

Biosimilars: Surveying the Market Landscape

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Abstracts

Worldwide, the story is the same. Governments want cheaper drugs for their populations, while the number and kinds of diseases affecting them continue to evolve and grow.

Since 1976, when Genentech became the world's first biopharmaceutical company, treating the more devastating diseases such as genetic disorders has been taken up by biologicals, medicines that copy or closely resemble endogenous human proteins.

And while biologicals will represent 50 percent of the industry's top 100 products by 2014, they have drawbacks: they're 20 times more expensive to consumers than standard drugs, and many will soon lose patent protection.

What will fill the void? Already, several biosimilars have entered the market around the world, as regulators in the US, EU, Japan, Canada and Australia pave the way for competition between biologics and their generic cousins.

But unlike generics, biosimilars face several significant hurdles. A lack of stakeholder confidence in generics also exists for biosimilars, which are far more complex to develop and have, in some cases, created more medical issues than they solved.

Obtaining approval is costly and because biosimilars are extremely complex, they cannot follow the abbreviated approval process that generics enjoy. What's more, manufacturing costs are high and distribution is complicated. Substitution is not permitted by pharmacists, yet marketing requires an approach directed to specialists.

Yet the biosimilar industry continues to expand. And in *Biosimilars: Surveying the Market Landscape*, FirstWord examines exactly how it is happening. The wide-ranging and thoroughly researched report examines early entrants to the market, in addition to

those shaping up to be the leaders in this still emerging industry. The report reviews all aspects of biosimilar production, from manufacturing and marketing to the regulatory landscape. It also provides a breakdown of the current EU and American markets, as well as a close look at key biopharmaceuticals, leading companies and innovators.

The report offers insights into:

The current regulatory environment worldwide

The leading biosimilar drugs and the companies making the most headway

Key features

Complete overview of the current issues facing biosimilars

Breakdown of the regulatory picture in the EU, United States and other markets

Review of target biopharmaceutical products

An up-to-date overview of leading biosimilar companies, innovator pharmaceutical firms and companies in emerging markets

Key biopharmaceuticals covered in this report include

Somatropin

Epoetin

Filgrastim

Insulin

Interferon alpha and beta

Low-molecular-weight heparins

Monoclonal antibodies and anti-inflammatory fusion proteins

Follitropin

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TARGET BIOPHARMACEUTICAL PRODUCTS

Somatropin (growth hormone)

Epoetin (erythropoietin)
Filgrastim
Insulin
Interferon alfa
Interferon beta
Low-molecular-weight heparins
Monoclonal antibodies and anti-inflammatory fusion proteins
 Immunomodulators – anti-TNF antibodies
 Cytotoxic mAbs
Follitropin (follicle-stimulating hormone; FSH)
Vaccines
Enzymes
 Imiglucerase
Blood coagulation factors

BIOSIMILARS COMPANIES

Generics manufacturers
Sandoz
Teva
Hospira
Stada
Mylan
Watson
Actavis
Apotex
Other generics manufacturers
Innovator pharmaceutical companies
 Merck & Co.
 Pfizer
 GlaxoSmithKline
 Eli Lilly
 AstraZeneca
Companies in India and other emerging markets
 Biocon
 Dr Reddy's
 Reliance Life Sciences
 Intas
 Wockhardt

Ranbaxy (Daiichi Sankyo)

Cipla

Other markets

FUTURE PROSPECTS

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