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Biosimilar: Drugs poised to penetrate market

Ibrahim A. Alsarra
King Saud University, Saudi Arabia

A biosimilar, or follow-on biologic, is a successor to a biologic medicine that has lost patent protection or exclusivity. Due to their relative complexity, biosimilars represent a separate regulatory class of medicines to small-molecule generics. Biosimilars are biologics, and are approved via stringently defined regulatory pathways on the basis that they have demonstrated comparability (high similarity) to their reference product. The introduction of biosimilars in the EU has already led to significant savings for patients and payers. With many more such products at various stages of the development pipeline, the number of therapeutic areas catered for by biosimilars will increase steadily over the next decade. The real benefit of biosimilars is the introduction of genuine competition into an area that has historically been unhealthily short of it. Competition not only reduces prices; it also frees up public funds to broaden overall access to healthcare. In addition, it provides a further incentive for the producers of patent-protected medicines to come up with fresh ideas and genuinely original new products – driving the 'virtuous circle' of innovation. Biosimilar development requires substantial time and investment. A typical biosimilar takes 7-8 years to develop, at a cost of between USD 75 and 250 million, with clinical trials that may involve about 500 patients. That compares to 8-10 years for a new drug application, at a cost of USD 800 million, including up to 1000 patients in clinical trials. For a small-molecule generic, by comparison, development may be completed in 2-3 years, at a cost of USD 2-3 million.

Biography

Ibrahim A. Alsarra received his Bachelor of Pharmacy (B.S.), in 1996 from College of Pharmacy, King Saud University, Kingdom of Saudi Arabia and his Ph.D. in Pharmaceutical Biotechnology and Drug Formulation Development, Division of Pharmaceutical Sciences, School of Pharmacy, University of Missouri-Kansas City, Missouri, USA. He joined King Saud University in 2002 and is currently the Deputy Director for Research and Technical Affairs, Centre of Excellence in Biotechnology Research, the only biotechnology center in Saudi Arabia, King Saud University. He is the President of Saudi Pharmaceutical Society and the Editor-in-Chief of Saudi Pharmaceutical Journal, a peer-reviewed and ISI-Indexed Journal.

ialsarra@ksu.edu.sa