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Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

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.