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PUBLISHER Lisa Banket
EDITOR Taren Grom
CREATIVE DIRECTOR Marah Walsh

DIRECTOR OF SALES
Darlene Kwiatkowski

MANAGING EDITOR
Denise Myshko

CONTRIBUTING EDITORS
Elisabeth Pena
Kim Ribbink
Lynda Sears

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Safety, efficacy, and ethics

Total sales of biotechnology drugs susceptible to generic competition by the end of 2005 are expected to be $13.5 billion, according to Datamonitor. The overall therapeutic proteins market will double in size by 2010 to more than $59 billion.

Pharmaceutical and particularly biotechnology companies must find ways to exploit opportunities in this attractive market as growth from other revenue streams slows. Compounding this trend is the threat of widespread biogeneric competition, which industry experts predict will become a reality by 2010. Thus, companies must aggressively protect patents and develop reformulations to remain competitive.

The therapeutic proteins market is becoming increasingly attractive to generic competitors, which pose a significant threat to the revenue streams of some of the more established classes. According to Datamonitor analysts, there are a number of drivers for the introduction of generic competition. Firstly, the market potential for biogenerics is sizable, with more than half of the 2001 therapeutic protein market being susceptible to generic erosion of market share by the end of 2005. Secondly, because of the high prices of therapeutic protein products, any cost savings to the payer, regardless of how small, could be a significant driving force. Consequently, many generics manufacturers are beginning to make strategic moves within this area.

There are high barriers to entry, however, and this will result in companies that develop biogenerics making considerable investments to gain access to the market. These include the high cost of manufacturing biologic products, the expense of gaining regulatory approval for this new class of products, and the investment required to reassure the medical community of the safety of the products.

In addition, generic companies can expect to come up against considerable opposition from pharmaceutical companies with branded biologic products, adding numerous court cases to the hurdles that must be negotiated. The absence of an approval pathway for generic biologic products is the only legitimate barrier to the introduction of generic competition. The high-market potential for biogeneric products, coupled with the significant cost savings experienced by healthcare payers, will ensure that within the next 10 years, a legal pathway will be established.


Dr. Christopher Searcy

While it is of interest to contemplate the concept of generic biologics, there are a number of issues that need to be addressed.

"While it is of interest to contemplate the concept of generic biologics, I believe there are a number of issues that need to be addressed before one can really say that a biologic manufactured by one process in one facility is equivalent to the same biologic manufactured by a different process in a different facility," says Christopher J. Searcy, Pharm.D., VP of corporate development at Nektar Therapeutics. "Until a track record has been established, demonstration of efficacy and safety will still be the norm rather than the exception for biologics."

The Biotechnology Industry Organization (BIO) has made public its position that the approval of follow-on biotechnology products, biogenerics, must be based on the same rigorous standards applied by the Food and Drug Administration (FDA) for the approval of pioneer biotechnology products. According to BIO, the science does not exist to provide an alternative to a full complement of data, including clinical evidence, to demonstrate safety and effectiveness for follow-on biotechnology products.

"Even if a generic company does submit a complete filing, it hasn't shown that the product is the same," says Gillian R. Woollett, MA, D.Phil., VP of science and regulatory affairs at BIO. "All that it has shown is that what was submitted has purity, potency, identity, and/or is safe and effective for the use for which it is proposed. But it doesn't show that the two products are substitutable."

Taren Grom
Editor