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Sneak Preview: R&D Investments Must Focus On India’s Competitive Advantages

India has unique capabilities for genomic databases, translational research and nanotechnology, which should spur research on cancer leads, according to a BCG report to be released May 11.

MUMBAI – Global drug companies and research institutions are expected to increasingly rely on India-specific capabilities to sharpen their competitive advantage for conducting research in India.

Companies should either build and maintain assets where India can offer an economic advantage, such as genomic databases, or they should outsource process-intensive areas where India can deliver efficiency in segments, such as translational research or nanotechnology, that combine the country’s abundant capabilities of engineering excellence and life sciences.

“A supportive environment is vital for India in particular as the commercial landscape does not create enough pull to drive these opportunities by themselves”

– BCG’s Bart Janssens

The findings are part of an exhaustive survey based on interviews with 45-50 senior level executives drawn from the global industry and academia by management consulting firm Boston Consulting Group, assigned to identify strengths that enable a practical, user-centric environment for research in India.

The study was commissioned by the USA-India Chamber of Commerce and will be released during the group’s annual BioPharma & Healthcare Summit in Boston May 11. This year’s conference will focus on how India can best play a role in oncology R&D.

Last year’s report and conference focused on diabetes research while also pointing at the potential of niche areas

and stem cell research in India (*“Sneak Preview: BCG Study Predicts Strong R&D Focus In India; Big Pharma May Leverage India For “Niche Busters” And Stem Cells”* — *PharmAsia News*, May 23, 2011).

In an exclusive sneak preview, BCG and USAIC sat down with *PharmAsia News* to discuss findings from the report and how to create the right ecosystem in India that plays to the country’s strengths.

Leveraging Unique Advantages

“We believe that an advocacy platform to coordinate efforts across stakeholders must be established and that policy makers need to focus on setting guidelines, streamlining processes, building capacity in the administration, and finally encouraging infrastructure investments,” said Bart Janssens, a BCG partner based in Mumbai.

“A supportive environment is vital for India in particular as the commercial landscape does not create enough pull to drive these opportunities by themselves,” he stressed

For example, for oncology research in India, companies should create “unique assets” like genetic information databases, translational research hubs or centers of excellence in areas like nanotechnology, he said.

With 70% of industry growth coming from emerging markets, global companies will be looking to tailor their R&D investments for each country based on local capabilities.

Given the backdrop of challenges to develop oncology drugs, due to complex pathways to identify valid targets with therapeutic potential, Janssens said genomic databases can help to better understand biomarkers indicative of cancer types for personalized medicines.

“Use of extensive patient information has been seen as a great benefit by stakeholders across the globe,” Janssens said, highlighting India’s large treatment-naïve patient base. Moreover, in India, databases can be done at a fraction

of the cost compared to the rest of the world and from resources that already exist, he said.

Similarly, translational research enables faster translation of promising molecules from bench to bedside, and India has significant potential in research of nanomaterials for targeting tumors and estimating toxicity.

“Investments will only flow to areas of real advantage as compared to others. If India has to attract investment dollars, the start should be made where India is strong not just within India but also globally,” he added.

Stressing the importance of genetic information databases, Janssens said MNCs are interested in mapping out future oncology research goals in India. At present, he said, companies are paying significant money for sample collections and many are exploring new ways to get access to this kind of data.

Big Policy Challenges

Similarly, research must be relevant to Indian patients, which is why global companies will need to invest in translational research hubs. However, one hurdle is that India does not allow Phase I or first-in-human trials for molecules discovered by global companies outside India.

In that context, Janssens shared the example of **Piramal Healthcare Ltd.**, which despite being an Indian company, initiated Phase I trials on its leading oncology compounds in Europe.

“The policy environment will need to be more predictable and much less cumbersome. We need to have a policy that doesn’t just allow Phase I trials, but one that is efficient to build translational research capabilities,” he explained (*“Launching Clinical Trials In India? Beware Of Long Delays And New Mandates” — PharmAsia News, Feb. 16, 2011*).

India’s National Institute of Mental Health and Neuro Sciences in Bangalore could be used for a diagnostics facility or for biomarkers to detect early-stage tumors, Janssens suggested. Institutes like India’s Bioinformatics Center, which works on DNA sequencing and mutation analysis, anti-cancer drug screening and expression profiling; and the National Institute of Biomedical Genomics were also highlighted as effective bodies for oncology research.

On the translational research side, Janssens painted a vibrant picture of industry-academia collaborations like the Medanta-Duke Research Institute to establish a global translational center of excellence. Another example shared by BCG is the Translational Health Science and Technology Institute, an alliance between the government of India and Harvard-MIT, which established a Center for Biodevices and Diagnostics for translational medicine.

India is turning out to be an “emerging innovator” in the nanopharma space, Janssens noted, with more than 100 pharma-based patents filed in nanosciences in the last five years, 40 of which were in oncology.

Even so, regulatory approval to start clinical trials is very slow in India and remains a concern, Janssens said, noting that the number of new trials started in India has remained at virtually the same level for the last five years. In 2011, in fact, there was a considerable drop off – only 169 new trials were approved in India last year compared to a high of 260 in 2008.

Janssens called for concerted action to shorten the approval time for regulatory processes in India and the need for confidence-building efforts. To accomplish these goals, an advocacy forum comprised of industry, academia and the government should be formed to identify common goals, he said

At the top of the list is reducing road blocks for clinical trials via single-window clearances or institutional mechanisms, such as pre-IND consultations, accreditation of sites and building better infrastructure, providing tax breaks and steps to encourage investments (*“Clinical Trials Flood India But Infrastructure Woes Stifle Cancer Trials” — PharmAsia News, Feb. 9, 2011*).

Janssens cited the example of Korea, which has been able to grow its clinical trial industry by implementing proactive policy steps and funding infrastructure that encouraged MNCs to conduct global trials in Seoul. In 2000, it took roughly 120 days to get an IND approved in Korea, according to BCG, but by 2003 the approval rate was down to 30 days.

Since then Korea has moved quickly up the ranks of global clinical trial destinations, from number 32 in 2005 to number 10 in 2009, and India could make similar moves, Janssens said.

And all those trials are starting to pay off for Korean patients. Earlier this year **Pfizer Inc.**’s lung cancer therapy *Xalkori* (crizotinib) reached the market in Korea second worldwide, behind only the U.S. – an approval made possible by trials Pfizer conducted in Seoul as part of its global data package (*“Pfizer Oncology Asia Chief Jorge Puente On Asia’s Role In Xalkori’s Success: An Interview With PharmAsia News (Part 1 of 2)” — PharmAsia News, Apr. 13, 2012*).

[Editor’s note: This story was contributed by **PharmAsia News**, which provides daily coverage of the Asia biopharmaceutical industry and regulatory policies. To learn more, sign up for a *free trial* – no credit card needed.]

- Vikas Dandekar, Joshua Berlin

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