

**SECTION 9: UNLICENSED MEDICINES POLICY**

**SECTION 9.2: UNLICENSED MEDICINES POLICY – FREQUENTLY ASKED QUESTIONS**

**1. What is the difference between an unlicensed medicine (ULM) and an off label medicine?**

In this policy an ULM is defined as a medicine with no marketing authorisation for any indication within the UK. An off label medicine is a medicine with a product licence but where the product licence does not cover the indication for which the medicine is being prescribed.

**2. Why are ULMs and off label medicines treated differently in the policy?**

ULMs have not been subject to the same scrutiny with respect to their quality, efficacy and safety and therefore careful consideration needs to be given to the risk and benefits of their use before they are prescribed. Off label medicines are licensed medicines within the UK and therefore there will be experience with their use. However, as they are not licensed for their prescribed indication, there may be limited knowledge and experience of their efficacy and safety in this setting (particularly if they are used at higher than the licensed dose). Therefore, in order to ensure that these issues are considered, the policy aims to identify, monitor and evaluate practice where medicines are prescribed off-label in high risk settings.

**3. I am not sure whether the off label medicine that I intend to prescribe would be considered high risk?**

Criteria for the risk assessment of off label medicines are given at appendix 1 of the policy. However, it is recognised that there is an element of subjectivity in assigning clinical risk category. The table provides guidance only and should not be considered as an exhaustive list. If you are unsure it may be helpful to discuss the issues with clinical peers or a clinical pharmacist. Medicines Information may also help to identify & assess the literature available to support the off label use.

**4. When do I need to fill in a form?**

The consultant looking after the patient must complete a form and submit it to the clinical director (or AMD if the medicine is high cost) in the following situations

- each time an **ULM** is prescribed. For the purposes of the policy, unlicensed extemporaneously prepared medicines such as oral suspensions, creams and ointments are exempt.
- For off label medicines a form must be completed if the medicine fulfils the high risk criteria (see risk matrix at appendix 1).

See question 5 if you think that an ULM or off label medicine is expected to be prescribed on a regular basis.

**5. Do I have to complete a non-formulary request every time I prescribe an ULM or off label medicine?**

No, for off-label medicines, only those that fall into the high risk category require a form. If an ULM or high risk off label medicine is expected to be prescribed frequently there is the potential to develop a policy for its use. Once the policy is approved by the clinical director it is no longer necessary to complete a form for an ULM or off label medicine. However, for ULMs, patients' names and CHI numbers would still have to be submitted to Pharmacy.

**6. Do I need to tell pharmacy every time I prescribe a patient an off label drug?**

No, this only applies to unlicensed medicines.

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***7. Why must I tell pharmacy about which patients have been given unlicensed medicines?***

The Health Board is required by the MHRA to keep a record of the dispensing of unlicensed drugs.

***8. Can an FY2 prescribe an unlicensed medicine?***

Yes, a qualified medical practitioner with full registration with the GMC can prescribe an unlicensed medicine.

***9. When do I need to take consent?***

It is good practice to inform and educate patients about all new medicines prescribed for them. This should always be documented in the patients notes. However, in the case of ULMs and high risk off label medicines informed written consent is required.

***10. My patient's GP is not keen to prescribe an unlicensed medicine. What can I do?***

The GMC states that 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.

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 parties to be in the patient's best interests. General Practitioners can be asked to continue to prescribe off label medicines i.e. used out with their licence indications.

However, the doctor signing and issuing the prescription bears responsibility for that treatment; it is therefore important that the prescriber understands the patient's condition as well as the treatment prescribed and can recognise any adverse side effects of the medicine should they occur. It is the responsibility of the Consultant to ensure that adequate information is given to the GP so that these conditions can be met.

***11. What is the balance of liability (manufacturer vs NHS) with the use of unlicensed and off label medicines.***

The manufacturer is unlikely to be found liable for any harm caused by that medicine, unless the medicine is shown to be defective and harm is directly attributable to this defect.

***12. What is the balance of liability within the NHS managed service (corporate vs individual) with the use of unlicensed and off label medicines.***

The principle is one of vicarious liability where the NHS Board (employer) is responsible for the actions and / or omissions of its employees.