Policy Number	SD36

COVID-19 DOCUMENT CHANGE FORM

NHS Mersey Care NHS Foundation Trust
Community and Mental Health Services

In light of the COVID-19 outbreak it has been necessary to make temporary changes to this Policy Document. Therefore when reading the policy document please take account of the changes highlighted in Part B and C of this form.

PART A – INFORMATION ABOUT THIS POLICY DOCUMENT

Policy Name	**Use of unlicensed and off-label medicines**			**Reference No**		**SD36**	
Executive Lead *(Trust-wide policies)*	**Executive Medical Director**						
Chief Operational Officer *(Clinical Division policies)*							
Policy Document *(Tick only one)*	Trust-wide (Board approved)	☐	Trust-wide (Executive Director approved)	☒	Secure & Specialist Learning Disabilities Division	☐	
	Community Division	☐	Local Division	☐			
Type of Policy *(Tick only one)*	Clinical Policy	☒	Non-clinical Policy	☐			
Clinical Policy Only *(Tick only one)*	Minor Change *(Not referred to the Clinical Cell)*	☐	Major Change *(Referred to Clinical Cell, then to SCG for approval)*	☒			
Approving Body *(Tick only one)*	Board of Directors	☐	COVID-19 Strategic Coordination Group	☒	Community Division Tactical Coordination Group	☐	
	Corporate Division Tactical Coordination Group	☐	Local Division Tactical Coordination Group	☐	Secure & Specialist LD Division Tactical Coordination Group	☐	

PART B – CHANGES TO THE POLICY DOCUMENT

Section / Paragraph No	Outline of the information that has been amended in this policy document
Appendix 1 Table on Page 15	**List of approved unlicensed and off-label medicines** Additional row in the list of approved unlicensed and off-label medicines to enable off-label use of clozapine for stable patients in the absence of blood monitoring during the COVID-19 pandemic

PART C – RATIONALE FOR CHANGES

Please explain why this document needs to be amended during the COVID-19 outbreak
The COVID-19 pandemic is presenting challenges on the requirement for closely monitoring clozapine management systems. Temporary additional arrangements are necessary to support the colleagues, service users and carers involved and ensure that clozapine can be safely supplied for those who require it and are stabilised on treatment. This temporary change will support in occasions where service users are shielding due to other co-morbidity and are prescribed clozapine, or may apply in the event of a significant and abrupt shortfall in staffing or during isolation and would otherwise need to cease clozapine treatment in the absence of blood monitoring.

PART D – APPROVAL (for completion by officer loading policy document onto intranet / website)

Date Referred to the Clinical Cell *(Clinical Policies only)*	24 April 2020
Date Referred by the Clinical Cell to the SCG *(Clinical Policies only)*	26 April 2020
Date Approved by the Approving Body	27 April 2020
Date Circulated to Relevant Staff	29 April 2020
Date Published on the Divisional Intranet / Trust Website	29 April 2020

Policy Number	SD36

COVID-19 DOCUMENT CHANGE FORM

Note – the Approving Body to send this form to the appropriate divisional officer (for divisional policies) or the Corporate Governance Team (for trust-wide policies) who will be responsible for adding this form to the front of the existing policy and then uploading these onto the intranet / trust website.

The following addition is required for the table detailing the list of approved unlicensed and off-label medicines during the COVID-19 pandemic in line with guidelines detailed on the following pages agreed by Clinical Cell in response to the COVID-19 pandemic only.

Medicine or Group	Unlicensed Indication	Comments
Clozapine	Off-label in the absence of a valid Green clozapine monitoring result for stable service users	The responsible clinician can make this decision on an individual basis for service users stabilised on clozapine and based on a careful assessment of the available options for obtaining and processing a full blood count test and when the benefits outweigh the risks

Clozapine Management during Covid-19 Pandemic

In light of some of the challenges presented by the current Covid-19 pandemic on the requirements for closely monitoring clozapine management systems, some temporary additional arrangements are necessary to support the colleagues, Service Users and Carers involved and ensure that clozapine is safely supplied for those who require it. This resource might support in occasions where service users are shielding due to other co-morbidity and are prescribed clozapine, or apply in the event of a significant and abrupt shortfall in staffing or during isolation.

The requirement for routine clozapine FBC monitoring prior to clozapine being supplied will remain as follows. Responsible clinicians do not need to request permission to supply clozapine within the licensed maximum cover period as detailed below:

Table 1: Shows maximum clozapine cover period for Clozaril® and Denzapine®

Monitoring Frequency	*Sample Due Day*	*Maximum Cover Period*
Weekly	Every 7 Days	10 Days (additional 3 days supply)
Fortnightly	Every 14 Days	21 Days (additional 7 days supply)
Four Weekly	Every 28 Days	42 Days (additional 14 days supply)

However, should a patient, due to contacting Covid-19 or they are self-isolating, be unable to access any sort of service that may be able to take this blood sample they may breach these timeframe requirements and become prohibited from continuing with their clozapine treatment.

Prescribing of unlicensed medicines should only follow careful assessment of the evidence, available options, potential risks and benefits of the proposed treatments and only used when the benefits outweigh the risks. As with any other treatment, the prescriber must act in the best interests of the service user when prescribing unlicensed medicines.

It is accepted by the trust Clinical Cell in response to the Covid-19 pandemic that the informed use of clozapine in the absence of a valid blood test result may sometimes be necessary. These cases will be supported by the Trust following a clinical review on a case by case basis. In such circumstances the following steps must be followed:

1. After exhausting the available options to obtain a blood test continuing clozapine is still desirable, this will remain the case throughout the Covid-19 pandemic.
2. The Responsible Clinician should contact Dr John Crosby (Deputy Medical Director, Medicines and Safer Prescribing and Chair of the trust wide Drugs and Therapeutics Committee) by email for review of the case and seeking approval, outlining the service users demographics (NHS/hospital number and DOB) and details with a view to determining a care plan for realistic blood sampling and wider management if necessary.
3. Once agreed the responsible clinician must approach CPMS or DMS and inform them that they wish to continue prescribing clozapine as an off-label medication.
4. The service user and carers must be fully informed of the off-label status of the medicine, perceived benefits and adverse effects to inform decision making about treatment.
5. The responsible clinician must document the care plan as part of the patient's clinical record on RiO, PACIS or Care Notes.
6. A record of the reasons for the off-label use and any discussions with service users and consent status should be kept in the case notes.

Issues to Consider

Normal monitoring of white cell count for service users prescribed clozapine may be unavoidably disrupted during the pandemic. Where possible, follow the licensed dispensing and testing interval extensions tabulated above. Where further extensions are required, these may fall outside the licence. Patients should be risk stratified and monitored as below:

1. Patients in the first 18 weeks of clozapine use are at the highest risk of neutropenia and agranulocytosis and should continue weekly monitoring within limits tabulated above
2. Patients in weeks 19 to 52 without a history of low white cell count related to clozapine should be reviewed on an individual basis. Some extension beyond manufactures' limits may be appropriate. Seek advice from the relevant clozapine manufacturer as well as local medical advice.
3. Patients with more than 1 year of use and without a history of low white cell count related to clozapine: consider temporary extension of blood tests from every 4 weeks to up to every 12 weeks
4. The most frequently reported symptoms of COVID-19 infection are fever, cough, myalgia, fatigue and shortness of breath. Patients with concurrent coronary heart disease, hypertension or diabetes tend to a more severe prognosis. Acute cardiac injury, acute kidney injury and secondary infection may follow. Management of these additional conditions can be further complicated by the lack of physical observations and pathology results.
5. Clozapine serum levels may rise during an infection. Therefore, consideration should be given to completing a clozapine plasma level for patients who have respiratory symptoms or fever, especially those with severe respiratory symptoms or where their most recent level was at the higher end of the range. Where patients are presenting with symptoms of clozapine toxicity such as drowsiness, sedation, lethargy, confusion, agitation, tachycardia, hypotension,

respiratory depression and seizures, a clozapine plasma level should be taken as soon as possible, and a temporary dose reduction or cessation should be considered.

Further supporting information is available from the following:

- The Clozapine Patient Monitoring Service (CPMS)
- The Denzapine Monitoring Service (DMS)
- Mersey Care Medicines Information Service
- Mersey Care trust-wide clinical policy on the use of unlicensed and off-label medicines, SD36
- Medicines Management Department Clozapine Service
- Medicines Management Department
- Sarah Rafferty, Interim Chief Pharmacist
- David Kitchen, Education and Training Pharmacist
- Dr John Crosby, Deputy Medical Director for Medicines and Safer Prescribing

Specialist Pharmacy Services resources for clozapine drug monitoring during Covid-19 for stable adult patients - https://www.sps.nhs.uk/articles/clozapine-drug-monitoring-in-primary-care-during-covid-19-for-stable-patients/

NHS
Mersey Care
NHS Foundation Trust

Community and Mental Health Services

TRUST-WIDE CLINICAL POLICY DOCUMENT

USE OF UNLICENSED AND OFF-LABEL MEDICINES

Policy Number:	**SD36**
Scope of this Document:	**All Clinical Staff**
Recommending Committee:	**Drugs and Therapeutics Committee**
Approving Committee:	**Executive Committee**
Date Ratified:	**January 2017**
Next Review Date (by):	**April 2020**
Version Number:	**2016 – Version 2**
Lead Executive Director:	**Medical Director**
Lead Author(s):	**Principal Pharmacist High Secure Services, Lead Medicines Information Pharmacist,**

TRUST-WIDE CLINICAL POLICY DOCUMENT

2016 – Version 2

Striving for perfect care and a just culture

TRUST-WIDE CLINICAL POLICY DOCUMENT

USE OF UNLICENSED AND OFF-LABEL MEDICINES

Further information about this document:

Document name	**USE OF UNLICENSED MEDICINES (SD36)**
Document summary	**What constitutes unlicensed and off-label use of medicines** **Procedure for prescribing, supply and administration of unlicensed and off-label medicines** **Approved list of medicine with routine unlicensed uses**
Author(s) Contact(s) for further information about this document	**Agatha Munyika** **Lead Medicines Information Pharmacist** **Telephone: 0151 250 6011** **Email: agatha.munyika@merseycare.nhs.uk**
Published by Copies of this document are available from the Author(s) and via the trust's website	**Mersey Care NHS Foundation Trust** **V7 Building** **Kings Business Park** **Prescot** **Merseyside** **L34 1PJ** **Trust's Website www.merseycare.nhs.uk**
To be read in conjunction with	**SD12 The Handling of Medicines Policy**
This document can be made available in a range of alternative formats including various languages, large print and braille etc	

Version Control:

		Version History:
Version 1.2	Update version approved by Corporate Policy Review Group	November 2013
Version 2	Approved by Executive Committee	January 2017
Version 2	Executive Committee - approved	February 2020

SUPPORTING STATEMENTS

this document should be read in conjunction with the following statements:

SAFEGUARDING IS EVERYBODY'S BUSINESS

All Mersey Care NHS Foundation Trust employees have a statutory duty to safeguard and promote the welfare of children and adults, including:

- being alert to the possibility of child / adult abuse and neglect through their observation of abuse, or by professional judgement made as a result of information gathered about the child / adult;
- knowing how to deal with a disclosure or allegation of child /adult abuse;
- undertaking training as appropriate for their role and keeping themselves updated;
- being aware of and following the local policies and procedures they need to follow if they have a child / adult concern;
- ensuring appropriate advice and support is accessed either from managers, *Safeguarding Ambassadors* or the trust's safeguarding team;
- participating in multi-agency working to safeguard the child or adult (if appropriate to your role);
- ensuring contemporaneous records are kept at all times and record keeping is in strict adherence to Mersey Care NHS Foundation Trust policy and procedures and professional guidelines. Roles, responsibilities and accountabilities, will differ depending on the post you hold within the organisation;
- ensuring that all staff and their managers discuss and record any safeguarding issues that arise at each supervision session

EQUALITY AND HUMAN RIGHTS

Mersey Care NHS Foundation Trust recognises that some sections of society experience prejudice and discrimination. The Equality Act 2010 specifically recognises the *protected characteristics* of age, disability, sex, race, religion and belief (or lack thereof), sexual orientation, gender reassignment, pregnancy and maternity and marital and civil partnership status. The Equality Act also requires regard to socio-economic factors.

The trust is committed to promoting and advancing equality and removing and reducing discrimination and harassment and fostering good relations between people that hold a protected characteristic and those that do not both in the provision of services and in our role as a major employer. The trust believes that all people have the right to be treated with dignity and respect and is committed to the elimination of unfair and unlawful discriminatory practices.

Mersey Care NHS Foundation Trust also is aware of its legal duties under the Human Rights Act 1998. Section 6 of the Human Rights Act requires all public authorities to uphold and promote Human Rights in everything they do. It is unlawful for a public authority to perform any act which contravenes the Human Rights Act.

Mersey Care NHS Foundation Trust is committed to carrying out its functions and service delivery in line the with a Human Rights based approach and the FREDA principles of **F**airness, **R**espect, **E**quality **D**ignity, and **A**utonomy

Contents

1. PURPOSE AND RATIONALE

1.1 The purpose of this policy is to clarify issues around the prescribing, supply and administration of unlicensed and off-label medicines in Mersey Care NHS Trust.

1.2 Unless exempt, any medicine for intended for human use within the UK must have a marketing authorisation (formerly called a product licence) before being placed on the market. The regulation and licensing of medicines on the UK market is undertaken by the Medicines and Healthcare products Regulatory Agency (MHRA) -a Government body set up to discharge the responsibilities of the Licensing Authority, in accordance with the Medicines Act 1968 and Regulations under the Act. The MHRA ensures that medicinal products conform to internationally-agreed standards, and that those medicines are manufactured, stored and distributed in compliance with the required regulatory standards.

1.3 Within the European Union, control of medicinal products is addressed by the new EU pharmaceutical legislation (http://www.emea.europa.eu). UK legislation relevant to unlicensed use includes the Medicines Act and the Consumer Protection Act.

1.4 The Medicines Act 1968 lays down regulations to control the manufacture, sale and use of medicinal products. Under this Act, medicines are required to have a marketing authorisation (product licence) which is issued by the MHRA. The marketing authorisation defines the therapeutic or diagnostic purposes and the clinical indications of which a product may be sold or supplied. The licensed clinical indications, dosage, age, method of administration, precautions, contraindications, drug interactions, side-effects and other information from the manufacturer are presented in the Summary of Product Characteristics (formerly data sheet). This information is also published in the BNF.

1.5 The Consumer Protection Act 1987 applies whether medicines are licensed or unlicensed. The significance of this is that under this Act a “producer” is automatically liable if a product is found to be defective. Note that producers, even if they are found to be strictly liable for their product, can nevertheless make their own claim against the Hospital or prescribers if a product was wrongly prescribed. Producers of medicines will often be able to claim exemption from this Act on the basis that the risk is one of development i.e. that in the passage of time risks that were not appreciated come to light at a later date. This means that the Hospital and/or its prescribers face potential liability to any claimant.

1.6 Prescribing of unlicensed medicines or licensed medicines for unlicensed uses alters (and probably increases) the prescriber’s professional liability. When prescribing unlicensed medicines, the prescriber must be able to justify his actions in accordance with a respectable, responsible body of professional opinion.

1.7 Prescribers are not prohibited from prescribing unlicensed medicines. Prescribing of licensed medicines outside the recommendations of the marketing authorisation increases the prescriber’s clinical responsibility and legal liability and must be justifiable in accordance with a respectable, responsible body of professional opinion. The manufacturer is unlikely to be found liable for any harm caused by that medicine, unless the harm is directly attributable to a defective medicine, rather than the way it was prescribed.

2. OUTCOME FOCUSED AIMS AND OBJECTIVES

2.1 This policy is based on the belief that while use of unlicensed medicines or licensed medicines outside the terms of their license is a necessary part of practice, reasonable steps must be taken to minimise potential risks of to service users.

2.2 Unlicensed medicines should only be used where use of a licensed alternative is not possible.

2.3 There are legal, ethical and professional frameworks which govern the use of unlicensed and off-label medicines. Across the trust, there should be a clear policy on the use of unlicensed medicines, which reflects the differences in liability which may exist.

2.4 Practitioners must be fully aware of their responsibilities when using unlicensed or off-label medicines and must have sufficient knowledge, information or experience and must be acting in the best interests of the service user

3. SCOPE

3.1 This policy applies to all clinical staff of the Trust.

4. DEFINITIONS

4.1 For the purposes of this Policy, the terms “unlicensed use of medicines” includes all uses of medicines as specified below:

4.2 Unlicensed Medicines (which do not have a product license) e.g.

- Products for which a licence has yet to be granted in the United Kingdom; a licence may exist elsewhere.
- Products that no longer have a licence because license been abandoned, suspended, revoked or not renewed.
- Products manufactured for export
- Products undergoing clinical trials

4.3 Unlicensed Uses of Licensed Medicines (i.e. off label use where licensed medicines are used outside the terms of their UK license) e.g.

- Unlicensed indications
- Doses outside licensed limits
- Use in pregnancy
- Handling and administration medicines outside the terms of the license (e.g. segments, crushing)

4.4 The provisions of the licence are usually summarised in the summary of product characteristics (SPC). SPCs are not always published (e.g. for generics) and are not usually consulted at the time of prescribing. Even if the contents of the SPC are known, there are occasions when non-adherence is justified e.g. where the licensed indications do not reflect current knowledge or do not include well proven uses or are over restrictive.

4.5 Extemporaneously prepared medicines, e.g.

- Products made from licensed medicines, e.g. low dose formulations for children/elderly; liquid formulations for elderly or those unable to swallow.
- Products made in a ‘specials’ manufacturing unit or prepared in a hospital pharmacy under a Medicines Act exemption.

4.6 Re-packed Medicines

- When a medicine is removed from its original container (manufacturer packaging) and re-packed, e.g. during normal dispensing or repacking of medication into compliance aids, it technically becomes ‘unlicensed’

5. DUTIES

5.1 **The Medical Director** is accountable to the Trust Board for the implementation of the Policy and ensuring that appropriate use of unlicensed or off-label use of medications within the trust.

5.2 **The Chief Pharmacist** is responsible for chairing the Drugs and Therapeutics Committee which reviews and has oversight of the policy and procedure for the use of unlicensed or off-label medications.

5.3 **The Drugs and Therapeutics Committee (DTC)** works within the governance structures of the trust ensuring that medicines are managed in an effective manner across the trust. The committee ensures that pharmacological treatments are provided for people with mental health problems in a safe manner under principles of ‘right person, right medication, right dose, right time’. Whilst supporting clinical governance within the Trust via effective policies and guidance

to ensure best practice. It also supports and advises on implementation of national guidelines; e.g. NICE and safety alerts. Via the Medicines Safety Group there will be review and analyses any medication related errors or incidents, with reports are tabled every two months.

5.4 Prescribers' responsibility and duties

When prescribing unlicensed medicines the prescribing prescriber's responsibilities include:-

5.4.1 To be aware that the product is unlicensed. To be aware of any known side effects and drug interactions and also to be aware that there may be side effects or drug interactions that are not yet known.

5.4.2 To prescribe such medicines only after careful consideration of the risks and benefits of the proposed treatment versus available licensed products.

5.4.3 To be familiar with the product or be acting on the direct advice of a specialist, SOAD, professional body or by following published precedent e.g. publication in a reputable medical journal.

5.4.4 Prescribers should inform service users and carers of the reasons for prescribing an unlicensed medicine or a licensed medicine for an unlicensed indication. They should inform them of the risks and benefits of using the medication.

5.4.5 The prescriber must make clear that:

That the drug is unlicensed and not approved by the MHRA for use in the UK
The known side effects
That the medicine may have side effects that are not known
That the drug has not been fully assessed and not been accepted as standard treatment.

5.4.6 To fully document this information.

5.4.7 The prescriber must obtain consent to the course of treatment and therefore the service user must have capacity. If a service user has capacity and refuses to have the treatment with the unlicensed product, then such treatment must not be given. If a service user does not have capacity the provisions of the Mental Health Act apply and it is recommended that a second opinion in respect of proposed treatment with an unlicensed product should be obtained. As with all consent it is essential that it be informed consent.

5.4.8 Discussions with service users about the proposed prescribing of an unlicensed product must be fully recorded in the service user's notes, but it is recommended that this be repeated in a letter to the service user to avoid a subsequent allegation that the consent was not an informed one.

5.4.9 If a prescriber is to prescribe an unlicensed product it is recommended that this is discussed with a pharmacist before treatment commences and from time to time during the course of treatment.

5.5 Pharmacists' responsibility and duties

5.5.1. To obtain unlicensed medicines only on the written "request" of a consultant

5.5.2. To explain to healthcare staff the practical implications of using unlicensed medicines or medicines for unlicensed uses

5.5.3 To inform prescribers of unlicensed uses of medicines when such uses can be identified from prescribing documents and other sources

5.5.4 To authorise the safe keeping and control of medicines used in clinical trials

5.5.5 To draw up specifications for all unlicensed medicines purchased by the hospital pharmacy and to seek quality control approval before such products are used

5.5.6 To keep an approved list of specials suppliers

5.5.7 To keep records of all specials purchases

5.5.8 To ensure that for all clinical trials involving medicines, undertaken within the hospital, the appropriate certificates or exemptions are available and that suitable indemnity is in place before the trial starts

5.5.9 It is recommended that pharmacists monitor the prescribing of unlicensed medicines.

5.5.10 Medicines Information to support with any available information in different languages, that may support the service user.

5.6 **Nurses responsibility and duties**

5.6.1 To question the prescriber or pharmacist if an instruction to administer a medicine is thought to be outside the terms of a product licence with regard to its dose, route of administration or other aspect.

5.6.2 Nurses may refuse to administer medicines being used outside the terms of their product licence if that is judged to be in the best interests of the service user. Refusal to administer should not occur solely because a medicine is unlicensed.

6. PROCESS

6.1 It is accepted that the informed use of some unlicensed medicines or licensed medicines for unlicensed applications is sometimes necessary. Absence of a license does not necessarily indicate an absence of evidence for the proposed intervention. A high percentage of products are not licensed for use psychiatry. However, it is accepted practice that unlicensed products are used when appropriate in this group of service users.

6.2 Prescribers are allowed to prescribe unlicensed or off-label medicines in that there is no prohibition. The responsibility for unlicensed or off label prescribing is a matter for the prescriber and must be based on careful assessment of the evidence, available options and the potential risks and benefits. Wherever practicable, licensed products should be used first. As with any other treatment, the prescriber must act in the best interests of the service user when prescribing unlicensed medicines.

6.3 The Drug and Therapeutics Committee has approved a list of medications that have routine unlicensed or off-label uses (Appendix 1). It is accepted that prescribers do not need further approval when prescribing from this list and the Pharmacy service will not routinely contact prescribers in such circumstances.

6.4 Requests for supply of unlicensed medicines not listed in Appendix 1 should be made on the appropriate form (Appendix 2 or 3) indicating that intention to use the unlicensed product for the treatment of an individual service user or for a group of service users.

6.5 Some unlicensed uses of medicines are routinely undertaken by the pharmacy service and so will not usually require completion of unlicensed forms. Examples include use of products from specials manufacturers, preparing segments from licensed medicines, re-packing medicines into dispensing packs or compliance aids, or preparing extemporaneous preparations.

6.6 Prescribing of unlicensed medicines should only follow careful assessment of the evidence, available options, potential risks and benefits of the proposed treatments and only used when the benefits outweigh the risks.

6.7 If the evidence base is limited, advice should be sought from specialists in the area or pharmacy.

6.8 The service user and carers should be fully informed of the unlicensed status of the medicine, perceived benefits and adverse effects.

6.9 In general, no additional steps, beyond those taken when prescribing licensed medicines, are required to obtain the consent of service users (and/or carers) for use of unlicensed medicines.

It should be documented in the case notes whether consent is obtained, not given or not possible.

6.10 A cautious trial of treatment, with monitoring and regular review should be carried out. Full documentation of effectiveness, side effects and tolerance is prudent. If the treatment proves unsuccessful, it should be gradually withdrawn and the reasons documented.

6.11 By law, all adverse drug reactions that occur in service users treated with unlicensed medicines should be reported to the Committee on Safety of Medicines Yellow Card Scheme.

6.12 General practitioners are typically involved in the continuing care of psychiatric out-service users. If asking a general practitioner to prescribe, the GP should be made aware of the unlicensed use and informed of the risks and benefits of treatment. The full agreement of the GP should be sought before transfer of clinical responsibility. Most GPs would be prepared to continue treatments recommended by colleagues, provided the rationale and practical arrangements have been clarified. General practitioners are however under no obligation to take on clinical responsibility.

6.13 Overall the prescriber should take responsibility for prescribing the medicine, informing the service user (or carers), overseeing treatment, monitoring and any follow up treatment, or liaising with general practioners as appropriate.

6.14 A record of the reasons for the unlicensed use and any discussions with service users and consent status should be kept in the case notes.

6.15 When processing prescriptions for unlicensed medicines, the pharmacy should take reasonable steps to establish reason for use and ensuring safe supplies

6.16 Records of unlicensed medicines purchased will be held in the pharmacy department and reviewed by the Drug and Therapeutics Committee. Such records must be kept for a minimum of five years and which should show

The source from which that person obtained the product.
The person to whom and the date on which the sale or supply was made.
The quantity of each sale or supply.
The batch number of the batch of that product from which the sale or supply was made, and,
Details of any suspected adverse reaction to the product so sold or supplied of

6.17 In the case of **clinical trials**, there must be ethical committee approval prior to such trials commencing, the service users written informed consent obtained, and any trials must be under the supervision of a pharmacist together with the service user's consultant psychiatrist.

6.18 **Procedure for unlicensed medicines with no UK license -** If any unlicensed medicine not previously assessed by the D&T committee is prescribed, the pharmacy department will advise the prescriber of the unlicensed status of the product and request that they contact the Chief Pharmacist. Where a prescriber wishes to propose a new unlicensed medicine, an application for its use accompanied by critical evidence based evaluation should be presented to the D&T Committee prior to its use. Urgent requests should be directed to the Chief Pharmacist.

6.19 **Procedure for prescribing licensed medicines for unlicensed uses (off-label use)** - It is recognized that many licensed medicines are used for unlicensed purposes. If a licensed medicine used for unlicensed purposes is not on the approved list then a request for supply should be made on the appropriate form (Appendix 2 or 3) indicating that intention to use the licensed product for the treatment of an unlicensed indication for an individual service user or for a group of service users

7. CONSULTATION

7.1 This version of the policy was reviewed and updated by the trust's Drugs and Therapeutics Committee.

8. TRAINING AND SUPPORT

8.1 Information on unlicensed and off-label use should be included in medical induction, nurse training, medicines update. Clinical pharmacists will highlight the unlicensed medicines policy in their areas of work.

9. MONITORING

9.1 The Medicines Safety Group will oversee the audit local prescribing of unlicensed medicines and report to the trust's Drugs and Therapeutics Committee.

9.2 All request forms will be held in the appropriate pharmacy supplying the service users and will be reviewed on a regular basis

10. EQUALITY AND HUMAN RIGHTS ANALYSIS

Mersey Care NHS
NHS Foundation Trust

Equality and Human Rights Analysis

Title: POLICY AND PROCEDURE FOR USE OF UNLICENSED AND OFF-LABEL MEDICINES
Area covered: TRUST-WIDE

What are the intended outcomes of this work? To ensure that if unlicensed or of label medicines are prescribed they are do so in a safe, effective and appropriate manner.
Who will be affected? Service users

Evidence

What evidence have you considered? Policy information, previous version of the policy, information from The Royal College of Psychiatrists, information from NICE
Disability (including learning disability) Appendices to take in to account prescribing practice in Specialist learning Disabilities Division
Sex No issues
Race Provision of information in different languages, 5.5.10 updated to reflect support from Medicines Information Services. Information leaflet in appendix documents is current available in English only.
Age No issues
Gender reassignment (including transgender) No issues
Sexual orientation No issues
Religion or belief No issues
Pregnancy and maternity No issues
Carers No Issues
Other identified groups None
Cross Cutting All individuals prescribed unlicensed or off-label medicines will be covered by the trust-wide approach as described in the policy and appended documents.

Human Rights	Is there an impact? How this right could be protected?
Right to life (Article 2)	Human rights based approach supported
Right of freedom from inhuman and degrading treatment (Article 3)	Human rights based approach supported
Right to liberty (Article 5)	Human rights based approach supported
Right to a fair trial (Article 6)	Human rights based approach supported
Right to private and family life (Article 8)	Human rights based approach supported
Right of freedom of religion or belief (Article 9)	Human rights based approach supported
Right to freedom of expression **Note: this does not include insulting language such as racism (Article 10)**	Human rights based approach supported
Right freedom from discrimination (Article 14)	Human rights based approach supported

Engagement and Involvement *detail any engagement and involvement that was completed inputting this together.*
All members of the drugs and therapeutics committee were consulted during this revision of the policy.

Summary of Analysis *This highlights specific areas which indicate whether the whole of the document supports the trust to meet general duties of the Equality Act 2010*
Eliminate discrimination, harassment and victimisation The policy creates a clear framework to support the prescribing of unlicensed or off label use of medications. The policy takes in to account all service users and provides clear guidance to trust staff.
Advance equality of opportunity No issues identified
Promote good relations between groups

No issues identified

What is the overall impact?

Creates a clear approach for the use of unlicensed or off label medicines.

Addressing the impact on equalities

N/A

Action planning for improvement

N/A

For the record

Name of persons who carried out this assessment:
L Knowles

Date assessment completed:
29/12/2016

Name of responsible Director:
Dr D Fearnley

Date assessment was signed:

11. Appendices

Appendix 1 List of approved unlicensed and off-label medicines

Appendix 2 Request form for unlicensed medicines – Groups of service users

Appendix 3 Request form for unlicensed medicines – Individual service users

Appendix 4 Request for unlicensed medicine – Pharmacy Letter

Appendix 5 Service user Information Leaflet- Unlicensed and off-label medicines

Appendix 6 Named service user medication record

Appendix 1

List of medicines recognised by the Trust Drugs and Therapeutics Committee as having routine unlicensed uses i.e. unlicensed medicines where there is published information and experience of use and which are endorsed by a respectable, responsible body of professional opinion.

Medicine or Group	**Unlicensed Indication**	**Comments**
Any medicine	Extemporaneous preparations prepared by pharmacy	
Any medicine	Segments prepared by pharmacy	
Antidepressants	Anxiety/Panic disorder	Some are licensed
Antipsychotics	Psychosis other than schizophrenia	
Benzodiazepines	Aggression / Rapid Tranquillisation; Substance misuse	
Benztropine	Extrapyramidal side effects	
Betablockers / Propranolol	Akathisia / Tachycardia	
Clozapine – crushed		No clozaril liquid available Denzapine suspension available
Carbamazepine	Acute Mania; aggressive or impulsive behaviour, addictions	
Clonazepam	Akathisia	
Dihydrocodeine	Opioid dependence	
Hyoscine hydrobromide	Hypersalivation	Kwells
Melatonin	ADHD, Learning disabilities, autism	
Metformin	Antipsychotic-induced weight gain	
Methadone tablets	Opioid dependence	Liquid licensed
Midazolam-Buccal (Epistatus)	Status epilepticus	Buccolam licensed
Omega-3 fatty acids	Schizophrenia	
Pirenzepine	Hypersalivation	
Psychotropics	Behavioural/ psychiatric symptoms in dementia	
Psychotropic medicines (High Dose)	*"the use of high dose antipsychotics should be an exceptional clinical practice and only ever employed when standard treatments, including clozapine, have failed. Documentation of target symptoms, response and side effects, ideally using validated rating scales, should be standard practice so there is on-going consideration of the risk – benefit ratio for the patient. Close physical monitoring (including ECG) is essential.*" Ref Maudsley Guidelines Ed.12	
Sodium Valproate	Bipolar Affective Disorder	Epilim
CNS stimulants Dexamfetamine and methylphenidate	ADHD in adults	
Valproate Semisodium	Bipolar Affective Disorder	Only licensed for acute treatment of manic episodes or continuation of treatment in responsive patients
Zopiclone	Substance misuse	

Mersey Care NHS
NHS Foundation Trust

Appendix 2

PHARMACY DEPARTMENT

REQUEST FOR UNLICENSED MEDICINES
(Use also for Unlicensed Use of Licensed Medicines)

I wish to use .....(Drug/Strength/Form)

in a number of service users in my care for

(Diagnosis).....

I understand that this medicine does not have a UK product license / is not licensed for this purpose***** and that I take full responsibility for this service user.
(A product licence is specific to the form of the preparation. If a tablet is then crushed before administration then the preparation will not have a full UK product license.)

CONSULTANT.....

SIGNATURE.....

DATE.....

I wish to authorise specific medical officers in my team to prescribe this medicine for this service user in future.

PRESCRIBER..... SIGNATURE.....DATE
PRESCRIBER..... SIGNATURE.....DATE
PRESCRIBER..... SIGNATURE.....DATE

Please return completed form to: Pharmacy Services

*Delete where appropriate

Mersey Care NHS
NHS Foundation Trust

Appendix 3

PHARMACY DEPARTMENT

REQUEST FOR UNLICENSED MEDICATION FOR INDIVIDUAL SERVICE USERS
(Use also for Unlicensed Use of Licensed Medicines)

I wish to use .....(Drug/Strength/Form)

for Service users
Name.....

Hospital Number.....

Date of Birth.....

Diagnosis.....

Previous therapy
for this diagnosis.....

Concomitant therapy.....

.....

.....

Proposed dose.....

I understand that this medicine does not have a UK product license / is not licensed for this purpose***** and that I take full responsibility for this service user.
(A product licence is specific to the form of the preparation. If a tablet is then crushed before administration then the preparation will not have a full UK product license.)

CONSULTANT.....

SIGNATURE.....

DATE.....

I wish to authorise specific medical officers in my team to prescribe this medicine for this service user in future.

PRESCRIBER..... SIGNATURE.....DATE
PRESCRIBER..... SIGNATURE.....DATE
PRESCRIBER..... SIGNATURE.....DATE

Please return completed form to:
Pharmacy Services
*** Delete where appropriate**

Appendix 4

Mersey Care NHS
NHS Foundation Trust

PHARMACY DEPARTMENT

REQUEST FOR UNLICENSED MEDICINES

Dear Dr .....

You have asked the Pharmacy to supply

.....

For the treatment of

.....

For

.....

This medicine does not have a U.K. license and the supply is made on a 'named service user' basis.
I wish to remind you that the responsibility for the use of an unlicensed medicine lies with the prescriber. The prescriber is professionally accountable and liable for any harm caused as a result of administration of the medicine, which is not due to a defect in the medicine.

Within this Trust the use of unlicensed medication is restricted to Consultants only.

I would be grateful if you could sign the enclosed declaration and return it to me in the Pharmacy **before** this medicine is obtained.

Should you require any further information regarding this medication or any other unlicensed medication do not hesitate to contact either myself or one of the other Pharmacists.

Yours Sincerely,

Pharmacy Department

Mersey Care NHS
NHS Foundation Trust

Appendix 5 Service user Information Leaflet

INFORMATION ON UNLICENSED AND OFF-LABEL MEDICINES

What is an unlicensed medicine?

In the United Kingdom and Europe, medicines are licensed by an organisation called European Agency for the Evaluation of Medicinal Products. A license is only granted if the medicine is safe and seems to help service users. However, some medicines are not licensed and these are called 'unlicensed' medicines. This does not necessarily mean they are dangerous.

What is off-label use of medicines?

Off-label use is where a medicine is used for a reason not covered by its license. In mental health, medicines are commonly used to treat conditions for which they do not have a license.

Why are medicines used outside their license?

There are many reasons why medicines are sometimes used outside license. Sometimes medicines are unlicensed because there is not enough information into how they work for a particular condition. Sometimes the product license covers a particular illness, but experts know that the medicine works just as well for other conditions. The doses used in drug studies are not enough and so doctors may need to give doses that are higher than those specified on the license, making an unlicensed use. Some medicines may not be licensed simply because they have not been prepared by the manufacturer in the form that is required, for example a liquid may not be available where this is required and it may need to be made up specifically.

Why have I been given this leaflet?

You have been given this leaflet because the medicine prescribed for you is not 'licensed' or is being used for a reason not covered by the license 'off-label). We want to reassure you that your prescriber has thought very carefully before suggesting this medication.

Should I be worried about taking these medicines?

Prescribers and pharmacists have a lot of experience with all medicines whether they are licensed or not. If you are still worried after reading this leaflet, please talk to your prescriber or pharmacist. They are looking after you and have carefully thought about the best medicine for you. If you do not wish to take unlicensed or off-label medicines, talk it over with your prescriber. They can tell you more about the information or advice that they have about the medicine. They can also tell you about the treatments available and why they think this is the best choice.

NAMED SERVICE USER MEDICATION RECORD

PREPARATION:……

Date	Name & Ward of Service user	Directions	Quantity Supplied	P/cist Init	Prescriber	Quantity On order	Quantity Received	Quantity of Stock Destroyed	Notes