



News Articles, FDA Update, Pharmacology

Extrapolation of adult efficacy data leads to pediatric indications for 4 seizure drugs

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The Food and Drug Administration (FDA) has approved four drugs to treat partial onset seizures (POS) in pediatric patients 4 years of age and older based on extrapolation of efficacy from successful adult trials.

Expanded indications, including for the pediatric population, were approved for eslicarbazepine and lacosamide in 2017 and for pregabalin and brivaracetam in 2018.

In general, a drug's efficacy in children may be extrapolated from adult data when the pathophysiology of a disease, the response to therapy and the relationship between drug exposure and therapeutic response are all similar between adults and children. Pharmacokinetic and safety data still must be collected in the pediatric population.

The FDA concluded that the pathophysiology of POS is similar in adults and pediatric patients 4 years of age and older. After reviewing data from clinical trials of POS medications previously tested in both adults and children, the FDA concluded that pediatric patients 4 years of age and older respond similarly to adults and have a similar relationship between drug exposure and response. Therefore, pharmacokinetic and safety data may be sufficient to support extending the indication of drugs approved to treat POS in adults to the pediatric population.

Resources

- [AAP News article "Anti-epileptic drug efficacy in adults can be extrapolated to pediatric patients"](#)
- [FDA guidance](#)
- [Sun H, et al. "Extrapolation of Efficacy in Pediatric Drug Development and Evidence-based Medicine: Progress and Lessons Learned," Ther Innov Regul Sci. 2017;52:199-205](#)
- [Additional AAP News FDA Update columns](#)