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U.S. Biosimilar Approvals Poised to Grow, but Market Uptake Faces Several Challenges

BOSTON – March 5, 2015 – Biosimilar approvals in the United States are expected to increase during the next five years, but safety concerns among physicians and the need for greater regulatory clarity concerning therapeutic interchangeability could hinder market uptake, according to a study recently completed by the Tufts Center for the Study of Drug Development.

A new U.S. regulatory pathway, called 351(k), is widely expected to speed the development and marketing of biosimilars, a process that began early this year with the first of nine biosimilars expected to gain approval by 2020, said Joshua Cohen, associate professor at Tufts CSDD and author of the study.

“Biosimilars will increase treatment options and slow the growth in spending on biologics, but lack of familiarity with biosimilars by physicians may hinder their use, as has been the case in Europe, where 17 biosimilars have been approved since 2006,” Cohen said.

He added that while new biologics in the same therapeutic class could slow the adoption of biosimilar use, payers in the U.S. will encourage biosimilar prescribing by offering lower patient cost-sharing for biosimilars, compared to originator biologics, much like they do today with generic vs. name brand prescription medicines.

Biosimilars are follow-on, approved biopharmaceuticals that are similar to an existing biologic, with no clinically meaningful difference between the two in terms of safety, purity, and potency.

Other findings from the analysis, reported in the March/April Tufts CSDD Impact Report, released today, include the following:

Development costs for a biosimilar are substantially less than similar costs for originator biologics, but creating biosimilars is more challenging than developing small-molecule generics due, in part, to greater chemical complexity of biologics and a more demanding manufacturing process.

Over the next decade, biosimilars could save more than $40 billion in worldwide biologics spending, as biosimilar pricing is expected to be 15% to 35% less than originator biologics pricing.

Approximately two-thirds of U.S. physician opinion leaders surveyed by Tufts CSDD said they would likely prescribe biosimilars to new patients, with about one-third saying they would be unlikely to switch an existing patient from an originator biologic to a biosimilar.
ABOUT THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

The Tufts Center for the Study of Drug Development at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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