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LinkedIn Biosimilars Post – **Biosimilar Medicines Conference**

(18th October 2022)

Earlier this month, experts gathered for the 18th Biosimilar Medicines Conference in Brussels, which aimed to expand the awareness of the potential of biosimilars to increase access for patients to life-changing biological therapies [1].

Biosimilars are becoming an increasingly important component of pharmaceutical expenditure. Biosimilar manufacturers launch at a discount to the reference product to give themselves a competitive edge in the markets, with the level of discount typically increasing as the number of competitors in the disease area expands [2].

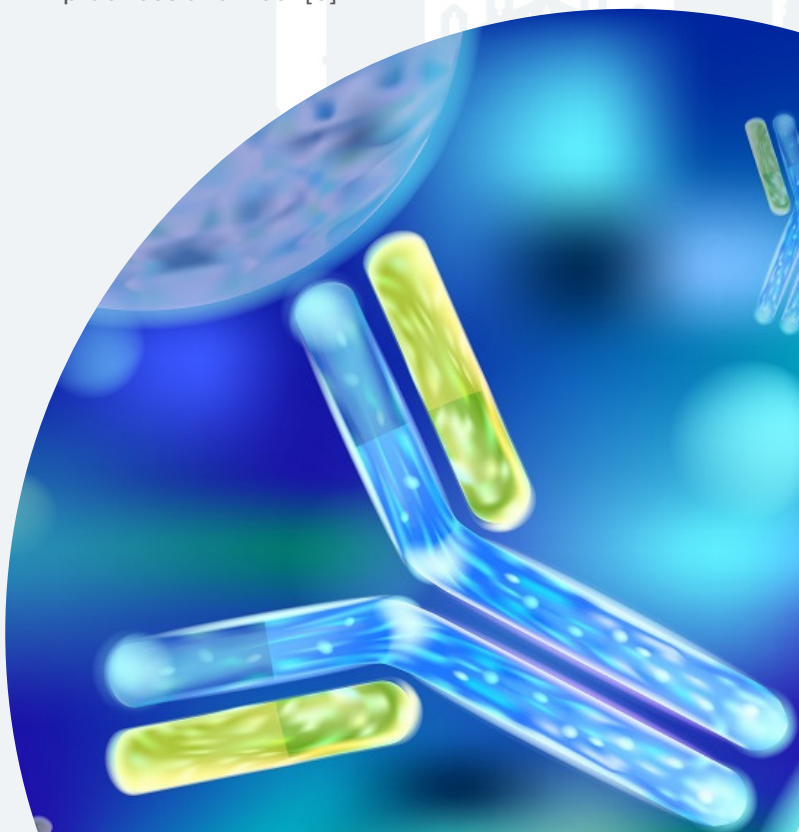
The adoption of biosimilars in Europe has been rapid, with biosimilars launched in 2021 achieving 50% market penetration within the first year of launch [3]. However, adoption in the US has been lower than in the EU due to how formulary decisions are made, confusion regarding interchangeability, and issues with disseminating biosimilar education, data extrapolation across indications, as well as patent disputes and settlements.

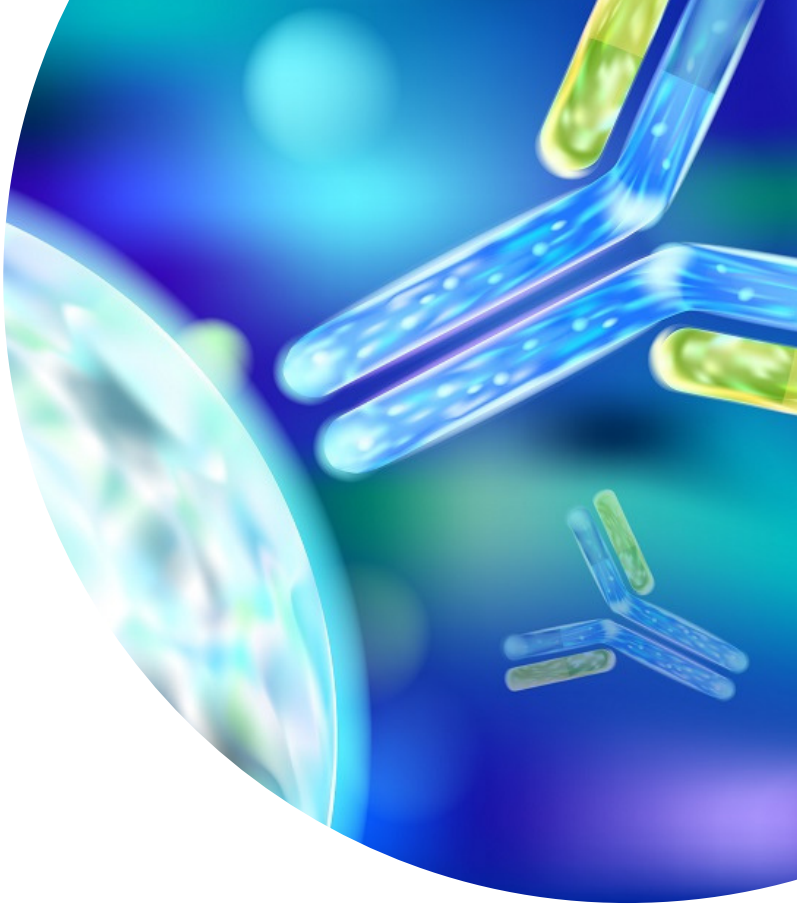
As more biological medicines lose patent exclusivity over the coming months and years, will this create more financial headroom either for increasing patient access to these treatments, or in funding new innovative interventions? Certainly, the biosimilar market is expected to grow at a greater than 20% CAGR to 2030 [4].

Interchangeability is central to this major shift, but there are many differing expert views on this and ultimate potential for substitution [5]. Fresh policy updates in Europe have been developed, aiming to further promote the uptake of biosimilars across member states. In a recent joint statement, the EMA and the Heads of Medicines Agencies (HMA) announced that biosimilars approved in the EU are now considered to be interchangeable with their reference product, or with an equivalent biosimilar. The statement was issued to increase the confidence of prescribers to prescribe a biosimilar ahead of a reference product, and thus further enhance the uptake of medicine for patients in need of treatment [6].

Elsewhere in the US, the Biologics Competition Act of 2022 (HR 8877), has recently been tabled aiming to make interchangeable biosimilars more accessible for patients [7].

Substitution would seem to be unlikely in the near future (even if it would be a potential societal goal and drive biosimilar costs downwards) [5]. It is likely that switching (i.e., exchange with physician involvement) rather than substitution (i.e., exchange without physician involvement) will drive uptake. Druedahl et al., (2022) conducted an interesting study which concluded that experts view interchangeability as more than a scientific question of likeness between biosimilar and reference products: it also pertains to regulatory practices and trust [5].





The high price of orphan drugs is often cited as a contributory factor to restricted access, and thus the development of biosimilars for orphan diseases creates a solution to help reduce spending in health systems throughout Europe [8]. Biosimilar candidates for Alexion's Soliris (eculizumab), one of the most expensive drugs in the world, are anticipated to soon be the first pure-play orphan biosimilars to enter the European market [9,10]. With each prescription representing such significant cost, the implications of any switching will be significant and will be eagerly tracked.

Biosimilars are an ever-increasing part of the treatment landscape, with their use driven by multiple and complex factors. There is the opportunity of reduced healthcare costs, increased access but the route is not simple. For developers, a clear value proposition, promotion, and education will still be needed, as well as shaping the regulatory and policy environment. Surely this is a great time to be a biosimilar company?

#biosimilars #BIOS22

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