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Prescribing Tip For Information

Understanding unlicensed medicines guidance from the All Wales Medicines Strategy Group

This guidance aims to improve the management of unlicensed medicines in all areas of healthcare within NHS Wales, however the information is applicable within England as well. The GMC define an unlicensed medicine as **'all medicines that are used outside the term or their UK licence or which have no licence for use in the UK'.**

Unlicensed medicines may include:

- **Licensed products being used outside of their licence (off-label use)**
- **Products that are imported which do not have a UK licence (but may have a licence in another country)**
- **Specials – products which are made specially, individually or in bulk to fulfil a specific need for a patient**

Changing a product's formulation for example by crushing and removing medicines from their original packaging such as when putting into a blister pack can represent unlicensed usage.

The MHRA hierarchy for the use of unlicensed medicines is:

1. **An unlicensed product should not be used when a UK licensed product is available.**
2. **Off-label in preference to an unlicensed product**
3. **An imported product should be considered, which is licensed in the country of origin.**
4. **If none of these options will suffice, then a completely unlicensed product may have to be used.**

Decisions should be **patient specific**. Sometimes an unlicensed medicine may be more appropriate than a licensed one (e.g. licensed phenobarbital oral liquid contains alcohol but the unlicensed 50mg/5mL oral liquid is alcohol-free).

If prescribing an unlicensed medicine, the prescriber must:

- **Ensure there is sufficient evidence or experience of the use to show safety and efficacy.**
- **Take responsibility for prescribing and for overseeing the patient's care or ensure arrangements are in place for another healthcare professional to do this.**
- **Record all medicines prescribed and include reasons for prescribing an unlicensed medicine.**
- **If continuing a supply of an unlicensed medicine initiated in secondary care, then the agreement of the primary care prescriber should be obtained before prescribing is transferred. When considering whether to continue the prescription ensure it is still appropriate. The ongoing need should be reviewed regularly. If declining to prescribe ensure timely communication with secondary care to minimise patient impact.**

Non-medical prescribers should check they are able to prescribe unlicensed medicines before issuing a prescription.	Patients should be reassured and informed regarding unlicensed medicine use. The patient should make an informed choice and should consent to treatment.
Prescribers should be aware their responsibility and potential liability is increased when prescribing off-label or unlicensed medicines.	Unlicensed medicines may have shorter expiry dates and particular storage requirements which patients should be informed of.
Community pharmacists should be informed of the indication, rationale for the unlicensed medicine and treatment plan in order to support the clinical check before dispensing as they have equal responsibility with the prescriber when supplying a medicine. Community pharmacies may need longer to source and order an unlicensed medicine	

The appendices of the guidance include **patient information leaflets** https://awttc.nhs.wales/files/guidelines-and-pils/understanding-unlicensed-medicines-pdf/

Further information is also available from SPS https://www.sps.nhs.uk/category/guidance/unlicensed-medicines/

To contact the Medicines Optimisation Team please phone 01772 214302

If you have any suggestions for future topics to cover in our prescribing tips please contact Nicola.schaffel@nhs.net