Antiepileptic Drugs: Guidance on switching between different manufacturer's products for a particular drug

Background

Treatment with antiepileptic drugs (AEDs) is complex. Therapy is usually generally recommended/ directed by specialists but prescribed by GPs. Over the last 20 years there has been an increase in the number of new AEDs and subsequent patent expiries allowing marketing of a huge number of generic equivalents. Many of the drugs are associated with problems such as drug-drug interactions, narrow therapeutic indexes, relatively low solubility or bioavailability, and therapeutic failure carries potentially serious consequences for patients. Concerns have been raised about switching between branded and generic products, and between different generic products of a particular drug. The MRHA issued advice in November 2013 which considered the drugs in 3 categories:

MHRA Advice on changing products November 2013
Category 1 – Phenytoin, carbamazepine, phenobarbital, primidone **For these drugs, doctors are advised to ensure that their patient is maintained on a specific manufacturer's product.**
Category 2 – Valproate, lamotrigine, perampanel, retigabine, rufinamide, clobazam, clonazepam, oxcarbazepine, eslicarbazepine, zonisamide, topiramate **For these drugs 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.**
Category 3 - Levetiracetam, lacosamide, tiagabine, gabapentin, pregabalin, ethosuximide, vigabatrin **For these drugs it is usually unnecessary to ensure that patients are maintained on a specific manufacturer's product unless there are specific concerns such as patient anxiety, and risk of confusion or dosing errors.**

Whilst helpful, this advice leaves most decisions up to the clinical discretion of the prescriber, of which the majority are GPs, and not specialists. The District Prescribing Committee felt it did not go far enough in addressing some of the practical issues in maintaining consistent supplies of medication and addressing patient specific factors in brand selection.

Aims of this Guidance

This guidance intends to provide pragmatic advice to GPs and pharmacists whilst respecting the intention of the MHRA guidance and that of NICE. The aim is to avoid unnecessary anxiety and confusion for patients and their carers, and minimise the risk of seizures and side effects.

This guidance relates only to AEDs used for the treatment of epilepsy and not for other indications**.**

This guidance was developed by clinical consensus with contributions from Dr Martin Prevett, Dr Emma Harris, Dr Jennifer Dolman, Rebecca Case, Sarah Kerley and Emyr Morgan, facilitated by Julia Wright.

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Guidance

In general, patients should be maintained on a specific manufacturers' product and brand for all their antiepileptic medication unless there is a compelling reason to switch.

Reasons for switching may include

- A requirement to change formulation, for example from a tablet to a liquid
- The need to manage side effects
- At a patient's request
- Product unavailability

Carbamazepine requires particular care- all patients able to take solid oral doses should receive **controlled release** preparations in accordance with NICE guidance.

Managing product unavailability:
Every effort should be made to reassure the patient (or their carer) that switching to an alternative product will most likely NOT cause harm. Missing doses due to product unavailability is far more likely to cause harm and should be avoided at all costs.

Information about product availability can be obtained from:

- Community Pharmacists
- Epilepsy Specialist Nurses, Wessex Neurological centre 02381 208623 (epilepsysupport@uhs.nhs.uk)
- West Hampshire CCG Medicines Enquiry Helpline 023 8062 7898
- Southampton City CCG Medicines Management Team 023 8029 6916
- Wessex Drug & Medicines Information Centre 023 8120 6908

Prescribing & Dispensing Advice

- Where it is possible / known, GPs should state the brand/manufacturer on the prescription.
- Pharmacists should ensure the continuity of supply of a particular product where the prescription, or patient record, specifies it.
- If a specific product is not stated on the prescription, the pharmacist should check the prescribed indication and confirm whether the patient needs to receive the same product as previously supplied.
- When making an initial supply for a patient with epilepsy, the pharmacist should explain to the patient (or carer) the need to continue with the same manufacturers' product and make the prescriber aware of which product which has been dispensed, if it has not been stated on the prescription.
- If the prescribed product is not available, it may be necessary to dispense a product from a different manufacturer to maintain continuity of treatment, but where possible, this must be discussed with the patient (or carer) and prescriber. Giving an alternative brand is likely to be beneficial rather than giving no dose, when a particular brand is unavailable.
- In the interest of patient safety, pharmacists and prescribers are encouraged to communicate effectively about patients' treatment.
- GPs should liaise with nursing homes regarding this advice

Managing missed doses:

- If the time the missed dose is remembered is closer to the time of the dose missed than the next dose, the missed dose should be taken. If the time the missed dose is remembered is closer to the next dose, the missed dose should not be taken. The next dose should be moved forward a few hours or taken at the correct time.
- In the event of repeated missed doses, the prescriber should be contacted immediately to review the patient's treatment