

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

Date	Version
February 2013	3

Purpose

The purpose of this policy is to set the standards for the correct management of unlicensed medicines, i.e. prescribing, risk assessment, procurement, ordering, administration and storage.

Who should read this document?

Trust Wide. All Medical, Pharmacy and Nursing staff.

Key messages

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).

Accountabilities

Production	Andrew Prowse, Associate Director Pharmacy
Review and approval	Medicines Governance Committee
Ratification	Dr Alex Mayor, Medical Director
Dissemination	Andrew Prowse, Associate Director Pharmacy
Compliance	Simon Mynes, Director of Pharmacy

Links to other policies and procedures

Medicines Management Policy
Injectable Drug Administration Procedure
Consent to examination or treatment Policy

Version History

2.0	February 2013	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	November 2018	Agreed at Medicines Utilisation and Assurance Committee to extend the Review date

Last Approval	Due for Review
February 2013	Extended to November 2019

PHNT 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, actively 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 the Trust Documents Network Share Folder. Larger text, Braille and Audio versions can be made available upon request.

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1. Introduction

1.1 Background

1.1.1 The term 'unlicensed medicine' is normally applied to those medicines which do not have a UK Marketing Authorisation (MA), formerly a Product Licence (PL), granted by the Medicines and Healthcare products Regulatory Agency (MHRA) or European Medicines Agency (EMA). The term is also applicable to licensed medicines when they are used for unlicensed applications.

1.1.2 Unlicensed medicines fall into the following categories:

- Medicines not available in the U.K.
- Medicines waiting for a U.K. Marketing Authorisation to be granted.
- Those medicines obtained from a manufacturer with a "Specials" Manufacturing Licence granted by the Medicines and Healthcare products Regulatory Agency (MHRA). These products are either made to the formulation of the purchaser, or are products for which it is not economically viable for the manufacturer to apply for a Marketing Authorisation (MA).
- Medicines undergoing clinical trials.
- Medicines that no longer have a Product Licence because they have been abandoned, suspended, revoked or not renewed.
- Medicines prepared by or under the supervision of a pharmacist in accordance with a prescription. For the purpose of this document only non-sterile products will be considered.
- Repackaging and Over-labelling a licensed medicine which has either been repackaged from its original primary packing into a different container or over-labelled in its original pack is rendered unlicensed. These products are not considered by this policy.
- Dietary oral supplements including vitamins, minerals and glucose powder do not routinely hold Marketing Authorisations. These products are not considered by this policy.

Additionally:

- Prescribers may wish to use a medicine, which has a Product Licence in a way not specified in the Summary of Product Characteristics (SPC), e.g. by a different route of administration or dose, for a different age group, or for a condition not covered by the licence. In these circumstances, the medicine should be treated as unlicensed ("off-label")
- When licensed medicines are mixed together, prior to administration, in a way not described in the SPC, then their Product Licences become invalid. This includes injections being reconstituted or diluted with diluents not specified in the manufacturer's package insert or SPC.

1.1.3 For good clinical reasons the use of unlicensed medicines is widespread in hospitals and community. It is important that such use continues, since if this

practice were to be curtailed, the treatment of many patients would be impeded. It is important however that all prescribers and pharmacists should be aware of the associated medico-legal implications of such practice.

- 1.1.4 Unlicensed medicines are not illegal. However, the use of unlicensed medicines (or medicines outside their licensed indications) poses risk to the patients, prescribers and pharmacists involved. Whilst a licensed product is subject to stringent controls by the MHRA or EMA, neither the prescriber nor pharmacist can make the same assumptions of quality, safety and efficacy about unlicensed products.
- 1.1.5 The reasons why a product has not been licensed, or why it has not been licensed for a certain route or use is often unknown. Animal toxicology in particular will not usually appear in the literature. The regulatory authorities are not permitted to make public why products are not licensed, and drug companies cannot be relied upon to tell.
- 1.1.6 The Consumer Protection Act (1987) introduced the concept of 'strict product liability' to medicines. This act makes the producer 'liable' for damage caused by a defect in their product. A product is defective if its safety is not such as persons are generally entitled to expect. Thus, if a patient can demonstrate he has suffered injury whilst undergoing a course of treatment and the medicinal product was defective, then he can bring an action for damages against the manufacturer of the medicines, without needing to prove negligence. This applies to medicines whether licensed or unlicensed.
- 1.1.7 The use of unlicensed medicines is the responsibility of the prescriber and, when procuring unlicensed medicines, the ordering pharmacist is considered to be the manufacturer.
- 1.1.8 If a medicine or form of a medicine is not listed in the British National Formulary (refer to eBNF if not found in the published version for drug recently licensed) then it is likely to be unlicensed. The BNF does list some unlicensed products or uses of medicines but does clearly identify these. Alternatively, access the electronic medicines compendium (<http://www.medicines.org.uk/emc/>) which has available most licensed monographs.

1.2 Responsibilities and Liabilities

1.2.1 Prescribers

A clinician has the right to use any material for any purpose in the treatment of his own patients, although he does so, on his own responsibility. However, if a patient is harmed by an unlicensed medicine or a licensed medicine used outside of license and not because of any defect in the product itself, then the prescriber is professionally accountable and liable for the harm and may be called upon to justify their actions.

1.2.2 Pharmacists

If a patient is harmed by a defective medicine, whether licensed or unlicensed, then the supplier of that medicine is liable for the harm. If the supplier can identify the manufacturer of the medicine, then liability passes to the manufacturer. If the

medicine has been prepared by or under the supervision of a pharmacist, then that pharmacist is liable for the harm, as the manufacturer of the medicine.

Furthermore, if the medicine has been procured from a 'Specials' manufacturer, then the pharmacist who placed the order is considered in law to be the manufacturer and is liable as such. At PHNT as the procurement of medicines are not directly ordered by a Pharmacist, this will default to the Director of Pharmacy.

It is therefore essential that the ordering pharmacist has in place an adequate system to ensure the quality of unlicensed medicines. The pharmacist must also give written advice to the prescriber if an unlicensed medicine has not been used before in the Trust (see annex 2) as the prescriber can avoid liability if he can demonstrate that he was unaware of the medicine's unlicensed status.

Furthermore, pharmacists should not feel that they have discharged their potential liability where the prescriber is prepared to sign a declaration to the effect that he is accepting full responsibility for any adverse affects of the prescribed medicine. The potential liability would be shared between the prescriber and pharmacist in any event.

All new unlicensed medicines used within the Trust will be subject to a critical, evidence-based evaluation by the Formulary Pharmacist or other Senior Pharmacist.

1.2.3 Drugs and Therapeutics Committee (DTC)

The DTC is responsible for the approval of new unlicensed medicines in the Trust. However, in the case of urgent clinical need, the Chair of the DTC or Director of Pharmacy (or nominated deputy) may authorise use subject to formal ratification at the next DTC meeting.

1.3 Purpose of this Policy

- 1.3.1 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 unlicensed medicines.
- 1.3.2 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.
- 1.3.3 This policy does not relate to medicines used in clinical trials, products extemporaneously prepared within the Trust or products prepared under section 10 of the Medicines Act 1968 (Part 1, Section 4 of The Human Medicines Regulations 2012).

2. Roles

2.1 Drug and Therapeutics Committee

The Committee approves, monitors and reappraises all unlicensed medicines used within the Trust. It reviews the risk assessments for unlicensed medicines and ensures that their use is justified by published evidence or sound therapeutic argument. The Committee also ensures appropriate audit systems are in place to monitor compliance with this policy.

2.2 Prescriber

At all times, prescribers are reminded that they must:

- Ensure that they are aware of the status of the medicine.
- Ensure that the use of the unlicensed medicine is justified by the clinical condition of the patient.
- Ensure that they alert the pharmacist as appropriate when specifically prescribing a medicine for an off-licence indication as a pharmacist may not always be aware of the indication for which the medicine will be used.
- Ensure that Trust policy relating to informed patient consent is complied with.
- Ensure that appropriate records are kept.
- 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.
- Subject to risk assessment, communicate with patients the implications of using the unlicensed medicine. An example of a suitable Patient Information Leaflet for this purpose is given in Annex 3.

In addition:

- unlicensed products in general are **not** intended for routine, ongoing use,
- where suitable licensed alternatives to unlicensed products exist these **should always** be used in preference to unlicensed medicines (unless specifically sanctioned by the Trust),
- whenever an unlicensed medicine is prescribed, the prescriber is **PROFESSIONALLY ACCOUNTABLE** for his judgement in so doing, and may be called upon to justify his actions,
- A General Practitioner is not obliged to prescribe an unlicensed medicine.
- Non medical prescribers may prescribe unlicensed medicines within their area of expertise and competence when there is no appropriate licensed alternative.

2.3 Pharmacy Staff

2.3.1 Director of Pharmacy (or Nominated Deputy)

- Ensures that written pharmacy department procedures to cover all aspects of the procurement and issue of unlicensed medicines are produced, authorised, and reviewed.

- Ensures that arrangements are in place to ensure, on an annual basis that Prescribers are made aware of the unlicensed status and accept the responsibility for the use of each unlicensed medicine.
- Ensures that arrangements are in place to make sure that unlicensed medicines are used only when an equivalent licensed product is unavailable.
- Monitors and audits the handling of unlicensed medicines in the Pharmacy Department.
- Monitors the range and quantities of unlicensed medicines purchased, keeping a list of unlicensed medicines currently approved by the Trust.
- Reports to the DTC the use of unlicensed medicines in the Trust
- Ensures that submissions are made to the DTC for approval to use unlicensed medicines that have not previously been used in the Trust.
- Quarantines all unlicensed medicines on receipt within the Trust until appropriate quality assurance assessment is carried out.
- Releases all batches of unlicensed medicines for use within the Trust.
- Submits completed request for use of unlicensed medicines forms to the DTC (see annex 4).

2.3.2 Pharmacy Staff involved in the Procurement of Unlicensed Medicines

- Ensure that the person making the request is authorised to do so.
- Ensure that purchases of unlicensed medicines are in accordance with written procedures
- Obtain advice from the Director of Pharmacy or other senior pharmacist as required.
- Liaise with the supplier as appropriate.
- Ensure any special requirements of suppliers are met.
- Process deliveries in accordance with procedure.
- Confirm the original approved use when reordering.
- Ensure correct storage arrangements.

2.3.3 Pharmacy Staff Involved in the Dispensing of Unlicensed Medicines

- Ensure that requests for unlicensed medicines are processed in accordance with Trust procedures.
- Issue an unlicensed medicines patient information leaflet as appropriate for all unlicensed medicines risk assessed as high risk (Annex 3)
- A copy of the patient consent form MUST accompany the first prescription (or if an emergency within 72hours) for all high risk unlicensed medicines (see Annex 6).
- If appropriate, continue supplies of treatment as instructed by the prescriber.

In addition:

- a pharmacist who manufactures, prepares or procures an unlicensed medicine in response to a prescription is **PROFESSIONALLY ACCOUNTABLE** for any harm caused by a defect in the medicine which is attributable to his own actions or omissions

2.4 Nursing Staff

- Must remain accountable for their actions and should acquire sufficient information to ensure the safe administration of the medicine. See BNF or Pharmacy website for catalogue of unlicensed medicines monographs for further information.
- In addition, wherever possible, nursing staff must be satisfied that there is acceptable evidence for the use of that product for the intended indication.
- By definition unlicensed medicines are not permitted to be supplied or administered under Patient Group Directions, apart from in exceptional and justified circumstances.

3. Prescriber Request and Risk Assessment Form

- 3.1 Where a clinician considers an unlicensed product essential for treatment of their patient, they should apply in writing (using annex 4) to the Formulary Pharmacist to request risk assessment of the product and consideration by the DTC for its use within PHNT. The clinician should state the rationale for the use of the unlicensed product and the patient group in which it will be used and provide evidence to support such use.

However, in the case of urgent clinical need, the Chair of DTC or Director of Pharmacy (or nominated deputy) may authorise use subject to formal ratification at the next DTC meeting.

4. Risk Assessment of Unlicensed Drugs

- 4.1 All unlicensed medicines identified for use within PHNT will be risk assessed by the QA Pharmacist using the risk assessment tool provided in annex 5.
- 4.2 Consideration is given to the clinical reasons for using an unlicensed product in preference to a similar UK licensed one. The risk assessment identifies the need for clear clinical evidence in support of the product use. Reference sources must be quoted.

Contraindications, side effects, precautions and the potential for harm must also be identified and accurately assessed in relation to the clinical condition.

- 4.3 The procurement risks are also assessed as part of the process including determination of the country of origin.

The language used on the packaging is determined along with details of who will supply the translation of the patient information leaflet and label.

An assessment of the supply chain is carried out, and the ease at which further supplies can be obtained. The cost of the drug and any special funding needs are determined. Responsibility for continued supply is identified.

The assessment process takes into account any issues raised by QA.

- 4.4 All risk assessments will be reviewed by the Drugs and Therapeutics Committee and a risk category agreed. This can be a retrospective process in the case of urgent clinical need. When considering a request to approve an unlicensed medicine, the Committee must be certain that there is no suitable licensed

alternative product available. It reviews the supporting clinical data and takes a view on the likelihood of supply chain difficulties, the possibility of interruptions to patient treatment, and any consequences.

- 4.5 Details of all assessed products and their risk category will be kept on behalf of the Trust by the QA Pharmacist.

5. Risk levels of unlicensed products

On the basis of the risk assessment unlicensed products will be classified as being low or high risk.

5.1 Use of Unlicensed Products Assessed as LOW Risk

- 5.1.1 Plymouth Hospitals NHS 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.
- 5.1.2 The Pharmacy Department will maintain the list of low risk products to which this approval applies.
- 5.1.3 An unlicensed medicines patient information leaflet (Annex 3) to be given to all patients on dispensing as appropriate.
- 5.1.4 Although not essential, clinicians are advised to seek written patient consent for use of these products (Annex 6).
- 5.1.5 Examples of **low risk** products:
- Preparations purchased from a trusted manufacturer or licensed within the EU or a country with a mutual recognition agreement
 - A preparation obtained from a trusted 'Specials' manufacturer
 - Commonly prepared extemporaneous topical dermatology preparations are usually considered low risk
 - A preparation licensed in the EU (or a country with a mutual recognition agreement) to replace a licensed preparation temporarily unavailable in the UK
 - A preparation where a UK licence has never been sought, although some exceptions do exist.
 - Extemporaneously prepared products with limited stability information available to justify shelf life and / or lacking in other evidence to support clinical use

5.2 Use of Unlicensed Products Assessed as HIGH Risk

- 5.2.1 Prescribers are reminded that Plymouth Hospitals NHS Trust will NOT automatically accept liability for the use of unlicensed products assessed as posing a high degree of risk. Liability will only be accepted where the following provisions have been adhered to:
- 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.

- A written treatment protocol is in place
- Written informed patient consent is sought and obtained when a patient is treated with a high risk unlicensed medicine (see Annex 6). A copy of this consent form MUST accompany the first prescription to Pharmacy (or if an emergency within 72hours).
- The use of the high risk product is risk assessed within the department/specialty and entered into their risk register and that of the Trust together with robust controls for managing the risk.

5.2.2 Once use of a high risk product has been endorsed by the DTC, further applications concerning the product need only be made if there is a material change in the usage of the product e.g. indications for use, treatment protocol etc.

5.2.3 An unlicensed medicines patient information leaflet (Annex 3) to be given to all patients on dispensing as appropriate.

5.2.4 Examples of **high risk** products:

- Preparations which have been withdrawn from the UK market on safety grounds
- Preparation manufacturer outside of the EU or country with a mutual recognition agreement
- Preparations with a significant clinical risk.
- Preparations which pose a risk to the staff administering them
- Preparations which are imported but which are unlicensed or prepared extemporaneously in the country of origin (regardless of whether they are sourced within the EU or not)

5.3 Use of an Unlicensed Product where a Licensed Alternative exists

5.3.1 Only in *exceptional* cases may a clinician seek to use an unlicensed product or unlicensed formulation where a licensed alternative exists. In such circumstances the clinician must:

- follow the procedure set out in section 3.1 and
- seek a signed endorsement of this treatment option by the relevant clinical director. (NB - the Clinical Director may wish to consult the Chairs of the Trust Ethics Committee and Drugs and Therapeutics Committee before giving such an endorsement). (See flow chart 2 given at Annex 7B)

5.3.2 The unlicensed product or formulation will only be procured and supplied by the Pharmacy Department upon approval of the DTC.

5.4 Use of Licensed Products for Non-Licensed Indications

5.4.1 Drugs are often used for non-licensed indications within hospitals. Prescribers should take steps to ensure they are aware when they are using a drug for an unlicensed indication. Pharmacists are available to assist in this respect.

5.4.2 The Trust will generally accept liability in the event of untoward events happening in connection with the use of a licensed medicine for an unlicensed use provided that the unlicensed use is widely recognised as accepted practice and would command substantial peer group support.

- 5.4.3 Where the practice is less well recognised, or where the treatment could be described as novel or is based mainly on theoretical grounds and/or only limited clinical experience, approval from the Drugs and Therapeutics Committee must be sought prior to commencement of treatment. In such situations clinicians should follow the procedure as set out in 3.1 above. (See also flow chart 3 given in Annex 7C)

5.5 Ongoing Treatment

- 5.5.1 In the event that the patient requires ongoing treatment with an unlicensed product the hospital consultant **must** discuss this with the patient's General Practitioner. In some circumstances (e.g. for products categorised as high risk) it will not be appropriate for prescribing responsibility to transfer to the GP; consultants should respect this situation and retain prescribing responsibility for this treatment.
- 5.5.2 In other situations (e.g. for unlicensed medicines in the low risk category) it *may* be appropriate for the GP to continue supply in which case the consultant must provide **full** details of the medicine including formulation etc to the GP. It will be for the GP to decide whether he/she will accept liability for the continued use of this medication and prescribe accordingly.

5.6 Use of Unlicensed / Off Label Products in Children

- 5.6.1 Many drugs do not have a license to be promoted by a pharmaceutical company for use in childhood but are required for the effective management of conditions in this group of patients.
- 5.6.2 For the purposes of this policy the Trust recognises the *BNF for children* as the definitive guide on medicines use and dosing in children.
- 5.6.3 Clinicians prescribing in accordance with the latest edition of the *BNF for Children* will be considered to be working in accordance with Trust policy.
- 5.6.4 Clinicians using unlicensed/off label products for children should ensure patients and carers have access to the relevant information sheets, i.e. as developed by the Joint Royal College of Paediatrics and Child Health/Neonatal and Paediatrics Pharmacists Group Standing Committee on Medicines or other locally developed documents.

5.7 Use of Liquid Pharmaceutical Specials

- 5.7.1 Although the crushing or breaking of tablets may be outside of a product's licensed use, liquid pharmaceutical specials are also unlicensed. If a pharmacist recommends crushing a tablet and patient harm results from the medicine, then the pharmacist could assume a greater degree of liability
- 5.7.2 An option could be to ask for the tablet to be dissolved in water by writing this requirement onto the prescription directions. Some solid-dose formulations may also allow the 'sprinkling' of contents onto food.

5.7.3 Clinicians administering/advising in accordance with the White and Bradman reference text will be considered to be working in accordance with Trust policy

5.7.4 Before prescribing an unlicensed liquid medication, consider alternatives such as Oro-dispersible tablets (e.g. lansoprazole oro-disperible, mirtazepine oro-dispersible) and soluble/dispersible tablets (e.g. soluble prednisolone). For further information refer to the BNF.

5.8 Use of Unlicensed / Off Label Products in Pregnancy and Breast feeding

Many medicines are not licensed for use in pregnant or breast feeding women, however many may be prescribed relatively safely, taking into account the risk-benefit ratio and utilising all available information on a particular drug's safety record in pregnancy or breast feeding (TOXBASE database – part of the National Teratology Information Service, Drugs in Pregnancy – Briggs et al, 2005)

5.9 Mixing of Injectable medicines

The vast majority of drugs are not licensed to be administered in the same bag or syringe as another drug, and very few are licensed to be infused via a Y-site or 3-way tap together with another drug solution. This has implications for the mixing of drugs in syringes for subcutaneous infusion in palliative care, and for running different intravenous drug solutions together in critical care and on other wards.

A PHNT-approved subcutaneous drug compatibility chart is provided in each syringe driver kit supplied by MEMS, and a PHNT-approved compatibility chart for intravenous infusions is provided in the PHNT Injectable Drug Administration Procedure. For specific compatibility information that is not provided on these charts, staff should contact Medicines Information for advice.

Staff practicing in accordance with this guidance will be considered to be working in accordance with Trust policy.

6.0 Adverse Drug Reactions and Defective Products

6.1 Adverse drug reactions and defective products are handled and reported in the same way as licensed medicines. Doctors, pharmacists or nurses should report all adverse drug reactions to unlicensed medicines to the Medicines and Healthcare Regulatory Agency, using the Yellow Card System (copies available in the BNF or on the website: www.yellowcard.gov.uk), and through the Trust's incident reporting scheme.

6.2 Suspected defects in unlicensed medicines must be reported to the Pharmacy Department who will report them to Regional Quality Control following the Regional Drug Defect Reporting procedure.

7.0 Record Keeping

7.1 Records to be kept for obtaining unlicensed medicines include:

- Name of the product
- Its specification

- Manufacturer and (if different) supplier
- Date ordered
- Quantity ordered
- Batch number received

7.2 Records to be kept for supplying of unlicensed medicines include:

- Name of the product
- Source
- Date of supply
- Quantity supplied
- Batch number
- Consent forms for high risk unlicensed medicines
- Prescriber Authorisation forms for the use of Unlicensed Medicines

For unlicensed medicines classified as high risk, the following must also be recorded:

- Person to whom the product was supplied (including hospital number)
- Prescriber's name

7.3 Records retention schedule:

- All records regarding the use of unlicensed medicines **MUST** be kept for a minimum of **FIVE YEARS** for adults (this is an MHRA requirement).
- In the case of children and young people, all records should be kept until the patient's **25th birthday**, or 26th birthday if the young person was 17 at the conclusion of treatment or 8 years after death.
- In the case of use during pregnancy, all records should be kept for **25 years after birth of the last child**.

8. Storage

High risk unlicensed medicines are stored separately from licensed medicines in dispensaries and stores.

9. Overall Responsibility for the Document

Overall responsibility for this document lies with Simon Mynes, Director of Pharmacy.

10. Consultation and Ratification

The policy has been reviewed and ratified by the Medicines Governance Committee.

11. Dissemination and Implementation

Following approval and ratification by the Medicines Governance Committee this policy will be rolled out across the Trust.

12. Monitoring Compliance and Effectiveness

The use of unlicensed medicines will be reviewed annually by the Drug & Therapeutics committee. The review will include a review of any new clinical data or any newly licensed product which would negate the need to obtain the unlicensed medicine.

In addition, medicines-related incidents reported via the Trust Incident reporting system are collated by the Risk and governance pharmacist and reviewed by the Medicines Governance Committee on a monthly basis. The Medicines Governance Committee will then nominate a committee member to resolve any identified issues.

13. References

- 'The use of unlicensed drugs: advice for managers'. Hilary Pickles. British Journal of Health Care Management, 1996, Vol2. No 12. 656-658.
- The Use of Unlicensed Medicines in Pharmacy. Legal and Ethical advisory service: Fact Sheet 5 Royal Pharmaceutical Society of Great Britain Sept. 2007
- 'The purchase and use of unlicensed medicines in hospitals'. Guild of Health Care pharmacists, Policy Statement No 006, May 2000
- 'Off-label and off-license prescribing explained'. Nicholas Norwell (MDU) Prescriber 19 April 2001, 115-116
- Medicines Act Leaflet. MAL 1, Guide to the Licensing System. MCA
- Medicines Act Leaflet, MAL 14, Special Dispensing Services. MCA 2002
- Medicines in Children, Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacists Group, RCPCH Publications, London.
- MHRA Guidance Note 14. The Supply of Unlicensed Relevant Medicinal Products for Individual Patients. MHRA January 2008
- Good Practice in Prescribing medicines (Sept. 2008). General Medical Council.
- Standards for Medicines Management. Nursing and Midwifery Council, 2007
- Information and Guidance on the Prescribing and Use of Unlicensed Pharmaceutical Specials. East of England NHS Collaborative Procurement Hub. January 2010
- Pharmaceutical Press book - Handbook of Drug Administration via Enteral Feeding Tubes, Rebecca White and Vicky Bradman
- Guidance for the purchase & supply of unlicensed medicinal products. NHS Quality Assurance Committee June 2004.
- Records Management: NHS Code of Practice. Department of Health. April 2006.

Dissemination Plan**Appendix 1**

Core Information				
Document Title	Policy for the Procurement, Prescribing, Supply and Administration of Unlicensed Medicines.			
Date Finalised	February 2013			
Dissemination Lead	Andrew Prowse, Assistant Director of Pharmacy			
Previous Documents				
Previous document in use?	Yes			
Action to retrieve old copies.	Nil – all electronic			
Dissemination Plan				
Recipient(s)	When	How	Responsibility	Progress update
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	

Review and Approval Checklist

Appendix 2

Review		
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?	NA
	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	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Y

Compliance & Effectiveness	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 3
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Core Information	
Manager	Andrew Prowse
Directorate	Pharmacy
Date	February 2013
Title	Policy for the Procurement, Prescribing, Supply and Administration of Unlicensed Medicines.
What are the aims, objectives & projected outcomes?	<p>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.</p> <p>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.</p> <p>This framework is based on national guidance from the Royal Pharmaceutical Society of Great Britain and the Medicines Healthcare Products Regulatory agency (MHRA)</p>
Scope of the assessment	
See names and contributors on page one of the policy	
Collecting data	

Race	<p>Consideration will be made if information provided to patients is required in a different language.</p> <p>Data collected from Datix incident reporting and complaints will ensure this is monitored.</p>
Religion	<p>There is no evidence to suggest that there is an impact on religion or belief and non-belief regarding this policy.</p> <p>Data collected from Datix incident reporting and complaints will ensure this is monitored.</p>
Disability	<p>Consideration will be made if information about unlicensed medicines is required in different formats for people with disabilities/learning disabilities</p> <p>Data collected from Datix incident reporting and complaints will ensure this is monitored.</p>
Sex	<p>There is no evidence to suggest that there is an impact on sex regarding this policy.</p> <p>Data collected from Datix incident reporting and complaints will ensure this is monitored.</p>
Gender Identity	<p>There is no evidence to suggest that there is an impact on gender identity regarding this policy.</p> <p>Data collected from Datix incident reporting and complaints will ensure this is monitored.</p>
Sexual Orientation	<p>There is no evidence to suggest that there is an impact on sexual orientation regarding this policy.</p> <p>Data collected from Datix incident reporting and complaints will ensure this is monitored.</p>
Age	<p>Consideration is made in section 5 of the policy regarding unlicensed medicines for children and a separate process is required</p> <p>Data collected from Datix incident reporting and complaints will ensure this is monitored.</p>
Socio-Economic (Consider inequalities arising from social class, background, income, where they were born/live)	<p>There is no evidence to suggest that there is a disproportionate impact on socio-economic issues regarding this policy</p> <p>Data collected from Datix incident reporting and complaints will ensure this is monitored.</p>
Human Rights	<p>Consideration needs to be made when requesting written consent for those with mental health/ disabilities/learning disabilities</p> <p>Data collected from Datix incident reporting and complaints will ensure this is monitored.</p>
What are the overall trends/patterns in the above data?	<p>No comparative data has been used to date which means that no trends or patterns have been identified</p>
Specific issues and data gaps that may need to be addressed through consultation or further research	<p>No gaps have been identified at this stage but this will be monitored via data collected from datix incident reporting and complaints.</p>

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				

Glossary of Terms

Annex 1

Certificate of Analysis

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

Extemporaneously Dispensed

This is a medicine which has been prepared by or under the supervision of a pharmacist in response to or in anticipation of a prescription.

Manufacturers Specials License

This is a license issued by the Medicines and Healthcare products Regulatory Agency to organisations wishing to place unlicensed medicines on the market in the UK.

Off-label use

Medicines are considered to be being used off label when they are used for clinical indications which are not included in the list of approved indications for that product in its Marketing Authorisation details.

Section 10 (Part 1, Section 4 of Human Medicines Regulations 2012)

This is a section of the Medicines Act 1968 describing the exemption from the need to hold a manufacturers license by Pharmacists when preparing medicinal products

Specials

These are unlicensed medicines which have been specially prepared by the holder of a Manufacturers Specials License or

imported in response to or in anticipation of the order of a doctor or dentist to meet the special needs of individual patients.

***Unlicensed
medicine***

These are medicines which do not have a UK Marketing Authorisation (MA), formerly a Product Licence (PL), granted by the Medicines and Healthcare products Regulatory Agency (MHRA) or European Medicines Agency (EMA)

***Wholesale
dealer's license***

This is a license issued by the Medicines and Healthcare products Regulatory Agency to organisations carrying out wholesale dealing of licensed and/or unlicensed medicines.

PRESCRIBER AUTHORISATION FOR THE USE OF UNLICENSED MEDICINES

Plymouth Hospitals NHS Trust

Pharmacy Department

Dear Consultant:..... Date:.....

Patients Name: Hospital No.

Supply of:..... Indication:.....

The above named product is an unlicensed medicine. The term ‘unlicensed medicine’ is normally applied to those medicines which do not have a UK Marketing Authorisation (MA). Formerly a Product License (PL), granted by the Medicines and Healthcare Products Regulatory Authority (MHRA) or European Medicines Agency (EMA). Such products are not subject to the strict licensing controls of the MHRA/EMA and neither the prescriber, or pharmacist can make the same assumptions of safety, quality and efficacy that they would with licensed items.

The use of unlicensed medicines is the responsibility of the prescriber.

Prescribing and supply of unlicensed medicines (or medicines to be used outside their licensed indications) presents a **RISK to INDIVIDUAL PATIENTS, PRESCRIBERS, NURSES and PHARMACISTS**, and by implication, to the Trust.

Prescribers are therefore reminded of the following:

- Unlicensed products are **not** intended for routine, ongoing use.
- Where suitable licensed alternatives to unlicensed products exist these **should always** be used in preference to unlicensed medicines (unless specifically sanctioned by the Trust, see Policy for the Procurement, Prescribing, Supply and Administration of Unlicensed Medicines).
- Wherever an unlicensed medicine is prescribed, the prescriber is **PROFESSIONALLY ACCOUNTABLE** for his judgement in so doing and may be called upon to justify his actions.
- A pharmacist who manufactures, prepares or procures an unlicensed medicine in response to a prescription is **PROFESSIONALLY ACCOUNTABLE** for any harm caused by a defect in the medicine which is attributable to his own actions or omissions.
- A General Practitioner is not obliged to prescribe an unlicensed medicine.
- Where this product has been assessed by the Drugs and Therapeutics Committee as ‘high risk’ (see Policy for the Procurement, Prescribing, Supply and Administration of Unlicensed Medicines) you must inform the patient or their representative of the status of this medicine to seek and obtain informed written consent and supply a copy of the consent form to Pharmacy with the prescription.

We require written confirmation that you have read and understood the above before a supply of this medicine can be made. Please sign below and return form to pharmacy. If you wish, a second copy can be issued to be held in the patient’s notes. This form is valid for a period of one year from the date shown below. At that time you will be asked to sign a new form if you still wish to prescribe this product. Thank you for your co-operation in this matter.

I have read the above, and confirm that I request the supply of this unlicensed preparation.

Consultant Signature:..... GMC No. Date:.....

Form received by.....Pharmacist Reg No. Date:

Plymouth Hospitals 
NHS Trust

Pharmacy department

Patient Information

Unlicensed Medicines

Derriford Hospital
Derriford Road
Plymouth
PL6 8DH
0845155 8155
www.plymouthhospitals.nhs.uk

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 licenses.

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 may have.

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 ‘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 have a clinical trial.

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 doctors 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 Direct (nhs.direct.nhs.uk)
3. Your GP or local pharmacy

How to obtain a further Supply of an unlicensed Medicine

If you require a further supply of an unlicensed medicine, please go to your GP to obtain 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.

Further information can also be obtained from
the Pharmacy Department:
Tel 01752 439976

**This leaflet is available in large print and other
formats and languages. Please contact**

Andrew Prowse,
Associate Director
Pharmacy

Date Produced: February 2013
Review Date: February 2015
Ref: F-31/Pharm/AP/Unlicensed Medicines

Request Form for use of Unlicensed Medicine

This form should be completed by the consultant assuming responsibility for the use of an unlicensed product and sent to the Formulary Pharmacist as part of the submission for approval to use the product.

Before completing this form, you must have read the Trust Policy on the Procurement, Prescribing, Supply and Administration of Unlicensed Medicines and must be aware of your responsibilities under this policy.

Consultant:	Department
Product Name:	Proprietary Name (if known):
Strength:	Pharmaceutical Form:
Manufacturer (if known):	
Route:	Duration of Treatment:
Dose:	Frequency:
Indication for which the medicine is to be used:	
If the product is licensed in another country please state licensed indication.	
Approx. no. of patients per annum:	
Why is an unlicensed Medicine being considered? (indicate as appropriate)	
1. Pharmaceutically Equivalent Licensed product temporarily unobtainable	Yes / No
2. Equivalent UK licensed product unavailable / unsuitable	Yes / No
3. Other (give details)	Yes / No
Is the product completely new to the Trust	Yes / No
Is the product for a clinical trial	Yes / No
Is there any evidence to support its use for the proposed indication?	Yes / No
• If not, is there evidence to support its use in other indications?	Yes / No
Is there evidence to support its proposed administration schedule?	Yes / No
Is the active drug currently in a licensed product for use via the same route?	Yes / No
Is the marketing authorisation (MA) for the specified indication in an EU member state?	Yes / No / Unknown
Is the product licensed for the specified indication in a non-EU member state?	Yes / No / Unknown

Are other centres using this medicine?

- If yes, state name of centre.....

Yes / No

Summarise below the supporting evidence, list references and attach copies where available.

What are the risks to the patient of not using this drug?

What side effects or toxic effects have been reported?

Is any monitoring required? Yes / No. If so, describe

Give details any significant interactions.

Give details of contraindications and any other risks to the patient.

Give details of any precautions in use.

Give details of any other safety and governance issues in particular are there any issues with medicine preparation, and administration?

Proposed usage:	Tick box
1. General use in both secondary and primary care	<input type="checkbox"/>
2. Initiation in secondary care with subsequent prescribing in primary or secondary care	<input type="checkbox"/>
3. Secondary care	<input type="checkbox"/>
a. Any doctor to prescribe	<input type="checkbox"/>
b. Initiation by named consultant(s) then any doctor to prescribe	<input type="checkbox"/>
c. All prescriptions to be signed by named consultant(s)	<input type="checkbox"/>

Cost/Funding Implications

<u>Medicine</u>	<u>Maintenance Dose</u>	<u>Cost per 28 days/course</u>	
		<u>Hospital*</u>	<u>Primary Care</u>
_____	_____	_____	_____
<u>Formulary Alternatives</u>	<u>Maintenance Dose</u>	<u>Cost per 28 days/course</u>	
		<u>Hospital</u>	<u>Primary Care</u>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

*To include VAT @ 20%

Estimated number of patients treated per year in hospital. This may be cumulative for year 2 onwards, i.e. it may

not be just new patients if the hospital is continuing treatment. N.B. It is highly likely that all prescribing will have to be performed in hospital as GPs may decline to prescribe unlicensed medicines.

	Year 1	Year 2	Year 3	Year 4	Steady State
Number of patients					

	Year 1	Year 2	Year 3	Year 4	Steady State
Total additional cost per annum for hospital					

Estimated number of patients treated per year in the community. This may be cumulative for year 2 onwards.

N.B. It is highly likely that all prescribing will have to be performed in hospital as GPs may decline unlicensed medicines.

	Year 1	Year 2	Year 3	Year 4	Steady State
Number of patients					

	Year 1	Year 2	Year 3	Year 4	Steady State
Total additional cost per annum for community					

Please describe any other financial implications such as cost of monitoring or cost of additional equipment or staff required.

List of named consultants

Signature of Consultant

Date

Where the above product is required for routine use for several patients a "blanket" disclaimer can be made by:

- An individual consultant, for patients under their care
- By several consultants within a directorate, directorate approval is required signed by the Clinical Director
- On behalf of the Trust by the Medical Director or Chairman of the Drugs & Therapeutic Committee

Declaration by Directorate Manager

Financial case: Supported: Funding: Available from within directorate
 Not supported: Not available
 Outside tariff

Name / Position _____

Signature _____

Date _____

For a request for an unlicensed product where a licensed alternative exists, the disclaimer MUST also have a signed endorsement by the Clinical Director

Name / Position _____

Signature _____

Date _____

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

Product Name:	Manufacturer:
RISK LEVEL ASSIGNMENT: SCORING GUIDELINES	
Supplier	
MHRA licensed importer with full Pharmacovigilance in QMS (IDIS)	1
Known NHS Unit with QA managed by qualified person or pharmacist	1
Other NHS Specials Unit (not local)	2
Commercial Specials Manufacturer (UK)	2
Supplier not manufacturer (e.g. wholesalers)	3
Registered Pharmacist (extemporaneous preparation)	4
Origin	
UK manufacturers with Specials licence	0
EU / USA / Canada / Australia / NZ and licensed in country of origin	1
Elsewhere - licensed in country of origin	3
EU / USA / Canada / Australia / NZ and not licensed in country of origin	3
UK - no Specials licence (Section 10)	HIGH
Certification	
Full analytical report available	0
Fully licensed product with EMA / PL number (Imports)	1
Certificate of Analysis and GMP compliance available (Specials)	1
Certificate of Conformity available product analysed (Specials)	2
Certificate of Conformity but no product analysis (Specials)	3
No Certificate available / no analysis carried out (Specials / Section 10)	4
Documentation	
Product TSE compliant with English-translated SPC	1
Product TSE compliant with no English-translated SPC	2
Packaging & Labelling	
English	0
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 Pharmacopoeial monograph	1
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
Therapeutic Agent	
Established therapeutic agent - no special problems	0
Recognised therapeutic agent - minor problems or little experience of use	2
Novel therapeutic agent of unusual use	4
Unrecognised therapeutic agent with some supporting information for use	6
Unrecognised therapeutic agent with no information available	HIGH
Recognised therapeutic agent with known problems	HIGH
Products containing material of animal or human origin	HIGH
Total Score	
LOW	0 to 14
HIGH	15 to 29
Risk Level Assignment Signed off by:	

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 or European medicines regulatory organisations and so is not allowed to be promoted/marketed within the UK; or
- does have a license from the UK or European medicines regulatory organisations 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.

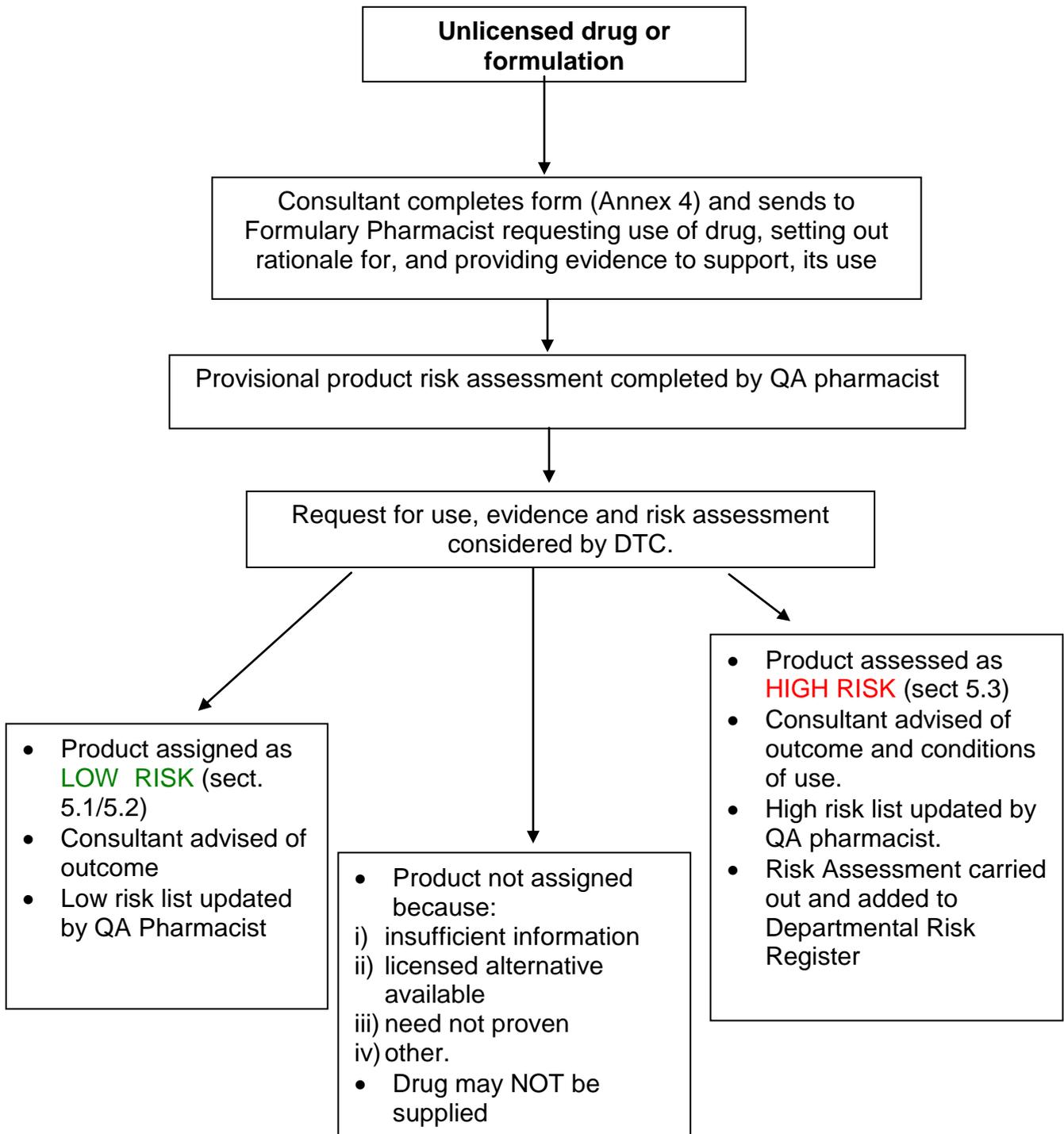
Name of Doctor (please print)..... Date.....

Signature of patient..... Date.....

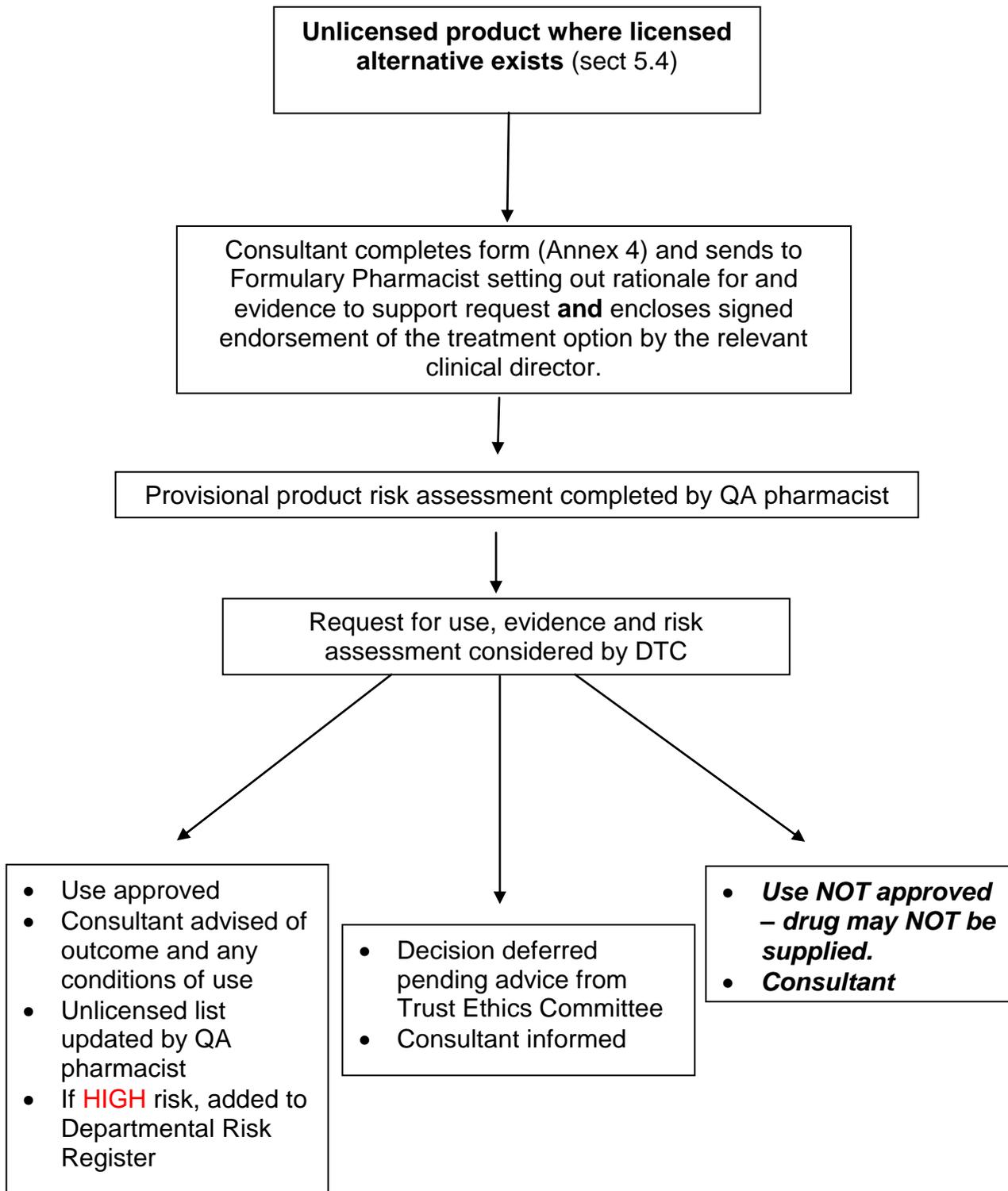
PRESCRIBER INFORMATION

- **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.

POLICY FOR THE USE OF UNLICENSED MEDICINES FLOW CHART 1



**POLICY FOR THE USE OF UNLICENSED MEDICINES
FLOW CHART 2**



**POLICY FOR THE USE OF UNLICENSED MEDICINES
FLOW CHART 3**

