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Commenters Want Change in Biosimilars Naming Policy

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By Bronwyn Mixter

Oct. 30 — A pharmaceutical industry group said in recent comments that it generally supports the FDA draft guidance on the naming of biologics and biosimilars, but said the agency should require meaningful suffixes rather than random suffixes.

The Biosimilars Forum said it applauds the FDA for advancing a naming approach "that recognizes that each biosimilar is a unique, single source drug and that the naming convention of biosimilars should be the same as that applied to all biologics."

The forum is a nonprofit organization whose mission is to advance biosimilars in the U.S. Its founding members include Actavis, Amgen, Boehringer Ingelheim, Coherus BioSciences, EMD Serono, Hospira, Merck, Pfizer, Samsung, Sandoz and Teva.

Meanwhile, the American Pharmacists Association (APhA) said it opposes adding a suffix to product names because it would create confusion and impede the substitutability of interchangeable products. A group of health insurers also said it opposes the use of suffixes.

Additionally, the U.S. Pharmacopeial Convention (USP) voiced objections to the draft guidance, saying the nonproprietary naming system was never intended to convey regulatory status.

The Federal Trade Commission also has voiced objections to the guidance, saying it may have unintended, anticompetitive consequences.

August Draft Guidance

The draft guidance, issued by the Food and Drug Administration in August, proposes that reference products and biosimilars have nonproprietary names (also called proper names in the guidance) that share a core drug substance name and, in order to better identify each product, an FDA-designated suffix that is unique for each product. This suffix would be composed of four lowercase letters that won't carry any meaning.

The agency will consider the comments as it works on the final version of the guidance.

The Affordable Care Act created a pathway for the FDA to approve biosimilars. The FDA defines a biosimilar product as a biological product that is approved based on a showing that it is highly similar to an already-approved biological product, known as a reference product. The law also allows for approval of interchangeable biologics.

So far, the agency has approved only one biosimilar drug, a Sandoz version of Amgen Inc.'s cancer drug Neupogen (filgrastim). The FDA said in March that the biosimilar, known as Zarxio, would have a "placeholder nonproprietary name" of filgrastim-sndz. The FDA issued this placeholder name before the naming guidance was issued.

Industry Weighs In

The Biosimilars Forum said that while it doesn't take a position on whether a suffix should be included in the U.S. proper name, it believes that if the FDA goes forward with adding a suffix, it should be affixed to all biological products developed by a given company and "the four letter suffix should be unique to the original product sponsor and meaningful, as opposed to random, and preferably derived from the company name."

"This approach would ensure that the name is more easily remembered, which in turn would better meet the stated FDA goals of safety and enabling enhanced pharmacovigilance," the forum said. "The FDA should also support the implementation of meaningful suffixes in its discussions with the World Health Organization (WHO) and other global regulatory bodies, in order to align biologic naming policies, to the extent possible."

The forum said it doesn't believe the naming convention should be used to designate whether a product is interchangeable and the name shouldn't match the reference product.

“Rather, interchangeability should be addressed in the Purple Book, label, and summary basis of approval that is published on the FDA website,” the forum said.

The FDA's Purple Book is a list of licensed biologic products and biosimilars that is meant to be similar to the Orange Book for small-molecule drugs.

The Biosimilars Forum said it believes that the FDA must ensure that there is flexibility in the implementation of the naming system to address case-by-case scenarios that may arise as experience is gained. The forum also requested that the FDA provide specific guidance to industry on how currently marketed and future biologics and biosimilars are to be converted to the new naming scheme.

“The Forum urges the FDA to carefully evaluate outstanding issues, such as suffix changes, that could affect the naming process; to seek advice on timing and sequencing of events for on-market biologics, and to do everything within its power to provide a level playing field for biosimilars in the U.S.,” the forum said.

Pharmacist Concerns

The APhA said it supports the FDA's proposal to require the same naming conventions for all biologics, rather than applying a unique system for biosimilars. However, the APhA said it opposes the use of suffixes.

“We believe the addition of a suffix could lead to general confusion relative to the appropriate use, safety, and efficacy of these medications and may impede the substitutability of interchangeable products through state policies,” the APhA said. “However, APhA is pleased that FDA recognizes that any suffix requirement should be imposed on all biologic products, not just biosimilars.”

The APhA said that if the FDA decides to use a suffix, it recommends that the agency “develop a suffix structure that conveys information to prescribers and dispensers through a means other than the use of the manufacturer's name.” The group said that if suffixes are tied to the manufacturer's name, a merger or other type of ownership change would make it necessary to change the name of a product, “which could unnecessarily negatively impact patients.”

"Specifically, FDA and stakeholder costs associated with name changes could be passed through to patients," the APhA said. Name changes also could confuse providers and delay treatment, the group said.

The APhA said it agrees with the FDA that reference products and interchangeable products should share the same nonproprietary name.

"Using unique nonproprietary names for interchangeable products could unnecessarily impede patient access to safe alternatives which may be more cost-effective," the group said. "Using unique names could also raise questions about the appropriate use, safety, and efficacy of biologic/biosimilar products, which could, in turn, lead to clinical and policy decisions that are not scientifically justified."

The APhA also said it "strongly supports the development and use of the Purple Book as a tool for reinforcing interchangeability and guiding safe substitution practices."

Another pharmacy group, the Academy of Managed Care Pharmacy (AMCP), said it is concerned that barriers to adopting biosimilars, "including confusing and complex naming conventions, may result in lower patient access to these products, and may result in medication dispensing and utilization errors."

"The FDA must address the potential unintended consequences and unnecessary challenges that arise from the proposals and must provide an opportunity for additional stakeholder feedback prior to finalizing naming conventions for biologic and biosimilar products," the AMCP said.

Health Insurer Objections

America's Health Insurance Plans (AHIP) said it has "significant concerns with the FDA's proposed naming approach and believes it would seriously impede the adoption of biosimilars."

AHIP said biosimilars and biologics should have the same name without any suffix. The group said the use of an FDA-designated suffix is unnecessary and would cause confusion among physicians, pharmacists and patients.

"We believe that pharmacovigilance related to biologics and biosimilars would be effectively accomplished through using existing indicators, such as National Drug Code (NDC) identifiers, rather than the creation of a new naming system," AHIP said.

AHIP said that if the FDA decides to use a suffix, "we encourage the FDA to work with stakeholders to ensure that the use of suffixes does not create any new barriers to the adoption of biosimilars."

"The advent of a robust biosimilars market in the U.S. promises to have profound implications for our health care system and consumers who rely on affordable access to safe and effective prescription drugs," AHIP said. "The potential savings, coupled with the fact that biosimilars must meet rigorous safety and efficacy requirements and show no meaningful clinical difference from the reference product, make it critical that the nonproprietary naming convention adopted by the FDA facilitate and not hinder the availability of biosimilar products."

USP Explains Unintended Risks

The U.S. Pharmacopeial Convention (USP) said it is "critically important to maintain a uniform and scientifically based naming approach that does not create unintended risks for patients and practitioners."

The USP sets public standards for the identity, purity, quality, strength, packaging and labeling of drugs and biologics.

The USP said there already is a scientifically-based nonproprietary naming system, in which USP is a participant, for drugs and biologics "that has protected patients for over a century." The USP said that since it began publishing the United States Pharmacopeia in 1820, the U.S. government and the public have relied on that compendium to provide nonproprietary names for medicines.

"USP appreciates the challenge of ensuring safe use and facilitating pharmacovigilance in the implementation of the new licensure pathway for biosimilar and interchangeable biological products under BPCIA," the USP said. "However, USP is concerned that in attempting to address some of these challenges through the nonproprietary naming system, which was never designed or intended to serve such purposes, the proposal in the draft guidance could create unintended consequences."

The nonpropreietary naming system was intended to establish simple and scientifically useful names and has never been intended to convey regulatory status, the USP said. "Establishing nonproprietary names based on shifting regulatory expectations, as proposed by FDA in the draft guidance, could dilute well-established scientific principles and understanding of drug and biologic substances and products."

The USP also said the draft guidance could create confusion because prescribers and dispensers may not be able to recall non-distinctive suffixes.

“The proposal could also create obstacles to global trade and harmonization, creating requirements that are viewed by other countries as an unfair restraint of trade, balkanizing national approaches, and making it more difficult to create globally interoperable systems,” the USP said.

The USP said that labeling is a potential way to address the concerns that prompted the FDA's approach in the draft guidance. “Specifically, we would propose the inclusion of a suffix in USP labeling requirements, without designating it as part of the nonproprietary name, to ensure that the qualifier remains closely linked to the name and can be used to identify and trace products back to their manufacturers,” the USP said.

The USP said that such an approach would facilitate a common global approach to the naming of biologics.

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The draft guidance is at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInfor

The Biosimilars Forum's comments are at http://src.bna.com/Qv, the APhA's comments are at http://src.bna.com/Qw, the AMCP's comments are at http://src.bna.com/Qx, AHIP's comments are at http://src.bna.com/Qy and the USP's comments are at http://src.bna.com/Qz.

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