International Journal of Risk & Safety in Medicine 21 (2009) 111–113
DOI 10.3233/JRS-2009-461
IOS Press

Appendix 2

IMS Health reports global biotech sales grew 12.5 percent in 2007, exceeding $75 billion [1,*]

IMS news releases

Norwalk, CT, June 17, 2008 – Global prescription sales of biotech drugs increased 12.5 percent in 2007 to more than $75 billion, according to a new report by IMS Health (NYSE: RX), the world's leading provider of market intelligence to the pharmaceutical and healthcare industries. The global biotech market grew at nearly double the rate of the global pharmaceutical market, which increased 6.4 percent in 2007.

"The biotech market has expanded dramatically during the past five years, consistently exceeding overall pharmaceutical market growth two-to-three fold", said Murray Aitken, senior vice president, Healthcare Insight, IMS. "Recent innovations, the continued expansion of approved indications for existing products, and the gradual uptake of biotech products outside the US have fueled that growth, and improved the quality of life for millions of patients across a growing number of disease areas".

During the past five years, the range of biotech products and their use in multiple therapy areas have steadily increased, creating a major source of market growth. Twenty-two biotech products generated sales exceeding $1 billion in 2007, compared with just six products in 2002. Last year, targeted oncology therapies, auto-immune agents, anti-diabetic agents, and pure vaccines represented both the majority of the market and majority of growth. The US remains the largest market for biotech products, representing 56 percent of total sales last year. The five major European countries have steadily increased their share of this market over the past five years, to 24 percent in 2007. Japan's share of the market has declined slightly and now represents 5 percent of global biotech sales.

New reality for biotech products

IMS expects that, during the next five years, the global biotech market will more closely parallel the traditional pharmaceutical marketplace, reflecting changing industry dynamics. "After 20 years of what some would call a 'charmed life', biotech is now facing a new reality", said Aitken, who noted that biotech market growth last year moderated from the 18.2 percent rate experienced in 2006. "Loss of

[1] Available at http://www.imshealthcanada.com/ims/portal/front/articleC/0,2777,6599_3665_84051170,00.html, accessed 07 January 2009. Republished with permission.

[*] Address for correspondence: Gary Gatyas. E-mail: ggatyas@us.imshealth.com.

exclusivity and competition from biosimilars, crowded therapy areas with weaker sales growth, payers showing more reluctance to fund innovative drugs without compelling value propositions, and safety concerns for some therapies will all contribute to a more moderate growth environment through 2012. Yet, we expect the biotech sector to remain one of the most robust segments of the marketplace with a continued strong flow of innovative products to the market".

The IMS 2008 Global Biotech Perspective report identifies the following key market dynamics influencing future market growth:

- *Continued strong flow of innovative products*. The depth and breadth of the biotech R&D pipeline has never been stronger. Biotech products currently represent 25 percent of the total pharmaceutical pipeline. Although only three new biotech products were launched in 2007, a sharp reduction from 2006, the near-term pipeline is robust and includes six products that are expected to be launched by the end of 2009 that will potentially reach $1 billion in sales. These include innovative treatments for respiratory synctial virus, melanoma and osteoporosis.
- *Intensifying scrutiny by payers to demonstrate the effectiveness and value of biotech products*. As new innovative biotech therapies are introduced, the level of scrutiny by payers around the world regarding their value will continue to intensify. Health technology assessment agencies are increasingly being used to assess the value of all biopharmaceutical products and recommend their inclusion on reimbursement lists at both the national and regional levels in countries that include the UK, Spain, Italy, Canada and Germany. In the US, health plans also are more rigorously assessing both the clinical efficacy and economic rationale for using new products relative to existing, less expensive treatments.
- *Greater impact from product safety issues*. The challenge of balancing patient safety with efficacy of treatment is particularly acute in many of the therapy areas where biotech products have become an important part of treatment protocols. The impact of last year's regulatory reviews and a labeling change by the FDA for erythropoeisis stimulating agents (ESAs) led to fewer patients using ESAs, as well as an adjustment in reimbursement guidelines by the Centers for Medicare and Medicaid Services. ESA sales growth declined 9 percent in 2007, compared with a 12 percent increase in sales in 2006. And this month, the FDA released an early safety communication indicating that it is evaluating anti-TNF treatments as a potential cause of lymphoma and other cancers in children taking the drugs to treat juvenile idiopathic arthritis or Crohn's disease.
- *Growing competition among biotech products*. In several key therapy areas, there is a growing level of competition between biotech products and alternative treatments, as well as among biotech products. Market expansion increasingly will be predicated on the ability of companies that bring biotech products to market to use biomarkers or other means of differentiating treatment response in patient segments.
- *Emerging competition from biosimilars*. Biosimilars, or follow-on biologics produced by companies other than the originator, are expected to have only a modest impact on the market over the next 5–10 years. The introduction of biosimilar epoeitin alfa in European markets in 2007, for example, has had a negligible impact in the market to date. And biosimilar omnitrope, introduced in 2006, has captured less than 1 percent of the somatropic human growth hormone market. Yet, they represent a shift in the biotech marketplace that over time will bring emerging competition from biosimilars following the loss of exclusivity of original products. The regulatory approval process for biosimilars in the US remains subject to legislative action and implementation by the Food and Drug Administration, and is expected to be resolved in the near-term.

Added Aitken, “In today’s market environment and for the foreseeable future, companies with biotech products in their portfolios will succeed only if they meet increasingly demanding regulatory standards, deploy effective commercial models that are accompanied by compelling evidence of their products’ value, and develop pricing and market access strategies that ensure that patients have access to the benefits that these new products deliver”.