The Use of Unlicensed and Off-Label Medicines Policy

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Purpose of Agreement	This Policy sets out the standards for the prescribing, ordering, supply and administration of unlicensed medicines within Solent NHS Trust
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Contents

Amendments Summary:

Amend No	Issued	Page	Subject	Action Date
1	Feb 18	1	Medical Director name changed to Dan Meron	
2	Feb 18	Various	Medicines Committee changed to Medicines Management and Safety Group	
3	Feb 18	4.1 pg 7	Text deleted regarding lack of in house pharmacy	
4	Feb 18	Pg 24,25	Appendix 7 unlicensed drug list removed	

Review Log:

Version Number	Review Date	Lead Name	Ratification Process	Notes
1	May 2018	Raj Parekh	Approved at MMG Feb 18 Submitted to Policy Steering Group	
3	September 2021	Luke Groves	Chair's action approved extension request to December 2021 to allow sufficient time to review	

1. Introduction and Purpose

This Policy sets out the standards which the organization expects its directly and indirectly employed staff to adhere to in relation to the prescribing, supply and administration of unlicensed medicines or medicines used in an off-label way.

The Policy takes account of current legislation, official guidance, recommendations and professional codes of practice. These, however, change with time and all staff has a responsibility to identify where new guidance may conflict with this Policy.

This Policy lays out the key use of unlicensed and off-label medicines. Individual services may then develop local procedures within this framework in consultation with the Chief Pharmacist. The local procedures must be approved by the relevant clinical director, senior practitioner or other suitable professional and the Chief Pharmacist via the organization's Medicines Management and Safety Group.

It is recognized that in some specialties such as pediatrics, there are a significant number of medicines used in an unlicensed way however as their use is covered in recognized pediatric texts, they fall within the lower risk category (see section 5.2)

Failure to follow this policy and procedure or to ensure that there is an adequate risk assessment and evidence base may mean that the prescriber is not indemnified for any liability arising out of the use of that medicinal product.

2. Scope and Definitions

Under the Medicines Act 1968, all medicinal products should be marketed for sale, or supply with an appropriate Marketing Authorization (MA) (formerly known as Product License), although there are exemptions. The MA is intended to guarantee the quality, safety and efficacy of medicinal products and states the indication, dose, and route of administration and the age group of patients for which the drug may be used. To some extent, it places liability on the MA holder for adverse effects arising from the use of their product.

In effect, licensing arrangements apply to pharmaceutical companies, but not prescribers or pharmacists, as the Medicines Act and European legislation make provision for doctors to use either 'off label' or unlicensed medicines. The law allows a pharmacist to dispense medication without an MA or to dispense items to be used outside their product license in response to a prescription.

The use of unlicensed and off label medicines is an area of potentially increased risk, since it means that the MHRA has not examined the risks or benefits of using these drugs for that particular indication.

Where a prescriber prescribes an unlicensed/off label medicine, they are professionally accountable for this judgment in so doing, and may be called upon to justify their actions. Prescribers should satisfy themselves that they could obtain a professional body of support in relation to the unlicensed product.

2.1, Scope

This policy applies to bank, locum, permanent and fixed term contract employees (including apprentices) who hold a contract of employment or engagement with the Trust, and seconded (including students), volunteers (including Associate Hospital Managers), Non-Executive Directors, governors and those undertaking research working within Solent NHS Trust, in line with Solent NHS Trust's Equality, Diversity and Human Rights Policy. It also applies to external contractors, Agency workers, and other workers who are assigned to Solent NHS Trust.

This policy and procedure covers the use within the Trust of the following:

- Unlicensed medicinal products: products that have not received a Marketing Authorization in the UK. These may be imported, or alternatively produced as "Specials" in the U.K. by large reputable companies, small independent companies or within Hospital Pharmacies.

Examples
• Estrogen implants: Imported as no longer commercially available in UK • Melatonin liquid: made as a "special" by commercial manufacturer, and supplied without a license.

A drug may be unlicensed for a variety of reasons for example:

- It is undergoing clinical trials.
- It has been imported from another country.

- It has been prepared extemporaneously (i.e. mixtures made by pharmacists against a prescription, or when products are mixed together before being administered, e.g. mixing a local anesthetic with a steroid prior to injecting a joint.).

- It has been prepared under a specials license (frequently liquid preparations for those with swallowing difficulties, low dose products for children, colour or allergen free formulations).

- Products where the license has been suspended, revoked or not renewed (usually for commercial reasons), but where the company continues to make product available for named individuals, e.g. thalidomide used for leprosy.

- The product is not a medicine but is being used to treat a rare condition (e.g. a metabolic disease)

2.2, Off-Label Prescribing: Licensed products being used outside of the terms of the Marketing Authorization.

This includes prescribing for unlicensed indications, at higher than licensed doses, by routes and to age groups not included in the license, etc. Also included are those situations where the form of a preparation is changed before administration (e.g. tablets need to be crushed, capsules opened, etc.).

Examples:
• *Olanzapine prescribed in excess of the maximum licensed dose of 20 mg per day* *Hyoscine hydrobromide (Kwells) prescribed for hypersalivation Circadin* • *MR being crushed in order for a child to swallow it.*

The use of unlicensed medicinal products in clinical trials is outside the scope of this policy.

3. Unlicensed Medicines – General Statements

Medicines with the appropriate Marketing Authorization should be used to treat patients in preference to unlicensed or off label medicines whenever possible. However, use of unlicensed / off label medicines may be necessary in order to provide the optimum treatment for patients, but they should only be prescribed if their use can be clearly justified from a clinical / pharmaceutical perspective. In some specialties, such as pediatrics, many medicines are prescribed off label due to lack of MA in the pediatric setting.

No ULM or off label medicine should be used routinely in preference to a licensed alternative solely because of cost.

Risk assessment is an integral part of the approval process for the use of ULMs and off label medicines and is a fundamental part of the policy governance arrangements. Application Instruction is provided in Appendix 4 of this document.

Evidence supporting the prescribing and contributing to the risk assessment should be made available as appropriate to those members of staff involved in the prescribing, distribution or administration of an unlicensed/ off label medicine to facilitate awareness of its unlicensed status and effective management of any risks identified.

The decision to prescribe higher risk unlicensed medicines are the responsibility of the consultant or dentist in charge of the patient's care.

Independent prescribers may prescribe unlicensed and off -label medicines, where it is accepted clinical practice or for high risk off label prescribing, within an approved protocol. Supplementary prescribers may prescribe unlicensed medicines within an approved clinical management plan.
Purchasing is the responsibility of the designated pharmacy department for that area and appropriate information surrounding clinical risk assessment and evidence supporting use of the drug may need to be provided by the consultant/lead clinician to the relevant pharmacist prior to procurement.

Medication errors, adverse drug reactions etc. should be reported in the same way as for all other medicines i.e. via Ulysses and the yellow card scheme. Adequate records must be kept regarding the requisition, procurement, supply and administration of unlicensed medicines.

Patients / guardians / carers must be made aware that an unlicensed medicine has been prescribed. They must be given any relevant information and consent must be obtained prior to administration. A sample Patient Information Leaflet is shown in Appendix 3

4. Risk Assessments

Prior to initiating therapy with an unlicensed medicine/off label medicine, the clinician must:

- Assess suitability of licensed alternative agents for the patient
- Be aware of current peer group opinion of treatment options for the patient
- Consider the evidence base for the ULM/ off label medicine
- Consider the risks of the ULM/ off label medicine including route of administration, possible side-effects, contraindications and precautions which may be required when using the medicine e.g. intrathecal and epidural routes are, by their very nature, higher risk and side-effects are more likely to be severely disabling /life threatening. (see below)
- Weigh up the risk / benefit to the patient or patient group in the proposed setting. Higher risk medicines require prior approval documentation

4.1, Risk Assessments

In order to ensure a workable yet practical system for the use of unlicensed medicines is in place within Solent NHS Trust, all requests for new medicines which fall into the higher risk category must have a risk assessment & request for unlicensed product form completed and reviewed by the Medicines Management and Safety Group prior to use.

From a clinical perspective all unlicensed medicines can be considered as more risky than licensed products and treated accordingly. Products, which have had their marketing authorization revoked due to concerns over product quality and/or safety, must be considered as “very high” risk. An extensive assessment will be required in each individual case to weigh up risk versus patient benefit before use of the product.

Unlicensed medicines/off label medicines used in Solent NHS Trust should be assessed whether they are higher or lower risk.

4.2, Lower Risk Category

This group of unlicensed medicines consists of a range of medicines that meet all of the following criteria:

- Medicines licensed for the same indication and the same route in a country with mutual recognition from the MHRA1 or are licensed in the USA (with the availability of Transmissible Spongiform Encephalopathy Statement) and are either provided in English language or purchased pre-labeled in English language according to national Quality Assurance Standards2.

Or

- Batch produced medicines procured from NHS units holding Specials manufacturing license, or other UK Specials license holders.

- Are considered to be of a suitable pharmaceutical quality.

Medications whose unlicensed use is supported by the latest version of following texts are considered lower risk provided the prescribing information in that text is followed:

- British National Formulary
- British National Formulary for Children
- Medicines for Children
- Palliative Care Formulary
- SIGN Guidelines
- Antibiotic guidelines Hampshire & Isle of Wight
- NICE Guideline
- BAP Guidelines – British Association of Psychopharmacology
- BASHH - British Society for Sexual Health & HIV
- Faculty of Sexual Health
- BHIVA – British HIV Association
- BDA – British Dental Association Guidelines
- Crushing Medication where this is supported by standard PEG administration guides
- Maudsley Guidelines
- Psychotropic Handbook

4.3, **Higher Risk Category**

Unlicensed medicines that are not classified as lower risk would automatically default to the higher risk category. This category will include the following:

- Medicines obtained from out with the EU or from manufacturers without a license and off-label use of products where consensus does not support their use. Unlicensed medicines given via high risk routes such as intrathecal.

- Medicines licensed in the UK or in a mutually recognized country1 and the USA where the intended route of administration is different from that included in the license.

- Medicines imported from countries without mutual recognition.

- Medicines labeled in a foreign language.

- "One-off" medicines procured from NHS units holding a Specials Manufacturing license or other UK Specials license holder i.e. not batch produced.

- Written patient consent is required. Medicine specific patient information must be supplied.

The Medicines Management and Safety Group will review all requests to initiate higher risk unlicensed /off-label medicines and will also advice on whether such medicines are suitable for prescribing within primary care. A database has been developed (appendix 6) detailing all unlicensed medicines currently in use and their risk category.

5. Patient Information & Consent

Patients and, where appropriate, carers have the right to participate in the making of properly informed decisions about their health care. Wherever possible, patients should be made aware that they are being prescribed an unlicensed or off label medicine and that this may increase the risks associated with treatment because there is less information available with regard to efficacy and side effects in the off label and unlicensed setting. In addition, the quality of manufacture etc., of unlicensed medicines is more difficult to establish. The MHRA recommends that prescribers should provide patients/ carers with the following:-

Sufficient information about the proposed treatment, including known serious or common adverse reactions, to enable them to make an informed decision
Where current practice supports the use of a medicine outside the terms of its license, it may not be necessary to draw attention to the license when seeking consent. However, it is good practice to give as much information as patients or carers require or which they may see as relevant
Explain the reasons for prescribing a medicine off-label or prescribing an unlicensed medicine where there is little evidence to support its use, or where the use of a medicine is innovative. This must be fully documented in the patient's notes

There are patient information sheets for the adult unlicensed medicines (appendix 3) - Prescribers MUST advise patients/ carers that they are being treated with an unlicensed medicine.

5.1, Off Label Medicines

It is good practice when starting a patient on any new form of therapy that benefits and significant side effects are discussed. In the 'high risk' setting this discussion should be documented and consent (verbal/ written) obtained.

6. Primary Care

Medicines are frequently used off label in pediatric specialties and there are a number of unlicensed medicines also in common usage. The dosage, side-effects, monitoring etc. of these drugs for each indication will be well known to Solent medicines management and medical/dental staff and be documented in the patient's notes.

However, the primary care team may not be familiar with the use of the agent at all, or not in the setting for which it is being used. Unless adequate information is supplied to the primary care team errors in dosing, response assessment etc. can be made, particularly where drugs are used off label as, although information will be readily available from sources such as the BNF it may not be applicable to the current setting.

Where it is intended that either unlicensed or off label treatment will be continued after patient discharge, clear arrangements MUST be agreed between primary and secondary care regarding clinical, prescribing and dispensing responsibilities. A decision on final responsibility should depend primarily on the best interests of the patient in terms of safety and convenience. However, General Practitioners are at liberty to refuse to prescribe within primary care if they have not been given sufficient information to prescribe safely or that this is outside their level of expertise.

Where initiation of treatment with an off label medicine/ unlicensed medicine occurs in a specialist Solent setting, the consultant/practitioner recommending the medicine is responsible for ensuring that appropriate information is provided to the GP and arrangements are made, for relevant information to be passed on to community pharmacists.

In general, General Practitioners should not be expected to prescribe any unlicensed medicines as defined by the policy. However, there may be circumstances where this is considered by both clinicians to be in the patient's best interests. The Medicines Management Team must be involved in this process to ensure continuity of supply.

General Practitioners can be asked to continue to prescribe off label medicines i.e. used outside their license indications e.g. amitriptyline for neuropathic pain. However, within the intermediate and high risk categories, off label prescribing is best done where there is a written protocol for use. These instances must be discussed with the GP on a case by case basis.

The Solent specialist who has initiated treatment with the unlicensed / off label medicine is responsible for ensuring that the relevant General Practitioner is given sufficient information about the product. The following information should be provided:-

- Name of Drug
- Dose and formulation
- Licensed status of drug
- Reason for prescribing
- Monitoring requirements if any
- Duration of treatment
- Common side effects

7. Safe and Secure Handling of Unlicensed Medicines

It is a requirement of Guidance Note 14 (Medicines and Healthcare Products Regulation Agency) that all patients receiving unlicensed medicines can be identified and that the use of that medicine can be accounted for.

Whilst this is straightforward if an unlicensed medication is dispensed individually from a pharmacy, this is

less straightforward if medication is held as ward/clinic stock. In these cases records must be made at ward/clinic level and stored securely for 8 years.

Where specials are held as ward/clinic stock within the Trust, the service clinical director will be supplied with an up to date list of these products and will be asked to authorize the use of these products by clinicians within their directorate (see appendix 5)

8. Non-Medical Prescribers - Unlicensed Medicines

All Independent Prescribers (V300) are permitted to prescribe unlicensed medicines (MHRA April 2012).

Non-medical prescribers (NMP) may prescribe an unlicensed medication as a Supplementary prescriber as part of a clinical management plan providing:

- The doctor/dentist and, NMP acting as a supplementary prescriber, have agreed the plan with the patient/client in a voluntary relationship
- The NMP is satisfied an alternative, licensed medication would not meet the patient/client's need
- The NMP is satisfied there is a sufficient evidence base and/or experience to demonstrate the medications safety and efficacy for that particular patient/client
- The doctor/dentist is prepared to take the responsibility for prescribing the unlicensed medicine and has agreed the patient/client's clinical management plan to that effect
- The patient/client agrees to a prescription in the knowledge that the drug is unlicensed and understands the implications of this
- The medication chosen and the reason for choosing it is documented in the clinical management plan

8.1, Off-label Prescribing

There are a number of circumstances in which independent V300 NMPs may prescribe licensed medicines for the purposes for which they are not licensed (this is most likely to be the case when prescribing for children). It is possible under current legislation for non-medical prescribers to prescribe off-label as independent prescribers. However in order to do so the NMP must ensure the following conditions are met:

- NMP is satisfied that it would better serve the patient/client's needs than an appropriately licensed alternative
- NMP is satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy. Where the manufacturer's information is of limited help, the necessary information must be sought from another source in line with guidance in this policy.
- NMP should explain to the patient/client, or parent/carer, in broad terms, the reasons why medicines are not licensed for their proposed use.
- NMP makes a clear, accurate, and legible record of all medicines prescribed and the reasons for prescribing an 'off-label' medicine.

NMPs who are supplementary prescribers may prescribe a medicine for use outside the terms of its license providing:

- There is a clinical management plan in place, written in conjunction with the doctor/dentist and in voluntary partnership with the patient/client or parent/carer

- A doctor/dentist takes responsibility for prescribing the medicine and you jointly oversee the patient/clients care, monitor and ensure any follow-up treatment is given as required.

Further information is available in the Non-Medical Prescribing Policy

V100 prescribers may not prescribe unlicensed/off-label medicines apart from Nystatin in neonates

8.2, Dispensing

Pharmacy staff involved in the dispensing of unlicensed medicines will ensure that requests for unlicensed medicines are processed in accordance with Trust procedures. This will include the following:

- where appropriate, communicate with patients the implications of using the unlicensed medicine
- if appropriate, make arrangements for patients to have continuing supplies of treatment
- make appropriate records of supply
- ensure an English translation (or equivalent) patient information leaflet is issued with all unlicensed medicines where available
- communicate clearly and in a timely manner with the patient and prescriber on the procurement, availability and supply of the unlicensed medicine

9. Monitoring Policy Effectiveness

The responsibility for monitoring this policy will be vested in the Chief Pharmacist.

A suggested audit template is included below. The organization's Chief Pharmacist will ensure periodic assessment of compliance with this policy through this audit and report outcomes to the Medicines Management and Safety group.

The effectiveness of this policy will be reviewed by the Medicines Management and Safety Group and will be discussed prior to the stipulated review timeframe at the Medicines Committee meeting. Details of these discussions will be documented in the minutes.

The policy will also be monitored through various other methods including adverse incident reporting, significant event review, other medicines management audits and clinical prescribing audits, as required and agreed on a regular basis. Audits will be completed on an annual basis.

Quality Improvement and Risk (QIR) will be responsible for overseeing risk management and clinical or corporate governance issues.

The policy will be assessed by the Policy Steering Group who will review the policy and any updates being presented to the Group to ensure that they conform to Trust procedures and format. This Group will determine subsequent ratifying groups that the policy should be presented to.

9.1, **Audit**

	Monitoring and audit			
	Method	By	Committee	Frequency
Monitoring Trust Approval & Documentation	An audit will be undertaken of all forms submitted to Medicines Committee during previous year	Medicines Management Team	Medicines Management Committee	Annually

10. Review

This Policy may be reviewed at any time at the request of either staff side or management, but will automatically be reviewed after 3 year

11. References/Bibliography

The Medicines Act (1968)

12. Links with Other Policies/Procedures

Adverse Event Reporting Policy
Deprivation of Liberty Safeguards and Mental Capacity Act Policy
Consent to Examination and Treatment Policy
Non-Medical Prescribing Policy
Medicines Policy

13. Glossary of Terms

BNFc – British National Formulary for Children MA – Market Authorization
MHRA – Medicines & Healthcare Products Regulatory Authority PEG- Percutaneous Endoscopic Gastrostomy
ULM – Unlicensed medicine

Appendix: 1 Equality Impact Assessment

Step 1 – Scoping; identify the policies aims	Answer		
1. What are the main aims and objectives of the document?	This policy sets out the standards for the care and control, prescribing, supply, storage and administration of unlicensed medicines within the organization.		
2. Who will be affected by it?	All staff employed directly and indirectly by the organization whose work involves them in any way with ordering, prescribing, dispensing, supplying, transporting, administering, storing or disposing of unlicensed medicines.		
3. What are the existing performance indicators/measures for this? What are the outcomes you want to achieve?	That all staff refers to the policy and follow all the principles it contains with regard to the use and handling of unlicensed medicines.		
4. What information do you already have on the equality impact of this document?	None		
5. Are there demographic changes or trends locally to be considered?	No		
6. What other information do you need?	None		
Step 2 - Assessing the Impact; consider the data and research	Yes	No	Answer (Evidence)
1. Could the document unlawfully discriminate against any group?		X	This policy is to ensure equality of access to unlicensed medicines across the organization in safe and effective manner. It applies equally to all groups.
2. Can any group benefit or be excluded?		X	This policy specifies the safe and effective use of unlicensed medicines equally to all groups, albeit that some requirements are specific to certain care settings, e.g. in community nursing.
3. Can any group be denied fair & equal access to or treatment as a result of this document?		X	This policy specifies the safe and effective use of unlicensed medicines equally to all groups, albeit that some requirements are specific to certain care settings, e.g. in community nursing.
4. Can this actively promote good relations with and between different groups?	X		All groups are treated equally within this policy and gives opportunity for shared training and learning.
5. Have you carried out any consultation internally/externally with relevant individual	X		Policy is formed by circulating widely to service

groups?			managers and the Medicines Management team.
6. Have you used a variety of different methods of consultation/involvement		X	Not necessary – most policy based on legislation.
Mental Capacity Act implications			
7. Will this document require a decision to be made by or about a service user? (Refer to the Mental Capacity Act document for further information)			Does not involve individual patients directly. Areas specific to Mental Capacity Act are dealt with according to best practice and legislation.
External considerations			
8. What external factors have been considered in the development of this policy?		X	
9. Are there any external implications in relation to this policy?		X	
10. Which external groups may be affected positively or adversely as a consequence of this policy being implemented?			None

If there is no negative impact – end the Impact Assessment here.

Step 3 - Recommendations and Action Plans	Answer
1. Is the impact low, medium or high?	
2. What action/modification needs to be taken to minimize or eliminate the negative impact?	
3. Are there likely to be different outcomes with any modifications? Explain these?	
Step 4- Implementation, Monitoring and Review	Answer
1. What are the implementation and monitoring arrangements, including timescales?	
2. Who within the Department/Team will be responsible for monitoring and regular review of the document?	
Step 5 - Publishing the Results	Answer
How will the results of this assessment be published and where? (It is essential that there is documented evidence of why decisions were made).	

Retain a copy and also include as an appendix to the document

Appendix 2 – Extract Of GMC Advice to Doctors Regarding Unlicensed Medicines

Prescribing unlicensed medicines

You can prescribe unlicensed medicines but, if you decide to do so, you must:
Be satisfied that an alternative, licensed medicine would not meet the patient's needs
Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy
Take responsibility for prescribing the unlicensed medicine and for overseeing the patient's care, including monitoring and any follow up treatment (see also paragraphs 25-27 on prescribing for hospital outpatients)
Record the medicine prescribed and, where you are not following common practice, the reasons for choosing this medicine in the patient's notes.

Prescribing medicines for use outside the terms of their license (off label)

You may prescribe medicines for purposes for which they are not licensed. Although there are a number of circumstances in which this may arise, it is likely to occur most frequently in prescribing for children. Currently pharmaceutical companies do not usually test their medicines on children and as a consequence, cannot apply to license their medicines for use in the treatment of children. The use of medicines that have been licensed for adults, but not for children, is often necessary in pediatric practice.
When prescribing a medicine for use outside the terms of its license you must:
Be satisfied that it would better serve the patient's needs than an appropriately licensed alternative
Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy. The manufacturer's information may be of limited help in which case the necessary information must be sought from other sources
Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring and any follow up treatment, or arrange for another doctor to do so
Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing the medicine.

Information for patients about the license for their medicines

You must give patients, or those authorizing treatment on their behalf, sufficient information about the proposed course of treatment including any known serious or common side effects or adverse reactions. This is to enable them to make an informed decision (for further advice, see Consent: patients and doctors making decisions together).
Some medicines are routinely used outside the scope of their license, for example in treating children. Where current practice supports the use of a medicine in this way it may not be necessary to draw attention to the license when seeking consent. However, it is good practice to give as much information as patients, or those authorizing treatment on their behalf, require or which they may see as significant. Where patients, or their carers express concern you should also explain, in broad terms, the reasons why medicines are not licensed for their proposed use. Such explanations may be supported by written information, including the leaflets on the use of unlicensed medicines or licensed medicines for unlicensed applications in pediatric practice produced by the Royal College of Pediatrics and Child Health/Neonatal and Pediatric Pharmacists Group Standing Committee on Medicines.

However, you must explain the reasons for prescribing a medicine that is unlicensed or being used outside the scope of its license where there is little research or other evidence of current practice to support its use, or the use of the medicine is innovative.
For specific information on prescribing medicines for children see the websites of the Royal College of Pediatrics and Child Health and the British National Formulary for Children.

Responsibility for prescribing medicines for hospital outpatients

Where a patient's care is shared between clinicians, the doctor with the responsibility for the continuing management of the patient must be fully competent to exercise their share of clinical responsibility. They also have a duty to keep themselves informed about the medicines that are prescribed for their patient. They should take account of appropriateness, effectiveness and cost when prescribing any medicine. They should also keep up to date with any relevant guidance on the use of the medicine and on the management of the patient's condition.
If you are the doctor signing and issuing the prescription you bear responsibility for that treatment; it is therefore important that, as the prescriber, you understand the patient's condition as well as the treatment prescribed and can recognize any adverse side effects of the medicine should they occur.
There should be full consultation and agreement between general practitioners and hospital doctors about the indications and need for particular therapies. The decision about who should take responsibility for continuing care or treatment after initial diagnosis or assessment should be based on the patient's best interests rather than on the healthcare professional's convenience or the cost of the medicine.
For specific information on prescribing medicines for children see the following websites: Royal College of Pediatrics and Child Health www.rcpch.ac.uk and the British National Formulary www.bnf.org.

Appendix 3 Patient Information Leaflet

ADULT INFORMATION LEAFLET

What is this leaflet about?
In the UK most medicines are 'licensed' but some are not. This leaflet explains why medicines are licensed and why some useful medicines do not have licenses.

You will have been given this leaflet by your doctor, dentist or pharmacist because the medicine prescribed is not 'licensed' or is being used for a reason not covered by the license. We want to reassure you that your clinician has thought very carefully about the best medicine for you and to answer any questions you may have.

Why are medicines 'licensed'?
The makers of medicines must ask the government for a 'Product License or Marketing Authorization' if they want to sell their medicine in the UK. They show the government's Medicines and Healthcare Products Regulatory Agency (MHRA) that their medicine works for the illnesses to be treated, does not have too many side effects or risks and has been made to a high standard.

How do the makers test medicines?
To be sure that a medicine works and is safe the maker has to try it first on a small number of people in what is called a 'clinical trial'. Information from clinical trials such as side effects and effectiveness is given to the MHRA when the maker asks for a Product License.

Why don't all medicines have a license?
There are several reasons why some medicines are used for illnesses or conditions not covered by their original license. Also, some medicines do not have a license at all. Sometimes the clinical trial (and so the license or authorization) is for one illness but doctors find that the medicine works very well for another illness for which it does not have a product license. However, there will be clinical evidence to support the use of this medicine for your condition that your doctor will discuss with you. Some medicines do not have a license at all.
This may be because it may be too expensive to have a clinical trial or the illness is too rare to have a clinical trial. Sometimes it is because the medicine has not yet been given a product license/marketing authorization and is still being tested. In this setting your doctor will discuss the information about the drug and discuss with you why this drug is more suitable for you than a medicine with a product license.

Appendix 4 Unlicensed Medicines for Children

There is a PDF available for download from the following link from Medicines for Children which partners with the Royal College of Pediatrics and Child Health
http://www.medicinesforchildren.org.uk/search-for-a-leaflet/unlicensed-medicines/

Appendix 5: Unlicensed Medicines Request Form

Unlicensed Medicine Request – Higher risk medicines	Solent NHS NHS Trust

INTRODUCTION

This form should be completed by the prescriber / supporting pharmacist for all requests to use a higher risk unlicensed medicine for individuals or groups of patients.
The prescriber must take full responsibility for the use of the unlicensed medicine.
The patient must be informed and consent to receiving an unlicensed medicine and this must be documented in the patient's medical records.

Section 9 of the Medicines Act 1968 permits the use of an unlicensed medicine on a named patient basis. A Doctor prescribing an unlicensed medicine does so entirely on his/her own responsibility.

Prescribing of an unlicensed medicine may have medico-legal implications. The supplying pharmacy will take all possible steps to ensure the quality and safety of the unlicensed medicine but this cannot be guaranteed.

SECTION 1: DETAILS OF SUBMITTING CLINICIAN / SUPPORTING PHARMACIST

Requesting Clinician:	
Service Line / Specialty:	
Designation:	
Clinical Director	Yes / No

SECTION 2: MEDICINE DETAILS

Medicine Name:	
Formulation:	
Strength:	
Indication:	
Dose:	
Supplier:	
Anticipated duration of treatment:	
No. of patients likely to require treatment p.a.:	
Cost (annual cost, or cost for one of course of treatment if duration likely to be less than 12 months):	(Tick which one applies) Annual cost Course of treatment

Prescribing to be by (For boxes 1-4, tick one box which applies):

Suitable for prescribing / initiation in primary care	
Initiation restricted to or on the advice of a specialist	
Specialist / Consultant use only	
Restricted to Hospital/clinic use only	

To be used in accordance with protocol (attach a copy of the protocol with the submission) ☐

SECTION 3: EVIDENCE FOR UNLICENSED MEDICINE

Clinical Evidence (attach relevant references)

Provide a summary of the key evidence for the use of this medicine e.g. guidelines, peer support, on advice of a specialist

SECTION 4: PLACE IN THERAPY / ALTERNATIVE TREATMENT OPTIONS

Explain why the unlicensed medicine would be the best option. What are the advantages of this medicine compared to other medicines listed in the local Formulary; medicines already licensed for the same indication or used off-label for this indication.

SECTION 5: SERVICE IMPLICATIONS e.g. specialist assessment, monitoring requirements, blood tests, pharmacy time, nursing time,

SECTION 6: COMPARATIVE SAFETY

SECTION 7: OTHER INFORMATION

State any other information which may assist in the decision making process

SECTION 8: DECLARATION OF INTEREST (IN THE LAST 12 MONTHS ONLY)

It is important that any interests in pharmaceutical companies that may be relevant to this submission are declared. Please complete this section regardless of whether you have any declared interests or not. (See separate information sheet).

Clinician Declaration of Interest	
I have an interest in the following pharmaceutical companies that are relevant to this application -	
Current Personal Interests (shares, consultancy fees etc.):	
Non-Personal Interests (department resources, sponsorship etc.):	
Clinician's Signature	
Date	

Send the completed form and any supporting evidence to:
Chief Pharmacist, Medicines Management team, Western Community Hospital, William Macleod Way, Southampton SO16 4XE

FOR USE BY THE MEDICINES COMMITTEE		
Final decision	Date discussed at MMC	Rationale behind decision

Appendix 6 List of Unlicensed Medicines for Wards/Clinics

List of Unlicensed Medicines for Wards/Clinics

I hereby sign that I have approved the use of the attached list of unlicensed medicines for the wards/clinics indicated and that all of the prescribers within service are aware of the legal status of these medicines.

_____

I understand that records must be kept at ward/clinic level of all patients who receive and unlicensed medicine.

Name of Clinical Director _____

Signature of Clinical Director _____

Date _____

Please return to Medicines Management Team, St. Mary's Hospital, Milton Road, Portsmouth PO3 6AD

Note** In using an unlicensed drug or a drug in a way incompatible with the product specification, the doctor must act responsibly and with reasonable care and skill. When prescribing outside a license it is important that the doctor does so knowingly, recognizing the responsibility that such prescribing entails and when obtaining consent to treatment should, where possible tell the patient of the drug's license status and document all the above in the health record. If such prescribing falls outside local or national guidelines the patient's consent must be recorded. The unlicensed form is to be used when it is not accepted practice or supported by national guidance.

Appendix 7 - Prescribing Of High Dose Antipsychotics in Mental Health Services

Prescribers should also refer to the Solent NHS Trust Unlicensed Medicines Policy once the maximum BNF dose of a drug is exceeded it becomes unlicensed.
This means that the prescriber is professionally accountable and liable for any harm caused by the drug. High dose-antipsychotics can be defined as either a single antipsychotic which exceeds the daily BNF maximum or a combination of antipsychotics which exceed the maximum daily dose using the percentage method. Research has not shown any benefits or efficacy of high dose antipsychotics, but there is evidence of increased adverse effects and drug interactions. Because of these risks high-dose antipsychotics should only be used when:

Evidence-based strategies have failed for the individual patient

The patient has been involved in, and informed of the decision to use high-dose antipsychotics, and consent has been documented in SystmOne

There has been an MDT discussion, and consultant involvement, before the high-dose antipsychotic is started

The use of high-dose antipsychotics has been authorized by the consultant responsible for the patient who is aware of the legal implications and liability of prescribing off – license

High-dose antipsychotics should not be used in rapid tranquilization

The decision to prescribe high-dose antipsychotics should be documented in SystmOne, including risks and benefits of the strategy, aims, and how outcome will be assessed