

Requirements for generic anti-epileptic medicines: a regulatory perspective

J Neurol published online

Maliepaard M, Hekster YA, Kapelle A, Van Puijenbroek EP, Elferink A, Welink J, Gispen-de Wied CC, Lekkerkerker FL

Summary

Bioequivalence requirements are very strict and are the basis of therapeutic equivalence between innovators and generics. Therefore, switching to a generic anti-epileptic medicine appears to be safe based on pharmacokinetic grounds, and does not appear to provide a plausible pharmacological explanation for those cases where seizure frequency or seizure patterns change during antiepileptic treatment. Other causes may contribute, such as pharmacokinetic or pharmacodynamic drug–drug interactions.

Another important factor may be lack of compliance, due to poor acceptance of a generic medicine. Frequent switching to other generics could negatively influence compliance and should be avoided.

There is a major discrepancy between the actual number of reported adverse events upon switching and the opinion on this subject in clinical practice. It is crucial that both prescribers and pharmacists report adverse events, in order to allow them to take appropriate action when necessary. By doing so, prescribing physician, pharmacist and patient can contribute to an optimal surveillance of generic medicines, and thus contribute to the wellbeing of the patients at stake.