

Generics/Biosimilars - Key to health expenditures control?

In international healthcare news rarely a week goes by without a warning that a developed country's healthcare system is on the verge of bankruptcy. Invariably, the reason for these crises is the inability of governments to effectively monitor and control healthcare expenditures. To address this problem, many governments decide to decrease reimbursement rates on selected drugs, discontinue reimbursements, or suppress new drug approvals.

However, the pharmaceutical industry is not only threatened by these economic realities, but also by new biodrugs coming on the market, directly competing with traditional chemical formulations. Pharmaceutical companies who are seeking potential profits released by patent expiration are finding a rockier economic path than expected.

Given these numerous threats, "How will the 'Big Pharma' face the challenge?" Some companies have created their own "generic" division; others have turned to medical devices as a source of revenues. While no ideal strategy seems to have emerged, many of the historically powerful players in the market are spending tremendous resources in order to protect their profitability.

Market Overview: The Market of Generics

Key Figures:

- The worldwide pharmaceutical generic market is estimated at \$50 billion in 2006.
- The market is growing at about 10% annually and is expected to continue at this pace until at least 2010.
- Revenue from new products will not offset losses associated with expired patent protection of branded drugs.

Main players:

- The US market represents almost half of the total world market for generics.
- US, Germany and Japan account for over 70% of total sales of generics.

Drivers:

- Branded drugs compete on efficacy and low side-effects. In contrast, generics' market shares depend largely on price: the greater the price differential between the branded and generic product, the greater the generic market opportunity. Overall, the more profitable the originator drug, the greater appeal for generic production.
- Patent expiration initiates market demand for and supply of generics.
- Between 2004 and 2009, almost 40 of the major branded drugs are expected to lose patent protection, resulting in a potential loss of over \$40 billion for the originators. Many originators plan to market generics by partnering with a generic drug manufacturer or by producing generics themselves.

- The potential of the generics drug market is affected by the willingness of governments to implement cost containment policies. These policies are seen as a solution to reducing the growing health cost expenditures related to drug manufacturing, shortening the cost gap between the drug originators and the production of generic drugs.

Sources: LEEM, The French Pharmaceutical Companies Association, <http://www.leem.org>
Amegen, a leading human therapeutics company in the biotechnology industry

CASE STUDY: New product formulation testing

- The Company: A large pharmaceutical company, an international leader in type II diabetes treatment, is looking for an alternative formulation to compete with generics.
- The Challenge: Identify the best prototype out of three potential designs and develop the ideal market communication strategy. The project scope included contacting patients and pharmacists in France, UK and Germany.
- Our Solution: TMTG utilized focus groups with patients and pharmacists in several medium and large cities. Small rural areas (cities less than 2,500 inhabitants) were covered by performing face-to-face in-depth interview at patient homes and in pharmacies. Role playing exercises tested key market issues related to product choice, purchasing, and inventory management.
- The Impact: TMTG was able to help the client ,
 - 1) Gain understanding of the behavior of both patients and pharmacists in regard to type II diabetes treatment.
 - 2) Identify the prototype that would be best suited for launch after comparing economic potential, relevant added-value criteria, key success factors and possible communication strategies.



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HOT TREND

of the Quarter: Is biosimilar production a threat?

Marc de Garidel, Vice President of Southwest Region, Amgen

Q: Where do we stand today with regards to biodrug market shares?

A: Today, the biodrug business represents 10% of all drug sales, i.e. approximately \$50 billion. Its growth rate is 2.5 times greater than that for chemical based drugs, i.e. a yearly growth of 15-16%, versus 5-6% for chemical based drugs. The drug market is built on well established blockbuster drugs and new products; 50% of which are biodrugs.

Q: Do you believe that biodrugs sales are expected to reach a growth level that would surpass chemical based drug sales in the near future?

A: With a yearly growth rate of 15% and biodrugs representing 50% of new products, biotechnology should be responsible for 15% of all drug products, and a market turnover of \$100 billion within the next five years.

Q: Do you feel the pharmaceutical biotech industry is about to face the same challenges that the chemical based pharmaceutical industry faced against generics years ago?

A: There is striking evidence which demonstrates that biodrugs will face a unique challenge with generics.

Conventional drugs are:

- simple to copy
- easy to characterize regarding equivalence to princeps
- and easy to produce

The production of biodrugs on the other hand involves costly plants and complex processes, that are difficult to copy, requiring immense knowledge, PhD level staff and quality control steps to be carried out properly.

Minor differences in the production process may lead to unexpected side effects, which will mandate clinical stage III studies with the biosimilar product to check efficacy and safety across hundreds of patients.

These types of barriers set biodrugs apart from conventional drugs in terms of competition from generics, as it is much more difficult for a drug producer to enter the biosimilar drug market.

Q: What is the expected impact of biosimilar drugs on your Company?

A: Continuous innovation and current product improvement are key: for instance, we have spent years working to improve our genuine epoetin (Epogen®) which lead to the development of darbepoetin alpha (Aranesp®), helping us to fight back against biogenerics.

Q: Assuming that "Generization" is a larger problem that affects many other healthcare industries (device, etc), what is the appropriate response of leading players to preserve margins and market share?

A: The answers to such a general issue may be summarized in the following statements:

- Keep innovating to become and/or stay a leader in one's field of expertise;
- Decrease the risk by getting into the production of generics. Novartis, for instance, keeps innovative products for the brand and produces/commercialises generics through a subsidiary under Sandoz brand;
- Diversify into related fields of expertise such as Over The Counter (OTC) drugs.

For more information about Amgen, please visit <http://www.amgen.com>

Long version of this interview: www.themarketechgroup.com/minute/tmtg-min19-Garidel.pdf

ON THE HORIZON: Future of Biodrugs

HIGHLIGHTS

- In 2006 biotech product sales increased by 20%, up to \$40.3 billion
- For now, the impact of biosimilars on princeps drugs remains limited - In 2004 biosimilars accounted for only approximately 0.5% of the total biodrug market, compared to 7% for generics in traditional pharmaceuticals
- The 2006 FDA approval of Sandoz's Omnitrope seemed to open the way for biosimilars in the US market

AT STAKE!

- The EU has already passed bills defining the bio-similarity concept within the European community
- Not only are biodrugs complex and difficult products to characterize, but regulatory bodies hardly agree on a single definition for bio-generics - "biosimilars" for the EMEA are called "generic biologics" by the FDA

SO WHAT?

- Sales of biodrugs are expected to grow to reach 14% of the total pharmaceutical market by 2011, approximately \$114 billion
- Several new brands (Biotech products) launched in 2005 became block busters in 2006: Pfizer's Lyrica®, Sepracor's Lunesta®, and Amylin/Lilly's Byetta®.
- This emerging market will probably stimulate increased investment

Sources: LEEM, The French Pharmaceutical Companies Association, <http://www.leem.org>

THE ASSOCIATE CORNER: FDA regulation of generic biologics

The FDA continues to grapple with the regulatory pathway for "generic biologics", or "follow-on protein products" in its official language. Whereas the generic pathway for chemical drugs is well understood, the same regulation does not apply to follow-on biologics. This problem arises from historically established regulation of biologics under Public Health and Safety Act (PHSA), which lacks certain patent and generic provisions enjoyed by chemical entities.

In addition, biological complexity poses problems in determining the "sameness" of a follow-on biologics and a drug it is trying to copy. In some cases the FDA is able to use 505(b)(2) paragraph of the Food Drug and Cosmetic Act, a regulatory loophole, to enable a quasi "generic" route for a biologic product.

Otherwise, FDA works with each company on a case-by-case basis to determine what experimental data may be required to prove the sameness and bioequivalence of biologic drugs.

Kate Marusina, Ph.D. is a Life Sciences Consultant and is located in Sacramento, CA. She can be contacted at kmarusina@gmail.com. For additional information, go to www.yourSBIR.com

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