Conflicting Opinions Flood FDA on Its Proposal for Biosimilar Naming

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What’s in a name? When it comes to biosimilars, apparently everything. That message is loud and clear about the Food and Drug Administration (FDA) proposal for naming biosimilars.1,2 Whether biosimilars have the same nonproprietary name as their innovator drugs or a name with a suffix will determine how widely they are prescribed by physicians and dispensed by pharmacists—at least if one listens to the arguments expressed by different sides of the very fractured pharmaceutical industry.

The FDA’s proposed rule is essentially a follow-up to its approval in March 2015 of Sandoz’s Zarxio, a biosimilar of the brand-name drug Neupogen (Amgen) that bears the nonproprietary name filgrastim. However, other biosimilars are in the queue at the agency. When Zarxio was approved, the FDA named it filgrastim-sndz. The “sndz” is a shortening of Sandoz. The proposed rule the FDA issued in August, which is controversial on all sorts of levels, would change that nonproprietary name to filgrastim-jcwp.

The proposal also alters the nonproprietary names of long-approved biologics such as Amgen’s Epogen and Janssen’s Procrit; the nonproprietary names of both would be changed from epoetin alfa to epoetin alfa-cgkn. But the FDA also raises the possibility of adopting an alternative set of suffixes based on the name of the company marketing the six drugs that are the immediate concern of the proposed rule.

The Biologics Price Competition and Innovation Act of 2009 allowed copies of brand-name biologics to be sold in the United States. The FDA has been working on a regulatory structure for approving those drugs ever since. These copies will be approved as either biosimilars or interchangeable biologics, with the latter requiring submission of additional data to the FDA. If a biologic is approved as interchangeable, a pharmacist can substitute it for the reference drug without prior approval from the prescribing physician. Biosimilars, interchangeable and not, have been sold in Europe and Asia for some time.

Now that the FDA has approved Zarxio, the agency is under pressure to finalize additional components of its regulatory structure. The names awarded by the FDA are important as a means of distinguishing biosimilars from their innovator reference drugs and for reasons of after-market surveillance, although some parties don’t think there ought to be any name differentiation.

Steve Galson, ADA’s Senior Vice President for Global Regulatory Affairs and Safety, says the company opposes “jcwp,” doesn’t particularly like “amgn,” and prefers “amgb.”

The splits among professional and patient groups on one side and the insurance companies and pharmacy benefit managers on the other is just as profound. Edith A. Rosato, Chief Executive Officer of the Academy of Managed Care Pharmacy, is disappointed with the FDA proposal. Her group has been urging the FDA to use the same INN (from the World Health Organization [WHO] Program on International Nonproprietary Names) for both biosimilars and biosimilars with no prefix or suffix. “The use of a suffix may result in the potential for more prescribing and dispensing errors,” she says.

Complicating the debate is the position of the American Society of Health-System Pharmacists (ASHP). Christopher Topoleski, ASHP’s Director of Federal Regulatory Affairs, says his group supports a biological product naming convention that is consistent with international naming standards developed by recognized authorities such as the WHO INN program, the U.S. Adopted Names Council, and the U.S. Pharmacopeia. Those dictate that products essentially share the same nonproprietary name but can be individually identified through their unique National Drug Codes, other unique codified identifiers, and trade names.

The FDA’s final decision on naming won’t satisfy everyone. Important regulatory decisions rarely do. But the good news is that whatever naming format the FDA adopts won’t stop biosimilars from penetrating the U.S. market, finally, and saving consumers significant sums of money.

REFERENCES