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Sneak Preview: Clinical Trial Policies Top IP As Biggest Obstacle To Indian Innovation

Despite recent news flow focused on a challenging patent environment, India's pharma market is expected to grow 13% annually to reach \$45 billion by 2020, according to a McKinsey report to be released June 21 during the annual U.S.-India BioPharma & Healthcare Summit in Boston.

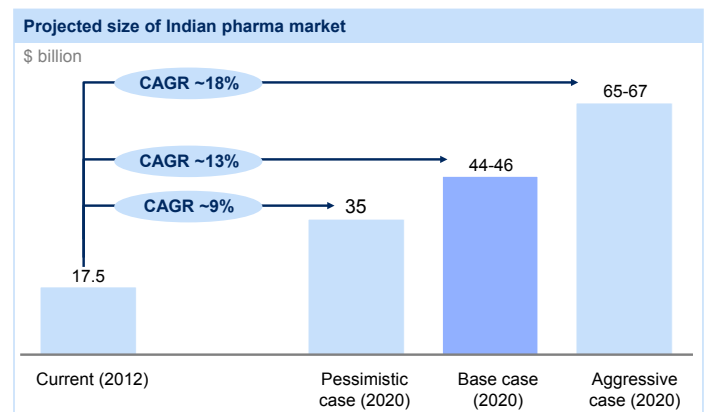
Although IP policies often receive the lion's share of attention when discussing India's failure to reach its R&D potential, a new report from McKinsey & Co. says that clinical trial policies and infrastructure are in fact the largest obstacles to India's success.

The report, which lays out a series of facts, myths and imperatives related to India's role in global biopharma innovation, concludes that India contributes more to innovation than many stakeholders realize, but less than its full potential due to adverse policy issues. Titled "Will India Play A Meaningful Role In Global Biopharma Innovation?", the position paper was commissioned by the USA-India Chamber of Commerce (USAIC) and will be released during the group's annual biopharma and healthcare summit, June 21 in Boston.

Overall, McKinsey paints a bullish picture of the India pharma market, forecasting a 13% compound annual growth rate through 2020 with the market expanding from \$17.5 billion in 2012 to \$44-46 billion on the back of a rising middle class and patients' willingness to pay a premium for drug quality.

In terms of innovation, the report points to Indian pharmaceutical companies winning approval for two new chemical entities (NCEs) – Zydus Cadila's Lipaglyn (saroglitazar) and Ranbaxy Laboratories Ltd.'s Synriam (arterolane/piperazine) – during the past two years, and an industry pipeline that could lead to more wins (*"Braving The PPAR Storm, Zydus Cadila Says Its Potential Blockbuster Is Approved In India"* — PharmAsia News, Jun. 5, 2013 6:27 PM GMT) and (*"Ranbaxy's Anti-Malarial Approval Makes It First Indian Firm To Fully Develop An NCE"* — PharmAsia News, Nov. 2, 2011 10:00 AM GMT).

We believe the overall India pharma market will maintain a strong trajectory of ~13% CAGR and become ~\$44-46 billion by 2020



SOURCE: McKinsey report - India Pharma 2020

McKinsey & Company

McKinsey also singles out India's capacity to deliver "reverse innovation at scale" in the generics market, with India pharma companies capturing 17% of the prescription market share in the U.S. and 25% of U.S. FDA Paragraph IV filings.

Under the Paragraph IV process, a generic company generally faces litigation with the innovator company, claiming that a patent held on the product is invalid or that the generic would not infringe the innovator's patent. If the generic company wins the litigation, it receives 180 days of marketing exclusivity upon FDA approval, a reward for the company's efforts to bring to market a low-cost generic alternative (*"In U.S. Market, Small Indian Drug Firms Turn Up The Heat On Their Big Brothers"* — PharmAsia News, Feb. 29, 2012 4:30 PM GMT).

But despite India's potential for R&D innovation, "the opportunity has not played out as expected," the report states.

That conclusion is unlikely to surprise industry stakeholders, who have seen India as ground zero in a barrage of intellectual property controversies – from compulsory licensing to the patenting of incremental innovation – that have reverberated across the global pharma industry (*"War Of Words: Pfizer Battles With Top Indian Pharma Lobby On Key Policy Issues"* — *PharmAsia News, May 24, 2013 6:31 PM GMT*).

Yet in a telling slide from the report, McKinsey lists several "myths" about India's potential for biopharma innovation. In one example of a myth, the report states: "IP is the biggest obstacle in realizing India's potential in R&D innovation – in fact, it is infrastructure and policy for clinical trials."

Intellectual property trailed both "clinical trial policy and infrastructure" and "research talent," coming in third in answer to a survey question about the biggest obstacles India faces to drive R&D at scale.

"The findings should help senior management of biopharma companies fine tune their R&D strategy and help leverage India's pockets of R&D strengths," said Karun Rishi, president of USAIC. The report is based on an industry survey and more than 50 interviews with senior pharmaceutical executives, government officials and academics from the U.S. and India.

As in previous years, USAIC shared key findings of the report with PharmAsia News in advance of its release. In addition to the annual report and meeting in Boston, USAIC also holds an annual strategy session in New Delhi and a series of smaller meetings that bring together policymakers and industry in an environment to foster collaboration and improve the ecosystem for innovation in India (*"Is India Falling Behind Its Neighbors In Attracting Clinical Research?"* — *PharmAsia News, May 21, 2012 5:18 PM GMT*).

Three Imperatives

In an interview, McKinsey Director Ajay Dhankhar, lead author of the report, acknowledged that Indian IP policies remain a concern, particularly among a "vocal minority" of U.S. pharma R&D heads. But he said that in private moments most big pharma execs acknowledge that IP protection does not hold back investment in India nearly as much as clinical trials policies or research talent.

"The last seven or eight years have been classic India," Dhankhar said. "It's been a total paradox. Nothing is very straightforward about India, and the same thing with Indian pharmaceuticals. The potential has continued

to be tremendous. There have been some real clear success stories. ... But we have seen some real shortcomings in the opportunity, and we have pointed them out."

As an example, Dhankhar discussed a recent Indian policy on compensation requirements for clinical trial victims, saying it increases investment risks and creates uncertainty for innovative pharmaceutical companies, both multinationals and domestics. The rules have created an uproar in the clinical trial community, with some stakeholders saying studies would be impossible to conduct as companies could be held liable if a patient receives a placebo, or if an investigational product fails to provide its intended therapeutic effect (*"India's Compensation Rules For Clinical Trials May Make It Impossible To Build Data: Indian Society Of Clinical Research"* — *PharmAsia News, Feb. 6, 2013 4:12 PM GMT*).

The McKinsey exec also pointed to a "material shortage of manpower" in the India R&D industry as a key concern for innovative companies.

"Industry and academia have not come together to raise the level of training for a country as large as this," said Dhankhar, noting that lack of manpower leads to clinical trial delays and discourages additional investment from multinationals.

The report lays out three "imperatives" that could have an immediate effect on biopharma innovation in India.

First, industry leaders should work with the Indian government, perhaps in collaboration with U.S. FDA or the National Institutes of Health, to create greater awareness of "ethical but practical" clinical trial regulations and policies, Dhankhar said. "Indian regulators are open to receiving ideas from a joint group rather than any one individual group, particularly if the joint group can be composed of both Indian and multinational innovators."

Second, industry groups and academia should create a formal vehicle that will scale up to train India researchers and principal investigators on best practices for both clinical trials and basic research.

And third, India must invest in "debunking myths and clarifying success stories" so that the global pharmaceutical industry understands the "India advantage," which includes everything from the size of the market, to the ability of local companies to develop NCEs, Dhankhar said.

This final point is critical, according to USAIC's Rishi, who noted that communication issues have often contributed to India's woes. With multiple ministries and officials overseeing the pharmaceutical and health care industries, the government has "not been able to articulate

their point of view in a very clear and constant manner,” Rishi said. “There are too many stakeholders; everyone is talking a different language.”

Look To The IT Industry?

But the pharmaceutical industry should not think its problems are unique or unsolvable, Dhankhar said, citing a similar situation in the Indian IT industry. In the 1990s, “the credibility of the IT players, partly from a result of their own mistakes, was literally zero,” he said. “They were not viewed as people who could be equal partners” like today.

Dhankhar credits an Indian trade group, the National Association of Software and Services Companies, for taking the lead to position the Indian IT industry as “credible technology partners to global companies.”

In contrast, the Indian pharma industry today is fragmented, Dhankhar said, with multiple voices and several trade groups representing various viewpoints.

What is most needed is a credible group “that starts to become the voice of the innovation part of the Indian industry,” he said.

By Joshua Berlin

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