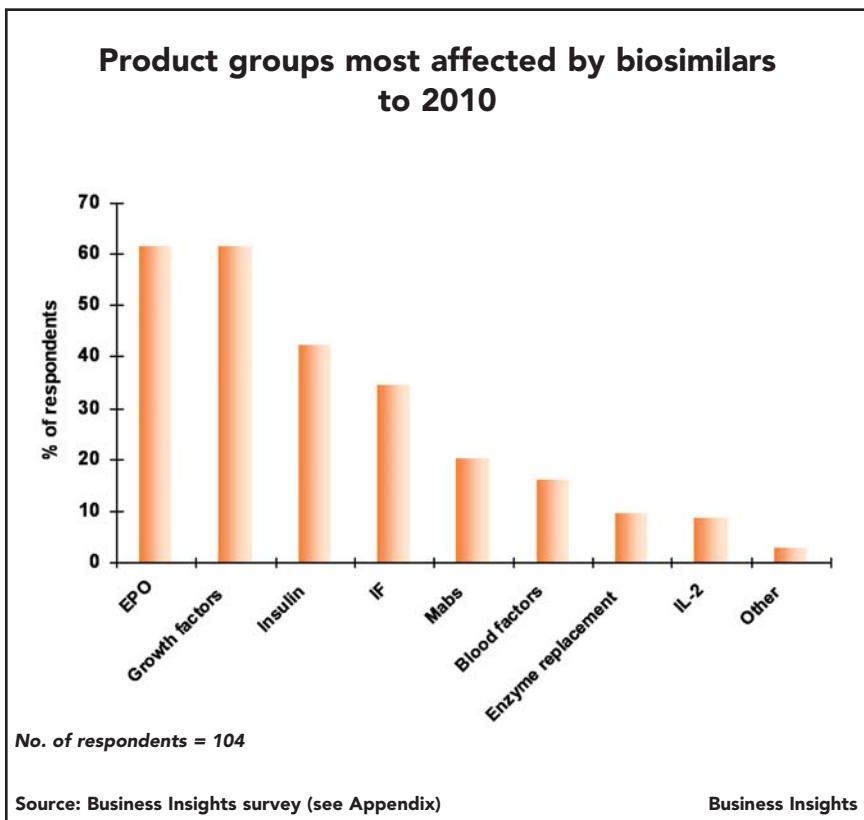


# The Future of Biosimilars

## Key opportunities and emerging therapies

**New Healthcare Report - Published September 2007**

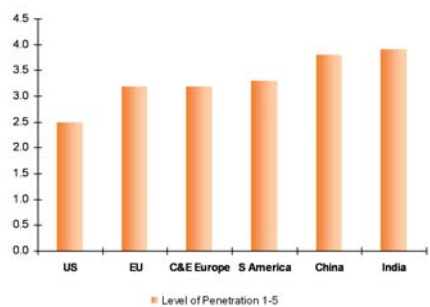


**Use this new report to help you answer the following key questions:**

- Who will be the early market leaders in the global biosimilars industry?
- What are the planned biosimilar launches of major companies and how advanced is their development?
- How can developers differentiate biosimilar products from their competitors?
- What will be the major entry barriers facing biosimilars and how can these be overcome?
- Which are the best performing biosimilars in the market?
- To what extent do biosimilars threaten established brands?

## Key issues examined in this report...

**Fig 3.3: Markets with highest potential for biosimilar penetration**



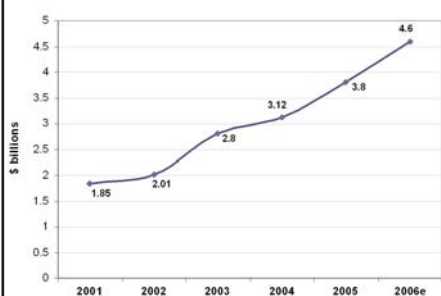
Source: Business Insights Survey Business Insights

"The headstart achieved by biosimilars in China and India is reflected in the responses to the Business Insights survey which asked respondents to rate biosimilars' greatest penetration in geographical markets by 2010, on a scale of 1-5; where 1 is the lowest and 5 the highest. The US received the highest number of responses with the lowest score, giving an average score of 2.5..."

- **Regulatory hurdles.** The future US biosimilars market is dependant upon the provision of a regulatory framework, facilitated by the Congressional enactment of legislation. It is speculated that the earliest introduction of biosimilars is unlikely to occur before 2010.
- **Competition from India and China.** The strength of Indian and Chinese product pipelines indicate that they are ready to exploit market opportunities on a global scale.
- **Key development opportunities.** Original brand sales within the \$12bn market for Erythropoietin are likely to be drastically eroded when biosimilar competition reaches the EU market in 2007.
- **Pricing Strategies.** With biosimilar prices expected to be 10% to 20% lower than the reference brand, pricing tactics are finely poised between recouping investment and incentivizing brand switches.
- **Marketing Strategies.** The need for biosimilar marketing activities to incorporate patient-oriented educational campaigns to overcome negative perceptions, rather than mimic generic drugs' marketing.

## Some key findings from this report...

**Fig 3.4: Development of Chinese biopharmaceutical market, 2001-2006**



Source: National Statistics Bureau of China; BioPlan Associates

"Development of the Chinese biopharmaceutical market has been rapid since the first biotech product – Shenzhen Kexing Biotech's human interferon- $\alpha$ 1b – was introduced in 1989, with sales doubling between 2001 and 2005. Although accounting for just 7% of the pharmaceutical market in 2005, sales of biopharmaceuticals (including biological and biochemical products) grew 21.8% during the year to reach \$3.8 billion..."

- **Major brands of Erythropoietin products have become key targets for biosimilars**, after accounting for 18.7% (\$12bn) of global pharmaceutical sales in 2006. Amgen's Aranesp held 55% of the EPO market in 2006, typifying the rapid growth of long-acting products.
- **Generics companies with a strong European presence, particularly Sandoz, will take early command of the biosimilars industry.** Indian companies including **Reliance life Sciences, Ranbaxy** and **Intas Biopharma** will also make an early challenge.
- **The Chinese biopharmaceuticals market grew an estimated 21% in 2006 to reach \$4.6bn.** Although Chinese biosimilar companies will continue to derive the majority of their revenues domestically, exports to developing markets are becoming increasingly important.
- **A biosimilar costs in the region of \$10mn to \$40mn to develop, compared to \$1mn to \$2mn for a small molecule generic**, with development timelines comparable to new biologics. Low initial profitability will be reflected in few standalone competitors, and industry traits are to include alliances, partnerships and acquisitions.

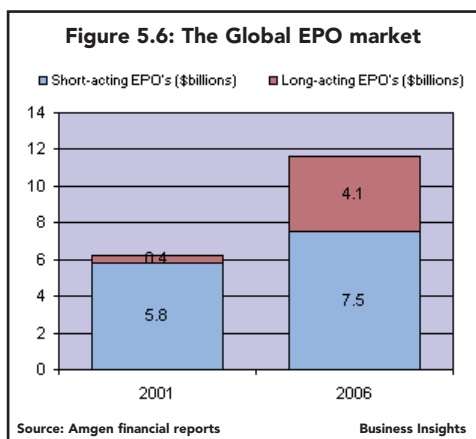
## The Future of Biosimilars

Biotechnological products are continuing to exhibit substantial revenue gains, with the top 12 biologics registering sales growth of 20% in 2006, amassing a market share of \$64 billion. However, the impending patent expiry of many leading products has created a number of highly attractive market opportunities for biosimilars. To exploit this significant potential, a complex route to market must first be negotiated, including numerous barriers to entry and regulatory hurdles. Prominent obstacles include the sizeable investments in time and expertise associated with biosimilars development, in addition to the fundamentally higher levels of cost and risk incurred by manufacturers. Legislative restraints in the US and a recently established regulatory framework in the EU have also contributed to industrial obtrusiveness, but for those developers who persevere, biosimilars are set to offer lucrative returns.

**The Future of Biosimilars: Key opportunities and emerging therapies** is a new report published by Business Insights, examining the current market and regulatory environment for biosimilars in Europe, India, China and the US, whilst identifying the trends that will shape future market development. The market penetration strategies of individual companies are analysed and the opportunities and challenges involved in the development of biosimilars are highlighted. Finally, an exclusive Business Insights survey will offer a unique perspective into the biosimilar pipelines that are set to mould the future competitive landscape of the industry.

**Use this report to enhance the performance of your biosimilar strategies, identify potential market opportunities and respond effectively to the imminent threat of biosimilar competition...**

## Top five reasons to order your copy today



"Neose is targeting the long-acting erythropoietin market, represented by Amgen's Aranesp (darbepoetin alfa), which generated sales of \$4.1 billion in 2006. Aranesp now accounts for over 35% of the global EPO market valued at \$11.6 billion in 2006. Of Aranesp's total sales, \$2.8 billion were generated in the US and the remaining \$1.3 billion derived from international sales."

- **Discover which strategies can overcome the barriers to establishing biosimilars**, and adopt the necessary measures to compete effectively in the international marketplace.
- **Compare the product portfolios of the early leaders** in the international market, including **Teva, Sandoz, Barr (Pliva), Stada (Bioceuticals), BioGeneriX (Ratiopharm)** and **Bitoton**.
- **Identify key product opportunities and potential competitive threats** across the major biotech product groups in the **EU, India, China** and the **US**.
- **Gain insights into key industrial trends** that will shape the future development of the biosimilars market landscape.
- **Evaluate prospective business opportunities, including strategic alliances and partnerships** in research, manufacturing and marketing.

## Sample Information: 'The Future of Biosimilars'

### Chapter 1: Introduction to biosimilars

#### Key trends in biosimilar product development

Patent expiry, market potential and ease of product development are key factors that determine product targets for biosimilar developers. The leading biotech drugs have achieved blockbuster status, with the top 20 biotech products all recording sales of over \$1 billion in 2006, and patents have expired or are due to expire on many leading products.

While the lack of a regulatory framework has impeded the development of the biosimilars market in the US and Europe, companies in countries such as India and China have not encountered the same barriers to market entry. As a result, the biosimilars industry has launched a broad range of products in emerging markets.

Recombinant protein therapeutics and monoclonal antibodies (MAbs) account for the major share of over 90% of biotech sales. The obstacles in developing genuine MAb biosimilars are considered more challenging than rDNA proteins since the innovator's cell line plays a key role in defining the MAb's characteristics. As a result, most biosimilar development has focused on rDNA proteins. Human growth hormone (hGH) products account for the majority of biosimilars that have reached the commercial market. hGH products are relatively simple, non-glycosated proteins for which it is comparatively easier to prove similarity with the original, reference biotherapeutic than for more complex molecules such as erythropoietins. Unlike many other categories, there are no second-generation hGH products.

Despite the potential market for biosimilar insulin, with many of the major patents on standard insulin having expired and its relatively simple protein structure, biosimilar insulin does not feature in many major companies' product portfolios. The insulin market poses certain challenge which makes this sector less attractive to biosimilar developers. It is dominated by Lilly, Novo Nordisk and Sanofi Aventis and has the added complexity of the need for advanced delivery systems. Insulin analogs, which have eroded the market for standard insulin in the US, remain patent-protected until 2013.

Nevertheless, demand for cheaper alternatives to branded insulin in developing markets has seen the introduction of biosimilar versions of insulin in these markets. The resources needed to develop and market biosimilars will define the players in the international marketplace. Since development of biosimilars entails...

**Table 1.3: Marketed biosimilars by product group**

Product group	EU	US	China	India
hGH	✓	✓	✓	✓
Insulin			✓	✓
EPO	*		✓	✓
IF			✓	✓
IL-2			✓	
G-CSF			✓	✓
GM-CSF			✓	✓
MAbs			✓	✓
Vaccines			✓	✓

\* Recommended for approval

Source: Author's research; Company Reports Business Insights Ltd

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