FDA Accepts Its First Biosimilar Application

However, the Agency's Requirements Are Still Unclear

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Sandoz’s announcement that the Food and Drug Administration (FDA) has accepted its application for approval of filgrastim as potentially the first biosimilar drug to be licensed in the U.S. set off one of the periodic fits of attention paid to the absence of biosimilars in the U.S. The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was supposed to set off a run by companies seeking FDA approval of biosimilars they already sell in Europe and Asia. That law was passed as an amendment to the Affordable Care Act, which Congress approved in 2010.

But in the ensuing four years, the FDA has not filled in the gaps on some key approval issues, such as how a biosimilar will be named and whether pharmacists need to notify physicians when the pharmacist substitutes a biosimilar for the product’s brand name. Generic manufacturers oppose that, arguing it will encumber substitution. The WHO suggested that the current system for choosing INNs remain intact but that a four-letter code be attached to the end of every drug name that “uniquely identifies directly or indirectly the manufacturer and manufacturing site of the active substance in a biological product.”

The Biotechnology Industry Organization generally applauded the WHO draft decision. The Generic Pharmaceutical Association noted that the WHO move will be advisory and that the FDA, the European Medicines Agency, and other regulatory bodies will decide the best approach.

Some states are not waiting for the FDA to issue final guidance documents. In August, Raoul S. Frear, PharmD, of Boise, Idaho, President-Elect of the Academy of Managed Care Pharmacy (AMCP), testified before the Idaho State Board of Pharmacy on its proposed definitions of biosimilars and interchangeability.

Interchangeability will dictate the success of biosimilars because a pharmacist can substitute an “interchangeable” biosimilar without getting a physician’s prior approval. The FDA will decide what constitutes interchangeability. The AMCP is concerned that Idaho will adopt a definition of “biosimilar” that varies from the one in the BPCIA. That would diminish interchangeability.

There is no argument that biosimilars will save U.S. consumers, and the federal government, billions of dollars a year once they penetrate here as they have in Europe and Asia. The FDA has either been overly cautious about approving biosimilars or tangleged in its own bureaucratic stasis. Neither explanation casts the agency in a positive light.

REFERENCES
