

2015 life sciences outlook India

India's pharmaceutical sales were an estimated \$18.3 billion in 2013. They are forecast to rise an average of 10.3 percent annually in 2014-18 (in nominal local-currency terms) to reach \$33.8 billion. This growth will be driven by increasing personal incomes and the escalation of chronic diseases.¹

India's pharmaceutical market is dominated by generic drugs, which account for around 75 percent of the market by volume. Supplied mainly by domestic companies, generics have helped to keep pharmaceutical prices low and the market is expected to continue expanding rapidly. Still, India's growing middle class is increasing demand for more advanced and costly medicines.²

India's pharmaceutical market =
\$18.3 billion in 2013

Growth rate = 10.3 percent (in local
currency terms) annually in 2014-2018

Although domestic pharmaceutical companies were established primarily to supply the local market, they have taken advantage of their low labor and research costs to export generic drugs to developed countries, notably the U.S, its largest export market.⁴ India is also a major supplier to other emerging markets and has become the biggest supplier to UN health care programs.⁵

Domestic and international pharmaceutical companies operating in India face issues ranging from the new Drug Price Control Order (DPCO), which prescribes a ceiling on the prices of several essential medicines, to drug and clinical trial quality, patent issues, and the misclassification of medical devices.

- **Drug Price Control Order (DPCO) 2013** — The National Pharmaceutical Pricing Authority (NPPA) announced in July 2014 that it plans to add 50 drugs in the cardiovascular and anti-diabetic segment to the 348 drugs that were brought under price control following the implementation of the new Drug Price Control Order (DPCO) in July 2013.⁶ The move could have far-reaching implications for branded pharmaceutical manufacturers with patented products.

With a population of over 1.2 billion, India represents a major market for pharmaceutical companies. Yet the country also posts an impressive export turnover of over \$10 billion spread across 200 countries.³

¹ *Industry Report, Healthcare: India*, The Economist Intelligence Unit, July 2014

² *Ibid*

³ "Challenges facing India's pharmaceutical industry," UK Centre for Health Solutions, Deloitte LLP, January 20, 2014. <http://blogs.deloitte.co.uk/health/2014/01/challenges-facing-indias-pharmaceutical-industry.html>. Accessed October 10, 2014

⁴ *Industry Report, Healthcare: India*, The Economist Intelligence Unit, July 2014

⁵ *Ibid*

⁶ "How new price control list impacts Indian pharma companies," moneycontrol.com, July 23, 2014. http://www.moneycontrol.com/news/business/how-new-price-control-list-impacts-indian-pharma-cos_1134746.html?utm_source=ref_article. Accessed October 10, 2014

- **Drug quality** — India is the biggest foreign supplier of medicines to the U.S. and has about 200 U.S. Food and Drug Administration (FDA)-approved drug manufacturing facilities. India produces nearly 40 per cent of generic drugs and over-the-counter products and accounts for 10 per cent of finished dosages in the U.S.⁷ The FDA has highlighted a growing number of quality issues and taken a series of actions against Indian pharmaceutical companies (e.g., for documentation and data maintenance issues),⁸ restricting India's shipments to the U.S. Based on these actions and quality concerns raised by other importers of Indian pharmaceutical products, the Indian government is working with the FDA to resolve its issues, as well as with the World Health Organization (WHO), and the Partnership for Safe Medicine (PSM) to put in place initiatives to combat counterfeit drug manufacturing. These include equipping state drug testing laboratories, enforcing serialization, non-clonable packaging and 2-D barcoding, and investing in more drug manufacturer inspectors.⁹
- **Clinical trial quality** — India's clinical trials industry has seen substantial growth in the last decade due to its large pool of patients with diverse treatment needs and access to a large, scientifically skilled, workforce.¹⁰ While the number of clinical trials has increased, the country's capacity to regulate trials has not kept pace, resulting in some unethical practices. The Indian government has enhanced regulatory controls like mandatory trial registration, and is creating committees to oversee trial approval, trial execution, and ethical treatment of patients. All of these measures have had a positive impact; however delays in drug approvals following the

new regulatory controls are prompting multinationals to rethink their strategy of conducting clinical trial activity in India. Even Indian pharmaceutical companies are now conducting some trials outside the country.¹¹

- **Patent issues** — To make health care affordable to all, the Indian government is promoting the use of generics and ensuring that prices of lifesaving drugs are not governed by market forces. As a result, some pharmaceutical multinationals have been entangled in legal battles with the government over patent issues, with several long-running court cases centering on how India's stringent Patents Act defines innovation.¹²
- **Misclassification of devices as drugs** — Medical devices currently fall under the purview of India's Drugs and Cosmetics Act and foreign direct investment (FDI) in the sector is governed by the same rules as for pharmaceuticals, which is stunting green field medical device projects. The Indian government is actively considering a proposal to have a separate policy for allowing 100 per cent FDI in the manufacture of medical devices,¹³ which could help to boost investment and generate interest in the medtech sector.

The Indian pharma sector is at the threshold of exponential growth. However, to be a true player on the world stage, the sector needs to continuously invest in development of global R&D capabilities and its well-established Contract Research and Manufacturing Services (CRAMS) segment. Strong international collaborations and partnership will support India's efforts to deliver more value-added products to the global market.

⁷ "Challenges facing India's pharmaceutical industry," Centre for Health Solutions, Deloitte LLP, January 20, 2014. <http://blogs.deloitte.co.uk/health/2014/01/challenges-facing-indias-pharmaceutical-industry.html>. Accessed October 10, 2014

⁸ "Indian drug makers face problems in U.S. due to documentation and data maintenance: Report," The Economic Times, May 6, 2014. http://articles.economicstimes.indiatimes.com/2014-05-06/news/49661819_1_usfda-toansa-indian-drug-makers. Accessed October 10, 2014

⁹ "Challenges facing India's pharmaceutical industry," UK Centre for Health Solutions, Deloitte LLP, January 20, 2014. <http://blogs.deloitte.co.uk/health/2014/01/challenges-facing-indias-pharmaceutical-industry.html>. Accessed October 10, 2014

¹⁰ Ibid

¹¹ Ibid

¹² *Industry Report, Healthcare: India*, The Economist Intelligence Unit, July 2014

¹³ "FDI policy for medical devices on the cards," *Business Standard*, August 30, 2014. http://www.business-standard.com/article/economy-policy/govt-plans-separate-fdi-policy-for-medical-devices-114082601119_1.html. Accessed October 10, 2014



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