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The Indian Opportunity in pharmaceutical R&D and manufacturing

Prepared by Bain & Company

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Defining the opportunity

Faced with increasing cost and commercialization pressures, global pharmaceutical companies are looking at how to tap India's fast growing domestic market and "faster and cheaper" value proposition in manufacturing and R&D. The hope inside India is that the country's pharma firms can replicate the success of its Business Process Outsourcing (BPO) companies as preferred international partners, both in terms of competitive costs and world-class capabilities. One key is the important transition already underway in some Indian pharmaceutical firms as they shift from developing imitative drugs to also focusing on innovation.

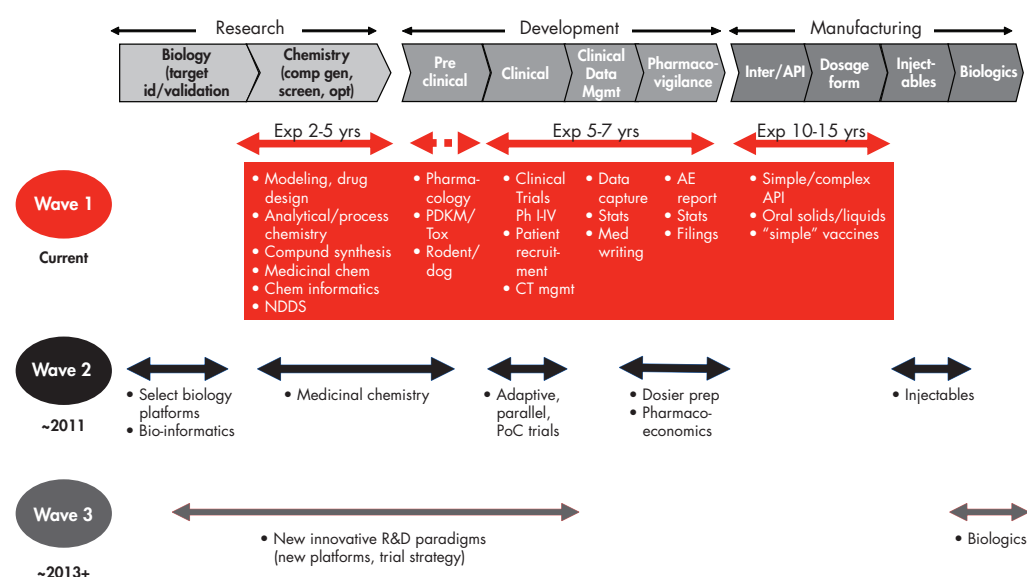
To accelerate this change, India's pharmaceutical industry needs to ensure that its current "faster and cheaper" value proposition is sustainable and scalable. The industry also needs to expand and create broader and more differentiated offerings, which will allow Indian companies to move up the

value chain and provide the base for end-to-end offshoring and outsourcing. Making India a preferred global hub for pharmaceutical offshoring/outsourcing will also require formulating more conducive regulatory and intellectual property protection policies, encouraging greater investments via public-private partnerships to create the hard and soft infrastructure, and enhancing pharmaceutical upstream capabilities in basic sciences and related fields.

Three waves of opportunity

India offers three distinct waves of opportunities in offshoring over the next decade (see Fig 1). The first wave focuses on developing drugs "faster and cheaper" and extends from chemistry research to clinical trials to manufacturing. The sources of advantage are twofold: a cheaper skilled talent base—chemists, MDs, nurses, quality control personnel—along with the ability to expedite recruiting for trials due to a large naïve patient base (see Fig 2, page 2).

Figure 1: Three waves of opportunity for pharma R&D and mfg in India



The second wave, that will likely become mainstream over the next 3 to 5 years, will extend the breadth of capabilities to include more complex manufacturing to produce injectables; targeted and cutting edge clinical trials, including adaptive and proof of concept trials; and more sophisticated biology-based research platforms.

The third opportunity wave is expected to occur around 2013-2015, when Indian drug manufacturers are likely to start manufacturing biologics (recombinant proteins) and offer cutting-edge disruptive R&D platforms such as pharmacogenetics and cheminformatics.

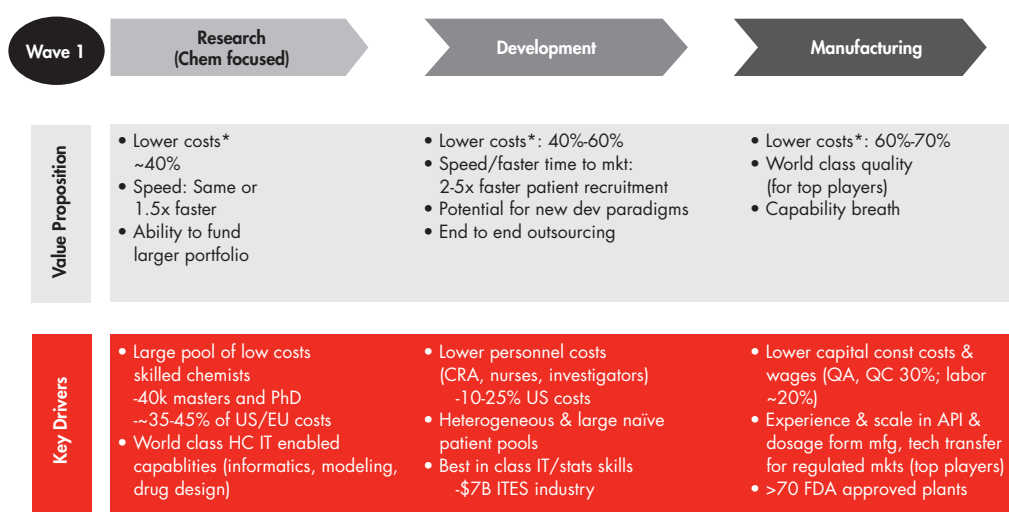
Manufacturing: Muscle in basic small molecules

Indian companies have established scale manufacturing operations, with more than a decade of experience in making Active Pharmaceutical Ingredients (APIs), oral

solids and liquids, and simple vaccines. This experience has helped create world-class Indian contract manufacturers with globally competitive cost structures. As a result, manufacturing costs in India are 30-40% less than developed markets, primarily due to lower personnel and capital construction costs (see Fig 3).

India's muscle in small molecule manufacturing has resulted in approximately 100 FDA-approved plants, the largest number outside the US and around double that of China. India currently enjoys a 3- to 5-year head start over China in dosage form and complex API manufacturing with Indian companies also actively sourcing less costly, mass-produced simple APIs from China (see Fig 4). Indian companies are also investing significantly in drugs that are complex to manufacture such as injectables and biologics and in oncology therapeutics.

Figure 2: Wave 1 value proposition is faster & cheaper at western quality standards

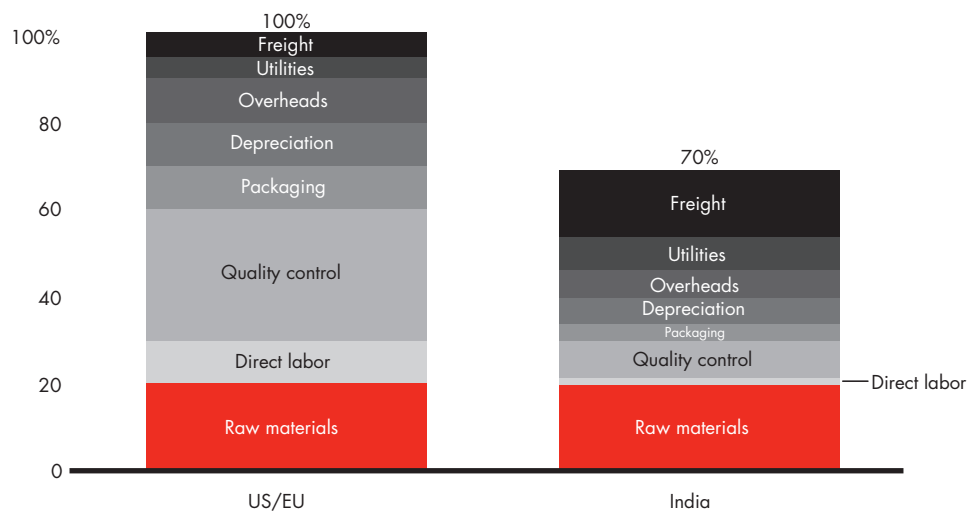


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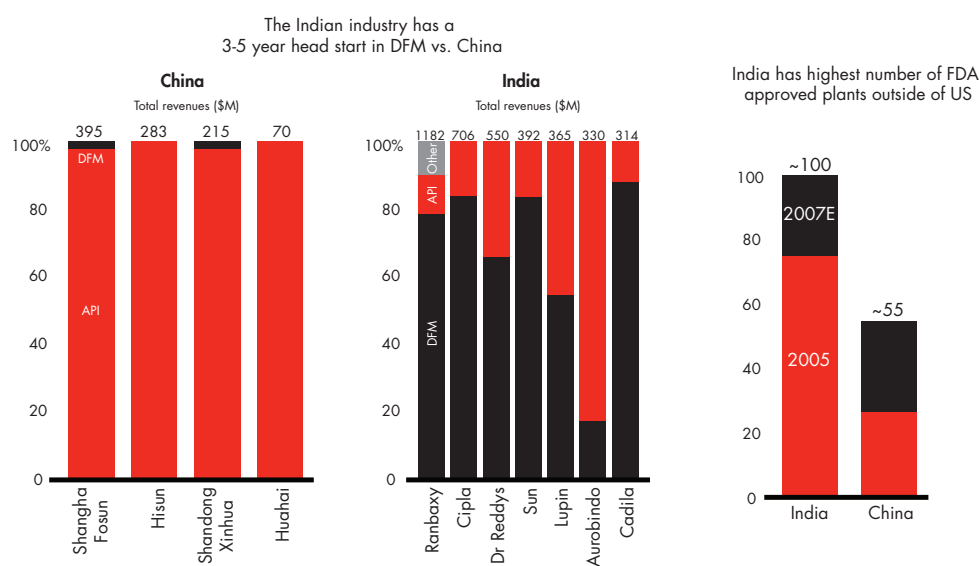
Figure 3: Indian manufacturers have a 30-40 pts cost advantage vs. developed markets in oral solids

Dosage form mfg. cost comparison—Bain estimate



Source: Plant visits; OPPI report; UBS: China India pharma manufacturing report; OPPI study on pharma outsourcing; Analyst reports; Expert Interviews; Bain Analysis

Figure 4: Indian players have a strong presence in dosage form manufacturing



Note: Sales figures represent last fiscal year reported
Source: Company websites; Company annual reports

Development: Growing prospects

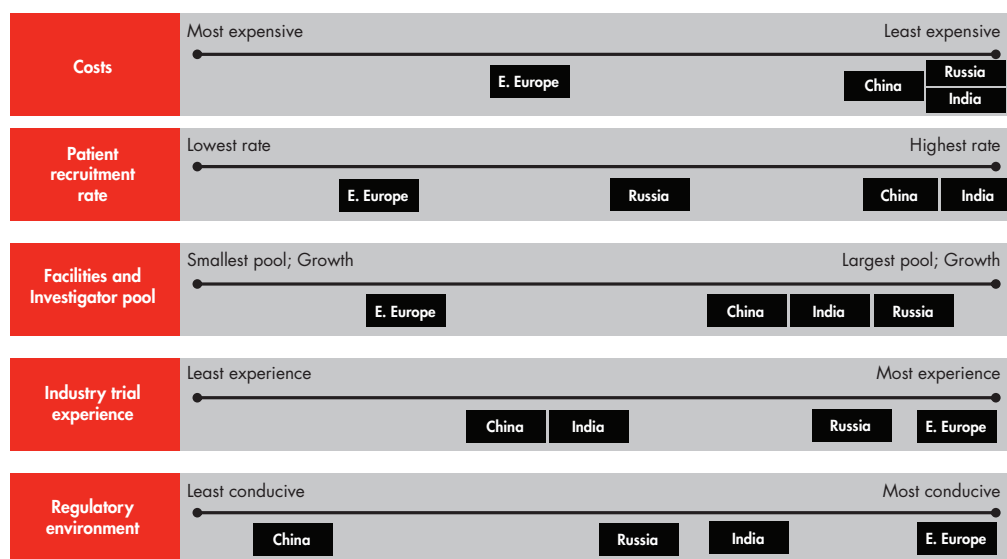
India's drug development prospects are attractive compared to those of developed markets. Indian trial costs are about 50% lower than developed markets and comparable to China and Russia (see Fig 5, page 4). India's cost advantage here comes from its large naïve patient base that spans a range of diseases and typically supports patient enrollment rates 2 to 5 times faster than in most other countries. IT capabilities that allow for the integration of global clinical data management in India are another advantage. In some cases, India's core advantages—low costs and large patient base—have the potential to enable new development paradigms such as parallel oncology trials and to develop or validate biomarkers in order to create targeted drugs.

Research: Playing catch up in innovation

Indian companies have only recently started to invest in developing new capabilities and pipelines for innovative drugs. India adopted WTO's TRIPS in 2005, and initiated legal protection for product patents the same year. However, over the last couple of years, several global companies have entered into research alliances with Indian companies (see Fig 6) to take advantage of India's lower costs for skilled scientists and chemists.

India's rapidly growing domestic market is another important consideration for global companies looking to invest in India. India's domestic pharmaceutical market is expected to be worth \$20 billion by 2015, which would be the third largest increase in market size after the United States and China. India is

Figure 5: India clinical trial value proposition is attractive vs. other emerging markets



expected to have over 100 million people suffering from chronic lifestyle diseases such as cardiovascular illnesses and diabetes by 2015.

Global companies like GlaxoSmithKline Plc have become leaders in the Indian market by customizing its approach, including using India-specific pricing models for some of its drugs to increase accessibility.

Achieving full potential

To realize its current and future offshoring potential, India's pharmaceutical industry needs to address four issues raised by Indian and global pharmaceutical companies.

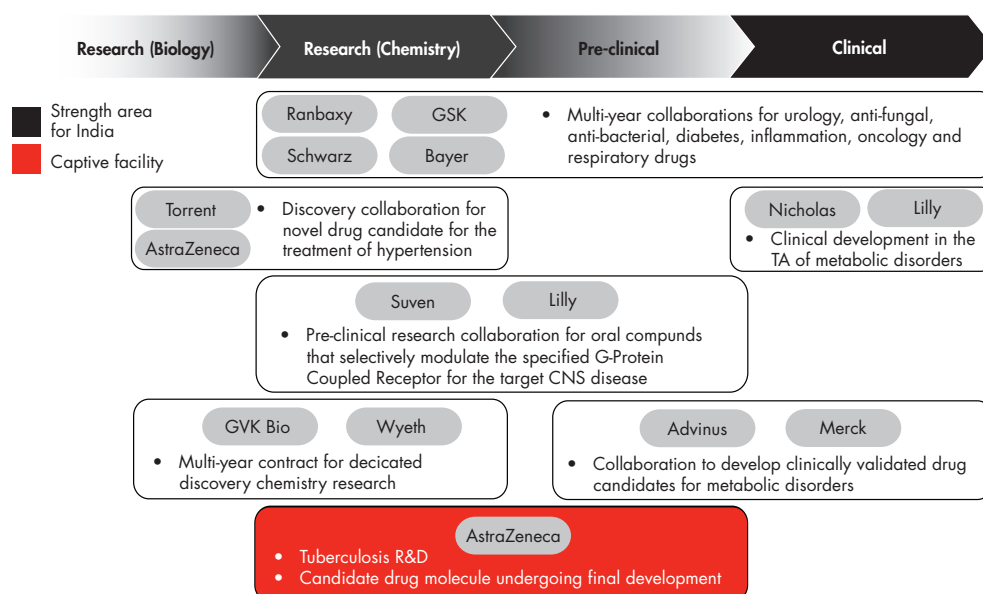
1. **Harmonizing regulations to global standards:** Several of India's regulations relating to pre-clinical and clinical trials are restrictive such as prevention of first-in-

man testing for drugs developed outside India. India can also benefit by harmonizing guidelines such as Good Clinical Practices with international standards to reduce complexity.

2. **Strengthening and evolving the IP regime:** India needs to clear the significant backlog of patent applications and consider whether to provide data protection, a mechanism offered by many markets across the world. Indian patent law also needs to clarify the definition of "incremental innovation" which is not currently covered under patent protection and, thus, creates uncertainty for both Indian and global firms.

3. **Building the talent pipeline:** Ironically, one of the key sources of India's advantage—skilled talent—may become a

Figure 6: Indian companies are increasingly focusing on researching and partnering with global firms



Source: Company websites; News articles

bottleneck to scaling up and meeting robust growth expectations. Significant talent shortfalls are expected for biologists, medicinal chemists and clinical investigators. Increasing the pipeline of graduates in the long term and enhance training/accreditation programs to fill gaps in the near future will require public/private partnerships.

4. **Enhancing healthcare investments:** India not only has low R&D spending in terms of share of GDP at 0.9% compared to 1.2% for Brazil, 1.4% for China and 2.5% for the United States, but its portion of public healthcare R&D to total public R&D spending is just 2%. In the United States, the figure is 23%. India needs policies to allow for greater private and public investment in healthcare.

India has potential to be an attractive market for commercialization and for offshoring and outsourcing for global companies. Global investment will depend on how quickly the government amends rules, improves patent protection, and upgrades infrastructure to develop India's talent pipeline. Global pharma firms are also watching closely to see how rapidly Indian companies step up investments in R&D. The opportunity is large: the question now is whether India's pharma industry can move quickly enough.

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