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Biosimilar globalization, a silver lining in untested waters! Biosimilars in China: Balance of risks and opportunities

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Biotherapeutic products are the fastest growing medicines in the pharmaceutical market. Historically, 40% of China's $1.5 billion biologic product sales come from biosimilars, which have made approximately 25-30% of CAGR over the past decade. Today, the China biosimilar market is equivalent to ~20% of the global market. There are several factors driving the China biosimilar market: (1) Disease burden shifts from the infectious diseases to chronic diseases associated with diet and environmental changes, (2) Significant price discounts, around 60% compared to originator products, encourage reimbursements, (3) As the first wave of biologic originators hadn't adequate protection on IPs in China, a number of Chinese players took advantage of this window of opportunity. Biosimilars represent a growing market that is still facing some major difficulties related to clinical trials and market penetration both in USA and EU. Twenty-four countries have already approved biosimilars. Nevertheless, biosimilars approval poses a number of substantial regulatory challenges for local regulatory authorities. Overall, the WHO perspective drives the similar biotherapeutic products globally. The WHO promotes a stepwise comparability exercise indicating that more work is done in pre-clinical comparability, less work is needed in clinical studies. The clinical requirements vary accordingly to existing knowledge of the reference product and the claimed therapeutic indications. Our presentation focuses on challenges that are common across the globe and impact cost and timelines in biosimilars' development. Clinical studies are necessary to demonstrate comparative efficacy. In EU, UK and the Netherlands have invested resources for the validation of biosimilars in the marketplace by promoting clinical studies designed to answer physicians' and patients' uneasiness regarding biosimilars with immunogenicity being an element of uncertainty that can only be assessed in clinical trials. Extrapolation of safety and efficacy data can be justified from one indication to another with a comprehensive comparability program when the target receptor and the mechanism of action are identical. Specifically, the dialogue on extrapolation has elicited new interest as the FDA confronts core issues with special attention devoted to immunogenicity which must be always investigated with due consideration to risks in different indications. While most existing Chinese players follow a 'China for China' strategy, a few leading players with more advanced quality standards and manufacturing capabilities have set their sights on other less regulated emerging markets as well as developed markets. BBCR Consulting developed a framework based on evidence-based strategies and design-centered trials that identify the range of factors that affect the potential of cost saving in biosimilar development.

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