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Biosimilar drugs have the potential to save more than USD 54 billion

RAND Corporation and the Moran Company issued reports discussing the cost savings associated with biosimilars.

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Follow-on versions of complex biologic drugs for diseases such as arthritis and cancer have the potential to yield billions in cost savings in the United States if legal and regulatory hurdles can be overcome, according to recent reports.

The drugs, known as biosimilars, could lead to a USD 54 billion reduction in direct spending on biologic drugs from 2018 to 2027, according to a study by the RAND Corporation that was supported by Sandoz.

“Biologics account for the fastest-growing segment of prescription drug spending, but biosimilars have the potential to help slow some of the increase,” says Andrew Mulcahy, lead author of the study and a policy researcher at RAND. “However, there remain many important industry, regulatory and policy decisions to be made that will influence whether such savings are realized.”

Biosimilars are biological medicines produced from living organisms. They match the safety, efficacy and quality of their reference products, whose patents have expired. Biosimilars have been used in Europe for more than a decade, but the market in the US is still in its infancy. In 2015, Zarxio® (filgrastim), launched by Sandoz, became the first biosimilar approved by the US Food and Drug Administration (FDA) under the 2010 Biologics Price Competition and Innovation Act (BPCIA).

In an earlier study, RAND estimated the potential cost savings to reach USD 44 billion by 2024. The added savings, RAND says, reflect real-world evidence from the launch of Zarxio, as well as its better understanding of the timelines involved in biosimilar development and market entry. Over the next decade, several biologic originator drugs will lose their patent exclusivity.

RAND cites several barriers that could undermine the full healthcare savings potential of biosimilars. Besides uncertainty regarding intellectual property, the report also highlights the lack of legal clarity around the so-called interchangeability designation, which is being discussed by US lawmakers. Under this designation, a biosimilar is expected to be substituted for its reference product without the involvement of the prescriber.

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In addition to the potential healthcare savings calculated by RAND, another study by the Moran Company, a healthcare research and consulting firm, found that administrative changes involving Medicare – the US federal government’s health insurance for the elderly – could potentially have a big impact on savings. Based

on the current reimbursement scheme, biosimilars need to be grouped under a specific billing code and payment rate. The report estimates that the reversal of this policy by the Centers for Medicare and Medicaid Services, which was recently announced and will take effect in January 2018, could result in savings of USD 11.4 billion to the US federal government over the 2018 to 2027 budget period.

Savings from biosimilars could benefit payers, providers, patients and taxpayers in the US. Insurers expect lower biologic prices and may transfer some of those savings to patients over time by helping to slow the growth of insurance premiums and co-pays. Furthermore, lower costs for Medicare from increased competition in biosimilars are set to ultimately benefit taxpayers. Providers, meanwhile, could benefit from lower costs of biologics that are administered in their offices, RAND adds that a competitive marketplace could also lead to increased access to biologics for patients.

Sandoz has been the leader in working to break down market entry barriers for biosimilars. In April, the US Supreme Court unanimously ruled in favor of Sandoz in a dispute with US peer Amgen Inc. that notice of commercial marketing can be provided before FDA approval. Thanks to this ruling, access to future US biosimilars could be accelerated by some 180 days.

Additionally, Sandoz provided comments to regulators to inform the finalization of their guidance on the interchangeability designation. The comments from Sandoz state that the interchangeability designation is just a request for more information and that the safety and efficacy profiles of biosimilars and their reference medicine are the same.

Potential Cost Savings of Biosimilars

RAND Corporation and the Moran Company issued reports discussing the potential cost savings associated with biosimilars.

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