Northern Devon Healthcare NHS Trust

Document Control

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Unlicensed Medicines Policy			
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CONTENTS

1. Purpose

1.1. The purpose of this document is to describe the Trust policy for the procurement and use of unlicensed medicinal products (often called "specials"). These are unlicensed medicines which have been specially prepared by the holder of a manufacturer's "specials" licence or imported in response to or in anticipation of a prescriber to meet the special needs of individual patients.

1.2. The policy covers the off-label usage of medicines, but does not cover those prepared under a Section 10 exemption or clinical trials.

1.3. The policy applies to all Trust staff involved in the above activities.

1.4. Implementation of this policy will ensure that:

- The Trust is acting in accordance with the Medicines Act, 1968 regarding the use of unlicensed medicines
- Patients are safeguarded against the risk of harm and to minimise the likelihood of litigation resulting from the consequences of using unlicensed products
- The responsibilities of the Trust and its employees when dealing with unlicensed medicines

2. Definitions

Certificate of Analysis

2.1. 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

Designated Pharmacist

2.2. This is a pharmacist employed by the Trust who has been designated as having responsibility for the procurement and supply of unlicensed medicines within the Trust

Extemporaneously Dispensed

2.3. 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, when a licensed alternative is not readily available

Licensed medicine

2.4. Medicines with a UK marketing authorisation; when prescribed within the terms of the marketing authorisation the manufacturer is likely to be found liable for any harm caused by that medicine

Manufacturers Specials Licence

2.5. This is a licence issued by the Medicines and Healthcare products Regulatory Agency to organisations wishing to place unlicensed medicines on the market in the UK. Further details of the controls applying to Manufacturers Specials Licences are given in the Medicines and Healthcare products Regulatory Agency (MHRA) Guidance Note 14

Unlicensed ('Off-label') use

2.6. Medicines are considered to be being used 'off label' when used for a clinical indication which is not included in the list of approved indications for that product in its product licence

Sections 9, 10 and 11

2.7. These are sections of the Medicines Act 1968 describing the exemption from the need to hold a manufacturers licence by doctors (Section 9), pharmacists (Section 10) and nurses (Section 11) when preparing medicinal products

Specials

2.8. These are unlicensed medicines which have been specially prepared by the holder of a Manufacturers Specials Licence or imported in response to or in anticipation of the order of a doctor or dentist to meet the specific needs of an individual patient

Unlicensed medicine

2.9. Medicines without a UK marketing authorisation

Wholesale dealer's licence

2.10. This is a licence issued by the MHRA to organisations carrying out wholesale dealing of licensed and/or unlicensed medicines

3. Responsibilities

Role of the Prescriber Responsible for the Care of the Patient

3.1. Prescribers must always comply with the overarching Trust Medicines Policy and associated SOPs.

3.2. Prescribers must ensure that they are aware of the licensed indications of a medicine and should routinely prescribe licensed medicines in accordance with the terms of the licence. Unlicensed medicines should only be used where:

- on the basis of assessment of the individual patient, the prescriber concludes, for clinical reasons, that it is necessary to do so to meet the specific needs of the patient and
- the use is clearly justified and
- the clinical and pharmaceutical benefits are considered to outweigh the risks involved

3.3. The clinician must be satisfied that an alternative, licensed medicine (even if used for an unlicensed indication) would not meet the specific clinical needs of the individual patient and be satisfied that there is sufficient evidence base and / or experience of using the medicine to demonstrate its safety and efficacy.

3.4. In prescribing the unlicensed medicine the clinician is also taking clinical responsibility for overseeing the patient's care, monitoring and any follow up treatment and documenting a clear, accurate and legible rationale for prescribing the unlicensed medicine.

3.5. Junior medical staff and non-medical prescribers must not initiate unlicensed medication assessed as being of high risk.

3.6. Patients have the right to participate in making properly informed decisions about their health care. Individual patients (and/or their carers/parents) must be given adequate information about any unlicensed or 'off-label' medicines they are prescribed, so that the patient can make an informed decision about their treatment. Clinicians should obtain informed consent to the unlicensed or 'off label' use of a medicine where appropriate and particularly where the unlicensed medicine carries a significant, or unknown risk of causing serious adverse reactions, for example those that have been previously withdrawn from the market because of serious toxicity problems). A patient information leaflet is available for this purpose.

3.7. Inadequate provision of information to the patient is likely to increase the clinician's liability in the event of unforeseen or adverse reactions or events that result in a complaint and possible litigation. A generic unlicensed medicines information leaflet is available to assist patients. The leaflet explains why it is necessary to prescribe unlicensed medicines and should be widely available to help allay any concerns that patients and carers may have.

3.8. Prescribers are reminded that:

- Unlicensed products are not intended for routine, on-going use.
- Where a suitable, licensed alternative to an unlicensed product exists, this should always be used in preference to an unlicensed medicine, even if for an unlicensed indication.

- Whenever an unlicensed medicine is prescribed, the prescriber is PROFESSIONALLY ACCOUNTABLE for doing so, and may be called upon to justify their actions,
- A General Practitioner may decline to prescribe an unlicensed or off-label medicine for the above reason.

Role of Pharmacists

3.9. Pharmacists must be aware of and abide by relevant standards of professional conduct and current MHRA guidance on unlicensed medicines as follows:

- Medicines are used in accordance with their marketing authorisations wherever possible. Selection between different licensed options for individual patients is guided by considerations of safe use, effectiveness, tolerability and value.
- If individual clinical need cannot be addressed safely or appropriately by a licensed medicine, 'off-label' use of a licensed medicine should then be considered. An unlicensed medicine should be used only where licensed or off-label medicines are inappropriate for an individual patient's specific clinical needs.
- Pharmacists should work closely with patients and their carers and other healthcare professionals to reach a joint, informed decision on which treatment option best suits an individual patient's need. This should be based on the risks and benefits of each option and supported by high quality information that includes the licensed status.
- The rationale for use of an unlicensed or 'off label' medicine must be clearly documented.
- The Trust Chief Pharmacist has overall responsibility for the purchase and supply of unlicensed medicines within the Trust (otherwise known as the 'designated pharmacist').

3.10. The Pharmacy department will take all reasonable steps to assure the pharmaceutical quality of all unlicensed medicines purchased and supplied. The assessment of the quality of a product will involve the assessment of the supplier, the product specification and production assurance processes. Unlicensed medicines will be risk assessed by the appropriate pharmacist and categorised according to their relative risk potential and managed accordingly.

3.11. A senior pharmacist will be responsible for risk assessing and categorising all new unlicensed products to define the procedures employed for purchase, assessment, supply and record keeping of the product. The pharmacist conducting the risk assessment is responsible for submitting each risk assessment to the Drugs and Therapeutics Committee (DTC) for review and ratification.

Role of Staff Administering Medicines

3.12. Staff administering unlicensed medicines must be made aware of the unlicensed status of any medicines prescribed for administration to a patient. It is the responsibility of the pharmacist and prescriber to inform staff of this.

3.13. Staff must:

- Ensure that they have information on the safe use of the unlicensed medicine before administration
- Follow the Trust Medicines Policy and associated SOPs regarding the administration of medicines
- Inform the staff on any ward /department that the patient is transferred to of the unlicensed status of the medicine and ensure that stocks are sent with the patient.

3.14. For any unlicensed medicine held as stock on the ward / unit / department, it is the responsibility of the registered practitioner in charge to ensure additional records are kept regarding administration of the unlicensed medication. The "unlicensed medication issue / administration record" proforma (**Appendix 4**) MUST be completed, to include the drug batch number, each patient's name, ID number and all other information on the proforma record provided. Stock will only be replenished on the return of the completed form to the Pharmacy department.

Role of Drugs and Therapeutics Committee

3.15. The Drugs and Therapeutics Committee (DTC) is responsible for authorising and maintaining a list of unlicensed medicines which are required for the clinical care of NDHT patients and which have been assessed as being of low risk (see **Section 5.5**). Clinicians wishing to prescribe medicines from this list may do so without further approval, provided that the medicine is judged by the prescriber to be in the best interest of the patient on the basis of available evidence and meets their specific clinical needs. of the individual patient and there is no alternative licensed medicine.

3.16. The DTC will consider requests for use of unlicensed medicines that are not on the Trust approved list, (http://ndht.ndevon.swest.nhs.uk/pharmacy-2/drugs-and-therapeutics-committee/) reviewing the clinical justification, risk assessments and ensuring that their use is justified by published evidence or sound therapeutic argument. If use of the unlicensed product is approved, the DTC will agree a risk rating for the item (low or high) which will determine the management arrangements required for the product as detailed in this document.

3.17. In the event of urgent clinical need, the consultant and a senior Trust pharmacist may authorise use of an unlicensed medicine subject to formal ratification at the next DTC.

4. Introduction

4.1. In order to ensure that medicines are safe, effective and of appropriate quality, their manufacture and sale or supply is controlled by national and European Union legislation. Accordingly, no medicinal product may be placed on the market unless a marketing authorisation (formerly product licence) has been granted. In order to preserve prescriber's clinical freedom, the legislation gives some exemptions from full control. Thus, medicinal products that are not licensed may be prescribed in order to meet specific clinical needs in individual patients, under the direct, personal responsibility of the prescriber).

4.2. Unlicensed medicines should only be used when there is no pharmaceutically equivalent licensed product or suitable licensed alternative available at the time the patient needs it.

5. Risk categorisation of unlicensed medicines

5.1. Where a clinician considers an unlicensed product that does not appear on the Trust approved list (http://ndht.ndevon.swest.nhs.uk/pharmacy-2/drugs-and-therapeutics-committee/) to be essential to meet the specific clinical needs of an individual patient, a "Request Form and Treatment Protocol for Use of New Unlicensed Medicine or new off-label indication" form (**Appendix 1)** must be completed and forwarded to pharmacy for risk assessment of the product and consideration by the Trust DTC.

5.2. All unlicensed medicines will be assessed, using the risk assessment tool (**Appendix 2**) by a senior pharmacist in order to categorise each on a risk matrix. The categorisation of the product will then define the procedures employed for purchase, assessment, supply (including patient consent) and record keeping of the product.

5.3. 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 (see section 3.17). When considering a request to approve an unlicensed medicine, the Committee must be certain that there is no suitable licensed alternative product available. In all situations the Trust Chief Pharmacist is required to be satisfied with the quality, formulation and the stability of the preparation before the DTC will ratify use of the unlicensed product.

5.4. The requesting prescriber will be notified of the outcome of the risk assessment of the unlicensed product / use by the senior / Formulary Pharmacist, who will complete and return **Appendix 3** to the prescriber.

5.5. The risk matrix:

LOW	HIGH / UNKNOWN
Established product with good evidence of therapeutic benefit	Evidence for therapeutic benefit is questionable or none exists
Produced by manufacturing licence holder with known record of acceptable supply, to approved specification	Produced by supplier (manufacturing licence holder) with unknown history
Product quality assessment documents available and approved	Product quality not assessed and/or no documentation available.
Product licensed in a country with EU mutual recognition status, or licence withdrawn for commercial reasons	No product licence or product licence withdrawn for safety reasons. Product licence for veterinary use only.

5.6. Relative risk potential – Low:

This group consists of a range of products that meet the following criteria:

- Have a good clinical safety record – these generally contain active drugs that have been marketed in the UK and/or are included in the current or previous editions of the BNF, excluding agents that have been withdrawn from the market due to safety concerns.
- Are manufactured in licensed NHS hospital pharmacy manufacturing units or by commercial 'specials manufacturers' who hold a manufacturing licence granted by the MHRA or by recognised pharmaceutical companies.
- Are of proven and acceptable pharmaceutical quality
- Although not essential, it is considered good practice for clinicians to seek patient consent for use of these products.
- Low risk products may be held as ward stock or supplied on a named patient basis.
- Prescriber notification of unlicensed usage will be undertaken annually as part of the ward stock list review.

5.7. Relative risk potential – High / unknown

5.7.1. A small number of high risk products may be used in exceptional situations, usually when all other therapeutic options have been exhausted. There may only be limited evidence in support of the product use, limited information about toxicity or risks, previous withdrawal of a marketing authorisation on safety grounds or there may be a lack of information confirming pharmaceutical quality.

5.7.2. Northern Devon Healthcare NHS Trust will only accept liability for use of an unlicensed product categorised as high risk where the following provisions have been adhered to:

- A written treatment protocol is in place (where required by DTC)
- Written informed patient consent is obtained and documented on each occasion that a patient is treated with a high risk unlicensed medicine.
- 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 an action plan for managing the risk (refer to Risk Management Policy).

5.7.3. Once use of a high risk product has been authorised 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.

5.7.4. High risk unlicensed items cannot be held as ward stock.

5.8. Summary of governance arrangements

Risk Rating	• Records	Allowed as Stock?	Unlicensed Form Required?	Patient Consent Required?	Example
LOW (ward stock items)	• Amount supplied to ward/dept • Batch number of stock supplied	YES	Yearly	NO	Paracetamol suppositories 60mg
LOW (named patient supply)	• Patient name • Amount supplied • Prescriber • Batch number of stock supplied	NO	Yearly	Where possible	Acetylcysteine tablets 600mg
HIGHER	• Patient name • Amount supplied • Prescriber • Batch number of stock supplied	NO	ONE per patient, then annually if required	YES	Co-proxamol tablets

6. Use of an unlicensed product where a licensed alternative exists

6.1. Only in very 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 5 **and**
- Seek 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).

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

7. Licensed medicines used for unlicensed indications ('off-label' use)

7.1. The marketing authorisation for a licensed product states the approved indications, doses and precautions for which the approved drug is licensed and hence the manufacturer is liable.

7.2. It is recognised that drugs are sometimes used for non-licensed indications within hospitals. Such practice is particularly common in certain areas of medicine: for instance, in paediatrics where difficulties in the development of age-appropriate formulations means that many medicines used in children are used 'off-label' or are unlicensed.

7.3. Prescribers should take steps to ensure they are aware when they are using a drug for an unlicensed indication. Pharmacists are available to provide advice in this respect, and where such prescribing is evident, will bring this to the attention of the prescriber and complete an 'off label' prescribing record form to be held in pharmacy for reference and audit purposes.

7.4. To be categorised as low risk licensed products used for an unlicensed indication must be supported by evidence of peer support for the use/indication often by inclusion in a recognised text e.g. BNF for Children, Palliative Care Formulary or NEWT guidelines, where the majority of medicines included will be licensed products.

7.5. 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 indication, provided that the unlicensed use is widely recognised as accepted practice and would command substantial peer group support.

7.6. 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 with limited clinical experience, approval from the Drugs and Therapeutics Committee must be sought prior to commencement of treatment. In such situations the requirements for the use of HIGH RISK unlicensed products will apply – see Section 5 above.

8. On-going Treatment

8.1. In the event that the patient requires on-going treatment with an unlicensed product the hospital consultant should discuss this with the patient's general practitioner. In some circumstances (e.g. for products categorized as high risk) it will not be appropriate for prescribing responsibility to transfer to the GP; consultants should respect this and retain prescribing responsibility for the treatment.

8.2. In other situations (e.g. for unlicensed medicines in the low risk category) it may be appropriate for the patient's GP to take on the prescribing responsibility, in which case the consultant must provide full details of the medicine including formulation, monitoring requirements, risks etc. to the GP. The GP will decide whether they accept clinical responsibility for the continued use of this medication and on-going prescribing.

8.3. The GP may wish to seek advice from the CCG Primary Care Medicines Optimisation Team in order to assess whether it is appropriate to take on the clinical responsibility by prescribing the drug in question. This assessment will include how common the condition is, the evidence base for the use of the medicine in question for that condition; the incidence of use for the condition; how long the medicine has been used for other licensed conditions and whether the medicine is available and used in other countries.

9. Use of unlicensed /'off label' products in children

9.1. Many medicines are not licensed for use in children, but are required for the effective management of conditions in this group of patients. For the purposes of this Policy the Trust recognises the BNF for Children as the definitive guide on medicines use and dosing in children.

9.2. Clinicians prescribing in accordance with the latest edition BNF for Children will be considered to be working in accordance with Trust policy.

9.3. Clinicians using unlicensed / 'off label' products for children should ensure that patients and carers have access to the relevant information sheets developed by the Joint Royal College of Paediatrics and Child Health / Neonatal and Paediatrics Pharmacists Group Standing Committee on Medicines.

10. Adverse drug reactions and defective products

10.1. All adverse drug reactions that occur in patients treated with unlicensed medicines must be reported to the MHRA via the Yellow Card scheme and through the Trust's incident reporting system.

10.2. Suspected defects in unlicensed medicines must be reported to the Pharmacy Department or the on-call pharmacist (out-of-hours) who will report them to Regional Quality Control following the Regional Drug Defect Reporting procedure.

11. Monitoring Compliance with and the Effectiveness of the Policy

Standards/ Key Performance Indicators

11.1. Key performance indicators comprise:

- Purchasing of unlicensed medicines
- The list of low-risk unlicensed medicines approved by Trust DTC
- Records of individual prescriber 'off label' prescribing record forms held by pharmacy

Process for Implementation and Monitoring Compliance and Effectiveness

11.2. Detail here the Implementation process.

- Implementation will be through the clinical pharmacists and wider pharmacy team

11.3. Detail here the monitoring process:

- Unlicensed Medicines Use will be monitored through the pharmacy dispensing system
- Monitoring of compliance will be done through the clinical pharmacists and pharmacy management team
- The processes be continually monitored

12. Equality Impact Assessment

12.1. The author must include the Equality Impact Assessment Table and identify whether the policy has a positive or negative impact on any of the groups listed. The Author must make comment on how the policy makes this impact.

Table 1: Equality impact Assessment

Group	Positive Impact	Negative Impact	No Impact	Comment
Age	√			This Policy supports the used of unlicensed medicines, which are frequently used in children
Disability				
Gender				
Gender Reassignment				
Human Rights (rights to privacy, dignity, liberty and non-degrading treatment), marriage and civil partnership				
Pregnancy				
Maternity and Breastfeeding				
Race (ethnic origin)				
Religion (or belief)				
Sexual Orientation				

13. References

- Guidance for the purchase and supply of unlicensed medicinal products notes for prescribers and pharmacists; NHS Pharmaceutical Quality Assurance Committee Third Edition; 2004

14. Associated Documentation

- Trust Medicines Policy and associated Standard Operating Procedures
- Trust Incident Management Policy
- Trust Risk Management Policy

Appendix 1

Request Form and Treatment Protocol for Use of New Unlicensed Medicine or new off-label indication

This form should be completed by the prescriber wishing to use a new unlicensed product or off-label purpose within the Trust. The form should be 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 and procedures for the use of unlicensed medicines and must be aware of your responsibilities under this policy.

Product Name:……....
(International Non Proprietary Name)

Proprietary Name: (if known)……..……

Pharmaceutical Form: ……..……..…

Strength:…….……

Manufacturer: (if known)……..…….……

Indication:……..……...……..…..

Dose:……..……..…… Frequency:…….……

Route:…….. Duration of Treatment:……...……..…

Why is use of this Unlicensed Medicine being considered? ……

……

..…….……..……

Please outline the clinical evidence to support use of this product in this manner ……..

…….....

Is any monitoring required? If yes, please specify…….

……..

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

……

Name of requestor……Signature……..

Date of request…….

Please send completed form to Pharmacy for the attention of the Formulary Pharmacist

Appendix 2

Pharmacy Department

Risk assessment tool for use with unlicensed medicinal products.

This risk assessment tool must be used to risk assess all unlicensed products used within NDHT in accordance with the Trust policy on unlicensed medicines. Each product will receive an overall risk rating of either HIGH or LOW which will be determined by considering both the level of potential risk posed by the product itself and the level of potential risk posed by the actions of the product on or within the body.

Risk assessments will be carried out by pharmacy staff and submitted to the Drugs and Therapeutics Committee for approval. The level of risk will determine the conditions of use of the product – see unlicensed medicines policy.

Product:	Risk rating:

PRODUCT INFORMATION			
Product name, form, strength			
Details of manufacture & supply (give both if different)			
Intended therapeutic use		Product type: Drug / Dressing / Food Supplement /Other……	
Reason required			
Proposed distribution (e.g. named patient/ ward stock etc)		Specialty/ Client group	
Level of clinical need for product (est. usage pa)			
Does the Manufacturer hold a Specials Licence for item? (note Specials Licence no.)	YES/NO Record Specials Licence No:……..		
In which country is the item manufactured?			
Is the product licensed in any country? If so where ?	YES Where Licensed: NO		
Is a batch specific Certificate of Analysis (CofA) available?	YES/NO	Is a batch specific Certificate of Conformity available?	YES/NO
Is there a specification available?	YES/NO	Where is specification available from ?	
Does the specification provide assurance of product quality?	YES/NO	What is the Quality Assurance? (e.g. compliance with any pharmacopoeial specification?)	Provide detail here:
Does labelling format conform to UK standards?	YES/NO	Is label legible?	YES/NO
Is label information unambiguous?	YES/NO	Does label contain all necessary information?	YES/NO
Is a PIL available?	YES/NO	Is any other product info available?	YES/NO
Has any info been translated from another language?	YES/NO	Are special storage conditions required? (i.e. refrigeration)	YES/NO
Is the packaging satisfactory?	YES/NO	Have non-English language packs been over-labelled in English language (required)?	YES/NO
Other information / comments: *For example, if the specific clinical need requires avoidance of specific excipients, list excipients here:*			

Risk assessment score for product		
Supplier;		
Local unit with QA managed by Regional QA Lab	0	
Commercial Specials Manufacturer (UK)	0	
Other NHS licensed specials unit (not local)	1	
Supplier **not** manufacturer (importers etc)	2	
Origin;		
UK manufacturer with specials licence	0	
EU/USA/Canada/NZ and licensed in country of origin	1	
EU/USA/Canada/NZ and **NOT** licensed in country of origin	2	
Elsewhere – licensed in country of origin	3	
Elsewhere – **NOT** licensed in country of origin	4	
UK – no specials licence	15	
Certification;		
Full analytical report available	0	
Batch specific Certificate of Analysis available	0	
Batch specific Certificate of Conformity available	2	
No certificate available (fully licensed product in country of origin)	3	
No certificate available	4	
Specification;		
BP/EP/USP monograph product	0	
Other Pharmacopoieal monograph	1	
Manufacturers specification available	2	
No external specification available	3	
Sub-total risk score for product		
Risk assessment score for actions of product		
Route of administration;		
Topical to intact skin (non-sterile)	0	
Mucous membranes or broken skin, oral (non-sterile)	1	
Sterile all routes except intrathecal	2	
Sterile intrathecal	3	
Therapeutic agent;	0	
Established therapeutic agent, no special problems	2	
Recognised therapeutic agent – minor problems or little experience of use	4	
Novel therapeutic agent or unusual use	6	
Unrecognised therapeutic agent with some supporting evidence for use	15	
Unrecognised therapeutic agent with no information available	15	
Recognised therapeutic agent with known problems	15	
Products containing material of animal or human origin	15	
Sub-total risk score for actions of product		

Total score = sub-total for product + sub-total for actions of product:
Products scoring a total of 0 - 14, = LOW risk rating Products scoring a total of 15 or above = HIGH risk rating **OVERALL RISK RATING FOR THIS PRODUCT: HIGH / LOW** (delete as appropriate)

Risk assessment carried out by: Date:

Risk assessment checked by: Date:

Risk assessment agreed by DTC: Date:

Appendix 3

NORTHERN DEVON HEALTHCARE NHS TRUST
PHARMACY DEPARTMENT

Dear Consultant:……..… Date:……..

Supply of:…… Indication:…….....

SUPPLY OF UNLICENSED OR OFF-LABEL PHARMACEUTICALS

The above named product is an unlicensed medicine categorised as HIGH / LOW risk.

The use of unlicensed medicines in the responsibility of the prescriber and, when procuring unlicensed medicines, the ordering pharmacist is considered to be the manufacturer and responsible as such.

Prescribing and supply of unlicensed medicines (or medicines to be used outside their licensed indications) presents a **RISK to INDIVIDUAL PATIENTS, PRESCRIBERS 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
- Wherever an unlicensed medicine is prescribed, the prescriber is PROFESSIONALLY ACCOUNTABLE for his judgment in so doing and may be called upon to justify his actions.
- 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 and Procedure for the Use of Unlicensed Medicines) you must inform the patient or their representative of the status of this medicine to seek and obtain informed written consent on each occasion that the patient is treated with this product.

Pharmacy requires written confirmation that you have read and understood the above. Please sign below and return form to pharmacy. 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:…… Date:……

Form received by……Pharmacist Date:……

Please send completed form to Pharmacy, for the attention of a senior / Formulary Pharmacist

Northern Devon Healthcare NHS Trust

Appendix 4

UNLICENSED MEDICINE ISSUE / ADMINISTRATION RECORD

DRUG NAME / FORM / STRENGTH	
PACK SIZE	
MANUFACTURER	

Date	Qty	Batch No	Pt Name	Pt No	DOB	Ward	Consultant

Further stock will ONLY be issued by Pharmacy upon receipt of a signed requisition accompanied by one of the forms completed with patient details
G:\PHARMACY\Maria P\Dispensary admin\Unlicensed Medicine Form.docx

Appendix 5

UNLICENSED MEDICINES – CONSIDERATIONS BEFORE APPLICATION

Is a suitable, licensed medicine available?

YES*

PRESCRIBE LICENSED MEDICINE (Section 3.3)

Use of a licensed product outside of the licensed indications may be considered where evidence supports safety and efficacy (Section 3.3)

* Use of an unlicensed product or unlicensed formulation where a licensed product exists – see Section 6

NO

CONSIDER USE OF UNLICENSED MEDICINE (a "special")

(See Sections 3.2, 3.3, 3.4 - considerations for use of an unlicensed product)

IS THE UNLICENSED MEDICINE ALREADY APPROVED FOR USE FOR THE REQUIRED INDICATION?

The Trust Drug and Therapeutics Committee is responsible for authorising the use of unlicensed medicines within the Trust (Section 3.15)

The list of unlicensed medicines and indications approved for use within the Trust can be found on the Trust website, Drug and Therapeutics Unlicensed Medicines page

YES

UNLICENSED MEDICINE MAY BE PRESCRIBED WITHOUT NEED FOR FURTHER APPROVAL (Section 3.15)

NO

IF URGENT CLINICAL NEED
Individual requests will be considered by a senior pharmacist and Consultant, prior to retrospective approval by the Trust DTC

APPLICATION FOR UNLICENSED MEDICINE WILL BE CONSIDERED BY TRUST DRUGS AND THERAPEUTICS COMMITTEE, DTC (Section 3.16)

APPLICATION PROCESS

see Appendix 6

Appendix 6

UNLICENSED MEDICINES – APPLICATION PROCESS

Before completing an application for use of an unlicensed medicine, please refer to Sections 3 to 9, which describe the criteria and considerations to be taken into account. Further advice may be sought from pharmacy if required.

UNLICENSED MEDICINES NOT PREVIOUSLY APPROVED FOR USE FOR THE REQUIRED INDICATION AND CONSIDERED ESSENTIAL TO MEET THE SPECIFIC CLINICAL NEEDS OF THE INDIVIDUAL PATIENT

The list of unlicensed medicines and indications approved for use within the Trust can be found on the Trust website Drug and Therapeutics Committee – Approved Unlicensed Medicines page

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Appendix 1 (the request form and for use of new unlicensed medicine) **to be completed by requesting Consultant and be returned to the Formulary Pharmacist c/o Pharmacy Department, NDDH**

Urgent clinical need – see Section 3.17

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Appendix 2 will be completed by trust senior / Formulary pharmacist; the unlicensed medicine will be risk assessed (as either 'low' or 'high / unknown risk'), which will determine considerations for use of the unlicensed medicine

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The **Trust Drugs and Therapeutics Committee** will consider the request to use the unlicensed medicine, together with the completed risk assessment and protocol (if submitted to accompany the request) at the next meeting or in an appropriate timescale (e.g. for urgent clinical need – see Section 3.17)

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The **Trust senior / Formulary pharmacist** will notify the requesting Consultant / prescriber of the decision / outcome, following consideration of the application by the Trust DTC.

Following approval by DTC, the Trust senior / Formulary pharmacist will complete **Appendix 3** (**Supply Of Unlicensed Or Off-Label Medicines**) and return the form to the requesting Consultant with outcome

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The requesting Consultant will sign and date the "**Supply Of Unlicensed Or Off-Label Medicines"** form and return the form to a senior / Formulary Pharmacist c/o the Pharmacy Department, NDDH