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Biosimilars: Less than a decade and a new paradigm already?

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The first biosimilar approval took place in Europe in 2006. Now, not even a decade later, EMA has granted 12 such product approvals, recently recommended MAA to two monoclonal antibodies, and dozens more are underway in the US under the "new-ish" (February 2012) biosimilar approval guidelines. Several molecules are racing to the FDA finish line to garner the title of first approval under these guidelines; most notably Hospira's EPOE biosimilar to Amgen's EPO.

Despite the frenzy, the Biologics Consulting Group predicts that the 2015 world market for biosimilar drugs will be $12 BN, down by $2BN from the 2010 global market. While upturns are projected for 2020 as markets emerge in the less developed, less regulated, but high growth regions such as the BRIC nations, it seems that the 25% CAGR of the less developed markets will carry the torch. In fact, the European market has shown a disappointing less than 1.5% CAGR over the last five years, despite earlier predictions of great wealth and market dominance provided by protein drugs' new era of me-too molecules.

In fact, while many new entrants pour into this space, as many old soldiers are exiting, especially in some of the blockbuster drugs (>$3BN annual markets). Surprisingly, many of those exiting are among the best capitalized, most experienced and globally dominant of the specialty pharma/generics players. The reasons given? Mostly "regulatory uncertainties" and high costs of development. It is daunting, indeed, to a new entrant to this field, to see battle savvy veterans retracting from such overtly attractive market propositions.

Market forecasts suggest that the current climate may just be taking "a breather" to see which way the regulatory winds are blowing. This discussion will focus upon some key strategic initiatives to be undertaken by companies developing biosimilar molecules, to pro-actively win this battle by avoiding the reactive behavior of the wait and see approach. As an example, development costs and timelines can be managed more effectively by combining global approval strategies. Markets in the West will be enriched by establishing clear-cut methods to establish interchangeability, thus fostering a new twist on Hatch-Waxman provisions. Market opportunities created by the exclusivity period ensuing will likely call the question on interchangeability to EMA and thereafter, to the developing regions of the world. The discussion will conclude with some likely scenarios that will play out as biosimilar product development, regulatory strategy, marketing and distribution globalize and mature.

Biography

Stephanie Finnegan is the President of bioRASI's Biotherapeutics Division. bioRASI is a Miami-based, global CRO with special expertise and focus on generics and biosimilar clinical development. The company is currently running the first clinical trial to be presented to FDA under the "new" 2012 Draft Guidance. She has been prominent in the South Florida biotechnology industry since founding Goodwin Biotechnology in 1993. Goodwin was the industry's first biologics contract manufacturer and specialized in the manufacture of diagnostic and therapeutic monoclonal antibodies and recombinant proteins for use in Phase I-III human clinical trials. She led Goodwin until it was acquired in 2004 by an Indian pharmaceutical company. After remaining as CEO for several years after that acquisition, she joined bioRASI to assist in ramping up the CRO's activities in biotherapeutics translational medicine, including cell therapies, innovative and biosimilar molecules. bioRASI has staked a prominent position in the biosimilars arena, leveraging both its expertise in CMC biologics as well as its long history of managing pivotal clinical trials of multi-specialty (generic) pharmaceuticals and 505(b)(2) drug approvals.

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