Advancing Complex Generics to Improve Patient Access to Medicines

This focus is critical because, first and foremost, these drug products provide people with important therapies.

February 6, 2019 By Food and Drug Administration (FDA)

Statement from FDA Commissioner Scott Gottlieb, MD, on 2019 efforts to advance the development of complex generics to improve patient access to medicines

As part of the FDA's efforts to promote drug competition and patient access, we've advanced many policies aimed at making it more efficient to bring generic competition to the market. We've been especially focused on a category of medicines known as complex drugs. These are drugs that, by nature of their formulation, delivery systems or the complexity of their active ingredients, for example, are harder to "genericize" under traditional approaches. As a result, these complex drugs often face less competition.

As a category, there are a number of complex drugs that are no longer protected by patents or exclusivities that would forestall generic approval, yet they continue to face no generic competition owing to the difficulty of developing generics. The agency has advanced many new policies to help promote generic competition to complex medicines once patents and exclusivities have lapsed, and we're planning additional policy steps in 2019.

To understand the challenges posed by complex generics, we need to go back to the pathway developed in 1984 under the Hatch-Waxman Amendments. This legislation put into place the framework for generic drug review at a time when brand drugs were often simple small molecules requiring straightforward and reproducible manufacturing processes. They were generally easy to characterize and evaluate through traditional methods, including human bioequivalence studies. In many cases, a drug's activity correlated directly with how quickly it got into the bloodstream and how long the drug stayed in the body, so it could have its intended effect on the anticipated site of action.

In contrast, complex drugs involve cases where the drug is often harder to develop and manufacture because it has a complex formulation or complex active ingredient. In other cases, the drug acts locally on the tissue rather than through the concentration in the blood. This includes, for example, inhaled drugs that act directly on the lungs, a topical patch that is activated directly on the skin, or eye drops that act on the surface of the eyes. The therapeutic effect of

these types of drugs does not necessarily correlate directly to the amount of drug in the blood, or it can be difficult to measure through the blood. They can raise other issues that make the traditional, metrics generally used to develop generic drugs harder to employ. In other words, it can be more difficult to meet the standards for generic approval.

In 2019, we'll advance additional policies to promote generic competition for complex drugs. Among other steps, we intend to issue additional guidance documents for developing specific complex generic drugs, as well as address categories of complex drugs that are hard to copy because of their complex formulation or mode of delivery. This will include the publication of a series of guidances to address regulatory and scientific challenges that make it generally more difficult to develop complex generics. As part of this, we intend to issue draft guidance with recommendations on establishing active ingredient sameness. In addition, we're going to help advance the development of new analytical tools and in vitro tests that may provide additional accurate, sensitive and reproducible tools to support approval of complex generic drugs. Better tools can reduce complex generic drug development time and cost and can inform regulatory decisions.

These are just some of the new steps that we're going to be taking in 2019 to promote access to complex generic medicines.

These new policy efforts are aimed at ensuring that we provide as much scientific and regulatory clarity as possible with respect to complex generic drugs. This focus is critical because, first and foremost, these drug products provide important therapies to patients. We believe that they're also becoming increasingly important to the economic stability of the generic drug industry. Being able to "genericize" a complex medicine can be a high-value opportunity for a generic drug developer.

Addressing the challenges related to complex generics, and promoting more generic competition to these medicines, is a key part of our Drug Competition Action Plan, and the agency's efforts to promote patient access and more affordable medicines.

This announcement was originally published on the Food and Drug Administration website on January 30, 2019.

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