Biosimilars

Biosimilars have been used safely and effectively around the world for nearly a decade and will impact additional markets, including the U.S., in the years to come.

2009 2010 2011 2012 2013 2014 2015

IN THE U.S.

In 2009, the Biologics Price Competition and Innovation Act (BPCIA) put formal steps in place to allow for biosimilar development in the U.S.[1]

IN THE EUROPEAN UNION

In 2005, the "Guideline on similar biological medicinal products" came into effect in Europe, providing a framework for obtaining approval for a biosimilar in Europe.[1]

SO, HOW DOES A COMPANY BRING A BIOSIMILAR TO MARKET? HERE ARE FIVE KEY STEPS:

One Two Three Four Five

BIOLOGICS
A biologic drug is developed using living organisms, which involves genetically engineering DNA to produce a particular protein. These biologic drugs are used to treat some of today's most common yet complex diseases, such as diabetes, cancer and autoimmune diseases.

One Two Three Four Five

BIOSIMILAR ENGINEERING
A company will identify a biologic to reproduce as a biosimilar. It will then work to engineer a biosimilar molecule which mirrors – as closely as possible – the product attributes of the original biologic (the reference product).

One Two Three Four Five

TESTING AND REGULATORY APPROVAL
Once the biosimilar drug is shown through testing to be as safe and effective as the reference product, the company developing the biosimilar will submit an application to the market's regulatory body.

One Two Three Four Five

REGULATORY BODY ASSESSMENT
Regulators assess the bioanalytical data to determine the degree of similarity between the biosimilar and its reference product. If proven, the biosimilar can move through an abbreviated development pathway.

One Two Three Four Five

APPROVAL AND SALES
Once the regulatory agency has approved the biosimilar and the patent(s) for the reference product have expired, the biosimilar can be marketed and sold.

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1 Dalgaard, Karsten, Matthias Evers, and Jorge Santos De Silva. "Biosimilars Seven Years On: Where Are We and What's Next?" McKinsey & Company, 1 Feb. 2013.