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‘First generic’ drug approvals provide more affordable options for safe, effective treatments

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The Food and Drug Administration (FDA) recently approved eight “first generic” applications for Vimpat (lacosamide) tablets indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

A first generic drug approval allows a manufacturer to market a drug in the U.S. for the first time after it has addressed any patents or exclusivities associated with the brand-name drug. The FDA prioritizes review of certain first generic applications because of the positive public health impact brought by increased marketplace competition, which can result in more affordable access to needed therapies for patients. About nine in 10 prescriptions filled in the U.S. are for generic drugs.

“Physicians should continue to be attentive to the rising costs of medicine and the implications for their patients, especially for conditions requiring long-term therapy like seizures,” said Iilun C. Murphy, M.D., deputy director of Clinical and Regulatory Affairs in the FDA’s Office of Generic Drugs.

A single generic competitor can lead to price reductions of 30%, while five competing generics are associated with price drops of nearly 85%.

Generic drug developers generally do not have to repeat the same costly research and development programs, including clinical studies, that are required of brand-name drug developers. However, generic drug developers must demonstrate that the generic drug meets certain requirements that allow the FDA to conclude it is substitutable with the brand-name drug. To demonstrate this, the company may be required to conduct studies with human volunteers who take both the brand and generic drugs. The FDA compares data from these trials to determine if the generic drug is bioequivalent to the brand-name product.

With limited exceptions, a generic drug approved by the FDA must have the same active ingredient(s), strength, dosage form, route of administration, conditions of use and labeling (with certain permissible differences) as its brand-name counterpart. It also must meet the same high standards for quality, purity, stability and manufacturing as the brand-name drug. All generic drug applications undergo rigorous review by the FDA’s Generic Drugs Program, which ensures the generic version meets these standards before approval. In addition, the FDA inspects facilities to ensure that the generic manufacturing, packaging and testing sites meet the same standards as those of the brand-name drug.

“The FDA applies rigorous standards to ensure generic drugs are as safe and effective as their brand-name counterparts,” Dr. Murphy said.

Some differences between a generic drug and its brand-name counterpart are allowed, if they do not affect the product’s performance, safety or efficacy. For example, inactive ingredients, colors and flavorings may be different.

Generic drugs approved through this process are considered to work in the same way and provide the same clinical benefit as the brand-name drug.

First generic approvals are the gateway to providing affordable access to treatments for many patients. Health care providers and patients can be assured that all generic drugs approved by the FDA have met the

same rigorous standards as the innovator drug.

The FDA's Office of Pediatric Therapeutics (OPT), Division of Pediatrics and Maternal Health (DPMH) and the Office of Generic Drugs (OGD) contributed to this article. OPT resides in the Office of Clinical Policy and Programs in the Office of the Commissioner. DPMH resides in the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine within the Office of New Drugs. DPMH and OGD reside in the Center for Drug Evaluation and Research.

Resources

Information from the FDA on generic drugs