The promise of biosimilars

These are exciting times for biosimilar developers. Earlier this year an FDA advisory committee unanimously recommended approval of the first biosimilar to gain regulatory clearance in the US. In Europe, the biosimilars market has entered the next stage of evolution; Celltrion and Hospira's biosimilar Remicade, sold under the brand names Remsima and Inflectra, was approved in September 2013 and has since been marketed in a number of European territories. Hospira – which recently announced it is to be acquired by Pfizer – launched Inflectra in some of Europe's largest markets in February this year, including France, Germany, Italy and Spain. Paul Greenland, Hospira's Vice President of biologics, explains what the company's aspirations are in this potentially disruptive market.

Mr. Greenland explains that biosimilars, , are less costly imitations of drugs known as biologics, which are used to treat a range of diseases including cancer, rheumatoid arthritis, diabetes, and anaemia. When compared to generics, in other words copies of conventional, small-molecule drugs, the savings with biosimilars are smaller because the development and manufacture of biologics are more expensive, and the regulatory challenges more complex. Biologic drugs are made using living cells that treat disease, usually by genetically modifying cells. The molecular makeup of each biosimilar treatment will look unique, even though they all have similar outcomes. Each new biosimilar has to run clinical trials to prove the outcome matches that of the biologic it's imitating, according to recently announced guidelines from the FDA.

Hospira is one of the first companies to submit regulatory applications for biosimilars to the FDA, with two applications already submitted, including one through its partnership with Celltrion, a South Korean company that specialises in monoclonal antibodies. Hospira also is the only US-based company with biosimilars approved in Europe, including Retacrit™ (epoetin zeta), which was launched in Europe in early 2008, and Nivestim™ (filgrastim), which entered the European market in 2010 and was approved in Australia in 2011. In 2013, Hospira received European Medicines Agency (EMA) approval for Inflectra™ (infliximab), the first biosimilar monoclonal antibody approved in Europe. Hospira's global biosimilar pipeline is one of the largest in the industry, comprised of a combination of biosimilars being developed in-house and biosimilars from Hospira's partners.

"The potential of biosimilars is huge, for both pharma and patients," says Mr. Greenland. "In the markets where we are currently commercialising biosimilars, we have seen biosimilars decrease the costs of biologics by 20 to 30 percent. This has allowed healthcare systems to reduce their healthcare spending, while at the same time increasing patient access to these important biologic medicines."

Underscoring the commitment of big pharma to biosimilars, Pfizer is spending $17 billion to acquire Hospira, which also is a leading provider of injectable drugs and infusion technologies.

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