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Stakeholders Draw Biosimilar Naming Insight From Biologic Approval

Drug industry stakeholders say a recent biologic approval that involves a prefix to create a unique nonproprietary name may offer insight into controversial naming issues associated with the health law's new biosimilars pathway. Teva Pharmaceutical Industries last week received approval for tbo-filgrastim, a biologic marketed as a biosimilar in Europe and similar to an Amgen product that does not have the prefix. FDA, however, says the decision to assign a unique nonproprietary name for the biologic is separate from future naming decisions for biosimilars.

Teva's application was filed in the United States before the the biosimilar pathway was established by the health reform law and the company will bring the product to market in late 2013 per a settlement with Amgen, the company said in press release. In the meantime, sources watching the development of the biosimilar pathway are analyzing the approval, specifically the naming decision, for insight into future biosimilar approvals.

"Perhaps that is FDA's way of signaling what they are going to do," said Steven Lucio, director of clinical solutions and pharmacy at Novation, a health care supply chain expertise and contracting company. Further, stakeholders will be watching the market uptake of the product to assess the viability of the biosimilar pathway versus the established Biologics License Approval pathway, the innovator approval process that Teva used in the United States for this product.

"Once the Teva product comes to market people will be watching closely," Lucio said.

Teva's tbo-filgrastim was filed under a BLA and contains a related drug substance to Amgen's Neupogen. The products are not biosimilar and have separate BLAs.

FDA debunked speculation that the use of a prefix signals future policies for biosimilars. "The FDA has not made a decision on how biosimilar or interchangeable products approved under section 351(k) of the Public Health Service Act will be named," the agency said in a statement. "The requirement for a unique nonproprietary name for tbo-filgrastim is separate from any future decision FDA will make regarding the naming scheme for biosimilar and interchangeable products."

The agency said the decision to use a unique nonproprietary name was used to minimize medication errors and facilitate safety monitoring.

"FDA determined that a unique nonproprietary name (tbo-filgrastim) is required to distinguish this product from Neupogen (filgrastim), a previously licensed biological product that contains a related drug substance," the agency said. "The nonproprietary name tbo-filgrastim is intended to differentiate this product from Neupogen to minimize medication errors and facilitate postmarket safety monitoring." The agency also said it intends to evaluate the need for distinct nonproprietary names on a product-specific basis.

But an industry source said FDA has assigned the same names for similar biologics that are more complex than filgrastim.

"What's key is that it's the same product as already has an (International Nonproprietary Name) in Europe," the source said. The source also noted that tbo-filgrastim is an FDA-assigned name, therefore it could be used on an interim basis. Further, the U.S. Pharmacopeial Convention has a role in naming and it has asserted its stance in comments to the FDA in response to biosimilar guidance documents released earlier this year.

"FDA-approved names in NDAs and BLAs are considered 'interim established names' that exist only unless and until USP designates a name," USP said earlier this year. "However, in almost all cases the nonproprietary name designated in the BLA is retained, or effectively ratified, by USP (after all, FDA government liaisons participate in all USP Expert Committees, including Nomenclature, and the Agency's views are accorded considerable respect and deference)." While it is rare, USP experts could approve a monograph with a nonproprietary name that differs from the interim name provided in the FDA license, USP said. FDA has the authority to change USP names, but the change must be done through the rulemaking process., USP says.

Michael Reilly, executive director of the Alliance for Safe Biologic Medicines, noted that the product presents a challenge on the international level because it is marketed and named differently in Europe. FDA's naming decision could garner feedback on how unique names will be applied in healthcare settings, he added.

"I think they want to see what the reaction is from the community in general," he said. Lucio also said the tbo-

filgrastim approval would stimulate conversations around educating stakeholders about biosimilars, including enhanced awareness for pharmacists.

But Reilly said stakeholders will not get a true sense of FDA's thinking until the agency starts clearing biosimilars.

"Until you start getting approvals for biosimilars, you don't know exactly what the FDA is going to do," he said. The Alliance, which includes membership from industry, has been in favor of assigning unique names for biosimilars. While industry groups have pushed unique names for purposes of safety monitoring, other groups, including pharmacists, worry that different naming schemes could create interchangeability barriers and increase drug costs.

Tbo-filgrastim is indicated to reduce the duration of severe neutropenia, a decreased number of white blood cells, in certain cancer patients, Teva says. — *Alaina Busch*