Lessons from the US and EU: How Can China Avoid Missteps in Biosimilar Adoption?

Clarivate Consulting Services

Jiang J. [1], Friedlander M. [2], Yu Z. [3], Cotten B. [4], Walsh K [5]

[1]Clarivate Commercial Strategy Consulting, Global Market Access & Pricing, Washington D.C., USA,[2]Clarivate Commercial Strategy Consulting, US Market Access & Pricing, New York City, USA, [3]Clarivate Commercial Strategy Consulting, US Market Access & Pricing, Philadelphia, USA, [4]Clarivate Commercial Strategy Consulting, New Product Planning, Boston MA, USA, [5]Clarivate Commercial Strategy Consulting, Global Market Access & Pricing, London, UK

Introduction

A biosimilar is structurally and functionally similar to and possesses no clinically meaningful differences in safety, efficacy, purity, and potency when compared to an existing approved reference biological product.[1] Once a biologic has lost exclusivity, biosimilars may enter the market, providing more cost-saving options for patients and healthcare systems. In China, a total of 26 biosimilars have been approved, and an additional 21 are currently undergoing review. Eighteen of the approved biosimilars have already launched. Rituximab, adalimumab, bevacizumab, etanercept, and infliximab account for 85% of the approved biosimilars.[2]

According to Clarivate forecasts, by 2029, sales of oncology biosimilars will significantly exceed that of immunology biosimilars. Biosimilars are expected to account for 80% of overall sales in these two therapeutic areas, predominantly driven by biosimilars for trastuzumab and bevacizumab in oncology and etanercept biosimilars in immunology.[3]

Figure 1: Trastuzumab Brand vs. Biosimilar Patient Shares in 2020 vs. 2024 and 2029

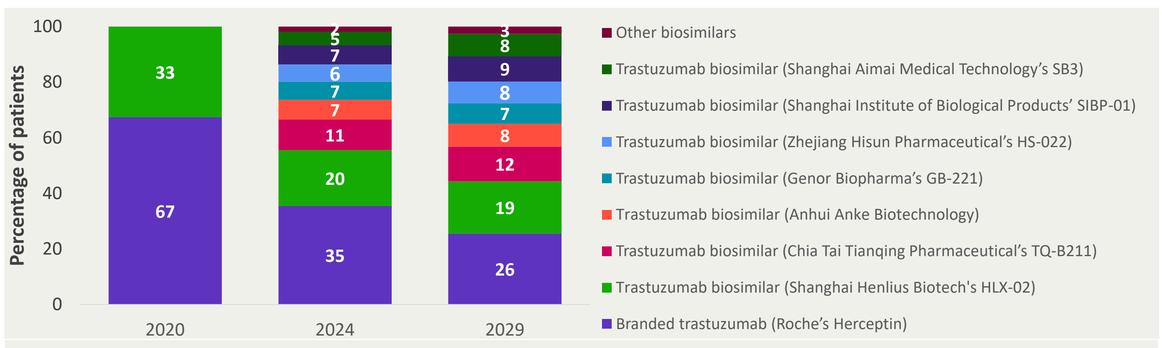


Figure 2: Bevacizumab Brand vs. Biosimilar Patient Shares in 2020 vs. 2024 and 2029

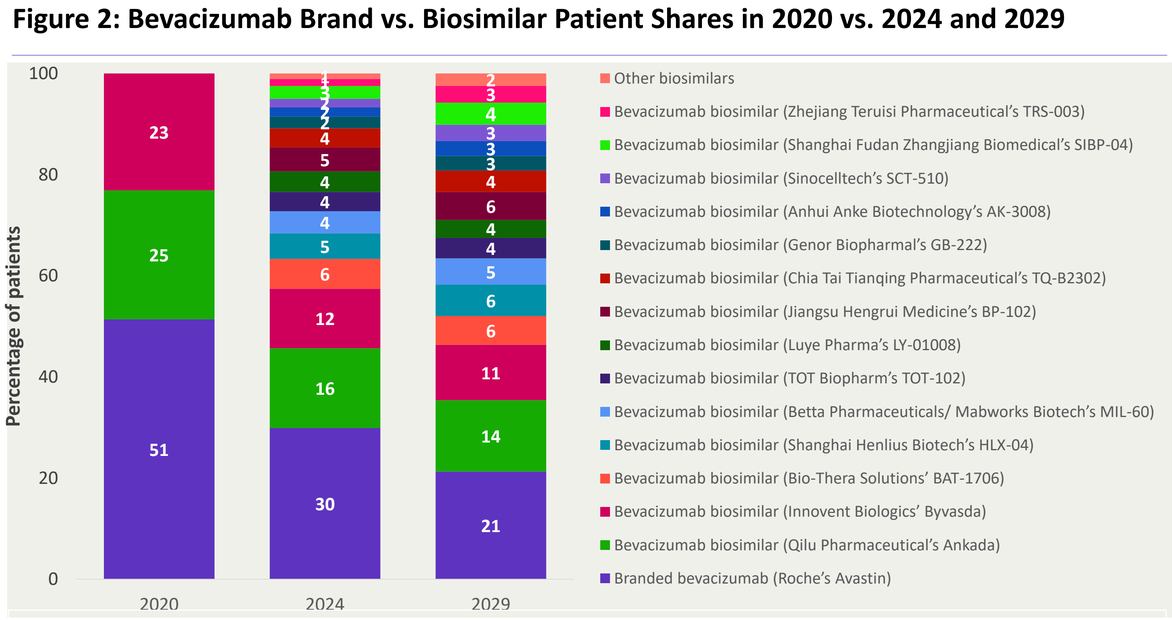
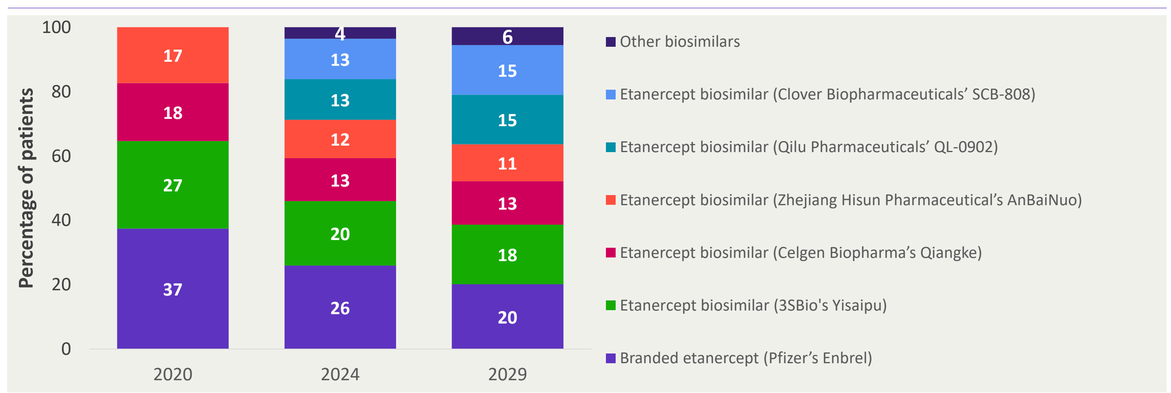


Figure 3: Etanercept Brand vs. Biosimilar Patient Shares in 2020 vs. 2024 and 2029



Objectives

The aim of this study was to assess the current regulatory environment for biosimilars in the US and EU and the market hurdles in pre-launch, launch and post-launch stages and provide recommendations as to how China could potentially avoid similar inefficiencies in developing a regulatory and commercialization framework for biosimilars.

Methods

Literature review was conducted to understand the current regulatory environment and biosimilar adoption in the US, China and EU. Qualitative and quantitative research was performed to analyze the future market share and physicians' confidence level of biosimilars in China.

- **Clarivate forecasting**: Clarivate creates ten-year annualized forecasts for biosimilars and reference brands from the bottom up, an approach also known as a patient-based or epidemiology-based methodology.
- **HCP survey**: 39 immunologists/rheumatologists and 37 medical oncologists in China completed an online survey from November 5 to November 15, 2020.
- **HCP Interview**: Three immunologists/rheumatologists and two medical oncologists in China were interviewed in November 2020. All experts interviewed have active medical practices with a specific interest in therapies included in the study.

Results

Recommendation 1: Avoid Market Hurdles Caused by "Interchangeability"

One of the most nebulous biosimilar concepts is "interchangeability". In the US, confusion over interchangeability has resulted in market distortions. For example, some originator companies have intentionally promulgated misinformation regarding interchangeability in effort to dissuade prescribers with inaccurate information.[6] In the US, an approved biosimilar can apply for "interchangeable" designation with the US Food and Drug Administration (FDA) and conduct additional clinical trials known as switching studies to support their application. If granted, interchangeability status allows for the automatic substitution of biosimilars by pharmacists where state laws allow.[4] Conversely, the European Medicines Agency (EMA) does not have the legal remit to designate a product as interchangeable. Once approved by the EMA, biosimilars are considered interchangeable by default, allowing for pharmacy-mediated substitution. One key recent development in the US is that the FDA has opened the door for interchangeable biosimilars to be approved without conducting the switching studies.[5]

Recommendation 2: Conduct Educational Campaigns for Winning Hearts and Minds

Across the US and EU, one common barrier to biosimilar adoption is misinformation and distrust of biosimilars among patients and physicians. This problem is also a major hurdle in China. Figure 4 demonstrates that Chinese physicians are less confident in generics compared to branded medicines, regardless of where the medicine was manufactured. The relative lack of confidence in generics serves as a proxy that highlights the importance of building trust for biosimilar uptake. The EMA and European countries have invested and launched several successful public campaigns on biosimilars.[7] Success in China requires educating key stakeholders including pharmacists, physicians, and patients on the safety and efficacy of biosimilars in order to increase acceptance, awareness, and access for biosimilars.

Recommendation 3: Adopt an Evidence-based Approach in the Procurement Process

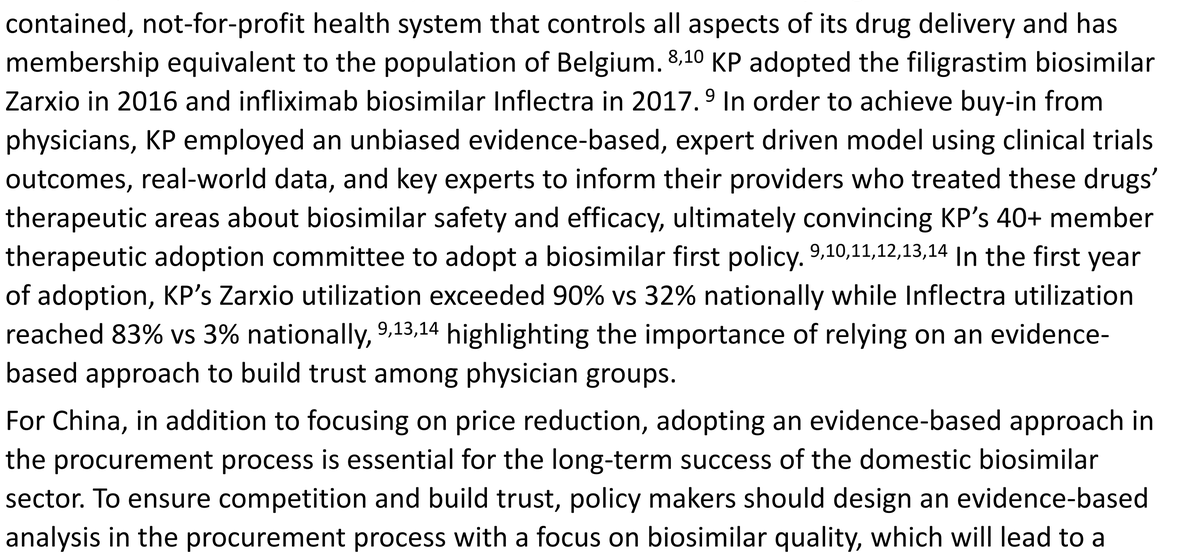
In the US, Kaiser Permanente (KP) has seen the most success adopting biosimilars. KP is a self-contained, not-for-profit health system that controls all aspects of its drug delivery and has membership equivalent to the population of Belgium. [8,10] KP adopted the filigrastim biosimilar Zarxio in 2016 and infliximab biosimilar Inflectra in 2017. [9] In order to achieve buy-in from physicians, KP employed an unbiased evidence-based, expert driven model using clinical trials outcomes, real-world data, and key experts to inform their providers who treated these drugs' therapeutic areas about biosimilar safety and efficacy, ultimately convincing KP's 40+ member therapeutic adoption committee to adopt a biosimilar first policy. [9,10,11,12,13,14] In the first year of adoption, KP's Zarxio utilization exceeded 90% vs 32% nationally while Inflectra utilization reached 83% vs 3% nationally, [9,13,14] highlighting the importance of relying on an evidence-based approach to build trust among physician groups.

For China, in addition to focusing on price reduction, adopting an evidence-based approach in the procurement process is essential for the long-term success of the domestic biosimilar sector. To ensure competition and build trust, policy makers should design an evidence-based analysis in the procurement process with a focus on biosimilar quality, which will lead to a healthy and sustainable biosimilar industry potentially expanding not only in China, but also competing at the global level.

Conclusion

The global biosimilar market has immense untapped potential. More fundamentally, in any local market, biosimilars are often more cost-effective options for patients and governments. As a result, the major players in China's healthcare system should examine the lessons from the US and EU and develop a framework that aims to expand biosimilar development and improve access to affordable biologics.

Figure 4: Confidence in Quality of Generics among Chinese Physicians



*MNC, Multinational Corporation; **I&I, Inflammation and Immunology; ***Rheum, Rheumatology; 37 Oncologists and 39 Immunologists/Rheumatologists were surveyed

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