Outlook 2016

As Patents Expire, Payers Are Bullish on Price-Reducing Potential of Biosimilars

When the FDA approved the first drug to use the 351(k) approval pathway for biosimilars last March *(SPN 3/15, p. 1)*, many industry observers thought the decision would unlock the door to approvals for many more biosimilars. Although there has been no shortage of manufacturers not only conducting clinical trials of these biologics but also submitting to the FDA abbreviated Biologics License Applications (aBLAs), Sandoz Inc.'s Zarxio (filgrastim-sndz) remains the sole FDA-approved biosimilar. But that could change in 2016, albeit at a slower pace than expected. With patent-expiration dates looming — or even passed — for some biologics, payers now are planning their management strategies for these drug, which are expected to bring some price relief to an industry under fire for steadily increasing prices.

In addition, biosimilars could feel the impact from reference drug manufacturers' launching "more next-generation products" in a similar way to what Teva Pharmaceutical Industries Ltd. did with Copaxone (glatiramer acetate), says Bill Sullivan, Principal Consultant for Specialty Pharmacy Solutions LLC. Faced with patent expiration and the prospect of generic competition for the long-time leader within the multiple sclerosis space, Teva released a new formulation of Copaxone in early 2014 *(SPN 2/14, p. 1)* and has managed to transition about two-thirds of its patients to the longer-acting version *(SPN 8/15, p. 5)*.

The issue of interchangeability will need to be resolved in 2016. "The FDA wants an additional human clinical trial as part of the requirements for approval as an interchangeable biosimilar. That study is expected to be a clinical switching study involving the innovator product and the biosimilar. Although Sandoz has already completed a switching study demonstrating. Interchangeability, the FDA asked Sandoz to apply just for biosimilar status because the biosimilar approval process is new, and the FDA wants to proceed prudently. Interchangeability provides additional assurances from prescribers relative to efficacy and safety 'similarity' and will create broader acceptability of biosimilars by prescribers."

David Lassen, Pharm.D., chief clinical officer for Prime Therapeutics LLC, points out that "There are still many unknowns with biosimilars because the issues of naming conventions and interchangeability by the FDA will have a major impact on this category." The agency released draft guidance on the naming of biosimilars in late August in which it proposed that both reference products and biosimilars share nonproprietary names indicating the core substance, but that each product has a four-letter, FDA-designated suffix attached with a hyphen that is unique to each product but otherwise has no meaning. This would apply to biologics already on the U.S. market, as well as ones yet to launch *(SPN 9/15, p. 1)*.

The FDA has yet to release guidance on interchangeability, which has the potential to really open up competition among biosimilars and their reference products. Asked what draft and final guidance the agency expects to issue in 2016, a spokesperson for the agency's Center for Drug Evaluation and Research (CDER) tells *SPN* that "The FDA expects to issue draft guidance on Considerations in Demonstrating Interchangeability to a Reference Product and other topics, as reflected on the CDER Guidance Agenda. However, FDA cannot otherwise comment on the time frame for issuance or finalization of guidances."

According to the CDER spokesperson, “as of Dec. 31, 2015, 59 programs were in the Biosimilar Product Development (BPD) Program. CDER has received meeting requests to discuss the development of biosimilar products for 18 different reference products.”

“We do not expect a ‘flood’ of biosimilars to be licensed in 2016. To better define the space, FDA has been issuing a series of biosimilar guidances that we expect to see more of in 2016.”