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Stanton R Mehr

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Where the US biosimilars market is going and when it might get there

Nine years after the passage of the biologics and biosimilars price competition and innovation act, 14 biosimilar agents have been approved by the US Food and Drug Administration but only 4 biosimilars have reached the US market. None have been designated as being interchangeable with the reference biologic. Of these 4 available biosimilars, only one (filgrastim-sndz) has attained competitive market share in its drug category. Lingering patent litigation, aggressive rebating by reference manufacturers and insufficiently aggressive pricing by biosimilar makers have contributed to the current situation. The federal government has taken recent action to alleviate specific challenges to biosimilar market entry. The biosimilar action plan announced in July by US FDA Commissioner Scott Gottlieb may be successful in clearing the path for biosimilar marketing, but the other action will need to be taken on a legislative level (e.g., drug rebates as a safe harbor). Biosimilars may also benefit from a move from Medicare part B to part D, where payers can employ more pharmacy benefit tools to restrict access to nonpreferred products. Payers can also employ preferred and nonpreferred specialty drug tiers to make biosimilars more attractive to patients. There are significant market opportunities in several drug classes, but biosimilar manufacturers will have to carefully balance the potential revenues with delayed launches and the viability of their business model.

Biography

Stanton R Mehr has more than 30 years of experience in healthcare publishing and project management, specializing in the payer markets, clinical issues, health policy and health delivery. He is Principal and Content Director of BR&R, a web resource, informational site and consulting service in the biosimilar arena since 2014. Since the founding of SM Health Communications in January 2007, he has been writing, editing and presenting on a variety of clinical, business and policy topics of interest to the healthcare industry, including health plans, insurers and PBMs. He consults with several sectors including health care agencies, healthcare publishers and other firms, helping them to better understand the payer market and achieve their organizational goals. He spent 20 years as Executive Vice President and Editorial Director of Medicom International Inc, where he was the Founding Editor of Managed Care Interface, the first monthly, peer-reviewed journal for the managed care industry and its sister publication Long-Term Care Interface. He received his Bachelors of Science degree in Biology from the State University of New York, Stony Brook.

stan.mehr@smhealthcom.com

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