Potential Savings from Accelerating US Approval of Complex Generics

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Accelerating the approval of complex generics represents an untapped opportunity for realizing savings for patients and healthcare payors, including Medicare, Medicaid, and commercial plans.

The US Food and Drug Administration (FDA) and other stakeholders have made efforts to facilitate a more robust complex generic marketplace, but these have thus far resulted in process improvements more than outcome gains. With more complex products on the verge of losing exclusivity, it is important for policymakers to achieve demonstrable progress in increasing access to complex generics in the US market — an objective supported by an array of current and former policymakers but not yet realized.

The FDA and industry stakeholders have an opportunity to pursue this goal in the ongoing negotiations around the reauthorization of the Generic Drug User Fee Amendments, due to expire in 2022.

This paper estimates the savings that the US healthcare system could realize from seven complex generics that are approved in Europe and/or Canada but not yet approved in the United States: Abraxane® (paclitaxel), Forteo® (teriparatide), Invega Sustenna® (paliperidone), Restasis® (cyclosporine), Risperdal Consta® (risperidone), Sandostatin LAR® (octreotide), and Venofer® (iron sucrose). If these seven complex generics were available in the United States, annual savings would total an estimated $600 million–$1.7 billion, with a median savings estimate of $1.3 billion.

*The full version of the report this document summarizes is available at **GetMGA.com**.*

$1.3B | Estimated median savings from generic competition in the United States for seven complex products already approved in Europe and/or Canada