PharmaAsia

A Tale Of Two Giants; Tracking India And China's Rise In The Pharmaceutical Market

August 04, 2008

SHANGHAI - The nature of business relationships between multinational pharma companies and Indian and Chinese firms varies significantly, according to a recent study released by the Ewing Marion Kauffman Foundation.

MNCs such as Merck, Eli Lilly and Johnson & Johnson have started to move their R&D to China and India as part of a larger and globalized business model, according to the study, "*The Globalization of Innovation: Pharmaceuticals. Can India and China Cure the Global Pharmaceutical Market?*

These companies, looking to broaden their R&D capabilities without raising costs, are increasingly forging partnerships and research collaborations with companies in India and China, the study said.

The nature of these relationships varies from captive and partnership models to milestone and direct buyout models. Some of these partnerships entail joint drug ownership and/or split-revenue arrangements rather than fixed-milestone payments.

The type of work done under these relationships includes drug discovery, manufacturing, clinical trials, and generics production.

"However, right now big pharmaceutical companies are being very cautious in not moving the most sensitive R&D," Vivek Wadhwa told *PharmAsia News*. Wadhwa, an executive in residence at Duke University and a fellow at the Labor and Worklife Program of Harvard Law School, led the team of researchers conducting the study.

Although MNCs are increasing the complexity of business relationships with external partners, they do guard against accidental disclosure or loss of intellectual property by not actively assigning their most lucrative projects to them, the study said.

"They are moving some sophisticated drug discovery on molecules, which they have already discovered and they think have potential," Wadhwa added.

Pfizer has not yet established any risk-sharing R&D partnerships with Asian companies, and has instead relied on building a network of CRO partners to support its research projects (PharmAsia News, July 28, 2008).

Although MNCs are exploring collaborations with companies in developing countries to complete their R&D activities, these relationships are emerging within a narrow band of trusted, highly qualified firms, mostly in China and India, Ben Rissing, Wertheim Fellow at the

Labor and Worklife Program of Harvard Law School and one of the study authors, told *PharmAsia News*.

"Partnerships with outside firms allow multinational corporations to pursue more drug candidates simultaneously," he said. "To date, these partnerships have not involved these multinational corporations' core intellectual property, and therefore have rarely involved the most cutting-edge compounds or molecules" he added.

Differences And Similarities

Indian and Chinese companies are making equal strides in the highest-value segments of global value chains, researchers found.

Chinese firms appear to be more prevalent in less lucrative segments such as preclinical testing, animal experimentation and manufacturing.

Indian and Chinese companies are both beginning to develop their own proprietary drug products, the study noted.

India is regarded as a more mature venue for chemistry and drug discovery activities than China. However, in general both countries rarely have the capital and regulatory expertise to develop a drug beyond Phase II clinical trials.

"Both countries are growing rapidly," Wadhwa said. "China is more dominant in things like clinical trials, and India because of its experience in the generics market seems to be doing more high-level research."

"India has an advantage because of its strength in generics," Wadhwa said. "But the Chinese government is investing massively to encourage R&D."

"Although wounded by well-publicized missteps involving adulteration and quality-control, Chinese firms have strong high-throughput chemistry capabilities," Rissing said. "Control over the supply of raw materials has enabled a number of firms to produce and distribute generic drugs at extremely low costs for consumers in emerging markets."

China has also emerged as a strong destination to source contract research functions, according to Rissing. "A number of firms in China have exceptional access to blood and tissue libraries in addition to research animals."

For example, Eli Lilly was unable to collect a series of specific human tissue samples in the U.S., and so it contracted ShanghaiBio, which was able to collect 100 relevant samples in China in the course of three weeks, the study noted.

Indian companies such as Ranbaxy, Aurigene, Advinus, Nicholas Piramal and Jubilant have negotiated long-term deals with Western pharmaceutical companies to discover and develop new chemical entities (PharmAsia News, July 25, 2008).

In a growing number of cases, the Indian companies have been sharing financial risk in discovery as well as the potential financial rewards, the study added. One Chinese company, Hutchison MediPharma, has formed a similar partnership with Eli Lilly (PharmAsia News, Nov. 20, 2007).

"India is unique in that a number of domestic pharmaceutical firms located there have established drug development relationships with multinational corporations that involve joint-ownership of a drug candidate if the drug reaches commercial markets," Rissing said.

India and China are also different in terms of management culture, the study said.

"India is by far much more Westernized and has advantages in its knowledge of English," Wadhwa said. "But China has superior infrastructure and strong government support."

"India succeeds despite its government, China succeeds because of it," he added.

As a result of MNCs' movement of R&D to their countries, Indian and Chinese scientists are rapidly developing the ability to innovate and create their own intellectual property.

In 2006, 5.5 percent of all global pharmaceutical patent applications named one inventor or more located in India, with 8.4 percent naming one or more located in China, a fourfold increase from 1995, according to the study.

Threat Of Counterfeits And Contaminated Drugs

However, recent reports of counterfeits and contaminated products from China have had a negative impact on the pharmaceutical industry in both China and India (PharmAsia News, May 12, 2008).

"This is a big issue, which could derail the entire industry," Wadhwa said. "Both India and China need improvement in their regulatory environments," Wadhwa added.

"Contaminated and counterfeit drug-products can easily damage and jeopardize a country's credibility as a safe or reliable destination to manufacture or purchase consumer drugs," Rissing said. "While this is now, and will long remain, a very significant issue from a supply standpoint, it appears unlikely that these counterfeiting issues will affect the internationalization of well-run and rigorous research and development efforts."

Experts Upbeat About The Future

It is too early to tell whether China and India will become important sources of new drugs, the study said.

"Worldwide, the pharmaceutical industry has one of the longest and most expensive development cycles of any industry," Rissing said. "Most of the new risk-sharing arrangements date from 2005, so it could be another decade before there are concrete results."

Still, many MNCs are increasingly approaching companies in emerging countries to expand their drug discovery and development capabilities.

"The success of this business strategy, and the potential drug candidates produced from these relationships, will become increasingly apparent in the years to come," Rissing said. "In the near-term, the global focus of drug research and development will include providing firms in emerging markets access to protocols, laboratory techniques and methodologies that may otherwise have taken years to develop internally."

Wadhwa concurred, adding that it will be good for the world as better and cheaper drugs will then be available.

"China and India will be less dependent on Western companies to develop cures for diseases which are common in their countries but not in the West," he said.

Wadhwa noted that MNCs are taking notice of these markets because they see opportunities, especially during the next few years as the middle-class develops in China and India, and their populations start getting the same diseases as westerners.

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Published by FDC REPORTS

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