

A black and white photograph of two hands, one from the left and one from the right, with their index fingers pointing towards each other to form a square frame. The background shows a sunset over a body of water, with the sun low on the horizon. The top right corner of the image is overlaid with an orange rectangle containing the text 'GLOBAL HEALTH SCIENCES'.

GLOBAL HEALTH SCIENCES

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# Partners With Vision

## Global Pharmaceutical Report

2002 Defining Issues

# Defining Issues in the Pharmaceutical Industry

January - September 2002

## Financial

### Issues

- Top pharma's market cap fell more than 37% in the first half of 2002, with investors remaining under-confident, despite a 3<sup>rd</sup> quarter rebound.

- Consumer spending on prescription drugs rose 17% in 2001 to \$154 billion.

### Implications

- Once immune to economic downturns, the pharma industry faces economic pressures from weak stock performance, including research failures, drug pricing issues, regulatory changes, and generic competition.

- Although approximately 90% of the increase attributable to demand and utilization trends, pharmas are under pressure from government payers, insurers, and consumers to slow the rising cost of prescription drugs.

## Product Development

### Issues

- The global pharmaceutical industry spent \$30.4 billion on R&D in 2001, up 17% from 2000. The percentage increase in R&D spending for 2002 is estimated to be in the high double digits.
- In 1995, there were 17 blockbuster drugs on the market; today there are 48, and eight of those are mega brands, with sales of \$3 billion or more.
- Eighty billion dollars worth of pharmaceutical products will go off patent by 2005.

### Implications

- Some pharmaceutical companies have reorganized R&D to capitalize on autonomy and innovation, speed drug development, and provide incentives for scientists and researchers.
- It is estimated that large pharma companies must bring three new drugs to market each year to maintain 10% revenue growth.
- The generic industry anticipates a great opportunity with the expiration of top brand name pharmaceutical patents, while brand name manufacturers must develop and commercialize new drugs to replace those lost to patent expiry.

## Strategic Alliances/M&A

### Issues

- In the 2<sup>nd</sup> quarter of 2002, the number of pharmaceutical-related alliance deals held steady at just over 200. The majority of these deals were with biotech firms; 37% of those were for drug discovery tools. Leading therapeutic alliances remained focused on major disease such as cancer (21% of deals), infection and anti-virals (19% of deals), and neurological disorders (15% of deals).
- Bristol-Myers Squibb's record \$2 billion alliance deal with ImClone for Erbitux became one of the biggest corporate debacles of the period.
- Following a slowdown in M&A activity in the first half of 2002, Pfizer announced its acquisition of Pharmacia in a \$53 billion deal in July.
- In the first deal of a foreign company taking over a Japanese drug maker, Abbott Labs purchased Hokuriku Seiyaku for \$292 million cash in April 2002.

### Implications

- Alliance activity, rather than asset transactions, was predominant and has become one answer to the need for continued development of new drugs.
- ImClone's stock price plunged, and in October, their CEO pleaded guilty to insider trading, changing the landscape of pharma-bioalliances.
- Pfizer gains Pharmacia's complementary pipeline and expands the already largest sales force in the industry. Speculation of other industry consolidation was rampant following the acquisition.
- The Japanese pharma industry recently opened the doors to foreign drug companies through deregulation and tighter laws.

**Strategic Alliances/M&A (Cont.)****Issues**

- India-based Dr. Reddy's Laboratories acquired BMS Laboratories and its wholly owned subsidiary, Meridian Healthcare, UK.
- The international pharmaceutical outsourcing market stands at about \$8 billion and is likely to reach \$10 billion by 2004. However, contract Service Organization (CSO) offerings are actually on the decline.

**Implications**

- The buy-out marked Dr. Reddy's first overseas acquisition and is a key step in the company's efforts to globalize its business.
- Big pharma is taking on the role of CSOs, reaching out to other pharma and biotech to co-promote and co-market drugs.

**Product Performance**

- New drugs' exclusivity periods declined significantly.

- Pharmaceutical industry revenues decline while increasing prices for new drugs.

- Legal battles over patents and increased generic competition negatively impacted brand name drug revenues.

- Major patent case losses to generic drug makers force brand name manufacturers to find new revenue channels, push pipeline development, and expend large amounts of capital defending their franchises.

- Pharma companies' expansion into global markets continued as a result of deregulation and a strengthening global economy. The U.S. remained the largest drug market with 42% of global sales, followed by Europe, Japan, Latin America, and Asia/Pacific.

- The move toward greater globalization not only brings new competitors to global markets, but also boosts economic development and trade.

**Industry Change****Issues**

- The September 11 terrorist attacks and the following anthrax attacks position the pharmaceutical industry as a defense contractor, partner against bioterrorism, and philanthropist.
- In 2001, the global generics market was worth \$27 billion, an 11% increase over 2000. The generics market is expected to grow 13% per year over the next five years.
- Pharmaceutical companies are divesting non-pharmaceutical products, focusing attention and capital investment on the discovery and development of new drugs.

**Implications**

- Drug makers provided national security-related research, development, production and warehousing of drugs that would help thwart a biologic terrorist attack.
- The generics market is growing at a faster pace than the proprietary drug companies, which are taking a retaliatory approach to generic competition by reinforcing patents and patent extensions, and through the legal system.
- Shareholders attracted to the high-risk, high-reward business of pharmaceuticals have found a more consolidated market in which to invest.

**Public Policy (Cont.)**

<b>Issues</b>	<b>Implications</b>
<p><b>Argentina</b></p> <ul style="list-style-type: none"> <li>The devalued peso led to an increase in prices for most imported goods, including pharmaceuticals.</li> </ul>	<ul style="list-style-type: none"> <li>The government and industry associates are working together to find solutions to this health crisis, including reference pricing, generic substitution, and prescribing by international non-proprietary name. (INN)</li> </ul>
<p><b>Australia</b></p> <ul style="list-style-type: none"> <li>The federal 2002/2003 budget introduced changes to the Pharmaceutical Benefits Scheme (PBS) in an effort to reduce spending growth.</li> <li>In August 2002, the federal government moved forward efforts to develop international tax reform measures.</li> </ul>	<ul style="list-style-type: none"> <li>Government deals with generics firms and new software will facilitate use of generic drugs in return for price reductions.</li> <li>While not directed specifically at pharma industry, future tax reforms could facilitate Australian and foreign pharma firms' investment, international expansion opportunities, and domestic R&amp;D.</li> </ul>
<p><b>Canada</b></p> <ul style="list-style-type: none"> <li>Canadian health officials considered overriding Bayer AG's patent for Cipro by ordering generic ciprofloxacin tablets from Apotex Inc; however, a deal was reached to preserve patent rights.</li> </ul>	<ul style="list-style-type: none"> <li>The surge in demand for antibiotics to treat anthrax in response to bioterrorism threats forced industry and governments to address capacity, stockpiling, and IP policies in light of emerging national security and public health concerns.</li> </ul>
<p><b>European Community</b></p> <ul style="list-style-type: none"> <li>To increase access to medicines in the developing world, the EC Commission announced the launch of a clinical development program for treatments for TB, HIV/AIDS, and malaria.</li> <li>In February 2002, the EC put forward proposals to increase the number of pediatric drugs.</li> <li>The European Parliament approved the Sixth Framework Research Programme for 2002-2006, prohibiting the financing of research involving human cloning for reproductive purposes, research intended to modify the human genetic heritage, and the creation of human embryos solely for research of stem cell procurement purposes.</li> </ul>	<ul style="list-style-type: none"> <li>The European industry federation, EFPIA, supports the program, but has cautioned that it must be scientifically driven and should promote a strong partnership between national and international public/private not-for-profit partnerships.</li> <li>The attitude of European regulators has changed from disapproving of clinical trials on children to encouraging them.</li> <li>The EC Commission believes that the framework will help achieve its stated goal of becoming the world's most competitive knowledge-based economy by 2010.</li> </ul>
<p><b>France</b></p> <ul style="list-style-type: none"> <li>In February 2002, the lower house of Parliament passed a bill allowing research on stem cells from supernumerary embryos.</li> <li>In March 2002, Parliament and the executive approved a law updating a charter related to patients' rights and the quality of the health care system.</li> <li>In June 2002, French physicians agreed to eventually prescribe medicines using the international proprietary name (INN).</li> </ul>	<ul style="list-style-type: none"> <li>A final decision on stem cell research is expected in 2003 when the upper house of Parliament and President Chirac decide on a bioethics bill passed by the lower house.</li> <li>The new law provides patients with expanded protections, including rights to access their personal health information.</li> <li>A new contract between doctors and the national health insurance body will ensure that prescribers use INN in return for higher fees; it is expected to increase the use of generic drugs.</li> </ul>
<p><b>Germany</b></p> <ul style="list-style-type: none"> <li>The arrival of a new health minister in January 2001 ushered in a series of health policy reforms throughout 2001 and into 2002. <ul style="list-style-type: none"> <li>the pharmaceutical and remedy budgets were eliminated;</li> <li>the upper house of Parliament passed the DRG law; and</li> <li>an embryonic stem cell law was enacted.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>These changes herald a new era of policies aimed at cost containment.</li> </ul>

**Public Policy (cont.)**

Issues	Implications
<p><b>India</b></p> <ul style="list-style-type: none"> <li>In May 2002, Parliament approved the Patents (Second Amendment) Bill.</li> <li>The Pharmaceutical Policy 2002 was approved by the Indian cabinet.</li> </ul>	<ul style="list-style-type: none"> <li>The bill marks the transition from process patent regime to product patent regime. The U.S. Trade Representative and multinational pharma companies claim the bill fails to provide adequate patent protection.</li> <li>The Policy provides basis for expected relaxation of drug price controls.</li> </ul>
<p><b>Italy</b></p> <ul style="list-style-type: none"> <li>The government adopted a controversial 5% across-the-board price cut for pharmaceuticals, a clause allowing for earlier generic competition for pharmaceuticals coming off patent, and a 50% reduction of the number of conferences sponsored by pharmaceutical companies.</li> </ul>	<ul style="list-style-type: none"> <li>The policy has caused an uproar in the Italian industry, which believes that it will severely impact major pharmaceutical companies whose drugs are coming off patent in the next several years.</li> </ul>
<p><b>Japan</b></p> <ul style="list-style-type: none"> <li>In July 2002, Parliament approved a plan issued by the Ministry of Health, Labor and Welfare (MHLW) to reduce state health care spending.</li> <li>MHLW outlined a broad strategy to enhance the international competitiveness of the domestic pharmaceutical industry by 2005.</li> </ul>	<ul style="list-style-type: none"> <li>Reforms will increase health care costs incurred by some senior citizens through higher co-payments, and for employees via higher premiums, beginning in 2003.</li> <li>Proposed plans include development of a basic pharma research institute, expansion of clinical trial capacity, and new approaches to collecting post-market data.</li> </ul>
<p><b>Kenya</b></p> <ul style="list-style-type: none"> <li>In 2001, President Daniel arap Moi declared AIDS a national emergency.</li> </ul>	<ul style="list-style-type: none"> <li>In June 2002, the government cleared the way for the parallel importation or compulsory licensing of patented HIV/AIDS drugs by re-amending an industrial property law.</li> </ul>
<p><b>The Netherlands</b></p> <ul style="list-style-type: none"> <li>In one of its first policy statements, the new Dutch government announced it will not lift the temporary ban on cloning of human embryos.</li> <li>As of July 2002, pharmacy customers are not required to have prescriptions for common medicines.</li> </ul>	<ul style="list-style-type: none"> <li>Cloning is banned, but legislation provides a legal framework for this type of research in the future.</li> <li>The law presents a new standard for medicines in pharmacies and drugstores.</li> </ul>
<p><b>South Africa</b></p> <ul style="list-style-type: none"> <li>In its 2002 national budget, the South African government tripled spending on the fight against HIV/AIDS. In July, the government was ordered by the Constitutional Court to provide nevirapine in all public health facilities to pregnant women and their babies to prevent transmission of HIV.</li> </ul>	<ul style="list-style-type: none"> <li>The court's judgment on the government's final appeal ends a five-year legal process to expand use of antiretroviral AIDS drugs in the public sector.</li> </ul>
<p><b>Switzerland</b></p> <ul style="list-style-type: none"> <li>In January 2002, a new Federal Law on Therapeutic Products was passed, creating a new Agency for Therapeutic Products, Swissmedic.</li> <li>In July 2002, a new advice-oriented remuneration system for pharmacies was enacted.</li> </ul>	<ul style="list-style-type: none"> <li>The new federal law and agency will encourage the safer use of products and devices and will improve harmonization with EC law.</li> <li>Pharmacists are now paid based on their advice task, independently of the quantity and price of medicines sold, which should encourage the use of generic products.</li> </ul>
<p><b>United Kingdom</b></p> <ul style="list-style-type: none"> <li>In June 2002, the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA) announced intent to merge effective April 2003.</li> <li>In January 2002, the Competition Commission Appeal Tribunals upheld an Office of Fair Trading ruling that Napp Pharmaceuticals breached the Competition Act 1998.</li> </ul>	<ul style="list-style-type: none"> <li>The merger of MDA and MCA will impact the review process for drugs, devices, and combination products. New corporate governance measures will also be introduced.</li> <li>The ruling calls into question the voluntary Pharmaceutical Price Regulation Scheme (PPRS) in regulating pharma prices.</li> </ul>

**Public Policy (cont.)****Issues****United States**

- In January 2002, President Bush signed the Best Pharmaceuticals for Children Act (BPACA) into law, reauthorizing incentives for drug makers to conduct research on products to determine additional information about how they work in children.
- The U.S. Department of Health and Human Services (HHS) released final rules for the Health Insurance Portability and Accountability Act (HIPAA) in August.
- In October 2002, the Senate confirmed Dr. Mark McClellan as Commissioner of the Food and Drug Administration.
- A proposal to add a prescription drug benefit to the Medicare program stalled in Congress.

**Implications**

- Pharmaceutical firms retain the option of receiving a six-month patent extension if they conduct additional tests to determine effects of drug on children.
- HIPAA compliance is due by April 2003, a deadline that will force most big pharma companies to closely examine how the rule applies to their business operations and connection to patients and consumers.
- The recent slow-down in FDA approval times has been linked to the vacancy in the FDA Commissioner's office since January, 2001. In nomination hearings, McClellan stated he would find ways to work with industry to improve the recently slowed-down drug approval process.
- The ongoing debate about a prescription drug benefit highlights the challenges behind expanding Medicare. The key issues in Medicare reform are eligibility, structure and financing, and benefits.

**World Trade Organization**

- In November 2001, the members of the WTO issued an historic Ministerial Declaration stating that the TRIPS Agreement should be interpreted and implemented so as to protect public health and promote access to medicines for all. In June 2002, the WTO council responsible for intellectual property extended the transition period during which least-developed countries (LDCs) do not have to provide patent protection for pharmaceuticals until 2016.

- These two acts symbolize efforts to ensure that IP protection supports rather than obstructs poorer countries' need to tackle serious public health problems.

**Zimbabwe**

- In June 2002, the government declared an AIDS emergency for a period of six months, thus allowing for importation of generic versions of HIV/AIDS drugs.

- While the declaration appears to comply with TRIPS, industry doubts that given Zimbabwe's current economic crisis, the government will have adequate resources to import patented drugs.

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