Biosimilar approval is long overdue

By Tom Schatz, November 11, 2014

Generic versions of brand-name chemically based drugs are well-established in the U.S. market. However, even though the Food and Drug Administration (FDA) was given the authority in 2010 to create a pathway to approve a "generic" version of a biologic drug, more properly called a "biosimilar," the agency has not approved a single one.

Prior to the passage of the 1984 Hatch-Waxman Act, which created a pathway for approval of generic drugs, only about 35 percent of brand-name drugs faced competition after their patent expired. Presently, about 84 percent of all drugs dispensed in the U.S. are generics. According to the Generic Pharmaceutical Association, generic drugs have saved the healthcare system a total of $1.2 trillion over the past decade.

The 2010 Patient Protection and Affordable Care Act included the Biologics Price Competition and Innovation Act, which created a shortened approval process for biological products that are highly similar, or biosimilar, to a biologic approved by the FDA. Biologics are promising new medical products made from living organisms, such as a human cell or microorganism, to treat complex diseases such as Alzheimer's and cancer.

Unfortunately, the agency has been slow to issue and finalize regulatory guidance. For example, the rules for when a biosimilar can be interchanged with its brand-name biologic are still pending. The FDA has also delayed its decision as to whether a biologic and its corresponding biosimilar should have the same international nonproprietary name (INN) or "generic" name for the active ingredient in the drug.

The World Health Organization (WHO) assigns INNs, which are unique names that clearly identify each active pharmaceutical substance. INNs make it easier to safely prescribe and dispense medicine to patients and to communicate and exchange information among health professionals and scientists worldwide. In Europe, where biosimilars have been on the market since 2006, biosimilars and their reference biologics drug share the same INNs. There have been no reported problems with that system.

However, a July 2014 WHO draft proposal proposes adding a biologic qualifier, in the form of a four-letter code, to all biologics and biosimilars in addition to the INN name. Such a qualifier will unnecessary confuse providers and users of biosimilars.

On July 16, 2014, several taxpayer groups signed a letter to FDA Commissioner Margaret Hamburg, urging the agency to use the same INN for brand-name biologics and an equivalent biosimilar. A coalition of insurance plans, labor groups, pension plans and pharmacies wrote a similar letter to the FDA, as did the American Consumer Institute Center for Citizen Research.

Indeed, the public strongly supports speedy access to biosimilars. A poll conducted by Citizens Against Government Waste between Sept. 30 and Oct. 2, 2014 of a cross-section of 1,000 likely U.S. voters indicated that 78 percent agree that healthcare costs are out of control and that FDA approval of biosimilars will encourage competition and lower prices. When informed that biosimilars provide the same benefit as biologics and can lower costs by as much as 40 percent, 88 percent of those polled agreed that biosimilars should be introduced into the marketplace. In response to a question about whether the FDA has taken too long to create a pathway and needs to complete the process right away, without more red tape, 77 percent of those polled agreed.

The delay in approving biosimilars is unfortunate for both taxpayers and patients. In June 2008, the Congressional Budget Office estimated that competition from biosimilars would reduce total drug spending by approximately $25 billion over 10 years, with nearly $6 billion in savings for the federal government. On Nov. 3, the RAND Corporation released a study that predicts biosimilars could save $44 billion in drug costs over the next decade.

Nonetheless, on top of the failure to approve a single biosimilar or resolve the naming issue, according to *Inside Health Policy*, some government officials are calling for price controls for biologics. This wrongheaded approach fails to recognize that competition reduces prices and encourages innovation, not government mandates.

It is long past time for the FDA to complete its approval process for biosimilars. Doing so would allow taxpayers and patients alike to experience competition for biologics as the Hatch-Waxman Act did to encourage the marketing of generic drugs for brand-name chemical drugs. Finally, to avoid causing unnecessary confusion for healthcare providers and patients, the FDA should follow the European model of naming biosimilars.