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Drugmakers look to forgo India edge in margin race

■ Expect costs to be offset by fast realisation in lucrative markets

Mumbai, Aug 29: Drugmakers in the country are fleeing a regulatory morass at home and moving some research and development (R&D) to Europe and the US as they try to boost margins by producing high-value drugs.

India's $15-billion-a-year pharma industry, the world's largest source of cheap generics, is already reeling under a string of drug recalls and quality control issues that have called into question the regulator's oversight.

Now, companies like Piramal Enterprises, Sun Pharmaceutical Industries and Lupin are investing millions of dollars and placing their growth in foreign regulators' hands as they seek to add more complex drugs to their product lines.

"We have lost what is called the India advantage," said Swati Piramal, vice-chair of Mumbai-based Piramal Enterprises, which last year moved some clinical trials for new drugs abroad.

"The India advantage was saying we can research molecules...and finish the clinical trials and the cost would be one-tenth of the West," she said.

"Now, we have to acquire small groups of highly specialised people who can work on a particular type of product and know exactly how to do it. That's the new alternative — to really invest in R&D abroad," she added.

Indian drugmakers rely on cheap generics for the bulk of their revenue, but like their global peers, they are focusing more on niche markets such as ophthalmology and oral contraceptives, and difficult-to-make products such as inhalers and injectables in a bid to achieve higher profit margins.

Some companies are also making copies of bio-drugs called biosimilars, the latest trend in the global pharma industry, which requires intensive R&D and a regulator with experience in handling such sophisticated medicines.

Like its peers, Piramal does not disclose how much it spends on R&D abroad. Industry research firm CRISIL, however, forecast R&D spending by India's top 20 pharma firms to rise to about 6.5% of total revenue by 2018 from about 5.8% now.

Company executives say the higher cost of moving abroad will be partly offset by the ability to bring high-value drugs to their main markets in the US and Europe more quickly: it takes nearly a year to get clinical trials approved in India compared to about 28 days in the US.

These high-value drugs hold so much potential that companies are willing to put up with long delays before they can launch them at home, a fast-growing market for more expensive medicines, as India's regulator only allows drugs that have been tested locally to be sold there.

Moving West

Drugmakers say they are frustrated by the lack of concrete regulations for clinical trials two years after the Supreme Court halted 162 studies citing unethical practices. GN Singh, the Drug Controller General of India said the regulator was working on hiring more staff and simplifying the process for clinical trials. He did not elaborate.

Analysts also partially blame weak regulatory oversight for the import bans imposed by the US Food and Drug Administration on Indian drugmakers in the past year.

In addition to a smoother regulatory process, drugmakers say moving R&D abroad allows them ready access to a pool of trained talent and better infrastructure, which is lacking in India.

"Investing in research abroad is specific to companies that want to grow in certain areas for which the best talent and regulatory expertise is available abroad," said Shakti Chakraborty, group president at Lupin.

So far, Indian drugmakers have looked to Europe and the United States as they expand their R&D. *Reuters*

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SWATI PIRAMAL
Vice-chairperson, Piramal Enterprises

SEEKING ALTERNATIVE THERAPY

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