

'Quality Concerns Point to Generic Drugs Shake-out'

REUTERS
BASEL

Recent manufacturing problems in India suggest some makers of generic drugs will struggle to compete in the face of a rising quality bar, pointing to a likely a shake-out in the low-cost sector, according to Novartis.

Chief Executive Joe Jimenez said the Swiss group's Sandoz unit - a world leader in making cheap off-patent medicines - as well placed to thrive in an era of tougher standards. Others, however, would not be able to upgrade and stay competitive.

"Some generic companies with lower margins are going to have a hard time building the quality into their systems," Jimenez told Reuters in an interview.

"You're talking about an industry where scale is going to become more important ... I see this as a competitive advantage for a company like Novartis."

In recent months, the US Food and Drug Administration, citing quality control problems ranging from data manipulation to sanitation, has banned the importation of products from Indian firms such as Ranbaxy Laboratories and Wockhardt.

India supplies about 40 % of generic and over-the-counter drugs used in the United States, and some US doctors are becoming concerned about the quality of Indian generic drugs following a flurry of recalls and import bans.

Jimenez said the challenge of a rising quality bar was not unique to India, with Western firms including Johnson & Johnson and Novartis itself having run into

problems in the past, but the issue would be acute for smaller players with limited resources.

"What was good enough five years ago is no longer good enough today," he said.

"I think it is going to become very, very hard to be a small, sub-scale generics company because they are going to have to invest disproportionately in quality assurance assets that significantly change their cost structure and they may not become competitive on price."

Some companies, as a result, may decide in future not to compete and sell their medicines into highly regulated markets like the United States and Europe, leading to a reshaping of the sector.

For Novartis, however, generic medicines would remain an important part of the company's future and Jimenez said low-cost generics from Sandoz were increasingly central to the company's business strategy, particularly in emerging markets. "Having a generic division in the portfolio allows me to sit down with health ministers and talk about how Novartis can help lower total healthcare costs," he said.

He also sees a bright future for Sandoz as a pioneer in developing copies of complex biotech drugs, particularly antibody-based products for cancer and rheumatoid arthritis that are now among the world's top-selling prescription medicines.

Sandoz hopes to launch some so-called biosimilar versions of these antibodies in major markets over the next three to four years, Jimenez said.

Miscellaneous