The Use of Unlicensed and Off-Label Medicines Policy

Solent NHS Trust policies can only be considered to be valid and up to date if viewed on the intranet. Please visit the intranet for the latest version.

Purpose of Agreement	This Policy sets out the standards for the prescribing, ordering, supply and administration of unlicensed medicines within Solent NHS Trust
Document Type	X Policy
Reference Number	Solent NHST/Policy/ MMT009
Version	Version 4
Name of Approving Committees/Groups	Policy Steering Group, Medicines Management Group, Clinical Executive Group
Operational Date	November 2021
Document Review Date	November 2024
Document Sponsor (Job Title)	Chief Medical Officer
Document Manager (Job Title)	Chief Pharmacist
Document developed in consultation with	Solent NHS Trust Medicines Management Group
Intranet Location	Business Zone > Policies, SOPs and Clinical Guidelines
Website Location	FOI policies
Keywords (for website/intranet uploading)	Medicines, Administration, Prescribing, Medicines Management, unlicensed medicines, Policy, MMT009

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	Sept 2021	Luke Groves	Chair's action approved extension request to December 2021 to allow sufficient time to review	
4	Sept 2021	Luke Groves	Approved at MMG Sept '21 then submitted to policy steering group	

1. Introduction and Purpose

1.1. This policy sets out the standards which the organisation 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.

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

1.3. This policy lays out the key use of unlicensed and off-label medicines. Individual service lines may then develop local operating procedures for unlicensed and off-label medicines 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 organisation's Medicines Management Group.

1.4. It is recognised that in some specialties such as paediatrics, there are a significant number of medicines used in an unlicensed way however as their use is covered in recognised paediatric texts, they fall within the lower risk category (see section 4.5)

1.5. 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

2.1. Under the Medicines Act 1968, all medicinal products should be marketed for sale, or supply with an appropriate Marketing Authorization (MA), 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 medicine may be used. To some extent, it places liability on the MA holder for adverse effects arising from the use of their product.

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

2.3. The use of unlicensed and off label medicines is an area of potentially increased risk since it means that the Medicines and Healthcare Products Regulatory Agency (MHRA) has not examined the risks or benefits of using these medicines for that particular indication.

2.4. 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.

Scope

2.5. This policy applies to locum, permanent, and fixed term contract employees (including apprentices) who hold a contract of employment or engagement with the Trust, and secondees (including students), volunteers (including Associate Hospital Managers), bank staff, Non-Executive Directors 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.

2.6. Solent NHS Trust is committed to the principles of Equality and Diversity and will strive to eliminate unlawful discrimination in all its forms. We will strive towards demonstrating fairness and Equal Opportunities for users of services, carers, the wider community and our staff.

2.7. **This policy and procedure addresses the use within the Trust of the following:**

- Unlicensed medicinal products: products that have not received a MA 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 licence

2.8. **A medicine 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 licence (frequently liquid preparations for those with swallowing difficulties, low dose products for children, colour or allergen free formulations).
- Products where the licence has been suspended, revoked or not renewed (usually for commercial reasons), but where the company continues to make the 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)

Off-Label prescribing: Licensed products being used outside of the terms of the MA

2.9. This includes prescribing for unlicensed indications, at higher than licensed doses, by routes and to age groups not included in the licence, 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 more than 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

3.1. Medicines with the appropriate MA 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 paediatrics, many medicines are prescribed off-label due to lack of MA in the paediatric setting.

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

3.3. Risk assessment is an integral part of the approval process for the use of unlicensed medicines and off-label medicines and is a fundamental part of the policy governance arrangements. Application instruction is provided in Appendix 5 of this document.

3.4. 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.

3.5. The decision to prescribe higher risk unlicensed medicines is the responsibility of the lead clinician (eg. Consultant, associate specialist or dentist) in charge of the patient's care.

3.6. 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.

3.7. 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 medicine may need to be provided by the consultant/lead clinician to the relevant pharmacist prior to procurement.

3.8. 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.

3.9. Patients / guardians / carers must be made aware that an unlicensed medicine has been prescribed. They must be given any relevant information (summary of the information and form in which provided should be documented) and consent must be obtained prior to administration. A sample Patient Information Leaflet is shown in Appendix 3 which if helpful may be used or adapted by specific services.

4. Risk Assessments

4.1. 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 unlicensed/ off-label medicine
- Consider the risks of the unlicensed/ 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.

Risk Assessments

4.2. 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 (appendix 5) completed and reviewed by the Medicines Management Group prior to use.

4.3. From a clinical perspective all unlicensed medicines can be considered as more risky than licensed products and treated accordingly. Products, which have had their MA 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.

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

Lower Risk Category

4.5. 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 MHRA or are licensed in the USA (with the availability of Transmissible Spongiform Encephalopathy Statement) and are either provided in English language or purchased pre-labelled in English language according to national Quality Assurance Standards.

Or

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

- Are of a suitable pharmaceutical quality.

- Medicines that are being used for HDAT (High Dose Antipsychotic Therapy) where the form in SystmOne has been completed and ongoing monitoring is in place.

4.6. 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 Association for Sexual Health & HIV
- FSRH - Faculty of Sexual and Reproductive Healthcare
- BHIVA – British HIV Association
- BDA – British Dental Association Guidelines
- Crushing Medication where this is supported by standard PEG administration guides
- Maudsley Guidelines
- Psychotropic Handbook

4.7. Unlicensed medicines that have prior approval by the relevant clinical service lines within Solent NHS Trust are listed in Appendix 8. These medicines do not require separate risk assessments or authorization prior to being dispensed.

Higher Risk Category

4.8. 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 outside the EU or from manufacturers without a licence 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 recognised country and the USA where the intended route of administration is different from that included in the licence.

- Medicines imported from countries without mutual recognition.

- Medicines labelled in a foreign language.

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

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

4.9. The Medicines Management Group will review all requests to initiate higher risk unlicensed /off- label medicines and will also advise on whether such medicines are suitable for prescribing within primary care. A database has been developed and managed by the medicines management team detailing all unlicensed medicines currently in use and their risk category.

5. Patient Information & Consent

5.1. 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 licence, 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

5.2. 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.

Off-Label Medicines

5.3. 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

6.1. Medicines are frequently used off-label in paediatric 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.

6.2. However, primary care 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 British National Formulary (BNF) it may not be applicable to the current setting.

6.3. 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.

6.4. 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 General Practitioner and arrangements are made, for relevant information to be passed on to community pharmacists.

6.5. 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.

6.6. General Practitioners (GP) can be asked to continue to prescribe off-label medicines i.e. used outside their licence 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.

6.7. The Solent specialist who has initiated treatment with the unlicensed / off-label medicine is responsible for ensuring that the relevant GP 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

7.1. 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.

7.2. 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.

7.3. 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 authorise the use of these products by clinicians within their directorate (see appendix 5)

8. Non-Medical Prescribers - Unlicensed Medicines

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

8.2. 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 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

Off-label Prescribing

8.3. There are several 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, 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.

8.4. NMPs who are supplementary prescribers may prescribe a medicine for use outside the terms of its licence 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

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

Dispensing

8.6. 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, plan 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

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

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

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

9.4. 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.

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

9.6. 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.

Audit

	Monitoring and audit			
	Method	By	Committee	Frequency
Monitoring & Documentation	All forms submitted to the Medicines Management Group will be reviewed each year and the quality of information provided reviewed.	Medicines Management Team	Medicines Management Group	Annually

10. Review

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

11. References/Bibliography

- The Medicines Act (1968)

12. Links with Other Policies/Procedures

- Incident Reporting, Investigation and Learning Policy
- Liberty Protection of 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

Appendix: 1 Equality Impact Assessment

Equality Analysis and Equality Impact Assessment

Equality Analysis is a way of considering the potential impact on different groups protected from discrimination by the Equality Act 2010. It is a legal requirement that places a duty on public sector organisations (The Public Sector Equality Duty) to integrate consideration of Equality, Diversity and Inclusion into their day-to-day business. The Equality Duty has 3 aims, it requires public bodies to have due regard to the need to:

- **eliminate unlawful discrimination**, harassment, victimisation and other conduct prohibited by the Equality Act of 2010;
- **advance equality of opportunity** between people who share a protected characteristic and people who do not;
- **foster good relations** between people who share a protected characteristic and people who do not.

Equality Impact Assessment (EIA) is a tool for examining the main functions and policies of an organisation to see whether they have the potential to affect people differently. Their purpose is to identify and address existing or potential inequalities, resulting from policy and practice development. Ideally, EIAs should cover all the strands of diversity and Inclusion. It will help us better understand its functions and the way decisions are made by:

- **considering the current situation**
- **deciding the aims and intended outcomes of a function or policy**
- **considering what evidence there is to support the decision and identifying any gaps**
- **ensuring it is an informed decision**

Equality Impact Assessment (EIA)

Step 1: Scoping and Identifying the Aims		
Service Line / Department	Medicines management	
Title of Change:	Review and update of unlicensed medicines policy	
What are you completing this EIA for? (Please select):	Policy	*(If other please specify here)*
What are the main aims / objectives of the changes	To update for current legislation and professional standards	

Step 2: Assessing the Impact

Please use the drop-down feature to detail any positive or negative impacts of this document /policy on patients in the drop-down box below. If there is no impact, please select "not applicable":

Protected Characteristic	Positive Impact(s)	Negative Impact(s)	Not applicable	Action to address negative impact: *(e.g. adjustment to the policy)*
Sex			x	
Gender reassignment			x	
Disability			x	
Age			x	
Sexual Orientation			x	
Pregnancy and maternity			x	
Marriage and civil partnership			x	
Religion or belief			x	
Race			x	

If you answer yes to any of the following, you MUST complete the evidence column explaining what information you have considered which has led you to reach this decision.

Assessment Questions	Yes / No	Please document evidence / any mitigations
In consideration of your document	Yes	Internally with professional colleagues in mental

development, did you consult with others, for example, external organisations, service users, carers or other voluntary sector groups?)		health services and across entire Trust through medicines management group.
Have you taken into consideration any regulations, professional standards?	Yes	GMC, Medicines Act, General Pharmaceutical Council

Step 3: Review, Risk and Action Plans			
How would you rate the overall level of impact / risk to the organisation if no action taken?	Low	Medium	High
	■	☐	☐
What action needs to be taken to reduce or eliminate the negative impact?	None		
Who will be responsible for monitoring and regular review of the document / policy?	Chief Pharmacist		

Step 4: Authorisation and sign off

I am satisfied that all available evidence has been accurately assessed for any potential impact on patients and groups with protected characteristics in the scope of this project / change / policy / procedure / practice / activity. Mitigation, where appropriate has been identified and dealt with accordingly.

Equality Assessor:	*Luke Groves*	*Date:*	*14th September 2021*

Additional guidance

Protected characteristic		Who to Consider	Example issues to consider	Further guidance
1.	**Disability**	A person has a disability if they have a physical or mental impairment which has a substantial and long term effect on that person's ability to carry out normal day today activities. Includes mobility, sight, speech and language, mental health, HIV, multiple sclerosis, cancer	• Accessibility • Communication formats (visual & auditory) • Reasonable adjustments. • Vulnerable to harassment and hate crime.	Further guidance can be sought from: Solent Disability Resource Group
2.	**Sex**	A man or woman	• Caring responsibilities • Domestic Violence • Equal pay • Under (over) representation	Further guidance can be sought from: Solent HR Team
3	**Race**	Refers to an individual or group of people defined by their race, colour, and nationality (including citizenship) ethnic or national origins.	• Communication • Language • Cultural traditions • Customs • Harassment and hate crime • "Romany Gypsies and Irish Travellers", are protected from discrimination under the 'Race' protected characteristic	Further guidance can be sought from: BAME Resource Group

4	**Age**	Refers to a person belonging to a particular age range of ages (eg, 18-30 year olds) Equality Act legislation defines age as 18 years and above	• Assumptions based on the age range • Capabilities & experience • Access to services technology skills/knowledge	Further guidance can be sought from: Solent HR Team
5	**Gender Reassignment**	" The expression of gender characteristics that are not stereotypically associated with ones sex at birth" World Professional Association Transgender Health 2011	• Tran's people should be accommodated according to their presentation, the way they dress, the name or pronouns that they currently use.	Further guidance can be sought from: Solent LGBT+ Resource Group
6	**Sexual Orientation**	Whether a person's attraction is towards their own sex, the opposite sex or both sexes.	• Lifestyle • Family • Partners • Vulnerable to harassment and hate crime	Further guidance can be sought from: Solent LGBT+ Resource Group
7	**Religion and/or belief**	Religion has the meaning usually given to it but belief includes religious and philosophical beliefs, including lack of belief (e.g Atheism). Generally, a belief should affect your life choices or the way you live for it to be included in the definition. (Excludes political beliefs)	• Disrespect and lack of awareness • Religious significance dates/events • Space for worship or reflection	Further guidance can be sought from: Solent Multi-Faith Resource Group Solent Chaplain
8	**Marriage**	Marriage has the same effect in relation to same sex couples as it has in relation to opposite sex couples under English law.	• Pensions • Childcare • Flexible working • Adoption leave	Further guidance can be sought from: Solent HR Team
9	**Pregnancy and Maternity**	Pregnancy is the condition of being pregnant or expecting a baby. Maternity refers to the period after the birth and is linked to maternity leave in the employment context. In non-work context, protection against maternity discrimination is for 26 weeks after giving birth.	• Employment rights during pregnancy and post pregnancy • Treating a woman unfavourably because she is breastfeeding • Childcare responsibilities • Flexibility	Further guidance can be sought from: Solent HR team

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

You should usually prescribe licensed medicines in accordance with the terms of their licence. However, you may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient.

Prescribing unlicensed medicines may be necessary in the following instances.

a. There is no suitably licensed medicine that will meet the patient's need. Examples include – but are not limited to – where:[29]

   i. there is no licensed medicine applicable to the particular patient, for example, if the patient is a child and a medicine licensed only for adult patients would meet the needs of the child
   ii. a medicine licensed to treat a condition or symptom in children would nonetheless not meet the specific assessed needs of the particular child, but a medicine licensed for the same condition or symptom in adults would do so
   iii. the dosage specified for a licensed medicine would not meet the patient's need
   iv. the patient needs a medicine in a formulation that is not specified in an applicable licence.

b. A suitably licensed medicine that would meet the patient's need is not available. This may arise where, for example, there is a temporary shortage in supply.

c. The prescribing forms part of a properly approved research project.

d. There is a serious risk to public health and the MHRA has temporarily authorised the sale or supply of an unlicensed medicine, such as a vaccine or treatment, in response.[30]

When prescribing an unlicensed medicine, you must:

a. be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
b. take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring and any follow up treatment, or make sure that arrangements are in place for another suitable doctor to do so
c. make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.

Information for patients about the licence for their medicines

You must give patients, or their parents or carers, sufficient information about the medicines you propose to prescribe, to allow them to make an informed decision.

Some medicines are routinely used outside the terms of their licence, for example in treating children. In emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the licence. In other cases, where prescribing unlicensed medicines is supported by authoritative clinical

guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population.[31] You must always answer questions from patients, or their parents or carers, about medicines fully and honestly.

If you intend to prescribe unlicensed medicines where it's not routine or if there are suitably licensed alternatives available, you should explain this to the patient, and give your reasons for doing so.

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 licences.

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 licence. 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 Licence 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 must 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 Licence.

Why don't all medicines have a licence?
There are several reasons why some medicines are used for illnesses or conditions not covered by their original licence. Also, some medicines do not have a licence at all. Sometimes the clinical trial (and so the licence or authorisation) is for one illness but doctors find that the medicine works very well for another illness for which it does not have a product licence. 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 licence 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 licence/marketing authorisation 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 licence.

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 and Risk Assessment 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 Prescriber 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, St Marys Community Health Campus, Portsmouth, PO3 6AD.

FOR USE BY THE MEDICINES MANAGEMENT GROUP		
Final decision	Date discussed at MMG	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 Community Health Campus, Portsmouth PO3 6AD

Note** In using an unlicensed drug or a drug in a way incompatible with the product specification, the prescriber must act responsibly and with reasonable care and skill. When prescribing outside a licence it is important that the prescriber does so knowingly, recognising the responsibility that such prescribing entails and when obtaining consent to treatment should, where possible tell the patient of the drug's licence 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 authorised by the consultant responsible for the patient who is aware of the legal implications and liability of prescribing off – licence

High-dose antipsychotics should not be used in rapid tranquilisation

The decision to prescribe high-dose antipsychotics should be documented in SystmOne, the HDAT form should be completed in SystmOne , completing this form supersedes the need to complete an unlicensed form as the information will be duplicated.

Appendix 8 - Unlicensed Medicines Pre-Approved for Use Within Solent NHS Trust

Medication – form & Strength	Clinic/ward & Service Line	Risk Category	Stocked on wards/clinic?	Comments
Estrapel (oestrogen implants) 25 & 50mg	Menopause clinic SMH – Sexual Health	Higher – imported from America but has not got a product licence in USA	Yes Sexual Health SMH	Reviewed by Medicines Committee, Clinical Governance & Assurance Committee. Patient specific information leaflet developed and prescribing restrictions in place to consultants only.
Tranexamic acid mouthwash	Dental clinics	No – supported by dental literature	Yes – Dental clinic Petersfield	
Intranasal Midazolam	Dental clinic where sedation clinic run	No – supported by dental literature and NICE guidance on intranasal sedation. Product batch produced at Guy's & Thomas' production unit	Yes – Dental clinics	
Epistasis – buccal midazolam	Dental Community Paediatrics	Lower – was widely used until licensed product (buccolam) was available.	Yes – in dental emergency boxes	Dental service are gradually switching over to licensed product as boxes replenished.
Midodrine	Community Hospitals	Lower – imported from EU. Licensed in USA, France, Germany, Ireland	No – individual patient and only rarely used	
Pirenzapine	Mental Health	Lower	No	Only used during hyoscine shortages
Benzathine Penicillin 2 4MU Injection	Sexual Health	Lower – national Guidance (BASSH syphilis)	Yes	
Procaine Penicillin 1.8MU Inj	Sexual Health	Lower – national guidance (NASSH syphilis)	No	Individual patient basis for neurosyphilis
Spectinomycin 2g Inj	Sexual Health	Lower BAASH national guidance	No	Second line only when cephalosporin allergy
Nysatin Pessary	Sexual Health		No	
Predinsolone Suppository	Sexual Health		No	
Gabapentin gel	Sexual Health		No	
Flucytocine & nystatin pessary	Sexual Health	Higher Paper to support use in SH literature. Made in manufacturing unit in Stoke when needed as rare in use.	No	Vaginitis with azole resistance