World Pharma Market **CONTINUES TO GROW** Amid Shifting Trends and Emerging Markets

Though the pharmaceutical industry remains one of the most profitable and stable industries, several broad variables are leading to fundamental changes in the way the industry is structured, according to a recent report by Business Communications Company Inc.

The report, World Pharmaceutical Markets, notes that the world pharmaceutical industry stood at $541.0 billion in 2002, with 8% year-on-year growth. This industry accounts for 24% of the healthcare sector, and its growth has been driven by issues such as an aging population, changing epidemiological patterns, an increase in healthcare awareness among consumers, and the ability of the industry to provide innovative treatments for various ailments. The world's per-capita spending on pharmaceuticals has increased steadily from $72 in 2000 to $87.1 in 2002.

Chief among the issues affecting growth are: the increasing role of generic pharmaceuticals; the threat of new entrants, including the emergence of biopharmaceuticals and the genome revolution; increasing buyer power of third-party payers, government buyers, and health maintenance organizations; increased health awareness among patients; changing suppliers; and enhanced outsourcing of manufacturing and R&D.

The industry is comprised of four major sectors: ethical, generic, OTC, and biopharmaceutical. Ethical pharmaceuticals account for 74% of the total world pharmaceutical market. The sector is growing at double-digit rates thanks to blockbusters and innovative medicines, but is under increasing pressure because of strong competition from generic and biopharmaceutical sectors. Lifestyle diseases will continue to drive the growth of this sector, fueling demand for cardiovascular, central nervous system, and alimentary/metabolism products.

The generic pharmaceutical sector, currently valued at $37 billion, holds 6% of the total world pharmaceutical market. This sector is expected to increase its penetration to 7% by 2008, helped by patent expirations worth $80 billion through 2010.

Increasing health awareness, patent expiration, and marketing activities by the OTC manufacturers have generated the growth of the OTC pharmaceutical sector, which is valued at $82 billion and is expected to reach $101 billion by 2008. Biopharmaceuticals are becoming a popular mode of treatment because of their efficacy, particularly in hard-to-treat conditions. The sector is currently valued at $36.5 billion and is growing at double the rate of the ethical sector.

Another key trend is consolidation. The top 10 companies' share has increased from 28% in 1990 to 46% in 2002. Mergers and acquisitions, in-licensing activities, codevelopment, and comarketing activities are a key focus to help companies remain competitive and create value for their shareholders. Leading ethical pharmaceutical companies also are venturing into biopharmaceuticals, generic pharmaceuticals, etc., to improve growth. Generic pharmaceuticals are becoming a formidable force in the market as they globalize and segment (super generics, bio-generics, specialty generics, etc.) in their quest for survival. Biopharmaceutical companies, such as Amgen and Genentech, are competing head-on with the big pharmaceutical companies in the marketplace.

North America is the biggest market for pharmaceuticals with about 50% share of the total world pharmaceutical market. Overall, the 10 leading markets encompass 70% of the ethical pharmaceutical market. Some key markets such as Japan and Latin America are declining because of economic crises, while Asia is emerging as a leading pharmaceutical market. The impending WTO/GATT implementation in 2005 is aligning the world's pharmaceutical markets into one global market.

GROWTH OF WORLDWIDE PHARMACEUTICAL MARKET BY SECTOR

	2000	2001	2002	2003	2008	AAGR % 2003-2008
Ethical	$317.1	$363.4	$401.0	$437.6	$677.8	9.1%
Generics	24.0	27.0	30.5	37.0	64.0	11.6
OTC	70.5	73.8	78.5	82.0	101.0	4.3
Biopharmaceuticals	22.1	26.3	31.0	36.5	58.6	9.9
Total World Market	$433.7	$490.5	$541.0	$593.1	$901.4	8.7%

Note: $ in Billions
Source: Business Communications Company Inc., Norwalk, Conn., and IMS Health, Fairfield, Conn. For more information, visit bccresearch.com and imshealth.com.

Pharma and Biotech Companies **PLACE INCREASED FOCUS ON PROTEINS**

Proteins continue to gain significant attention from the pharmaceutical and biotechnology industries as a valuable source of potential drug targets. This growing interest is fueled in part by successful, protein-centric drug development efforts and in part by the continued technological advancements that make protein identification, expression, and purification both more accessible and higher throughput. Sales in this area are expected to top $9 billion by 2006.

But studying the complex area of distinct and interactive proteins — estimated to number between 200,000 and 300,000 — poses substantial challenges, according to a recent report, Proteins: Strategies for Optimizing Drug Discovery, published by Cambridge Healthtech Institute. It is unlikely that a single, universal technology will emerge to enable researchers to accomplish all goals.

Protein expression technologies will play a major role in harnessing novel proteins as drug targets, for diagnostics, for protein chip applications, and for vaccines.

The report also notes that as interest in this area swells, the infrastructure needed to produce sufficient quantities of high-quality protein is driving the emergence of service providers where contract protein product occurs.

Leading Pharma Companies Seek to Optimize **R&D QUALITY**

As the Food and Drug Administration increases its regulatory scrutiny of R&D compliance, leading pharmaceutical companies are turning their attention to optimizing the quality organization that supports R&D, according to a recent report by Best Practices LLC.

"Centralized structures are overwhelmingly more cost efficient," says Chris Bogan, CEO of Best Practices. "On the positive side, this can bring better organized and managed quality controls. What may not be positive is that it can lead to an increased head count."

Best Practices has completed several extensive benchmarking studies on the strategy, structure, and processes of quality organizations in pharmaceutical manufacturing, looking at basic research, clinical trials, toxicology studies, manufacturing process development and supply, and related computer systems.

The report, Optimizing the R&D Quality Organization, finds that companies with a centralized structure for R&D quality enjoy considerable staffing efficiency compared with other organizational structures. But company executives who participated in the survey believe that R&D quality is not adequately staffed. They indicated that they would need up to 30% increases in staffing in some areas to maintain the desired level of consistent R&D quality.

One challenge participants cited was the responsibility for auditing clinical-trial sites with limited staff. Generally, R&D quality organizations audit fewer than 10% of clinical-trial sites. Several participants even reported smaller audit rates. A best-in-class practice would be to identify the sites most likely to be audited by the FDA.

INNOVATION, ALLIANCES, AND COMMERCIALIZATION ARE KEY STRATEGIES for Large Biotech

Product differentiation, increased M&A/alliance activity, and targeted innovation are key growth strategies for large biopharma companies, according to Deloitte & Touche LLP's latest study, "Growth Strategies for Large Biopharma Companies."

In just three decades, the industry's technological portfolio has exploded from a few basic methods to a broad array of technologies drawn from the frontiers of biology, chemistry, physics, and computer science. From 1994 to 2002, the number of biotech companies with at least one product on the market jumped from 13 to 97. Revenue generated from product sales represented 75% of total industry revenue in 1995, up from 25% in 1985.

Top-tier biopharmaceutical companies — those with product revenue ranging from hundreds of millions of dollars to billions of dollars annually — now face unprecedented challenges to further growth as a result of technological developments, shifting patterns of supply and demand, and unresolved political and regulatory issues.

"Biotech companies have always faced a competitive environment, but the fundamental nature of this competition is changing in response to the convergence of therapeutic platforms used by large biotech and big pharma, as well as the resulting convergence of therapeutic areas pursued by these two groups," says John Rhodes, managing partner for life sciences with Deloitte & Touche. "To sustain growth, large biopharma companies will need to address these challenges while continuing to evolve their business models to anticipate tomorrow's market trends."

THREE STRATEGIES FOR SUSTAINING FUTURE GROWTH

IMPROVED COMMERCIALIZATION

Biopharma companies need to differentiate their products by showing how value is defined for multiple stakeholders and to optimize product development for commercialization.

ENHANCED M&A/ALLIANCE CAPABILITIES

To succeed in a more competitive future, mergers, acquisitions, and alliances should be viewed as a core strategy rather than a supplement to internal R&D.

TARGETED INNOVATION

To sustain long-term growth, biopharma companies need to evolve their business model, moving beyond individual product development toward delivering integrated healthcare solutions.

Source: Deloitte & Touche LLP, New York. For more information, visit deloitte.com/us.

Men and Women PERCEIVE SCIENTIFIC RESEARCH ABILITIES Differently

There seems to be a real difference in the way men and women perceive their abilities when it comes to being a scientist. These results are taken from a recent report, The Science Advisory Board's Employment Overview Survey of the Life Sciences.

While men and women rate themselves as equally competent in research and planning-related skills, the two groups diverge when it comes to their competencies in communication and leadership skills. It is provocative to speculate whether these differences translate into two very different, gender-based styles of science.

From this study, women tend to emphasize their attention to detail, organizational skills, and levels of observation. In contrast, men stress their abilities to introduce and communicate concepts and to synthesize information.

While those with the Science Advisory Board say it is dangerous to generalize such differences into the female and male approaches to research, at the very least these results reaffirm that there are many recipes for achieving success in a scientific career.

The report is an assessment of the different elements that constitute life-sciences careers based upon both qualitative and quantitative data. These data were collected from the responses to an online questionnaire fielded by nearly 1,700 individuals employed in various sectors of the life sciences. Two-thirds of the respondents were male and one-third of the respondents were female, ranging in age from 21 years of age to over 65 years of age. But the majority of participants were between 31 and 50 years old.

European Life-Sciences Industry LAGS ON INNOVATION

Europe may lead the world in pharmaceutical manufacturing, but trails behind when it comes to innovation in life sciences. European success is hindered by a fragmented market, intense pressure to lower manufacturing and R&D costs, and a climate that fails to encourage or reward innovation, according to a report from Cap Gemini Ernst & Young.

But the addition of 10 new countries as part of the European Union's enlargement this year has the potential to strengthen Europe's position in the life-sciences sector in the long term. It will provide access to a wider pool of skills, a larger reservoir of patients for clinical trials, and more cost-effective facilities.

The new EU countries are well positioned to support clinical-development activities, potentially accelerating the time to market for new drugs.

"Investment costs, cultural issues, and regulatory requirements in Western Europe have traditionally prohibited the European Union from becoming the location of choice for conducting clinical trials," says Paul Nannetti, global leader life sciences at Cap Gemini Ernst & Young.

He says Central and Eastern European countries, which offer lower clinical-development costs, higher site productivity, and less local regulations, could relieve some of the current pressures on pharmaceutical firms in Europe.

"But it is not something that will happen in the short term," Mr. Nannetti says. "Because of complex patent regulations after EU enlargement and the more open environment for generic pharmaceuticals in the acceding countries, we expect that parallel trade will increase within the European Union. Looking at the market we see that Central and East-

KEY FINDINGS OF CAP GEMINI ERNST & YOUNG REPORT

- **THE INNOVATION GAP** between the European Union and the United States in the life sciences will close because of factors such as lower clinical-development costs, higher site productivity, less local regulations and ethics committees, and better patient participation in clinical trials. The new EU countries may emerge as a global drug-development partner.
- **THE MOVEMENT OF MANUFACTURING FACILITIES** toward the new EU countries will not be very fast. The necessary FDA and cGMP certification of manufacturing processes leads to high costs in establishing greenfield pharmaceutical manufacturing facilities. It is often easier and cheaper to invest in expansion of current facilities.
- **AFTER BECOMING** part of the European Union, it is of considerable significance that the large base of generic manufacturers will continue to be able to perform prepatent expiration commercial testing in a number of the acceding countries, such as Hungary, Poland, and Slovenia.
- **BECAUSE OF COMPLEX PATENT REGULATIONS** after the EU enlargement and because of lower prices for generic pharmaceuticals in the acceding countries, Cap Gemini Ernst & Young expects parallel trade will increase within the European Union. The R&D-intensive pharmaceutical industry did negotiate specific derogations to the principle of the free movement of goods in the European Union to provide them some protection to parallel importation.
- **THE NEW EU COUNTRIES** will have to further harmonize their laws — on issues such as data exclusivity, labeling, and advertising of medicines — with those of the European Union. This will require review and possible updating of dossiers on products already on the market in the new EU countries to ensure compliance with the requirements of quality, safety, and efficacy.
- **CHANGES WILL OCCUR** in the life-sciences network in the European Union. The R&D-intensive pharmaceutical industry will move from large integrated life-sciences companies (encompassing R&D, manufacturing, distribution, and sales) toward a life-sciences network approach where each part of the life-sciences chain could be a separate business entity. Continuing changes in distribution, sales and marketing, the biotechnology sector, and the new products pipeline will lead to further consolidation and specialization in the life-sciences industry, ultimately leading to a life-sciences network with specialized players in each part of the life-sciences chain.
- **R&D PROCESSES** will migrate toward new EU countries as their reputation for patent and intellectual property protection improves. Countries such as Slovakia and Hungary, with high education levels and low wages, will benefit especially.
- **WAGES AND BENEFITS** will rise toward EU averages over the long term causing some generics manufacturers to move from Eastern Europe toward Asia-Pacific.
- **NORDIC COUNTRIES** will become the hotbed for biotechnology research within the European Union because the Nordic countries score high on measures of R&D-intensive life-sciences facilities.
- **COMPETITION FOR INVESTMENTS** is increasingly taking place between different biotechnology clusters (mostly centered around a life-sciences university) instead of between countries.

Source: Cap Gemini Ernst & Young, New York. For more information, visit cpey.com.

ern Europe's highly skilled workforce, multilingual skills, and low-cost back-office activities such as finance, administration, and human resources could also be prime candidates for transitioning to Eastern Europe and provide a valuable complement to traditional offshore locations."

Historically, European countries developed and produced the majority of new pharmaceuticals but their share of new launches on the world market has been steadily declining in recent years.

Between 1990 and 2002, there was a five-fold increase in research and development investment in the United States, while in Europe R&D investment only grew 2.5 times.

The complexity of regulatory requirements makes Europe less attractive than the United States for life-sciences investment. Unlike the United States, which has only one regulatory agency for all states, Europe has 15 single regulatory authorities in the current EU and as many as 40 across the whole of Europe.

Follow up

BEST PRACTICES LLC, Chapel Hill, N.C., is a research and consulting firm. For more information, visit best-in-class.com.

BUSINESS COMMUNICATIONS COMPANY INC., Norwalk, Conn., has studied the major market, economic, and technological developments that have characterized industry to produce industry reports, newsletters, and conferences. For more information, visit bccresearch.com.

CAMBRIDGE HEALTHTECH INSTITUTE, Newton Upper Falls, Mass., publishes reports that highlight areas where biotechnologies meet the demands of a shifting competitive landscape. For more information, visit chadvisors.com.

CAP GEMINI ERNST & YOUNG, New York, provides consulting, technology, and outsourcing services to help businesses implement growth strategies and leverage technology. For more information, visit cgey.com.

DELOITTE & TOUCHE LLP, New York, is a professional services firms, providing audit, tax, consulting, and financial advisory services through nearly 30,000 people in more than 80 U.S. cities. For more information, visit deloitte.com/us.

THE SCIENCE ADVISORY BOARD, Arlington, Va., is an online panel of scientists, physicians, and other life-sciences and medical professionals from 62 countries. The Science Advisory Board was organized in 1997 by BioInformatics LLC, a research and consulting firm. For more information, visit scienceboard.net.