Biosimilars – The 411

Summary and Background

Approval Pathways

The Waxman-Hatch Act of 1984 provided an expedited approval process for small molecule drugs. By accelerating the approval process of generic small-molecule drugs, there became an immediate competition between the branded products and less costly generics.

This abbreviated approval process, however, cannot be used for such large molecule products as biologic agents. Before 2009, manufacturers looking to bring a follow-on product to market once the patent had expired on the reference biologic had to file through the Biologic License Application (BLA) pathway. This pathway was the same pathway that the reference biologic had to go through for initial approval.

Then in 2009, the Biologics Price Competition and Innovation Act (BPCIA), part of The Patient Protection and Affordable Care Act (Affordable Care Act), created an abbreviated licensure pathway for biologic products. What does this abbreviated pathway mean for manufacturers of biosimilars? Not only are approval times shortened, but the size and length of clinical trials are reduced as well.

What are Biosimilar Products?

The FDA defines a biosimilar as a biological product that is highly similar to a U.S. licensed reference biological product notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. In other words, the biosimilar does not have to be an exact replica but must at least produce the same clinical response as the reference product.

A biosimilar product can only be approved by the FDA if all of the following are the same as the reference product:

- Mechanism of action
- Route of administration
- Dosage form
- Strength
- Indication
- Condition of use
When a reference product is approved for multiple indications, a biosimilar may be approved for all or any single indication the reference product holds.

**Interchangeable Biosimilar Products**

An interchangeable biological product is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the healthcare provider who prescribed the reference product.

If a manufacturer wants a product to be reviewed as interchangeable, they must also submit information to show that the proposed product is expected to produce the same clinical result as the reference product in any given patient.

To date, there are no biosimilars that have filed for interchangeability status. They are therefore considered branded entities.

**What's in a Name?**

Historically, small molecule generics have been assigned a non-proprietary name, that it, the same name as the active ingredient of the product. This same approach was followed world-wide as biosimilars came to market. The first biosimilar to market in the U. S., however, was given its own unique trade name Zarxio, the biosimilar for Neupogen. Going forward, the FDA’s draft guidance on biosimilar naming recommends that all biosimilars (past, present, and future) be named based on a standard naming system including the non-proprietary name with an assigned hyphenated suffix. Sandoz’s non-proprietary name for Zarxio is filgrastim-sndz. Since there are supporters on both sides of the fence (trade name vs. non-proprietary name), the finalization of the naming convention is still to be determined.

**Analyzing the Savings Potential**

The price difference between biosimilars and originator biologics is likely to be smaller than the difference between small molecule generics and their originator products. Why is this?
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MedTrakRx realizes that endorsement of each biosimilar across the board, for now, may not be in the best interest of our clients. Instead, MedTrakRx’s approach is to assess each biosimilar individually upon market entry and review for suitable applications of management strategies. To put is simply, biosimilars for now do not automatically equal savings.

To date, only three biosimilars have been approved and only one has reached the market. None have interchangeability status:

- **Zarxio** (biosimilar for Neupogen). Neupogen is still preferred over Zarxio on the National and National Preferred formularies due to enhanced rebates contracts.
- **Inflectra** (biosimilar for Remicade). Inflectra’s launch date is TBD as J&J, manufacturer of Remicade, plans to appeal latest court decision on its patent for Remicade.
- **Erelzi** (biosimilar for Enbrel) approved on August 30, 2016 is already anticipated to have a delayed market entry due to legal disputes. Not only must the biosimilar manufacturer wait 180 days before beginning sales, but Amgen (manufacturer of Enbrel) is claiming patent protection until 2029.

Clinical will continue to evaluate status changes of existing biosimilars as well as monitor for approvals of new biosimilar applications currently under FDA review.

Contact your MedTrakRx Account Manager to discuss your Plan’s specific statistics and cost management strategies.

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Reference information: