



Short Communication

The Future of Biosimilars

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Abstract

Biosimilars are to Biologic products what generic drugs are to chemical products, a more affordable solution to the increasing drug pricing without sacrificing the quality of the treatment. There is much debate in the health care industry as to whether Biosimilars will deliver on the same success achieved by the generic products, which can amount to up to 80% in some cases. It is my view though that Biosimilars provide a viable path to cost reduction, quality improvement and affordable accessibility to medication. In fact, the introduction of lower costs Biologics as intended by the Biosimilar market will force competition within the therapeutics treatment market that will both exert pricing pressure as well as inspire innovation in the entire ecosystem.

Keywords: Biosimilars; generic drugs; quality improvement; ecosystem; BPCI Act.

Introduction

Will the Biosimilar products deliver on value and cost savings expectations while ensuring quality?

By way of background, in 1984 the Drug Price Competition and Patent Term Restorations Act (Hatch-Waxman Act) provided an abbreviated pathway for drug companies to reproduce the innovator sponsor drug after the patent expiry period. By demonstrating comparability to a "brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use" [FDA], by meeting the definition criteria, the drug manufacturer is allowed a shorter approval process known as Abbreviated New Drug Application (ANDA). This approach is effectively based on demonstrating science equivalence and manufacturing reproducibility, thus minimizing the more expensive development, clinical and non-clinical testing required for an innovator's drug approval.

The pathway derived as a byproduct of the Hatch-Waxman Act forged a step forward in achieving pharmaceutical drug savings as today more than 50% of prescription drugs are filed with generic products [FDA]. In 2010, the Patient Protection and Affordable Care Act (Affordable Care Act) was signed into law to amend the Public Health Service Act (PHS Act). The Affordable Care Act follows the pathway of allowing the pharmaceutical Biologics product to be developed, manufactured and marketed via an abbreviated approval process, under the designation of Biosimilars. This pathway is known as the Biologics Price Competition and Innovation Act (BPCI Act).

Biosimilars are not an exact replica of the innovator product; they can either be 'highly similar' or 'interchangeable', unlike the generic products that are required to be a 'generic copy' of the innovator product. It is the differences between the BPCI Act and Hatch-Waxman Act that puts into question the true quality attributable to

the Biosimilar products as a viable replacement for the branded Biologic products.

Upon closer look at the BPCI Act in combination with FDA guidance documents on Biosimilars, we are assured that these considerations are reflected in the more stringent requirements when demonstrating Biosimilars. More specifically, the guidance documents ascertain the need for.

Biosimilars to undergo both clinical and non-clinical testing prior to product approval, in conjunction with all international and domestic laws and regulations governing pharmaceutical products intended for human use.

Additional controls are set in place by the United States Food and Drug Administration (FDA) to stipulate the necessary transparencies and supplemental controls throughout the Biosimilar supply chain process in order to ensure safe delivery of the product to patients, addressing some key policy issues. For example, Biosimilar products will be labeled in such a way so as to differentiate between 'highly similar' or 'interchangeable' and whether a pharmacist will be able to make a substitution when dispensing the medications. The current provisions placed by the FDA guidance documents will ensure the safety and quality of Biosimilars as a mainstream treatment alternative in the future.

Biosimilars are projected to introduce 20% to 30% price reductions (vs Biologics), unlike the whopping 80% price reductions achieved by some generic products. This conservative estimate stems from the fact that the large molecules (Biologics and Biosimilars) manufacturing process is expensive and the industry, in general, is still in need of acquiring the necessary experience and expertise to streamline the processes. The BPCI Act will accelerate the technological competition among Biological and Biosimilar manufacturers in providing more robust models for the manufacturing process as well as the supply chain operation to expedite product access to market and to maintain strong market share.

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Biosimilar products are intended for the treatment of chronic and genetic diseases such as diabetes, auto immune disorder, oncology and arthritis, to name a few. The expected price reduction of 20% to 30% will be a considerable savings over the patients' life expectancy in the United State with an aging generation diagnosed with chronic diseases such as arthritis and diabetes where, in some cases patients are depending on one or more Biologic medications. Mulcahy et.al, 2015; estimates the potential savings of Biologics due to the introduction of Biosimilars among the main classes to be on the order of: (a) 21% for Anti-TNF products, (b) 15% for Long-acting insulins, (c) 13% for Monoclonal antibody antineoplastics, and (d) 11% for Fast-acting insulins.

The Biosimilars market will also drive pharmaceutical innovators to discover new therapies to maintain a technological edge in the field, thus stimulating overall economic growth in the health care sector

which constitutes approximately 40% of the US market. It will provide patients with more options and access to treatment alternatives.

In conclusion, the BPCI Act will serve as a catalyst in driving cost reduction in the Biologics therapeutic area by affording manufacturers, physicians, insurers and patients a menu of options at reduced costs. The congressional Budget Office in the US reported potential savings of USD 25 billion between 2008 and 2018 through the use of Biosimilars" [Sandoz, WEB]. It will increase health care access by providing patients with alternative therapies in general and reduced biosimilar in particular, all with the assurances of a well-defined quality expectation set forth by documented guidance and regulations.

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