Biosimilars entering the U.S. market are likely to face multiple challenges

Key issues include therapeutic interchangeability regulations, physician familiarity

- A new U.S. regulatory pathway, known as 351(k), is expected to increase the pace of biosimilar approvals, beginning with Zarzio, approved in January 2015.
- Biosimilars will increasingly compete with biologics, but new biologics in the same therapeutic class could slow the growth of biosimilar use.
- Over the next decade, biosimilars could save more than $40 billion in biologics spending, as biosimilar pricing is expected to be 15% to 35% less than originator biologics pricing.
- Since 2006, Europe has led the way in biosimilar approvals, compared to the U.S., but market uptake in the EU has been slow.
- One-third of physicians surveyed by Tufts CSDD said they would be unlikely to switch an existing patient from an originator biologic to a biosimilar, but payer pressure will likely drive U.S. market uptake due to the lower cost of biosimilars.

The introduction of the 351(k) pathway, which provides an abbreviated regulatory pathway for biosimilars, analogous to the regulatory pathway stipulated for small-molecule generics in the 1984 Hatch-Waxman Act, is widely expected to speed the development and marketing of biosimilars in the United States. Biosimilars will increase treatment options and slow the growth in spending on biologics. But how the commercial prospects for biosimilars will play out in the U.S. is uncertain. In Europe, where a regulatory pathway was established in 2006, market uptake has been slow due to lack of familiarity and safety concerns among physicians. Similar challenges will likely confront biosimilar developers in the U.S.

A newly completed Tufts CSDD study, summarized in this report, found that payers intend to promote biosimilar uptake by differentiating between the originator biologic and biosimilar through the use of lower cost-sharing for biosimilars. However, 25% of payers are reluctant to recommend switching an existing patient from the originator biologic to a biosimilar. In addition, nearly one-third of physicians report that they are unlikely to switch existing patients from originator biologics to biosimilars. Regulatory clarification on therapeutic interchangeability will be necessary.