Nottinghamshire Area Prescribing Committee (NAPC) recommendation on the use of generic Lamotrigine

The Commission on Human Medicines has published advice on switching between different manufacturers’ products for particular anti-epileptic drugs. The advice for lamotrigine is that “the need for continued supply of a particular manufacturer’s product should be based on clinical judgement and consultation with patient and/or carer taking into account factors such as seizure frequency and treatment history”.

The recommendations in this document are intended to provide further guidance to aid decision making when considering generic prescribing of lamotrigine.

- NAPC recommends that generic lamotrigine is used within its licensed indications, including treatment of partial and generalized seizures.
- Clinicians should prescribe lamotrigine generically on prescriptions, unless the prescriber has had a recommendation to continue branded prescribing by an epilepsy specialist.
- New and unstable patients should be prescribed lamotrigine generically.
  - When swapping patients from Lamictal® to generic lamotrigine, prescribers must make patients aware that the appearance of their tablets may change.
- Stable patients remaining seizure free for 6 months on Lamictal® should remain on their current brand. In the event of supply problems preventing the dispensing of Lamictal®, the specialist should be contacted for advice.
- If Lamotrigine is prescribed generically, the patient should not be advised to request the same brand or manufacturer from the community pharmacy. Patients should be made aware that the generic brand may change depending on availability.

Background
Primary care spent £277,500 on Lamictal® last financial year (59% of total spend on lamotrigine, for only 8% of all prescription items for lamotrigine)\(^2\). As such, the use of generic lamotrigine will provide significant cost savings to the Nottinghamshire Health Community.

Chart 1: Cost to GPs for 28 days treatment with lamotrigine. MIMS / DT July 2013

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REVIEW DATE: November 2016
DATE APPROVED BY THE NOTTINGHAMSHIRE APC: November 2013
Background continued
Generic lamotrigine tablets have been available in the UK since 2005. The Department of Health released a statement in advance of generic lamotrigine becoming available stating that, “some commentators have suggested that there should be no switching of products used in the treatment of epilepsy. But in this instance, there is no compelling evidence to suggest that switching from the originating brand to a generic alternative will have an adverse clinical outcome.”

The Medicines and Health products Regulatory Agency (MHRA) stated that it “considers generic lamotrigine products to be interchangeable with branded Lamictal® as they have been approved on the basis of satisfactory bioequivalence studies”.

The BNF acknowledges that; there may be a case for maintaining the same brand of phenytoin in some patients, care is needed in changing between sodium valproate products, and, to avoid reduced effect or excessive side effects, it may be prudent to avoid changing the formulation of carbamazepine. However, there is no such recommendation for lamotrigine.

NICE have stated previously that “Changing the formulation or brand of antiepileptic drug is not recommended because different preparations may vary in bioavailability or have different pharmacokinetic profiles and, thus, increased potential for reduced effect or excessive side effects.” However, the full guideline also states with regards to generic prescribing: “This was not a key clinical question, and therefore no evidence review was undertaken. This is an important issue in the prescribing of antiepileptic medicines, and the prescriber is advised to consult the BNF for specific advice for different AEDs [antiepileptic medicines].”

Bioequivalence data
Generic companies have had to demonstrate that their product is bioequivalent to the reference product – or as stated on the MHRA website, ensure that patients can be switched between the brand leader product and a generic version without causing therapeutic problems. In general these are small studies conducted in healthy volunteers to compare pharmacokinetic parameters of the generic medicine to the branded product.

Prescribing in primary care
Lamotrigine is listed in category M of the Drug Tariff (with the exception of lamotrigine 2mg dispersible tablets (category C)). As such, community pharmacists are reimbursed at the tariff price for the generic, unless the prescription specifically states Lamictal®. The difference between the Drug Tariff price and the branded Lamictal® is shown in chart 1.

References
2. ePact data: Financial year 2012/13. Nottinghamshire County CCGs and Nottingham City CCG.