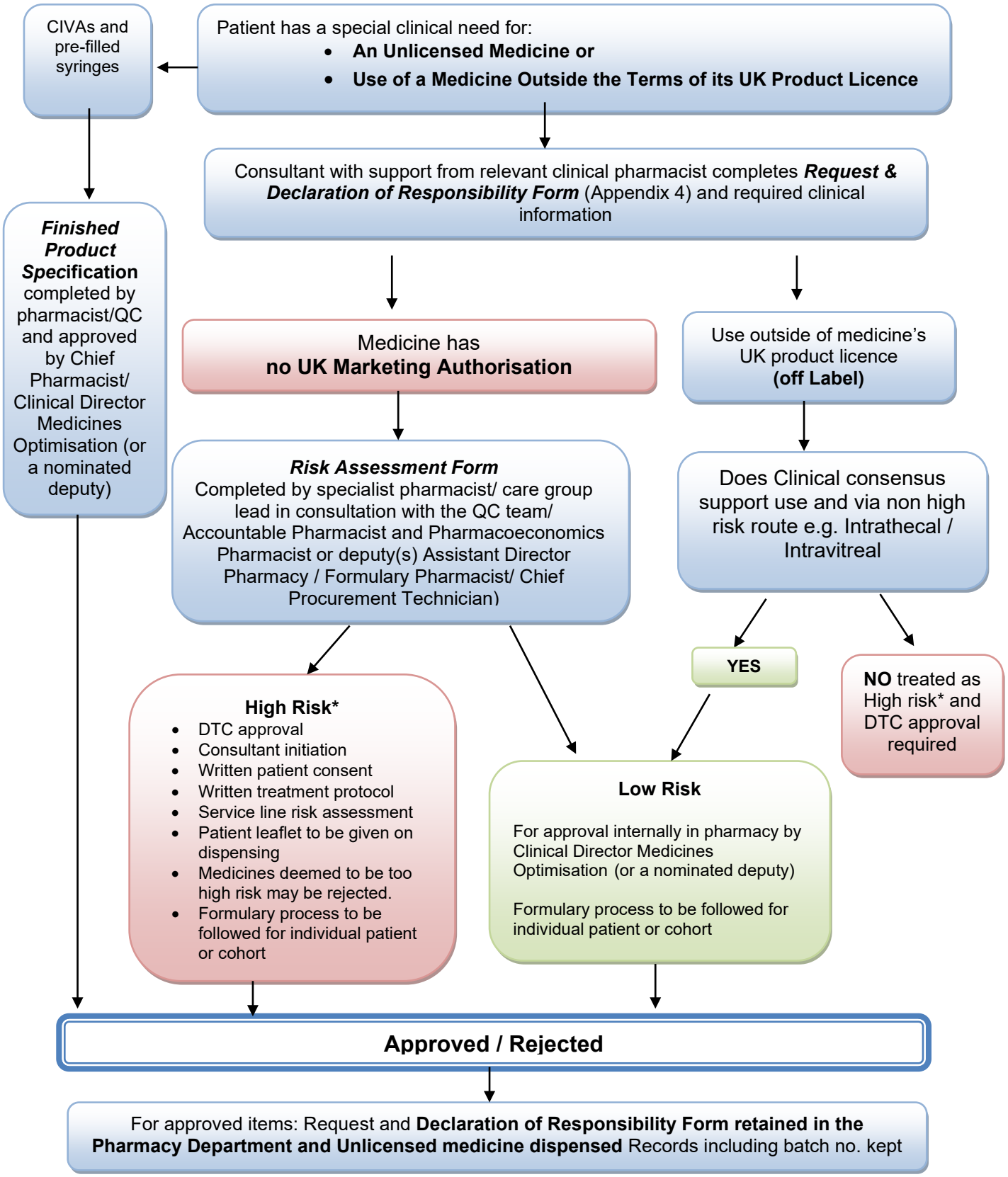
Sexual Orientation	There is no evidence to suggest that there is an impact on sexual orientation regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Age	Consideration is made in section 5 of the policy regarding unlicensed medicines for children and a separate process is required Data collected from Datix incident reporting and complaints will ensure this is monitored.
Socio-Economic	There is no evidence to suggest that there is a disproportionate impact on socio-enonomic issues regarding this policy Data collected from Datix incident reporting and complaints will ensure this is monitored.
Human Rights	Consideration needs to be made when requesting written consent for those with mental health/ disabilities/learning disabilities Data collected from Datix incident reporting and complaints will ensure this is monitored.
What are the overall trends/patterns in the above data?	No comparative data has been used to date which means that no trends or patterns have been identified
Specific issues and data gaps that may need to be addressed through consultation or further research	No gaps have been identified at this stage but this will be monitored via data collected from datix incident reporting and complaints.

Involving and consulting stakeholders	
Internal involvement and consultation	The Medicines Governance Committee Medical Director Director of Pharmacy
External involvement and consultation	No external consultation has been undertaken
Impact Assessment	
Overall assessment and analysis of the evidence	Consideration will be made if information provided to patients/carers is required in a different language Consideration will be made if information about unlicensed medicines is required in different formats for people with disabilities/learning disabilities Consideration needs to be made when requesting written consent for those with mental health/ disabilities/learning disabilities Consideration is made in section 5 of the policy regarding unlicensed medicines for children and a separate process is required

Action Plan				
Action	**Owner**	**Risks**	**Completion Date**	**Progress update**
Collect and monitor data collected from Datix on incidents and complaints				

Application for use of an Unlicensed Medicine or use of a Medicine outside of the terms of its UK Marketing Authorisation.

Appendix 3



Request and Declaration of Responsibility for Use of an Unlicensed Medicine or Off-label Use

1. The Medicine Required for the Patient(s) Below is:	
Unlicensed: Medicine is unlicensed in the UK/ being imported **OR**	Y / N
Off-label: Medicine is licensed in the UK but is requested to be used outside of the terms of product licence (e.g. unlicensed indication, route or dose).	Y / N
2. Use in Named Patient below OR Use in the Following Group of Patients (Records to be retained by Formulary Pharmacist)	

Affix patient addressograph or Name: …….. DOB:……/ ……/…….. NHS No:_ _ _ _ _ _ _ _ _ _	**Group of Patients:**	
	Name(s) of proposed prescriber(s):	**Service Line:**

3. Medicine details		
Name:	Strength:	Form:

4. Clinical details			
Indication:	Dose/range:	Frequency:	Course length/Ongoing

Note: For items that are non-formulary and for either a single patient or cohort the request and declaration form should be accompanied by a formulary or single named patient DTC approval

5. Declaration of Responsibility

Reason for request: (list any relevant evidence/ references if available)

I understand that it is UHP Policy to only use unlicensed medicines or a licensed product outside the terms of its product licence, in accordance with a responsible body of medical opinion. I accept responsibility for the use of this medicine and in my clinical judgment the use will benefit the patient. I will ensure the patient/ group of patients is informed:

- *That this product is unlicensed in the UK or being used for an unlicensed indication, dose or route.*
- *Of the following details of risks associated with using this product*

References:

Requesting Consultant	Signed:	Print:	Date:
Approved by Clinical Director on behalf of Service Line	Signed:	Print:	Date:
Specialist Pharmacist	Signed:	Print:	Date:
Chief Pharmacist / Clinical Director Medicines Optimisation/ Pharmacoeconomics Pharmacist or Deputy(s)	Signed:	Print:	Date:
DTC Committee (High risk only)	Signed:	Print:	Date:

Risk Assessment Form for an Unlicensed Medicine (Quality Assurance Details)

Product Name:	Manufacturer:	
RISK LEVEL ASSIGNMENT: SCORING GUIDELINES		
Therapeutic Agent		
CIVAS from pre-approved licensed NHS or commercial suppliers	LOW	
Established therapeutic agent - no special problems	0	
Recognised therapeutic agent - minor problems or little experience of use	2	
Novel therapeutic agent of unusual use e.g. in higher risk patient groups such as paediatrics	4	
Unrecognised therapeutic agent with some supporting information for use	6	
Unrecognised therapeutic agent with no information available	H	
Recognised therapeutic agent with known problems	H	
Products containing material of animal or human origin	H	
Alternative suitable licensed medicine is available	H	
Supplier		
MHRA licensed importer approved to supply e.g. via PPSA	1	
Approved NHS/Commercial specials licensed unit e.g. local or via PPSA	1	
Other NHS or commercial specials manufacturer (not currently approved contract)	2	
Supply chain not fully approved (acceptable supplier not manufacturer e.g. wholesaler)	3	
Registered Pharmacist (extemporaneous preparation)	4	
Origin		
UK manufacturers with Specials licence	1	
EEA / MRA (USA / Canada / Australia / NZ / Japan) and licensed in country of origin	1	
Rest of the world - licensed in country of origin	3	
EEA / MRA and **not** licensed in country of origin	3	
UK - no Specials licence (Section 10)	H	
Certification		
Fully licensed product within EMA / EU number (Imports)	1	
Certificate of Analysis and GMP compliance available (Specials) alongside product specification	1	
Certificate of Conformity available product analysed (Specials) stating compliance with product specification	2	
Certificate of Conformity but **no** product analysis (Specials) alongside product specification	3	
No Certificate available / no analysis carried out (Specials / Section 10)	4	
Documentation		
Product TSE compliant with English-translated SPC/PIL	1	
Product TSE compliant with **no** English-translated SPC/PIL	2	
Specials (No PIL SPC available)	1	
Packaging & Labelling		
English	0	
Foreign language or multilingual packs but overlabelled with English text	1	
Foreign language but easy to read critical data	2	
Foreign language and **not** easy to read critical data	4	
Specification		
BP / EP / USP monograph product	0	
Other Pharmacopoeia monograph	1	
Suitable Manufacturer's specification available	2	
No external specification available	3	
Route of Administration		
Topical to intact skin (non-sterile)	0	
Mucous membranes, broken skin, oral (non-sterile)	1	
Sterile all routes except intrathecal	2	
Sterile intrathecal	3	
Total Score		
LOW	**0**	
HIGH	**1**	
Risk Level Assignment Signed off by: Accountable Pharmacist / Pharmacoeconomics Pharmacist or Deputy(s) (Assistant Director Pharmacy / Formulary Pharmacist / Chief Procurement Technician)		

UNIVERSITY HOSPITALS PLYMOUTH HOSPITALS NHS TRUST

Patient Consent Form for treatment with

……..…

PATIENT INFORMATION

As the clinician in charge of your care, I consider that you may benefit from treatment with this product.

This drug either:

does not have a license from the UK regulators and is therefore not allowed to be promoted/marketed within the UK; or

does have a license from the UK but it does not cover your condition and so the drug is not allowed to be promoted or marketed within the UK for your condition.

Although the drug cannot be marketed it can still be used and there is evidence to support its use on specific conditions, such as yours.

Dr to specify here the following details:

Purpose of medication……..

Why the drug may be of benefit……..

What side effects or risks may be involved…….

Any other information that the patient should be aware of (eg need for monitoring)

……..……

……

Dr……. Date ……..

Print name…….. GMC Registration No.

PATIENT CONSENT

I ……..(name of patient (please print)) confirm that I understand that [name of

drug]…….. is not licensed for marketing in this country and that I consent for it to be used as part of my treatment plan.

The Doctor supervising this treatment has satisfactorily answered all the questions I have about this medication and its status.

Name of Doctor (please print)…… Date……

Signature of patient…….. Date……

PRESCRIBER INFORMATION

- **For all 'High Risk' unlicensed medicines (see Pharmacy website for list of unlicensed medicines and their associated risk classification), a copy of this consent form MUST accompany the first prescription to Pharmacy (or if an emergency within 72hours).**
- Ensure that all incidents of patient adverse reactions are recorded and reported to the MHRA via the yellow card scheme and through the Trust's incident reporting scheme
- Ensure that where responsibility for ongoing care is to be transferred to the patient's General Practitioner, that the General Practitioner is informed of the unlicensed status of the medicine and that he or she is willing to accept clinical and legal responsibility for prescribing.
- Ensure that continuing treatment is provided by the hospital if the GP will not accept responsibility for continuing care

UHP Unlicensed Medicines Patient Information Leaflet Appendix 7

University Hospitals Plymouth NHS Trust

Unlicensed Medicines

Pharmacy Department

University Hospitals Plymouth NHS Trust

Derriford Road

Crownhill

Plymouth

PL6 8DH

What is this leaflet about?

In the UK most medicines are “licensed” but some are not. This leaflet explains why medicines are licensed and why some useful medicines do not have licences.

You will have been given this leaflet by your doctor or pharmacist because the medicine prescribed for you is not “licensed” or is being used for a reason not covered by the licence. We want to reassure you that we have thought very carefully about the best medicine for you and to answer any questions you mayhave.

Why are medicines “licensed”?

The makers of medicines must ask the government for a 'Marketing Authorisation' or 'Product Licence' if they want to sell their medicines in the UK. They show evidence to the government's Medicines and HealthCare products Regulatory Agency (MHRA) that their medicine works for the illness to be treated and does not have too many side effects or risks and has been made to a high standard.

How do the makers test medicines?

To be sure that a medicine works and is safe the maker has to try it first on a small number of people in what is called a 'Clinical Trial'. Information from clinical trials is given to the MHRA when the maker asks for a 'Product Licence'.

Why don't all medicines have a licence?

There are several reasons why some medicines are used for illnesses or conditions not covered by their original licence. Also, some medicines do not have a licence at all. Sometimes the clinical trial (and Product Licence) is for one illness but doctors find that the medicine works very well for another illness. These doctors use medicines for reasons that are not written in the Product Licence. Some medicines have no licence at all. These may be medicines used for rare illnesses in which case it may be too expensive to licence them.

How do I know that these medicines are safe and will work?

This medicine may have been recommended by another doctor who is an expert, or your own doctor may have read information and research that says it is the best one for you. The Pharmacy Department will ensure that the medicine has been manufactured to a good standard and is of an acceptable quality.

How will I know that my medicine is not licensed?

Your doctor should tell you. Unlicensed medicines may be made specifically or may be more difficult to obtain. Your pharmacist may tell you this and make special arrangements for you to get your medicines.

Should I be worried about taking these medicines?

If you are still worried after reading this leaflet, please talk to your doctor or pharmacist. They are looking after you and have thought carefully about the best medicine for you.

What if I don't want to take unlicensed medicines?

Talk it over with your doctor and tell them what you are worried about. They can tell you more about the information or advice they have about the medicine. They

can also tell you about other treatments available and why they think this is the best one.

Can I get more information about my unlicensed medicine?

Your pharmacist may have a special information leaflet about your medicine or illness. Please ask. Often there are support groups for people with a particular illness or condition. Ask your doctor, nurse or pharmacist for information.

If I am confused what should I do?

Talk to the person who gave you this leaflet (usually your doctor or pharmacist). Ask them to explain.

Further information may be obtained from:

1. Pharmacy Department, Derriford Hospital, Plymouth
2. NHS website – www.nhs.uk
3. Your GP or local pharmacy

How do I get a further supply of an unlicensed medicine?

The doctor who first gave you the unlicensed medicine should tell you if further supply of it will come from your GP or how to get it from the hospital. If your further supply will be from your GP, please contact your GP to get a prescription. You will probably need to give the pharmacist one or two weeks to obtain the supply for you, so it is important that you do not let your supply run out before going to the GP.