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Drugs - Biologics - Devices

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Is India Falling Behind Its Neighbors In Attracting Clinical Research?

During the annual USA-India Chamber of Commerce biopharma summit, participants discussed the pros and cons of doing research in India, and pointed to key policy issues that must be resolved to spur more clinical trials.

CAMBRIDGE, Mass. – Despite a rich patient base and traditional strengths in the life sciences industry, India is no longer attracting as much clinical research as other up-and-coming markets like China and Korea due to policies that cause multinationals to turn elsewhere in an increasingly competitive space, according to delegates at the annual USA-India Chamber of Commerce Biopharma Summit May 11.

Unlike China, where Big Pharma is willing to cope with adverse R&D policies due to the large commercial opportunity and massive government funding, countries like India must put in place proactive policies to attract global clinical trials and industry investment, delegates said.

“India has not been a major part of our multinational clinical trial network.”

- Abbott SVP Pharmaceutical R&D John Leonard

The number of clinical trials in India has dropped in recent years, according to a Boston Consulting Group report commissioned by USAIC and released during the summit.

There are multiple reasons for the decline, according to BCG, from a shortage of qualified principal investigators to lengthy clinical trial approval times to restrictive Phase I trial policies, but they all lead back to the same hard truth: In a globally competitive world, with other emerging countries competing hard for R&D investment, India is falling behind.

To compensate, India must make policy changes that encourage more R&D investment from global players, and should leverage its competitive advantages to specialize in areas like genomic databases, translational research and nanotechnology, BCG says (*“Sneak Preview: R&D Investments Must Focus On India’s Competitive Advantages” — PharmAsia News, May 4, 2012 6:58 PM GMT*).

Abbott's Hesitation

The actions of **Abbott Laboratories Inc.** speak to the challenges India faces. With the acquisition of the domestic pharma business of **Piramal Healthcare Ltd.** in 2010, Abbott has vaulted to the top spot among India pharma companies (*“Piramal Deal Done, Abbott’s India Plunge May Fetch Big Returns, But Integration Challenges, Growth Momentum Critical” — PharmAsia News, May 24, 2010 10:41 AM GMT*). Yet despite having roughly 12,000 employees now in India, Abbott has not leveraged India for global clinical trials, instead focusing primarily on its commercial presence, according to John Leonard, senior VP of pharmaceutical R&D for Abbott.

Although Abbott has commissioned discovery programs with Indian companies to capitalize on cost advantages, and runs local clinical trials to support its Indian business, it has hesitated to open an R&D center or to conduct global clinical trials in India.

“India has not been a major part of our multinational clinical trial network,” Leonard told summit attendees. “Until we have a more permissive environment that’s far more efficient and welcoming, I think that India – despite the richness of the patient population – will be disadvantaged toward all the other regions of the world who are trying to break those barriers down.”

“When we look at how we do our work, there are solutions all over the world,” Leonard added, citing Latin America, Eastern Europe, China and South Africa as more attractive clinical trial destinations. “It’s a very, very competitive environment.”

BCG, in fact, recommends that India look to Korea as a model, noting that the country saw an explosion of global clinical trials after it put in place policies that support the industry, such as quicker IND approval times.

Given its status as India’s largest pharma company, however, Abbott’s stance on clinical trials risks playing into the hands of some local leaders who have worried about the impact of multinationals acquiring companies like Piramal (*“Indian Govt Move To Scrutinize MNC Investments In Indian Firms Could have “Chilling” Effect” — PharmAsia News, Oct. 11, 2011 11:00 AM GMT*).

During a Q&A period, N.K. Ganguly, a distinguished biotechnology research professor with the India government’s Department of Biotechnology, asked Leonard to define the “value” that Abbott contributes when it buys an established Indian business such as Piramal, suggesting that Abbott may not be investing in India as much as expected.

In response Leonard said that investment decisions for R&D are influenced by the “push and pull” of the local environment, and that more welcoming policies would help India attract research dollars from Abbott and other multinationals.

Phase I Challenges

One policy that is emblematic of India’s troubles is its stance on Phase I trials, which was highlighted in BCG’s report and brought up time and again by summit delegates. Indeed, it is a commonly cited issue: India does not allow Phase I trials unless the compound was discovered in India or has already gone through Phase I trials elsewhere.

Yet perhaps the most striking thing about the Phase I policy is the lack of agreement by key stakeholders as to what the policy actually says.

Speaking on a separate panel, Novartis AG Senior VP of Global Development John Orloff said that India needs to revise its Phase I policies to attract more R&D investment.

That comment was echoed by William Chin, executive dean of research at Harvard Medical School, and a former senior VP at Eli Lilly & Co., who emceed the meeting. Chin commented that India could find a niche by helping companies to repurpose drugs that had failed for efficacy reasons in another indication. But to do so, Chin suggested that India would need to revised its Phase I policies

In response, Ganguly said “it is a misconception that Phase I trials are not allowed,” citing two Phase I studies conducted in India for HIV vaccines.

“For many products it is happening, but it happens on a case-by-case basis,” he said, noting that India halted a Phase I trial for the multiple sclerosis drug Betaseron after deciding it was unlikely the drug would be brought to market in India.

Ganguly’s explanation, however, did not satisfy fellow panelist Savita Dhillon, medical director of the Medanta-Duke Research Institute in Gurgaon, India, who said the problem is that India has no clear guidelines on how much data are necessary to conduct a repeat Phase I trial. Regulators also have taken inconsistent views on the definition of “discovered in India,” claimed Dhillon, a former section head for clinical affairs with Johnson & Johnson.

Ganguly, however, disagreed, saying that India’s regulations on Phase I trials have been adapted from U.S. FDA regulations. “There is nothing which would prohibit a repeat Phase I, or a Phase I [for a compound] which has not been discovered in India,” he said.

Speaking to *PharmAsia News* on the sidelines of the summit, Ganguly explained that the criteria for allowing Phase I trials includes an assessment of whether the drug would be launched in India if approved and if it would be affordable for Indian patients.

But that explanation did not sit well with several delegates, who, like Dhillon, complained that India’s case-by-case policy leads to inconsistent decisions and uncertainty for the industry.

And that uncertainty means that India is at a competitive disadvantage to countries like Brazil, China and Korea, according to Harvard’s Chin, who argued that Indian leaders need to adopt “a sense of urgency” to address policy deficiencies and funding challenges.

Is India Worth The Risk?

One company conducting a sizeable number of clinical trials in India is Novartis, a fact that might surprise industry watchers given the Swiss pharma’s high-profile struggle to secure patent protection in India for *Glivec* (imatinib) (*“Supreme Court Judge Recused From Glivec Patent Case In India” — PharmAsia News, Sep. 9, 2011 11:00 AM GMT*).

But Orloff told summit attendees that Novartis conducts between 200 to 300 trials a year in India and has expanded its R&D operations in Hyderabad from roughly 250 employees in 2007 to more than 1,000 today.

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Novartis began its R&D efforts in India with back office tasks like safety, regulatory affairs, statistics and data management, Orloff said, and eventually expanded to include teams that execute regionally on the company's global clinical trials. He cited access to patients, cost savings and trial recruitment as benefits of conducting trials in India.

“Trying to avoid risks at all costs actually can damage you.”

*- Endo Pharma EVP
R&D Ivan Gergel*

But he also highlighted several challenges to clinical trials in India, including delays in the clinical trial approval process, a shortage of trained principal investigators and a need for more infrastructure such as centers of excellence that can conduct specialized studies.

Still, for a company that once hinted it might pull resources from India due to the Glivec controversy, it was noteworthy that Orloff didn't mention IP as an impediment to R&D investment for India.

And that, too, was the message **Endo Pharmaceuticals Holdings Inc.** Executive VP of R&D Ivan Gergel had for delegates. While acknowledging that India is a research destination for Endo in part because of cost-savings, he also noted that there is an “intellectual component and a high quality component” for doing research in India, and that IP is not the concern that some say it is.

All 12 of Endo's discovery programs are conducted via Indian partners, he noted, and Endo has about 200 external scientists in India working on its projects (*“Building Trust, Technology Competence Can Boost Partnering Prospects For Indian, U.S. Companies” — PharmAsia News, Jun. 16, 2011 1:00 PM GMT*).

“We are completely and totally dependent” on Indian scientists, he commented, noting that the ratio of internal to external R&D staff at Endo is 1 to 20.

And Endo, for one, believes conducting R&D is less risky than Abbott and some other Big Pharma might believe.

The problem, he says, is how you look at it. Rather than focusing only on the risk, pharma companies should also focus on the benefits of conducting research in India.

“Trying to avoid risks at all costs actually can damage you,” he said.

Yet it was a comment from the audience that seemed to draw the most nods about R&D and the challenges of doing business in India.

During a Q&A portion of the program, an executive from **Takeda Pharmaceutical Co. Ltd.** described his company's experiences in India since launching operations three years ago. The Japanese pharma has been “very successful” with its partnerships in India, including R&D, IT and manufacturing efforts, the exec said.

“We are very happy we have found the road maps now to continue it,” he explained. “But I wish the journey didn't have to be so painful.”

By Joshua Berlin

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