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AMCP To FDA: Tread Carefully On Biosimilar Naming As Policy Will Drive Pharmacists' Decisions

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As FDA gears up to decide on the first biosimilar as early as next week, the Academy of Managed Care Pharmacy says the agency needs to tread carefully on naming because new survey results suggest a move to give biosimilars distinct names could result in dispensing pharmacists being less comfortable substituting interchangeable biosimilars with their reference products. Nearly 75 percent of pharmacists said they would be confident or very confident substituting interchangeable biosimilars with their reference products if they share nonproprietary names, while only 25 percent said they would be confident substituting interchangeable biosimilars if they don't share the nonproprietary name of the reference product.

The study, published in the March issue of AMCP's Journal of Managed Care & Specialty Pharmacy, comes as FDA prepares to decide on whether to approve the first biosimilar -- Sandoz's filgrastim biosimilar of Amgen's Neupogen -- but has remained mum on how it will handle naming. The agency has signaled it does not plan to issue guidance on the naming issue, and many stakeholders believe the agency will show its hand with the name it assigns to the first biosimilar. An FDA official told Inside Health Policy this week that the agency is developing future policies on naming, but wasn't specific (see related story).

The survey findings suggest FDA's ultimate decision on naming may influence decisions by dispensing pharmacists, says AMCP, which favors a shared naming approach. “The imminent entry of biosimilars into the U.S. market highlights the need to carefully evaluate current processes of identification, reporting, and recording of the biological products dispensed.”

The debate continues to rage over whether interchangeable biosimilars should share the same international nonproprietary name as their reference biologics, with proponents of shared naming like AMCP and the Generic Pharmaceuticals Association (GPhA) saying market barriers to biosimilars would occur if interchangeable biosimilars do not share the same name with their reference product. Opponents argue that different names are needed for biosimilars to ensure safety and pharmacovigilance because biosimilars and biologics are complex and are not exact copies of each other in the way that small molecule generic drugs are in relation to their reference products. Sandoz has not applied for interchangeability for its filgrastim biosimilar, but says it may do so in the future.

The World Health Organization, which assigns international nonproprietary names (INN), is considering whether to add a four letter suffix as a qualifier to biologic INNs to help distinguish between reference biologics and their biosimilars.

The survey of members of AMCP, American Society of Health-System Pharmacists (ASHP) and American Pharmacists Association's (APhA) Government Affairs Committee and Biosimilar Taskforce found that only 37.3 percent of respondents would feel confident substituting a biosimilar for its reference biologic if they did not share the same name because of a prefix or suffix.

The studies authors -- Sara Fernandez-Lopez, Mohamed Bashir, Denise Kazzaz and Trent McLaughlin, who all work for consulting firm Xcenda, which developed the study for AMCP -- say that 74.6 percent of respondents said, given the dispensing systems they work with, they would be confident or very confident in substituting interchangeable biosimilars with their reference biologics if they share the same nonproprietary name, but confidence in being able to substitute the products fell to 25.3 percent if names are not shared.

The National Council for Prescription Drug Programs (NCPDP), which develops and promotes pharmacy industry standards, has told FDA that assigning different names to biosimilars relative to their reference biologics could wreak havoc with pharmacists dispensing systems.

“Any difference however big or small is a difference that will impact how data are pooled, sorted, and transferred unambiguously,” NCPDP wrote to FDA in a letter last May.

Edith Rosato, CEO of ACMP, said FDA should pay serious attention to the survey results as it prepares to approve the first U.S. biosimilar and answer the naming question.

“The Food and Drug Administration should heed these survey results of frontline practitioners -- that the naming convention will play a pivotal role in substitution practices for interchangeable biosimilars,” Rosato said in a press release. “Public health and the public interest will be best-served if biosimilars and their branded biologic counterparts share the same nonproprietary name.”

FDA has said it is not required to issue guidance on biosimilar naming under the Biologics Price Competition and Innovation Act. Industry experts have speculated the naming question may be answered with the agency's approval of the first U.S. biosimilar, or in labeling guidance FDA plans to release later this year.

The agency is widely expected to approve Sandoz's filgrastim biosimilar to Amgen's Neupogen as soon as next week. In early-January an FDA advisory panel unanimously recommended the agency approve Sandoz's biosimilar and one panel member offered support for shared names.

"I was impressed that so many of the public statements had to do with the name of the drug," said FDA's Oncological Drug Advisory Committee (ODAC) member James Liebmann, at the Jan. 7 meeting where ODAC recommended agency approval of Sandoz's filgrastim. "I think that this has been pretty clearly shown to be filgrastim in fact, and I think to name it anything else would be misleading.”

Pharmacy substitution is subject to state laws, and the AMCP study found that 52.7 percent of respondents said state statutes requiring them to notify prescribers of a switch after the substitution is made would not effect the likelihood that they would substitute a biosimilar for its biologic reference product.

Many states have been pursuing legislation that would require pharmacists to inform patients and providers before substituting an interchangeable biosimilar for its reference biologic, and in some cases require provider permission for substitution. In December, GPhA, Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization agreed to compromise language to present to states considering biosimilar substitution laws that would only require notification of providers after the substitution is made. -- Todd Allen Wilson (twilson@iwpnews.com)