



**FRENCH CHAPTER OF THE INTERNATIONAL LEAGUE AGAINST EPILEPSY (LFCE)
RECOMMENDATIONS ON THE USE OF GENERICS FOR THE TREATMENT OF EPILEPSY**

- Considering the expressed opinion of several Chapters of the ILAE and the opinion of the *American Academy of Neurology* (representing over 20,000 neurologists);
 - Considering the acceptance, in particular by the *Food and Drug Administration* (USA), of the existence of significant differences between name-brand and generic drugs (the standards of bioequivalence -20% ; +25% are too large for patients in antiepileptic drugs);
 - Considering the fact that even small variations in concentration between name-brand and generic drugs, or from generic to generic, may induce toxic effects or favour the recurrence of seizures;
 - Considering that epilepsy differs from other chronic disorders, by the fact that a single epileptic seizure may have serious and even irreversible physical and/or socio-professional consequences;
 - Considering that several surveys in different countries, and particularly in France, reached similar conclusions as for the recurrence of seizures and the appearance of side effects after substitution of a name-brand AED by a generic;
 - Considering that the studies allowing the generic drugs to be licensed (AMM) do not prove their equivalence, in terms of efficacy or tolerance, with the name-brand AEDs (lack of evidence-based data);
 - Considering the ambiguity in terms of legal responsibility in case of an incident or accident following substitution (is the physician who didn't prescribe it, the pharmacist who provided the generic form, the industry that produced a non-equivalent generic drug ...).
-
- The LFCE considers that the antiepileptic drugs constitute a particular class of drugs which makes problematic their substitution when they are used in this indication.
 - The LFCE recommends not to substitute by generics (and even more one generic by another) in the treatment of epilepsy without the agreement of the consulting physician, and of the patient, especially in patients with well controlled epilepsy.
 - The LFCE is opposed to the practice that allows the substitution of an AED at the points of sale without the prior consent of the prescriber and of the patient. Both the physician and the patient must be provided with full information and be able to give their consent.
 - The LFCE considers that both the autonomy of prescription and the free access of the patients to the prescribed treatments remain basic principles of medical practice.
 - The LFCE recommends, in case of break-through seizures or recurrence of seizures in well-controlled patients with epilepsy, to systematically measure the AED blood-levels, detail related compliance issues and substitution procedures and particularly report each case to the safety department.

REFERENCES

- Berg MJ. What's the problem with generic antiepileptic drugs? A call to action. *Neurology* 2007;68:1245-1246
- Biraben, B. De Toffol, F. Semah, T. Rouaud. Utilisation des médicaments génériques des anti-épileptiques en France : résultats d'une enquête auprès des neurologues et revue de la littérature. *Rev Neurol (Paris)* 2007 ; 163 : 455-461
- Heaney DC, Sander JW. Antiepileptic drugs: generic versus branded treatments. *Lancet Neurol* 2007; 6: 465-68
- Krämer G, Biraben A, Carreno M, Guekht A, de Haan GJ, Jedrzejczak J, Josephs D, van Rijckevorsel K, Zaccara G. Current approaches to the use of generic antiepileptic drugs. *Epilepsy & Behavior* 2007 In Press
- Liow K; Barkley GL; Pollard JR; Harden CL; Bazil. Position statement on the coverage of anticonvulsant drugs for the treatment of epilepsy. *Neurology* 2007;68:1249-1250
- Wilner AN. Therapeutic equivalency of generic antiepileptic drugs: results of a survey. *Epilepsy Behav* 2004, 5: 995-998.

Enseigner Former Coordonner Aider les jeunes médecins et chercheurs