Kim Ribbink

Coming of Age: India Grows in Stature

The third-largest pharmaceutical market in the world, India boasts a diverse population of more than 1 billion people, strong scientific and technological expertise, a skilled workforce, and a growing middle class.

India's pharmaceutical industry is now the third largest in the world in terms of volume and stands 14th in terms of value. The country's pharmaceutical market is expected to reach $55 billion in 2020 from $12.6 billion in 2009. And with a population of 1.1 billion, India is predicted to be the most populous nation in the world by 2050.

The Indian government is strongly supportive of the biopharma and biotech industries, providing infrastructure needed for the development of the industry, says Sreedhar Tirungari, M.D., senior manager, site management operations at MakroCare.

India ranks second in the overall country attractiveness index, a scale developed by the global consulting firm A. T. Kearney, which is based on patient pool, cost efficiency, regulatory conditions, relevant expertise, infrastructure, and environment, says Shubhangi Desai, Ph.D., Head of clinical operations, Asia and North America at SIRO Clinpharm.

India has a long scientific and medical history, and this continues to form the bedrock of the country's current advances in science and technology.

"We also have well-developed healthcare systems with fairly deep penetration, as well as a strong presence of Indian and international medical and pharma companies and a continuously modernizing practice," says Malavika Harita, CEO of Saatchi & Saatchi Health India.

Healthcare is a strong item on the Indian government's agenda, which is reflected in its intention to increase the public spend from the current level of about 1.3% to 2.5% GDP in the current five-year plan, says Hitesh Sharma, national life sciences leader and international tax services leader for Ernst & Young in Mumbai.

FAST FACT

BY 2028, ALMOST 199 MILLION INDIANS WILL BE 60 OR OLDER, UP FROM ABOUT 91 MILLION IN 2008.

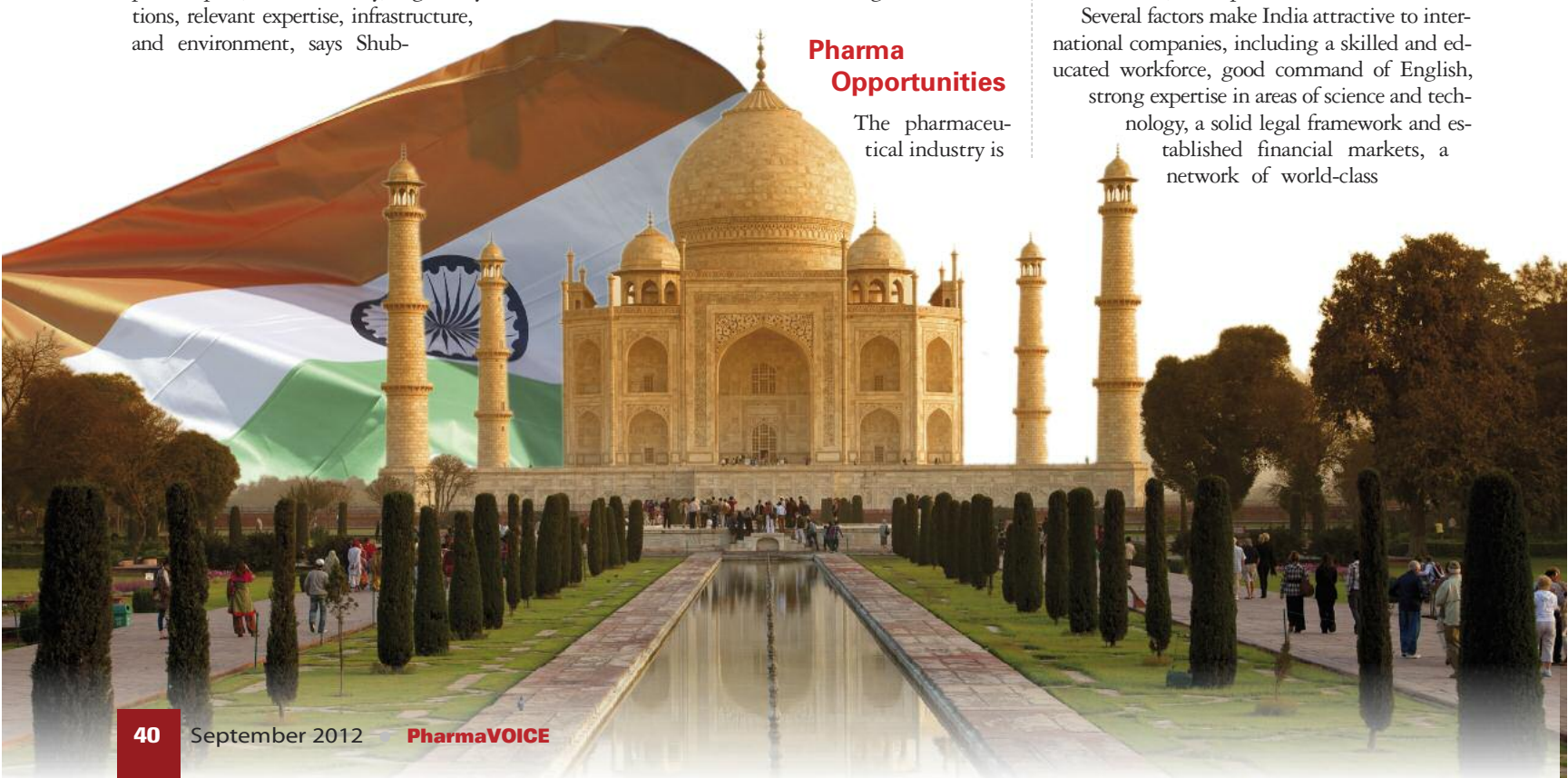
Source: India Pharma Inc.

Pharma Opportunities

The pharmaceutical industry is projected to grow faster in India than the average global rate; growth has been about 12% to 13% over the past several years, according to a report from Cutting Edge Information, Clinical Development in Asia.

India's domestic pharmaceutical industry has been built around generic companies, which account for eight of the top 10 companies in India, the report notes.

Several factors make India attractive to international companies, including a skilled and educated workforce, good command of English, strong expertise in areas of science and technology, a solid legal framework and established financial markets, a network of world-class



> **"India has a well-trained field force that commands the respect of the medical fraternity and is not treated as a necessary evil to be tolerated."**
>
> **MALAVIKA HARITA** / Saatchi & Saatchi Health India

> **"India has considerable manufacturing expertise, and Indian companies are among the world leaders in the production of generics and vaccines."**
>
> **SANJIT SINGH LAMBA** / Eisai Knowledge Centre

educational institutions, and a growing middle class.

The government of India is seeking to encourage more R&D in the pharma sector, including the creation of a $33.3 billion pharma R&D fund and a tax holiday program for R&D companies, Mr. Sharma says.

"The government has also set up a $640 million venture capital fund to boost drug discovery and strengthen the pharma infrastructure," Mr. Sharma says.

However, Sheila Khatri, president of Moti International, says generally speaking the country lacks knowledge for commercialization.

According to a report from the Boston Consulting Group, the Indian government has declared 2010 through 2020 as the "Decade of Innovation." According to experts, innovation in the life sciences will be essential to make innovation happen. And achieving the promise of spending 2% of GDP on R&D by 2017 will require a considerable focus from the current spend of about 1%.

India offers a unique combination of frontiers, such as biotechnology, which is flourishing alongside a revitalized faith in traditional and alternative medicines, Ms. Harita says.

"This creates a very positive climate, and if India's overwhelming response to technology and digital communication is added to the increasing role these other factors are playing in healthcare, it makes India unique and creates a particularly exciting future," she notes.

When it comes to commercialization, India's large population makes it a lucrative market. But the use of methods to control prices, including compulsory licenses, can be worrisome for companies, Ms. Khatri says. In March this year, the Indian government granted a compulsory license of a patented drug for the first time when it authorized an Indian manufacturer to produce and sell a generic copy of Bayer's Nexavar for the treatment of kidney and liver cancers.

The data protection and compulsory licensing clauses in the Indian patent law continue to be areas of concerns for MNCs doing business in the country, Mr. Sharma says.

He notes, however, that companies marketing drugs in India should benefit by government-sponsored initiatives to increase the rates of the insured, such as RSBY (Rashtriya Swastha Bima Yojna) and ESIC (Employees State Insurance Corporation).

And some multinational pharma companies are taking measures to reach a larger patient population by reducing drug prices and increasing affordability, notes Sanjit Singh Lamba, managing director and head, global procurement strategy, Eisai Knowledge Centre, India, part of Eisai Co.

Regulatory Opportunities and Challenges

Recent regulatory initiatives are creating new opportunities:

- Move to establish an integrated regulatory system through the constitution of a National Drug Authority so that quality regulation and price control is performed by the same agency
- Establishment of pharmacovigilance centers at national, zonal, and regional levels to monitor adverse drug reactions
- Move to bring about 374 bulk drugs under price control and regulate trade margins

Deficiencies and limitations of the current regulatory regime:

- Proliferation of spurious and substandard drugs in the Indian market
- Dual licensing mechanism acts as a deterrent to uniform implementation of regulatory procedures
- Lack of transparency in licensing procedures
- Inadequate regulatory expertise and testing facilities to implement uniform standards
- Need for greater thrust on institutional support to small-scale firms to enable speedy implementation of Schedule M upgradation and standardization of drug quality
- Need for greater clarity on patentability of pharmaceutical substances and conditions under which firms can apply for compulsory licenses to prevent legal battles between local firms, MNCs, and civil rights groups
- Need for greater coordination, accountability, and transparency among different ministries concerned with drug regulation

Source: Sanjit Singh Lamba, Managing Director and Head, Global Procurement Strategy, Eisai Knowledge Centre

> "Because of India's large population base, global pharmaceutical companies can get access to treatment- naive patients."
>
> **DR. SHUBHANGI DESAI** / SIRO Clinpharm

Merck, for example, he says has launched differential pricing for Januvia, its anti-diabetic drug, which is priced at about US$1 per dose in India — a fifth of its price in the United States. Similarly, Eisai markets its product Aricept, for Alzheimer's, in India at one-tenth of its price in western world.

One promising sign was the establishment of IP rights. A 2005 IP law has allowed for products, not just processes, to be patented.

"With the market becoming more organized, there will be more stringent laws coming into place, with clear guidelines on how content should be sourced and packaged to avoid plagiarism and ensure IPR," Ms. Harita says.

One of India's greatest strengths is in manufacturing and most major pharma companies have manufacturing interests in the country, Ms. Khatri says.

Today, India accounts for the maximum number of U.S. FDA-approved facilities for pharmaceutical manufacturing outside of the United States; current estimates are that India has more than 125 U.S. FDA-approved plants.

India has considerable manufacturing expertise, and in fact Indian companies are among the world leaders in the production of generics and vaccines, Mr. Lamba says.

"As both of these areas become more important, Indian producers are likely to take a large role on the world stage, and potentially partner with global pharma companies to market their products outside of India," he says.

Mr. Lamba notes that India's track record of development, particularly in the area of improved cost-beneficial chemical synthesis for various drug molecules, is excellent.

Pharma and Health Trends

Growth within the Indian pharmaceutical market will be dependent, somewhat, on partnerships between global and Indian pharma companies, which at times have proven to be disappointing. For example, a Sanofi-Aventis subsidiary in India, Shantha Biotechnics Ltd., failed to meet quality standards for the World Health Organization with regard to its Shan5 combination vaccine. A joint-marketing agreement between Pfizer and Indian company Biocon ended earlier this year. The two companies had planned to jointly market Biocon's biosimilar diabetes drug, and the decision has left Biocon seeking new marketing partners.

Indian companies have looked to M&A options in other parts of the world. While Ms. Khatri says the U.S. dollar compared with the rupee can make M&A in the United States somewhat prohibitive, there have been several European and eastern European acquisitions. In March 2006, Dr. Reddy's acquired Betapharm Arzneimittel, Germany's fourth-largest generics pharma company, from 3i for EUR 480 million. In 2005, Torrent Pharma acquired Germany's Heumann Pharma Generics, and in June last year Dr Reddy's, entered into an agreement with JB Chemicals to acquire its pharmaceutical prescription portfolio in Russia and other CIS regions.

India is one of the largest vaccine producers in the world, with many new vaccines set to be launched in the next five years. India currently exports vaccines to about 150 countries. It also meets between 40% and 70% of the World Health Organisation (WHO) demand for the DPT (diphtheria, pertussis or whooping cough, and tetanus) and the BCG (bacille calmette-guérin) vaccines against tuberculosis, and almost 90% of its demand for the measles vaccine.

Another growth factor, according to Mr. Lamba, is India's growing affluence, better hygiene practices, and aging population. In addition, there is a high proportion of people with diabetes, with more than 41 million suffering from the disease. These trends are causing a shift in the demand for medicines.

"In 2001, anti-infective and gastrointestinal drugs and vitamins accounted for 50% of the domestic market," he says. "By 2012, they are expected to account for just 36%. Conversely, drugs for cardiovascular problems, disorders of the central nervous system, and other chronic diseases will account for 64% of total sales, up from 50% in 2001."

Another notable trend, Mr. Sharma says, is an effort to increase the reach of pharma companies into non-metro markets.

"With 70% of India's population residing in rural areas, there are immense opportunities for pharma companies to tap this market," he says. "The demand for generic medicines in these rural markets has grown sharply and various companies are investing in distribution networks that will enable them to reach these consumers. For example, Ranbaxy and Pfizer have aligned with ITC, a major India-based fast moving consumer goods (FMCG) company to support their OTC product lines."

The use of technology to drive innovation in healthcare delivery is another trend, Mr. Sharma notes, adding that a number of corporate hospitals have introduced telemedicine initiatives.

FAST FACT

INDIA NOW PRODUCES MORE THAN 20% OF THE WORLD'S GENERICS.

Source: BioForum, PwC

Oncology: A Differentiated Role for India

Oncology constitutes the largest share of Indian pharmaceutical drug pipelines, but productivity has been low.

- Spend on oncology at about 15% outpacing other therapeutic areas at 6% to 8% (10 year CAGR)
- Oncology is an area of focus for all major players; largest share with about 30% of drug pipelines
- Higher cost of development and higher failure rate are leading to lower R&D productivity

The Boston Consulting Group analysts believe there are three key megatrends in oncology research:

1. Better understanding of the disease through genomics and related fields
2. Linked to personalized medicine, better preclinical studies, more relevant clinical trials
3. Increased understanding of tumor complexities and implications on drug effectiveness

These megatrends hinge on a few important capabilities/assets:

- Access to vast pool of patients for genetic information
- Data analytics capabilities to conduct studies
- Science and engineering to develop new technologies
- CROs to conduct trials

Source: BioPharma R&D: Moving the Needle on Innovation Delivering Affordable Innovation Through Global Partnerships, The Boston Consulting Group, 2012.
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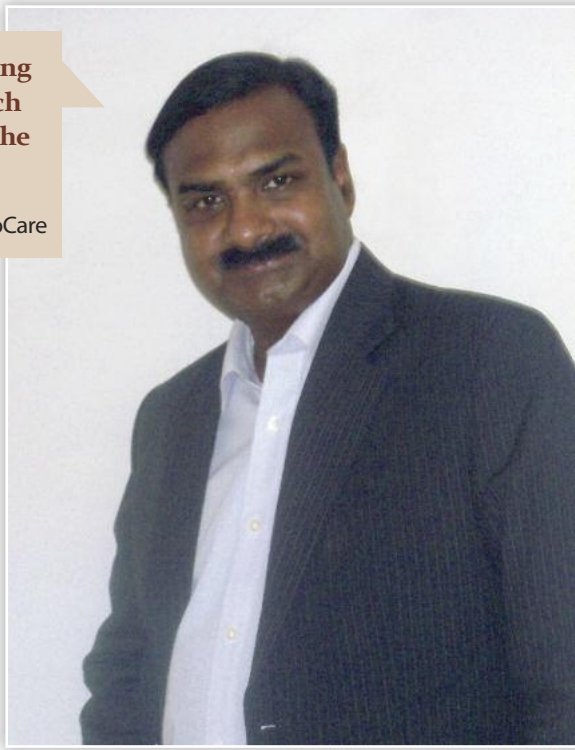
> "The government of India is supporting the establishment of biopharma/biotech markets in the country and providing the infrastructure needed for this field."
>
> **DR. SREEDHAR TIRUNGARI** / MakroCare

> "With 1.1 billion people, India is a very large market, but country officials like to use methods for controlling prices, including licensing, which can be worrisome for companies that make expensive drugs."
>
> **SHEILA KHATRI** / Moti International



Clinical Research

India has demonstrated strengths as a destination for clinical trials, thanks to its large and diverse patient population and scientific expertise.

In addition, the country has well-established rules and guidelines for conducting trials, which are in compliance with ICH-GCP, Dr. Desai says.

With local expertise critical to the success of clinical research, pharma companies are engaging local CROs more, which has led to rapid expansion of the Indian CRO industry, Dr. Tirungari notes.

Exhibiting disease profiles of both developed and developing nations, combined with having a large population base, global pharmaceutical companies can get access to treatment-naive patients, Dr. Desai says.

"Since India has diverse population groups, the patient pool is not usually a problem," she says. "The challenge can arise for some niche diseases, such as enzyme disorders or genetic diseases where the patient pool is limited globally, and in India as well. This can be more of a challenge since India lacks a robust patient registry."

Regulatory Climate

Drug manufacturing, quality, and marketing is regulated in accordance with the Drugs and Cosmetics Act of 1940 and Rules 1945. These acts have witnessed several amendments over the last few decades, Mr. Lamba says. The Drugs Controller General of India (DCGI), who heads the Central Drugs Standards Control Organization (CDSCO), assumes responsibility for the amendments to the Acts and Rules.

India has a dual system of regulatory control at both the central and state government levels. The central regulatory authority undertakes approval of new drugs, clinical trials, standards setting, control over imported drugs and coordination of state bodies' activities. State authorities assume responsibility for issuing licenses and monitoring manufacture, distribution, and sale of drugs and other related products.

Though an attractive market, India can be difficult to navigate because of the complexity of its regulations, Dr. Tirungari says.

Uncertain approval timelines are a hurdle for companies and can cause delays in study startups, Dr. Desai says.

There can be other complex issues to overcome. Ms. Khatri notes that DCGI recently suspended a number of clinical trials on allegations of bribes, and other wrongdoing.

"In the short term, developing a new product will take a very long time because of regulatory issues," she says. "In the long term, once DCGI puts better controls in place this should be resolved. India has taken the recent clinical trial scandals very seriously." PV

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