The Food and Drug Administration (FDA) has put one more piece of the biosimilar puzzle in place by issuing final guidance on naming of biological innovator products and biosimilars. The agency hewed close to the thinking it first noted in an August 2015 proposed rule and guidance that would “name” a biosimilar by using its nonproprietary name separated from a random four-letter suffix by a hyphen. That format satisfied almost no one, and brand-name and generics manufacturers, as well as pharmacy groups, got almost none of the changes they requested.

The American Society of Health-System Pharmacists (ASHP) is particularly unhappy with the decision and asked the White House Office of Management and Budget (OMB) to stay implementation of the final guidance until its economic effects could be better studied. The ASHP argues that the addition of a suffix will force drug companies to rename the thousands of biologics now on the market, causing particular financial distress to hospitals, which would have to spend thousands of hours on information technology redesign and reprogramming.

According to ASHP member Erin Fox, PharmD, FASHP, Director of the University of Utah Health Care’s Drug Information Service, “a reasonable estimate of burden is about 40 hours per product, which would include impacts on medication lists in electronic medical records, labels, scanning, billing, changing order sets, changing smart pumps, pharmacy automation, automated dispensing cabinets, etc.” Further, there are additional burdens associated with cycling through existing stock, Dr. Fox notes: “It will be nearly impossible to use up all of the ‘old’ product without the new suffix and then switch out to the new product with the suffix. The pharmacy will have to bear the cost of the unusable ‘old’ product because the system can’t handle a mixed inventory for the same item.”

It is possible, however, that the final naming guidance, published in January, may be stillborn. Under the Paperwork Reduction Act (PRA), the OMB must determine whether the requirement that companies submit up to 10 suffixes for existing biologics will be too costly. The FDA estimates that the time required to complete that task will average 420 hours per biologic. The OMB will have to green-light the 10-suffix requirement before the guidance can take effect.

The PRA does not require the OMB to evaluate nonpaperwork costs to the industry, such as those cited by Dr. Fox. However, the Trump administration has sent a memorandum to all federal agencies meant to temporarily squelch federal regulations, including guidance documents, that were either sent to the Office of Federal Regulations or published in the Federal Register in the waning days of the Obama administration. The FDA’s final biologic naming guidance doesn’t fit into either of those two categories, but the OMB could decide to review the guidance given that the memorandum calls for assessing new regulations and guidance on the basis of “questions of fact, law, and policy they raise.” That could also result in the guidance being withdrawn.

The guidance essentially follows the naming convention the FDA advanced in August 2015 for six products: filgrastim-sndz, filgrastim, tbo-filgrastim, pegfilgrastim, epoetin alfa, and infliximab. The FDA originally designated Sandoz’s Zarxio, when it was approved as the first biosimilar, as filgrastim-sndz. Amgen’s Neupogen (filgrastim) is its reference biological. Sandoz will now have to come up with a new suffix, unless, of course, it wants to test the FDA’s ability to enforce guidance, which has no legal standing.

Sandoz had vehemently opposed the use of nondescriptive suffixes. In its comments on the proposed rule, Novartis, Sandoz’s parent company, said: “Novartis disagrees with the underlying premise of the FDA’s proposed rule, namely that assignment of unique suffixes to the nonproprietary names of currently licensed biologics is necessary for patient safety and that such suffixes would provide additional value beyond the current naming system that has been used successfully for over six decades.” Moreover, it said the FDA approach “will create significant and serious challenges at multiple levels of the U.S. health care system, including those related to ordering, prescribing, dispensing, recordkeeping, and pharmacovigilance systems.”

The Novartis/Sandoz position was similar to others in the brand-name industry, including the Pharmaceutical Research and Manufacturers of America, the industry trade group, which endorsed the use of manufacturer names as suffix abbreviations.

The American Pharmacists Association (APhA) opposed the use of any suffixes but said that if the FDA went that route it “should develop a suffix structure that conveys information to prescribers and dispensers through a means other than the use of the manufacturer’s name.” Chad Clinton, APhA’s Associate Director of Communications, says: “Unfortunately, the FDA’s final guidance not only establishes a biologic naming framework that uses suffixes, but in allowing manufacturers to submit 10 potential random suffixes, FDA missed an opportunity to provide a standardized methodology for manufacturers to consistently convey useful information to health care providers—a potential benefit of the use of suffixes.”

There is a lack of clarity at this moment as to whether this final guidance is, in fact, final. It may very well be canceled or revised by the Trump administration. The FDA will have to make a decision on naming of biosimilars. But even if it makes changes to the January guidance, they are unlikely to please everyone.

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REFERENCES


