

Medicines Management Team Advisory Summary

Prescribers should endeavour to prescribe licensed drugs for licensed indications

Prescribing Responsibility

- When a clinician chooses to prescribe a product outside the terms of its licensing agreement, the product liability passes to the prescriber
- The **prescribing responsibility** would lie with the prescriber even in the case of secondary care recommendation. GPs are advised not to prescribe unlicensed products if requested to do so by secondary care unless they are prepared to accept clinical responsibility for the use of the product in each patient. The establishment of a *Shared Care Agreement* can be considered under these circumstances
- It is good practice to explain to the patient the reasons for prescribing unlicensed medicines or off-label when there is little evidence to support its use. It is advised to **annotate** the patient's medical records that this discussion has taken place and his/her/carer's understanding and agreement
- In many cases, **it is preferable to give a licensed product via an unlicensed route** (e.g. an injection given orally), than an unlicensed formulation of the drug
- For **very specific clinical or drug information**, local or regional Hospital Medicines Information services can be contacted (Bristol 01173422867 - Southampton 02381206908 /9)
- **For costs and licensed alternative products availability**, please contact your Medicines Management Team:

prescribingwiltshire@nhs.net - 01380 733881 - <https://prescribing.wiltshireccg.nhs.uk>

Relevant Bodies Position

MHRA:

- Before prescribing an unlicensed medicine, be satisfied that an alternative, licensed medicine would not meet the patient's need
- Before prescribing a medicine off-license, be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative

GMC - *When prescribing an unlicensed medicine you must:*

- be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
- take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable 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 an unlicensed medicine

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Paediatrics

- There are a high number of medicines initiated by secondary care paediatricians that are unlicensed, although their use is considered accepted practice
- If the **drug, its indication and dose are included in the Children's BNF**, a shared care agreement would not routinely be necessary for primary care to take over prescribing
- However, GPs are advised to seek advice from the Medicines Management Team and their medical defence organisation as appropriate

Swallowing Difficulties, Bariatric Surgery & PEG tubes

- **Crushing tablets or opening capsules**, when not explicitly mentioned on the medicine SPC, is considered off-label use of the medication and liability passes to prescriber
- Consider **soluble or orodispersible** tablets instead of unlicensed liquid preparations
- Consider equivalent products e.g. lansoprazole orodispersible instead of liquid omeprazole
- Patients who undergo **bariatric surgery** will usually need non-solid medicines for only 6 weeks
- Check with the Medicines Management Team for information regarding administration of medicines through PEG tubes

Community Pharmacists

- It is Pharmacists' professional duty to assist prescribers in ensuring that a unlicensed special is only used where there is no possible licensed alternative
- It is Pharmacists' professional responsibility to ensure that cost effective medicines are used
- Community Pharmacists are **encouraged to discuss with prescribers** when a more suitable product is available or when the price might seem unreasonable
- Pharmacists should consider the **amount prescribed in the light of expiry date** information and contact the prescriber if necessary:
 - To adjust the quantity prescribed to avoid **waste**
 - To minimise the need for patients to request repeat prescriptions less than monthly
- Pharmacists are likely to be the last point of contact with the patient. It is the **responsibility of the pharmacist** to remind the patient that the medicine is unlicensed and ensure they are fully informed about the medicine including its unlicensed status

Prescribing Data

- Over 1300 "special items" were prescribed in Wiltshire during 2015, totalling over £145,000 (**average £111** per item)

References

1. The Medicines for Human Use Regulations 2010
2. MHRA advice: <https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities>
3. GMC advice: http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp
4. RPSGB Good practice guidance on: The procurement and supply of pharmaceutical specials