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A strategic overview on biosimilars

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A competitive biosimilar marketplace with a sustainable pricing policy can generate saving and foster innovation. As the market for biosimilar products continues to grow, many biopharmaceutical companies trying to enter the space are struggling to overcome the unique challenges that developing such products presents. Going forward, the successful development and commercialization of a biosimilar product require a business strategy that integrates a regulatory strategic roadmap, appropriate clinical strategy, and trial design, regulatory compliance with scientific advice received, as well as commercial and market access considerations. Companies looking to develop biosimilars aim to ensure speed-to-market and minimize development costs, without sacrificing product quality. They must also address the unique challenges involved in developing and commercializing biosimilars, such as navigating an inconsistent global regulatory environment and identifying willing investigators and eligible patients for the required clinical trials. To ensure commercial success and maximize uptake of its biosimilar products, a company must ensure that physicians and patients are comfortable with the comparative efficacy and safety and with using its biosimilar products while optimizing access among payers. Furthermore, emerging market biosimilar players are now looking to expand into global markets through partnerships with international pharma companies. However, with the market shares of first-generation biologic drugs stagnating or declining, biosimilar monoclonal antibodies (MAbs) and second-generation biosimilars represent a high-value proposition for biosimilar manufacturers and key drivers of future growth.

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