Wrightington, Wigan and Leigh NHS
NHS Foundation Trust

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LINKS TO OTHER STRATEGIES, POLICIES, SOP'S, ETC.	**Medicines Management Policy TW10/037** **Assessment & Authorisation of Restricted Medicines SOP (42)** **Procurement, Quality Assurance & Storage of Restricted Medicines SOP (43)** **Dispensing, Accuracy Checking & Transfer of Restricted Medicines SOP (44)**

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AT ALL TIMES STAFF MUST TREAT EVERY INDIVIDUAL WITH RESPECT AND UPHOLD THEIR RIGHT TO PRIVACY AND DIGNITY

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Appendices

1 INTRODUCTION

1.1 This document describes the Wrightington, Wigan and Leigh NHS Foundation Trust (WWL) policy for the prescribing, procurement and supply of restricted medicinal products.

1.2 Restricted medicines refers to all medicines that are:

1.2.1 Unlicensed
1.2.2 Specials
1.2.3 Off label use

1.3 Licensed medicines - are subject to stringent control by the Medicines and Healthcare products Regulatory Agency (MHRA).

1.4 Unlicensed medicines - are medicines which have not been licensed for use and do not have a marketing authorisation (MA) by the Medicines and Healthcare products Regulatory Agency (MHRA) or European Medicines Agency (EMEA) respectively. Neither the prescriber nor the pharmacist can make assumptions concerning the quality, safety and efficacy of unlicensed products. As such, use of these medicines carries increased liability for the Trust and the prescriber.

1.5 Off Label use of medicines - refers to medicines that are licensed but used outside of the licensed indications. The use of the drug off-label may not have been subjected to the full clinical trial process.

1.6 Unlicensed medicines can be categorised as below:

1.6.1 Medicines prepared by a UK manufacturer but not on sale in this country.

1.6.2 Medicines prepared for a patient in accordance with a prescriber's instructions. This includes any form of extemporaneous preparation and dispensing.

1.6.3 Specials - Unlicensed Medicines obtained from a hospital or commercial supplier with a Specials Manufacturing Licence.

1.6.4 Re-packed Medicines - when a medicine is removed from its original container and re-packed, the product becomes unlicensed. This can include dispensing or the assembly of small packs for use as ward stock. Such operations can be commissioned from a packaging unit holding a 'Specials' Manufacturing (Assembly) Licence.

1.6.5 Imported Medicines - these medicines may have a full product licence in a European Union (EU) or non-EU country but do not have a licence in the UK. They are often imported directly from the manufacturer or through a specialist importer.

1.6.6 Orphan Products - these medicinal products are for diagnosing, preventing or treating rare life-threatening or very serious conditions that do not affect more than 5 in 10,000 persons in the EU. Pharmaceutical companies unwilling to develop such products under normal market conditions are able to apply for marketing authorisation for orphan designation; hence the product does not have a full product licence.

1.7 Restricted medicinal products should only be used when:

1.7.1 There is no pharmaceutically equivalent licensed product or suitable alternative licensed product available for use at the time the patient requires it

1.7.2 The clinical benefits are expected to outweigh the potential risks of treatment and the use of the product is clearly justified.

1.7.3 There may be an expert body of clinical opinion to justify that use.

2 POLICY STATEMENT

2.1 The purpose of this policy is to define the responsibilities of staff involved in the use of restricted medicines and should be used in conjunction with the associated Restricted Medicines Standard Operating Procedures.

2.2 This policy describes the assessments necessary for restricted medicines used within WWL to ensure that the provision of treatment for all patients is safe and effective.

2.3 The final responsibility for the provision of restricted medication to patients rests with the prescriber. They are responsible for ensuring that all requirements of this policy are enacted including giving informed consent to the patient prior to treatment.

3 KEY PRINICIPLES

3.1 This policy covers the prescribing, procurement and handling of restricted medicines. This includes:

3.1.1 Unlicensed medicinal products
3.1.2 Licensed products used outside their licensed indications ("off-label" use)
3.1.3 Specials

3.2 The document is intended for use by all healthcare professionals employed within the Trust who are engaged in the prescribing supply or administration of medicines. This document should be read in conjunction with all related procedural documents.

3.3 This policy does not cover:

3.3.1 Investigational medicinal products (clinical trial materials)
3.3.2 Over labelling of licensed medicines
3.3.3 Medicines exempt from licensing requirements under provisions of the Medicines Act 1968 (as amended into Human Medicines Regulations 2012)
3.3.4 Aseptically prepared products
3.3.5 Medical devices
3.3.6 Repackaged licensed products, for example A & E pre-packs.
3.3.7 The combination (mixing) of injectable medicines in palliative care
3.3.8 Cosmetic products

4 DEFINITIONS

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

4.2 An **Extemporaneously Dispensed** medicine is a medicine which has been prepared "from its individual ingredients" by, or under the supervision of a pharmacist, in response to or in anticipation of a prescription.

4.3 A **Manufacturer's Specials Licence** is a licence issued by the Medicines and Healthcare products Regulatory Agency (MHRA) to organisations wishing to produce batches of unlicensed products and place them on the market in the UK.

4.4 A **Marketing Authorisation** (previously a product licence) is a licence granted by the MHRA to manufacturers, but not to those holding a manufacturers specials licence, for medicines, which meet their standards of safety, quality and efficacy. A marketing authorization is normally necessary before a medicine can be prescribed or sold (unless made by a holder of a manufacturer's license). The legal status of medicines is part of the marketing authorization.

4.5 **Off-label Use** of medicines is when a licensed medicine is used for a clinical indication which is not in the list of approved indications for that product in its product licence/marketing authorisation details.

4.6 **Specials** are unlicensed medicines which have been especially prepared by the holder of a Manufacturer's Specials Licence, or imported in response to, or in anticipation of, the order of a doctor or dentist to meet the special needs of individual patients.

4.7 **Unlicensed Medicines** are medicines which do not have a UK product licence or European Market authorisation for use in the UK.

5 RESPONSIBILITIES

5.1 Prescribers

5.1.1 Prescribers are responsible for the patient's welfare and must be aware of this when they are considering prescribing a restricted medicine. In the case of adverse events they may be called upon to justify their actions.

5.1.2 By completing a restricted medicine request form (appendix 2), the prescriber acknowledges that an restricted medicine is being used.

The prescriber responsible for the care of the patient is responsible for:

5.1.3 Being aware of the licensed status of the medicines they prescribe, and if unlicensed or off-label, whether the medicine has been authorised for use in the indication.

5.1.4 Their knowledge, information or experience to show that they are acting reasonably in the best interests of the patient.

5.1.5 Ensuring that the use of the restricted medicine is justified by the clinical condition of the patient.

5.1.6 Ensuring that the use of a restricted medicine is recorded in the patient's medical record.

5.1.7 Ensuring that the patient has given consent to receiving the restricted medicine. Consent to use restricted medicine should be documented in the case notes.

5.1.8 Ensuring that where responsibility for ongoing care is to be transferred to the patient's General Practitioner (GP), that the GP is informed of the restricted status of the medicine and that the GP is willing to accept clinical and legal responsibility for prescribing. The hospital doctor is responsible for continuing treatment if the GP will not accept responsibility for continuing care.

5.1.9 Communicating to patients the implications of using the restricted medicine. A Patient Information Leaflet for this purpose is provided where available (Appendix 2a).

5.1.10 Ensuring that all incidents or adverse effects are recorded via DatixWeb and sent to the MHRA via the yellow card scheme

5.1.11 The discharge letter and outpatient clinic letter must include the following restricted medicine details:

5.1.11.1 Indication
5.1.11.2 Drug name, strength, form, dose and frequency
5.1.11.3 Duration of treatment
5.1.11.4 Specific formulation needs (e.g. alcohol-free for liquids for paediatric patient)

5.1.12 Whenever a restricted unlicensed or off label medicine is considered which has not been approved for use for the same circumstances, the consultant must complete and sign the 'restricted medicine request form' (Appendix 2)

5.1.13 Junior doctors acting under the direction of a consultant may be authorised to prescribe restricted medicines, provided the consultant has signed a restricted medicine request form to take responsibility for the use of the specified restricted medicine in accordance with this policy. The Consultant responsible for the care of the patient ensures that the junior doctor initiating treatment is familiar with the status of the medicine and any clinical guidance or treatment protocols relevant to its use.

5.1.14 Non-medical Prescribers can prescribe restricted medicines but cannot request new restricted medicines to be used within the Trust. It is also a requirement that Trust non-medical prescribers complete specific training before they can prescribe restricted medicines.

5.1.15 Supplementary prescribers may prescribe an restricted medicines as part of a clinical management plan.

5.1.16 For use of unlicensed medicines or off-label medicines in paediatric practice refer to the Royal College of Paediatrics and Child health (RCPCH) and the Neonatal and Paediatric Pharmacists Group (NPPG) website: rcpch.ac.uk/child-health/childrens-medicines/childrens-medicines#Unlicensed_medicines_statement

5.2 Trust Designated Pharmacist

5.2.1 The Deputy Chief Pharmacist (Clinical Services) is the 'designated pharmacist' with overall responsibility for controlling the procurement and supply of restricted medicines.

5.2.2 The designated pharmacist can delegate restricted medicines responsibilities to Clinical Lead Pharmacists.

5.2.3. Ensuring that prescribers are always aware that the medicine they have requested is only available as an unlicensed product, and ensuring that an equivalent licensed product is not available.

5.2.4 Ensuring that written procedures to cover all aspects of the risk assessment, procurement and issue of unlicensed medicines are produced, authorised and reviewed by the Pharmacy Quality and Safety Committee (PQSC).

5.2.5 Ensuring that any new restricted medicine requests undergo a risk assessment and are assigned a risk category prior to procurement. The consultant is informed of any restricted medicine being assessed as high risk (Red) (Appendix 3 – Unlicensed Medicine Risk Assessment Tool.

5.2.6 Ensuring that restricted medicines policy is covered at induction

5.2.7 Ensuring that all controls specified in the policy are applied, including the maintenance of appropriate records of use.

5.2.8 Ensuring that monitoring and auditing the handling of restricted medicines within the Pharmacy Department is carried out. This includes review of the six monthly audits.

5.2.9 Ensuring that six monthly reporting of restricted medicines usage to each Division takes place through assurance report

5.2.10 Ensuring that where a restricted medicine is purchased from a 'specials manufacturer', the manufacturer holds the appropriate licence to manufacture and that the product complies with the product specification. A current copy of this licence must be kept in the pharmacy procurement office as a record.

5.2.11 Ensuring that restricted medicines are procured from appropriate sources e.g. Quality Control North West (QCNW) approved suppliers and MHRA licensed suppliers/manufacturers.

5.2.12 Ensuring that submissions are made to Divisional D&T Committees or equivalent body for approval before new restricted medicines are used in the Trust. The submissions will be processed by the Clinical Lead Pharmacist

5.2.13 Ensuring that in the case of urgent clinical need, written authorisation has been given by the Clinical Lead Pharmacist to procure and use a new restricted medicine, subject to formal assessment and approval at the correct meeting.

5.2.14 Authorising the use of restricted medicines to manage a supply problem with a licensed medicine. This can be delegated to the Clinical Lead Pharmacist.

5.2.15 Communicating with the MHRA and the prescriber to process any reports of adverse reaction and report to Q&S via clinical/incident form.

5.2.16 Ensuring that product specifications for new unlicensed medicines are produced by the Clinical Lead Pharmacist in conjunction with Quality Control North-West (QCNW)

5.2.17 Ensuring that a procedure is in place for all new restricted medicines to be quarantined on receipt within the Trust until the relevant risk assessments are completed by the Clinical Lead Pharmacist

5.2.18 Ensuring that a procedure is in place that on receipt into the Trust, packaging and labelling of all restricted medicines are inspected, Certificates of Analysis are assessed by the Clinical Lead pharmacist

5.2.19 Ensuring that where available a product specific patient information leaflet is available for each restricted medicine used within the Trust in a language appropriate to the patient's needs.

5.2.20 Ensuring that a procedure is in place for releasing all batches of restricted medicines for use within the Trust.

5.2.21 Ensuring that QCNW are consulted in the procurement and risk assessment of unlicensed medicines e.g. sourcing unlicensed medicines from a non-QC approved country for importation.

5.3 Pharmacy staff
Pharmacists are responsible for:

5.3.1 Ensuring that prescribers are always aware that a medicine they have requested is only available as a restricted product, and ensuring that an equivalent licensed product is not available. This will need to be documented in the case notes or prescription form if outpatient.

5.3.2 Ensuring that the use of a restricted medicine is justified by clinical circumstances. Pharmacists must escalate to a Clinical Lead Pharmacist in any case of uncertainty

5.3.3 Ensuring that the patient is supplied with an English version of the product patient information leaflet (PIL). For paediatric patients refer to website : medicinesforchildren.org.uk

5.3.4 Ensuring that the patient, GP and community pharmacist have received a restricted medicine information leaflet know how to obtain further supplies (Appendix 2a contains the information leaflets and details for further supply)

5.3.5 Complying with the pharmacy procedures for receipt and releasing of restricted medicines within the Trust.

5.3.6 Ensuring that restricted medicines that are unlicensed or Specials are labelled appropriately to distinguish them from licensed products

5.4 Divisional Drugs and Therapeutics committee (D&T) or Equivalent
These groups are responsible for approving the introduction of new medicines, including restricted medicines into the Trust. Specific responsibilities of these groups include:

5.4.1 Ensuring use of restricted medicines is justified by published evidence or sound therapeutic argument

5.4.2 The risk assessment of the restricted medicine carried out by the Clinical Lead pharmacist must be reviewed by the committee

5.4.3 Monitoring all restricted medicines used within the Division

5.4.4 The Committee also ensures that appropriate audit systems are in place to monitor compliance with this policy.

5.4.5 Ensuring unlicensed or off-label use of medicines is justified by published evidence in the BNFc or 'Medicines For Children', has been used in other specialist centres, or is justified by published evidence or supported by appropriate academic body.

5.5 The Clinical Lead Pharmacist
The Clinical Lead Pharmacist for each Division is responsible for ensuring that all new requests for restricted medicines are dealt with according to the SOP TW16-008 SOP 42 Assessment and Authorisation of Restricted Medicines.

6 CONSENT OF PATIENTS, CARERS AND PARENTS

6.1 Health professionals must respect the right of patients, carers and parents to participate in discussions regarding the health care of the patient and to seek to ensure that these decisions are properly informed. Requirements under the Mental Capacity Act and Deprivation of Liberty Safeguards (DoLS) must be considered in this regard

6.2 Restricted medicines must follow the same requirements for informed consent of patients/carers as licensed medicines

6.3 Patient Information - when prescribing a restricted medicine, the responsibility for informing the patient resides with the consultant.

6.4 All patients, including outpatients, should receive a restricted medicine Patient Information Leaflet, (as shown in Appendix 2a).

6.5 The Patient Information Leaflet should help explain why it is necessary to prescribe restricted medicines and will be available from pharmacy departments. The information in the leaflet may help to allay any concerns that patients and carers may have about restricted medicines.

6.6 It remains for the consultant to decide the precise information a patient should receive about the medicine and the terms in which any warnings of risk should be given. A record should be made in the patient's clinical notes clearly indicating what information has been given.

6.7 In the case of off-label medicines, the patient information leaflet provided with the product must be issued to the patient, and the pharmacist should counsel the patient with regard to its off-label use.

7 REQUEST FOR RESTRICTED MEDICINES

7.1 New Restricted Medicine Requests
In addition to the standard application process for new medicines, Restricted Medicines requests must also include the following:

7.1.1 Restricted Medicine Request Form (Appendix 2)
If a new restricted medicine is needed, the prescriber responsible for the care of the patient is required to complete a NEW Restricted Medicine Request Form (Appendix 2) and forward it onto the relevant Clinical Lead Pharmacist. The prescriber will have been made fully aware of the clinical and legal implications of using the selected medicine by the Clinical Lead pharmacist appropriate to that clinical area, when asking them to complete a restricted medicines request form.

7.1.2 Restricted Medicines Risk Assessment Tool (Appendix 3)
The Clinical Lead pharmacist will complete a Restricted Medicines Risk Assessment From this a RAG rated risk level of extreme, high, medium-high, medium or low will be assigned

7.2 Urgent clinical requests for restricted medicines
The Clinical Lead Pharmacist for each directorate can grant approval for urgent new restricted medicines following completion of the restricted Medicines Request (Appendix

2) and restricted Medicines Risk Assessment (Appendix 3). These must be ratified by the relevant committees at the next available meeting.

7.3 Subsequent Requests for Restricted Medicines
Once approved for use by the relevant Committee, further supplies of the restricted medicine can be made against prescriptions written by:

7.3.1 The primary requesting Consultant or their team

7.3.2 Subsequent consultants wishing to use the restricted medicine for the same indication within the same Division must complete the new restricted medicines form but this does not require full approval by Committee

7.3.3 Subsequent consultants wishing to use the restricted medicine for a different indication or in a different Division will be required to go through the full approval process as detailed above

7.3.4 The consultant prescribing the restricted medicine is clinically responsible for its use and any untoward effects that may arise from its use.

7.4 Long term supply problem of licensed products

7.4.1 Where a long term supply problem of a pharmaceutical product is identified by the Procurement Team, and an unlicensed equivalent is available, then the Clinical Lead Pharmacist can authorise the procurement subject to the completion of a restricted Request Form (Appendix 2) and restricted Medicines Risk Assessment (Appendix 3)

7.4.2 The restricted Medicines Request Form can be completed by the Clinical lead Pharmacist for all patients within their Division. Trust-Wide use will require a form to be completed by each divisional Clinical Lead

8 RISK ASSESSMENT OF NEW RESTRICTED MEDICINES

8.1 All requests for new restricted medicines require a restricted Medicines Risk Assessment (Appendix 3).

8.2 Preliminary Restricted Medicine Risk Assessment. A restricted medicine risk assessment carried out by the Clinical Lead pharmacist, using the risk assessment tool (appendix 3). The procurement details that will be considered are:

8.2.1 The country of origin. For countries outside the EU or for those without a mutual recognition agreement, Quality Control North-West is contacted for advice.

8.2.2 The language used on the packaging and the availability of approved translations of the patient information leaflet.

8.2.3 Ease at which further supplies can be obtained through the supply chain.

8.2.4 Any issues raised by Quality Control North West.

8.2.5 Supplier/manufacturer

8.3 Restricted medicines may be obtained:

8.3.1 From the holder of a Manufacturer's Specials Licence, either a commercial company or an NHS hospital.

8.3.2 By importation from the holder of a Wholesale Dealer's Licence (for importing from member states of the European Economic Area) or a Wholesale Dealer's Import Licence (for importing from outside the European Economic Area).

8.4 In conjunction with the Medicines Information pharmacist, the Clinical Lead Pharmacist will discuss the clinical risk. This part of the assessment will identify if there is clear clinical evidence in support of the product and reference sources. Contraindications, side effects, precautions and the potential for harm will be assessed in relation to the clinical condition.

8.5 The Clinical Lead Pharmacist will assign an initial risk category of low, medium, medium-high, high or extreme will to the product prior to procurement.

8.6 Examples of low risk unlicensed medicines may be:

8.6.1 A direct drug for drug substitution of a licensed product when the UK brand is not available, usually to manage a long term supply problem.

8.6.2 A liquid preparation of a licensed medicine that is manufactured by a holder of a Manufacturer's Specials Licence.

8.7 Procurement Risk Assessment Review

8.7.1 Following procurement, the risk assessment tool (appendix 3) will be revisited by the procurement team including a review of whether the initial assigned risk category is still appropriate.

8.7.2 This is required as some details are only evident once the product has arrived in the department

8.7.3 An initial low risk restricted medicine may become medium or high risk if for example, the labelling details are entirely written in a foreign language or the product's brand name is too similar to an existing approved medicine name.

9 APPROVAL OF RESTRICTED MEDCINES

9.1 New Restricted Medicines

9.1.1 For new restricted medicines the following should be submitted to the relevant committee for consideration for approval:

9.1.1.1 Restricted Medicine Request Form (Appendix 2)
9.1.1.2 Completed Preliminary Restricted Medicines Risk Assessment (Appendix 3)

9.1.2 When considering a request to approve a restricted medicine, the Divisional Committee must be assured that there is no suitable licensed alternative product available. The supporting clinical data is reviewed with respect to supply chain difficulties, the possibility of interruptions to patient treatment, and any consequences these may have.

9.2 Urgent Clinical Requests of Restricted Medicines

9.2.1 The Clinical Lead Pharmacist of the Division can grant approval for the use of a restricted medicine prior to formal WWL approval. The continued use of these unlicensed medicines will require assessment by the appropriate Divisional committee at a later date (as per 9.1).

9.2.2 The following forms need to be submitted to pharmacy procurement:

9.2.2.1 New Restricted Medicine Request Form (Appendix 1)
9.2.2.2 Restricted Medicines Risk Assessment (Appendix 3)
9.2.2.3 New Item Request Form (Appendix 4)

10 PROCUREMENT AND SUPPLY OF RESTRICTED MEDICINES

10.1 Restricted Medicines must be sourced in line with the standard operating procedure, Procurement and Receipt of Restricted Medicines. (Pharmacy SOP 43).

10.2 Pharmacy will manage the safe and timely issue of approved Restricted medicines within the Trust using the pharmacy stock control system (EMIS Health). Specific consultant cost centre codes can be added against each restricted medicine. This restricts the supply of that particular restricted medicine to those prescribers approved by WWL to prescribe and use it.

10.3 Where a prescription is presented from a consultant not listed against a specific restricted medicine, they will be asked to complete a new restricted medicine request form before EMIS Health is then updated.

10.4 Restricted medicines will be dispensed against individual patient prescription requests and a record of the restricted medicine, patient identifiers (name, DOB, PAS/NHS number), dosage, batch number, expiry date and quantity is made each time a restricted medicine is dispensed.

10.5 Stocks of previously approved restricted medicines that are kept on wards can be supplied against a stock requisition/order.

11 MONITORING AND REVIEW OF RESTRICTED MEDICINES

11.1 The Medicines Information department will maintain a list of all restricted medicines in use within the Trust, and the consultants that have been approved to prescribe each medicine – this will be available for Pharmacy staff to view in the Restricted Medicines Folder on the Intranet. The Clinical Lead Pharmacist will review each product annually and re-evaluate using the current Restricted Medicine Risk Assessment documentation. The review will include a re-assessment of the original clinical data, any new clinical data and newly licensed products that may be appropriate.

11.2 Restricted medicines used to manage long term supply problems will be monitored and assessed accordingly.

12 FUNDING OF RESTRICTED MEDICINES

12.1 Apart from GMMMG approved medicines, prior funding approval is needed for all medicines and this includes restricted medicines. The Clinical Lead pharmacist will ensure that they have calculated the cost impact based on the request details.

12.2 The Funding Assessment Form to be completed and submitted to the relevant committee (Appendix 5)

12.3 If the restricted medicine is to continue in community then the GP must be consulted and agree to the transfer of that medication. If they do not wish to do so, then the responsibility for supply remains with the trust.

12.4 Further information on formulary status and responsibilities of trust and GP can be found on the website: GMMMG.nhs.uk.

13 CLINICAL EVIDENCE DATABASE

13.1 Quality Control North West (QCNW) maintains a clinical evidence database of restricted medicines.

13.2 The full documentation can then be requested directly from the originating Trust, however a full evidence based assessment must still be completed by the Clinical Lead Pharmacist as approval of restricted medicines is relevant to the location in which it is to be used and approval at other trusts does not transfer to approval at WWL

13.3 Responsibility for accuracy of data on the forms rests with the originating Trust.

14 RECORD KEEPING

14.1 All records of receipt and quality assurance for restricted medicines should be kept for 5 years in line with the relevant legislation

14.2 Records of issue should be kept for the timescales specified within the legislation. For example, this is 30 years for blood products.

15 ADVERSE DRUG REACTIONS AND DEFECTIVE PRODUCTS

15.1 Adverse drug reactions and defective products involving restricted medicines are handled and reported in the same way as licensed medicines. Doctors or pharmacists should report serious adverse drug reactions to the Medicines and Healthcare Regulatory Agency (MHRA) using the yellow card system, by either sending the form (copies available in the BNF, MIMS, and ABPI Compendium) or electronically at website: yellowcard.gov.uk or via the App.

15.2 Suspected defects in restricted medicines are reported to the Pharmacy Department or the on-call pharmacist (out-of-hours) who will follow the Pharmacy Department's standard operating procedure for reporting defects.

15.3 All suspected adverse drug reactions must be reported on the DatixWeb incident reporting system.

16 PATIENTS ADMITTED TAKING RESTRICTED MEDICINES

16.1 If a patient is admitted to the Trust and is already being prescribed a restricted medicine from another source (e.g. General Practitioner, a Consultant from another Trust), the prescriber responsible for the care of the patient on this admission must decide whether he/she will accept liability for the continued use of the restricted medicine.

16.2 If it is decided to continue to use the restricted medicine, then a restricted medicine request form (Appendix 2) is required and all other principles outlined in this policy will apply to the prescribing, supply and administration of the restricted medicine.

17 HUMAN RIGHTS ACT

Implications of the Human Rights Act have been taken into account in the formulation of this policy and they have, where appropriate, been fully reflected in its wording.

18 INCLUSION AND DIVERSITY

The policy has been assessed against the Equality Impact Assessment Form from the Trust's Equality Impact Assessment Guidance and, as far as we are aware, there is no impact on any protected characteristics.

19 MONITORING AND REVIEW

This Policy will be reviewed in line with the normal review processes for medicines management procedures via Medicines Management Standards Board.

Audit of compliance will be via Divisional Committees reporting to MMSB

20 ACCESSIBILITY STATEMENT

This document can be made available in a range of alternative formats eg large print, Braille and audiocd.
For more details please contact the HR department on 01942 77 3776 or email equalityanddiversity@wwl.nhs.uk.

Appendix 1

References

Relevant procedural and legislative documents used in production of this policy:

1. The Medicines Act 1968
2. Human Medicines Regulations 2012
3. Medicines and Healthcare products and Regulatory Agency. The supply of unlicensed relevant medicinal products for individual patients. MHRA Guidance note 14. January 2008
4. Quality Control North West. Model trust policy for the prescribing, supply and use of unlicensed medicines. Version 2. November 2003
5. NHS Pharmaceutical Quality Assurance Committee. Guidance for the purchase and supply of unlicensed medicinal products – Notes for prescribers and pharmacists. Third edition. June 2004
6. Royal Pharmaceutical Society of Great Britain: Medicines, Ethics and Practice (39) July 2015.
7. Non-medical Prescribing Policy TW11-10

Wrightington, Wigan and Leigh NHS
NHS Foundation Trust

Appendix 2

NEW RESTRICTED MEDICINE REQUEST FORM

This form should be completed by the prescriber responsible for the care of the patient. Before completing this form, the Trust's Policy for Restricted Medicines must be read and the prescriber responsible for the care of the patient must be aware of their responsibilities under this policy.

It is important that the pharmaceutical quality of a product can be assured and that there is evidence to support the clinical use of this product.

Restricted Medicine Details:

Product name: …….

Pharmaceutical form: …….

Strength:…….

Clinical indication for use: …….....

Dose range: …….....

Frequency: …….....

Route of administration: ……..... Duration of treatment: …….

Is the medicine for a specific patient? *Yes / No*

If no, please indicate approximate number of patients requiring treatment and cost per annum: …….....

What alternative treatment options exist?

……

……

……

Why is an unlicensed medicine being considered?

……

……

.....

Evidence to support use (list and attach references or other information to support your request):

……

……

……

……

Will the medicine be continued outside the hospital? *Yes / No*

If no, will hospital continue prescription? *Yes / No*

If GP is to continue prescription, is there a need for agreed shared care? *Yes / No*

If yes, describe:

……

……

……..

Will you obtain informed consent? Yes / No

When signing below, you accept full clinical responsibility in the prescribing of this restricted medicine, after considering the clinical benefits and associated risks.

Consultant Signature: …… **Print Name:** …….
Speciality: ……**Date**: ……..

This application form must be completed and forwarded to your divisional Clinical Lead Pharmacist.

The Clinical Lead Pharmacist will review the application based on the therapeutic need, available alternatives, clinical evidence base and quality assurance of the proposed restricted medicine.

The form will then be submitted to the appropriate Committee for approval

Wrightington, Wigan and Leigh NHS
NHS Foundation Trust

Appendix 2a

Pharmacy Department RAEI, Wrightington, TLC (*delete as appropriate)*

PATIENT INFORMATION LEAFLET

YOU HAVE BEEN GIVEN A SUPPLY OF:

(Attach Label)

This is a restricted medicine which means….

Currently, this product does not have a full U.K. pharmaceutical product licence or it is being used outside of the license or has been manufactured as a "Special" medication. Medicines are often used in this way. This can be for many reasons, for example:

- It is awaiting for the granting of a U.K. licence by the Government
- It is being tested in a clinical trial
- Use of the medicine is low and therefore it is not economical for the makers to send the product for approval
- It has been withdrawn from the U.K. market
- Lack of availability of a licensed version

However, please be reassured that your doctor and pharmacist have thought very carefully about the best medicine to give you. If you have any concerns regarding this medicine please contact the pharmacy department.

Medicines Information: 01942 822466 or 822296 (direct dial)

How to obtain a further supply of restricted medicine

- If you require a further supply of this medicine and you do NOT have a further hospital appointment, please either: (tick appropriate box)

  ☐ *Obtain a prescription from your GP and take it to your local pharmacy along with a copy of the "Restricted Medicines Information for Community Pharmacy" form that you have been given*

  ☐ *Contact your Consultant for further prescriptions to take to the hospital pharmacy for a further supply.*

- You will need to give the pharmacy one to two weeks' notice to obtain your medicine. It is therefore important that you order your prescription from your GP well in advance.

Wrightington, Wigan and Leigh NHS
NHS Foundation Trust

Appendix 2b

Restricted Medicines Information for Community Pharmacy & GP:

Your patient:

Name and address: …….....
…….
…….
…….
DOB: ……..

Your patient has been commenced on the following restricted medicine*:*

Copy of Label

Further supplies can be obtained from the following supplier/s:

Supplier	Address	Telephone No.

Completed by (PRINT and sign) ……..

Pharmacy Department RAEI / Wrightington / TLC

Date: ...../…../……..

Procurement Contact Number: 01942 7788

New Restricted Medicine Risk Assessment Tool

Appendix 3

Medicine:	**Requesting Consultant(s):**
Indication:	**Division:**
Manufacturer:	**Directorate:**

						Comments *(eg, how does the risk compare with alternatives, is the risk any greater or smaller than the usual product)*
Supplier	**Recognised UK importer (see Appendix 3)**	**Imported from mutually recognised country (see Appendix 3)**	**Known company but from non-mutually recognised country, or Specials Manufacturer with analytical testing (see appendix 3)**	**Specials Manufacturer producing untested preparations under Section 10**	**No experience or knowledge of company at all, WUTH black listed**	
Tick Box						
Route	**Topical/Eye/ Ears/ Transdermal**	**Oral/Orifices/ Intradermal**	**Intramuscular/Subcut/ Intra-vascular/Intra-articular**	**Intravenous/Epidural**	**Intrathecal/ Spinal**	
Tick Box						
Excipients or other ingredients	**None or conclusion 1 in FDA table***	**Conclusion 2 in FDA table***	**Conclusion 3 in FDA table***	**Conclusion 4 in FDA table***	**Conclusion 5 in FDA table* or not listed in table**	
Tick Box						
Ease of use by ward or patient	**Provided in unit-of- use**	**Dosage as a simple multiple of dosage units**	**Reconstitution required and/ or division of dosage form or calculation**	**Complex calculation required to determine dose**	**Serial dilutions required to prepare dose for administration**	
Tick Box						
Ease of use if	**Provided in unit-of-use**	**Dosage as a simple multiple**	**Reconstitution required and/ or division of**	**Complex calculation required**	**Serial dilutions required to prepare**	

prepared by pharmacy	if prepared by pharmacy	of dosage units if prepared by pharmacy	dosage form or calculation if prepared by pharmacy	to determine dose if prepared by pharmacy	dose for administration if prepared by pharmacy	
Tick box						

Table can be found on US Food and Drug Administration website (www.fda.gov; search for "Alphabetical list of SCOGS substances")

						Comments *(eg, how does the risk compare with alternatives, is the risk any greater or smaller than the usual product)*
Instructions for Administration / Labelling	**In English for indication from manufacturer or WWL prepared**	**In English but not for indication**	**Original information in a foreign language for indication**	**Original information in a foreign language but not for indication**	**None (Assess whether PIL or Label Admin instructions required)**	
Tick Box						
PIL/Technical Data Sheet	**In English for indication from manufacturer or WWL prepared**	**In English but not for indication**	**Original information in a foreign language for indication**	**Original information in a foreign language but not for indication**	**None (Assess whether PIL needs to be written)**	
Tick Box						
Licence Status	**UK Product licence but being used 'off label'**	**Licensed in mutually recognised country for specific indication**	**'Special' for routine clinical use**	**Not licensed or licensed in non-mutually recognised country (including food products)**	**Licence revoked by the UK or other mutually recognised country and non-pharmaceutical grade**	
Tick Box						
Evidence available	**Approved by Divisional D&T committee or Operational Management Group (MSK)**	**Established evidence base in peer-reviewed journals or other authoritative source eg NICE, Royal College**	**Few papers or inconclusive clinical trials, or used in patient group but dosage unknown**	**No supporting literature other than anecdotal reports for patient group**	**None, or not used previously in patient group**	
Tick Box						

Clinical Safety assessment	Known ADR profile with low risk and few CIs and little monitoring required	Known ADR profile with moderate risk and identifiable CIs with minimal monitoring	Known ADR profile with moderate risk and many CIs (eg renal) with significant monitoring	Unknown ADR profile and CIs unclear	Known ADR or not with serious complications/ death at an incidence of >1%	**Comments** *(eg, how does the risk compare with alternatives, is the risk any greater or smaller than the usual product)*

Assessing risk:
Consider how many of each coloured type:

- **one or more red box ticked will make the product extreme risk irrespective of other lower risk categories ticked**
- **one or more amber box ticked will make the product high risk irrespective of other lower risk categories ticked**
- **three or more yellow box ticked will make the product medium-high risk irrespective of other lower risk categories ticked**
- **two yellow boxes with the rest green will make the product medium risk**
- **one yellow with the remaining green boxes ticked will make the product a low risk**

Initial over risk score (colour):

Risk reduction measures needed:

Revised risk assessment score (colour):
(if risk reduction measures implemented)

Risk assessment completed by:
(name and designation)

Date:

Appendix 4

New Item Request Form

New Item Request Form

Date:

ALL ITEMS MARKED WITH AN ASTERISK * ARE MANDATORY AND YOUR FORM WILL BE RETURNED IF THEY ARE NOT COMPLETED

* Site Requesting New Item:

* Person Requesting New Item:

* New Item Required by (e.g date/time)

Reason for above date/time requirement:

e.g PM delivery of item

* New Drug Description:

Trade Name:

New Item Price:

* New Item Pack size:

Supplier:

Is there a contract for the Item: Yes No (If yes please fill in details overleaf)

C.O.S.H.H Yes No

* Formulary Status:

yes No Consultant Only Restricted

* BNF Chapter:Section:Subsection:
(If applicable)

* BNF Warning Codes required: Yes No

If yes, codes required:

* Licensed Drug: Yes No

* PBR Drug: Yes No

* Additional information required on the label? Yes No If yes, please enter in box below.

* New Item Setup Authorised by:
(Senior Pharmacist grade 8a and above)

Computer setup completed by:

Item not to be issued until the following checks are complete and all details are correct.-

Are instructions correct? Yes No

Is the item description correct? (Form, Strength etc.) Yes No

Are the warnings correct as per the BNF? Yes No

Does product match item label? Yes No

Sample label:

Stick Label here

Checked By: Date:
(Senior Pharmacist grade 8a and above)

To be completed by Distribution office staff:

Contract Details :

* Contract Number:

* Start Date: * End Date:

* Contract Price:

Annual Usage:

v10 NSV Code
v8 NSV Code

Usage Details :

* Re-order level:

* Re- order Quantity :

* Re- order outer

Unlicensed Details :

* Procurement Details form completed:

* Medicine Risk Assessment tool completed:

Appendix 5

Funding Assessment

Estimated cost per patient		**Estimated number of patients per year**		**Estimated cost per year**	

Funding approval request:					
	FOR ALL REQUESTS			**FOR URGENT REQUESTS (must go to D&T committee retrospectively)**	
	Clinical Lead Pharmacist	**Clinical Head of Division**	**Drug & Therapeutics Committee (WWL)**	**Clinical Lead Pharmacist**	**Clinical Head of Division**
Name					
Date contacted					
Contacted by:					
Funding approval Yes/No/N/A Comments					

WWL submission:		
WWL Outcome Approved/rejected & date		

Appendix 6

EQUALITY IMPACT ASSESSMENT FORM – STAGE 1
INITIAL ASSESSMENT (PART 1)

FOR USE WITH POLICY'S AND SOP'S

Division:	Medicine			**Department:**	Pharmacy
Title of Person(s) Completing Form	Claire Warburton – Lead Technician Medicines Information			**New or Existing Policy?**	New
Title of Policy being assessed:	Restricted Medicines Policy			**Implementation Date (Policy)**	Jan-2016
What is the main purpose (aims / objectives) of this policy?	This policy covers the use of restricted medicines within Wrightington, Wigan and Leigh NHS Trust.				
Will patients, carers, the public or staff be affected by this policy? Please delete as appropriate.	**Patients**	**Yes**			
	Carers	**Yes**			
	Public		**No**		
	Staff	**Yes**			
	If staff, how many individuals / Which Groups of Staff are likely to be affected? Doctors, Nurses, Pharmacy staff				
Have patients, carers, the public or staff been involved in the development of this policy? **Please delete as appropriate.**	**Patients**		**No**		
	Carers		**No**		
	Public		**No**		
	Staff	**Yes**			
	If yes, who have you involved and how have they been involved: Meetings, Emails, PQSC, MMSB				
What consultation method(s) did you use?	*For example: focus groups, face-to-face meetings, questionnaires etc.* Face-to-face, emails				
How are any changes / amendments to the policy communicated?	*For example: Meetings / Focus / Email etc.* *Via MMSB, PQSC and clinical teams, DQECs*				

QUESTIONS YOU MUST CONSIDER when completing the following Equality Impact Assessment Table:

- Are there any barriers which could impact on how different groups might benefit from this policy?
- Does this policy promote the same choices for different groups as everybody else?
- Could any of the following group's experience of this policy be different?
- Does this policy address the needs and potential barriers of these groups?

EQUALITY IMPACT ASSESSMENT TABLE – POLICIES (PART 2)

Equality Group	**Positive Impact** High Low None	**Negative Impact** High Low None	**Reason/Comments for Positive Impact** **(Why it could benefit any / all of the Equality Groups)**	**Reason/Comments for Negative Impact** **(Why it could disadvantage any / all of the Equality Groups)**	**Resource Implication** **Yes / No**
Men	None	None			No
Women	None	None			No
Younger People (17-25) and Children	None	None			No
Older People (60+)	None	None			No
Race or Ethnicity	None	None			No
Learning Difficulties	None	None			No
Hearing Impairment	None	None			No
Visual Impairment	None	None			No
Physical Disability	None	None			No
Mental Health Need	None	None			No
Gay/Lesbian/ Bisexual	None	None			No
Transgender	None	None			No
Faith Groups (specify)	None	None			No
Marriage & Civil Partnership	None	None			No
Pregnancy & Maternity	None	None			No
Carers	None	None			No
Other Group (specify)	None	None			No
Applies to ALL Groups	None	None			No

High: There is significant evidence of a negative impact or potential for a negative impact.
Low: Likely to have a minimal impact / There is little evidence to suggest a negative impact.
None: A Policy with neither a positive nor a negative impact on any group or groups of people, compared to others.

INITIAL ASSESSMENT (PART 3)

(a) In relation to each group, are there any areas where you are unsure about the impact and more information is needed?

(b) How are you going to gather this information?

(c) Following completion of the Stage 1 Assessment, is Stage 2 (a Full Assessment) necessary?

Have you identified any issues that you consider could have an adverse (negative) impact on people from the following Equality Groups?

(Please **delete YES/NO** as appropriate**)**

Age (Younger People (17-25) and Children / Older People (60+)		**NO**
Gender (Men / Women)		**NO**
Race		**NO**
Disability (Learning Difficulties / Hearing Impairment / Visual Impairment / Physical Disability / Mental Illness)		**NO**
Religion / Belief		**NO**
Sexual Orientation (Gay / Lesbian / Bisexual)		**NO**
Gender Re-assignment		**NO**
Marriage & Civil Partnership		**NO**
Pregnancy & Maternity		**NO**
Carer		**NO**
Other		**NO**

Any other comments

Assessment completed by (Job Title): **Lead Technician, Medicines Information**
Date Completed : **January 2016**

If 'NO IMPACT' is identified **Action: No further documentation is required.**
If 'YES IMPACT' is identified **Action: Full Equality Impact Assessment Stage 2 form must be completed. Refer to link below:**
http://intranet/Departments/Equality_Diversity/Equality_Impact_Assessment_Guidance.asp

PLEASE RETURN A COPY OF THE COMPLETED ASSESSMENT FORM (STAGES 1, 2 & 3) VIA E-MAIL TO:
DEBBIE JONES, EQUALITY AND DIVERSITY PROJECT LEAD (for Service related policies)
debbie.jones@wwl.nhs.uk
EMMA WOOD, EQUALITY AND DIVERSITY PROJECT LEAD (for HR / Staffing related policies)
emma.wood@wwl.nhs.uk

Appendix 7

POLICY/SOP MONITORING AND REVIEW ARRANGEMENTS

NAME OF POLICY: Restricted Medicines Policy

Para	Audit / Monitoring requirement	Method of Audit / Monitoring	Responsible person	Frequency of Audit	Monitoring committee	Evidence	Location
5.1.2, 5.1.11, 5.1.12, 5.2.5, 6.4, 7.1-7.4	Monthly check that all forms are completed fully as per paragraphs stated	Direct review	Deputy Chief Pharmacist (Clinical Services)	Annual	PQSC	Audit report	Unlicensed Medicines Folder Disp Info
5.1.7, 5.1.9	Ensuring that patients have been informed of unlicensed nature prior to dispensing (to include provision of a leaflet)	Patient counselling at OPD/discharge	Clinical Checking Pharmacist	Annual	PQSC	Audit forms	Unlicensed Medicines Folder Disp Info
5.2.7-5.2.9, 5.2.12, 7.1-7.4, 9.1-9.2	Ensuring that divisions are properly approving unlicensed drug requests in a timely manner	Minutes review	Clinical Lead Pharmacists	Quarterly Review	DQEC	Audit forms	DQEC minutes