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How to Label Biosimilars: Groups Disagree

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By Bronwyn Mixter

Aug. 4 — The drug industry, the AARP and pharmacists disagree on what information should be included in biosimilar labeling.

In comments on a draft guidance released by the Food and Drug Administration in March (10 LSLR 08, 4/15/16), the Pharmaceutical Research and Manufacturers of America (PhRMA) said that labels should say the product is a biosimilar. The drug industry group also said labeling should describe the relevant data from studies that support a finding of biosimilarity with the reference, or brand, product and should state whether the product meets a higher standard of interchangeability with the reference product.

Meanwhile, the AARP and the Academy of Managed Care Pharmacy (AMCP) said labels shouldn't include a statement that the product is a biosimilar because this could create confusion and discourage biosimilar adoption.

Comments on the draft guidance were due June 3, but the FDA extended the comment period until Aug. 2 (Docket No. FDA-2016-D-0643) (10 LSLR 12, 6/10/16).

A biosimilar is a biological product that is approved by the FDA based on a showing that it is highly similar to an already approved biological product, known as a reference product (RP) or brand biologic. The biosimilar also must show it has no clinically meaningful differences in terms of safety and effectiveness. The Affordable Care Act created an abbreviated pathway for the FDA to approve biosimilars.

So far, the FDA has approved two biosimilars: Zarxio (filgrastim-sndz), Sandoz's biosimilar of Amgen's cancer treatment Neupogen and Inflectra (infliximab-dyyb), Pfizer's and Celltrion's biosimilar of Johnson & Johnson's arthritis treatment Remicade.

Previous Comments

Also, in comments submitted before the original deadline of June 3, the Generic Pharmaceutical Association and 11 pharmaceutical supply chain groups and companies said that the agency shouldn't require labels to state that the product is a biosimilar and shouldn't include studies and analyses supporting biosimilarity (10 LSLR 12, 6/10/16).

Meanwhile, the Biotechnology Innovation Organization and a coalition of patient advocacy organizations said in separate comments that the labels should say that the product is a biosimilar, should state whether the product is interchangeable with the reference product and should include biosimilarity studies.

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

Drug Industry's Views

PhRMA said in comments that it “supports the draft guidance in several respects, including the proposed recommendation that biosimilar labeling should state that the product has been approved as a biosimilar for stated indications and identify the reference product.”

However, PhRMA said the draft guidance should be revised to require biosimilar labeling to include the relevant data that support a finding of biosimilarity and should state whether the FDA has made a determination of interchangeability with the reference product. The industry group said this information will “ensure that biosimilar labeling provides healthcare professionals with appropriate regulatory transparency” and will facilitate “informed choices by healthcare professionals and patients.”

Also, PhRMA said it agrees with the FDA that manufacturers should update their labeling to reflect new safety and effectiveness information about a biosimilar or a reference product. The group said the labeling for reference products and biosimilars will “need to evolve separately as a matter of public health.”

“Given that biosimilar and reference product labeling will be updated independently, we recommend that FDA provide guidance as to how it will evaluate new differences between the products' labeling that emerge over time and in particular, how it will assess whether these differences indicate the emergence of clinically meaningful differences between the reference product and the biosimilar,” PhRMA said.

AARP: Don't Stigmatize Biosimilars

AARP said in its comments that it “strongly supports the creation of a clear, workable biosimilar approval pathway that will provide consumers with access to safe, effective biosimilar products.”

AARP said it doesn't believe it is necessary to include a statement in the label that the product is a biosimilar.

“We are concerned that requiring a labeling statement that only applies to biosimilars could create confusion and discourage biosimilar adoption,” AARP said. “Unnecessary differentiation between biosimilars and reference products also reinforces the false narrative that biosimilar products are somehow inferior, reducing prescriber and patient comfort with these products.”

AARP said it “strongly” urges the FDA to reconsider this approach.

“The development of a robust and competitive biosimilar market is integral to the sustainability of our health care system,” AARP said. “More importantly, it will help ensure that consumers have affordable access to safe and effective prescription drugs.”

Pharmacy Group

The AMCP also said in its comments that requiring a biosimilarity statement is unnecessary.

“The FDA has never required a similar statement for generic products found to be therapeutically equivalent, and has not provided sufficient justification for its inclusion in biosimilar labels,” the managed care pharmacy group said. “This type of statement is unprecedented in medication labeling and may lead health care providers and patients to unnecessary conclusions that biosimilars are not safe and effective in comparison to the reference product.”

To contact the reporter on this story: Bronwyn Mixter in Washington at bmixter@bna.com

To contact the editor responsible for this story: Brian Broderick at bbroderick@bna.com

For More Information

The draft guidance is at http://src.bna.com/hup.

PhRMA's comments are at http://src.bna.com/htx.

AARP's comments are at http://src.bna.com/hty.

AMCP's comments are at http://src.bna.com/htz.