

Action urged on foreign takeovers of Indian drugmakers

NEW DELHI — On the face of it, the takeover of six of India's key drug firms by major foreign players in the past four years seems to be routine business. But people within the government and industry watchdogs in India have started to worry.

In 2008, Japan's Daiichi-Sankyo took control of India's largest drugmaker, Ranbaxy Laboratories, located about 20 miles south of New Delhi. Other Indian firms that have met a similar fate include Dabur Pharma, Shantha Biotech, Piramal Healthcare, Matrix Laboratories and Orchid Chemicals and Pharmaceuticals. Local concern grows out of the fact that these companies are major producers of cheap generic versions of essential medicines and vaccines, with wide market access in India and in other developing countries.

A paper circulated by India's commerce ministry in late November 2010 noted that there is "concern that [the companies'] takeover by multinationals will further orient them away from the Indian market, thus reducing domestic availability of the drugs being

produced by them." Ultimately, it added, the situation might lead to an increase in domestic drug prices.

The concerns go beyond India, which ranks third worldwide in terms of total volume of drugs produced and is often described as the pharmacy of the developing world. "Some [developing countries] have begun to privately ask India about the mergers," says Sachin Chaturvedi, senior fellow at the Research and Information Systems for Developing Countries, a public-funded think tank based in Delhi.

Sujay Shetty, associate director for pharma and life sciences at PricewaterhouseCoopers in Mumbai, dismisses fears of a price hike in the current drug market. "The Indian market is fragmented market and not monopolistic. There is way too much competition, and the Indian government is empowered to control drug prices if they get out of hand," he told *Nature Medicine*.

But Indian policy analysts fear the long-term implications. A primary concern is the future manufacturing capacity of low-cost generics, the production of which is permitted

in certain circumstances thanks to a clause in international patent laws pertaining to compulsory licensing of brand-name drugs in case of a national health emergency.

Should India need to issue a compulsory license, there might be few competent domestic firms stepping up to make the drugs, says Dinesh Abrol, senior scientist at the National Institute of Science, Technology and Development Studies, Delhi.

"As the control of foreign firms over the domestic market goes up, their leverage with distributors and bulk drug suppliers goes up," says Abrol, noting that foreign firms are unlikely to engage in the production of generic drugs that compete with their own brand-name products.

Newspapers, including the *Financial Times*, have reported that Indian leaders are now pondering the possibility of rules that would require foreign companies to seek government approval before going after anything more than a 49% stake in any Indian pharmaceutical firm.

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Transparency initiative moves ahead despite official's departure

An initiative to increase transparency at the US Food and Drug Administration (FDA) moved forward on 6 January with the release of a report detailing steps the agency says it is undertaking to make its inner workings more evident to the drug industry.

The report, *FDA Transparency Initiative: Improving Transparency to Regulated Industry*, includes 19 so-called 'action items' for implementation this year, ranging from posting presentations by agency employees online to responding faster to questions from industry. The document also lists five draft proposals—now up for public comment—to further improve transparency.

Both industry and advocacy groups greeted the new report positively. "It's a good first step," says Jeffrey Francer, assistant general counsel at the Washington, DC-based Pharmaceutical Research and Manufacturers of America (PhRMA).

Jeff Allen, director of Friends of Cancer Research, an Arlington, Virginia-based group that advocates for improvements in drug regulation, who described the report as "win-win" for the FDA and industry, applauded the proposal for the FDA to post timelines of when

it will aim to release new 'guidance documents' that outline policies relating to clinical trials and drug development. Drug companies, particularly smaller ones, currently have only a vague idea—often based on rumor—of when the FDA plans to release new guidelines, says Allen.

Increasing transparency in this area, says Allen, "will make things a little more clear to industry as they prepare their submissions and design their studies."

Among the other pledges that should please industry, the report stated that the FDA "is setting the expectation of responding to email questions about the regulatory process within five days."

Francer says the FDA took on many of the changes suggested by industry, but not others—such as an industry proposal calling for a mandatory meeting with industry halfway through the drug application process. Such a meeting could, for instance, help companies learn early that they might need to prepare additional data, thereby avoiding a lengthy second review process.

If there was a hiccup in the transparency project, it came one day after the report's

release. On 7 January, the FDA lost one of the initiative's biggest champions when Deputy Commissioner Joshua Sharfstein, who chaired the FDA committee in charge of the initiative, left the agency to lead the state department of health in Maryland. John Taylor, the top lawyer in FDA commissioner Margaret Hamburg's office, stepped in as Sharfstein's temporary replacement for two months, after which a permanent replacement will be appointed.

Despite Sharfstein's departure, transparency efforts at the FDA will not lose momentum, according to Afia Asamoah, the FDA official in charge of implementing the initiative. She notes that the initiative is "kind of a brainchild" of Hamburg's and has broad support throughout the agency. "Commissioner Hamburg is committed to insuring that the transparency initiative continues," Asamoah says.

Asamoah adds that the agency is on track to finalize a separate set of proposals it released last year to increase transparency to the public. Some of these proposals would increase public access to industry information, such as whether a drug application has been rejected or put on hold.

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