

# Daiichi may step in to resolve Ranbaxy's US FDA issues

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**D**aiichi Sankyo is planning a "comprehensive policy" to deal with the problems at Ranbaxy. The Japanese company has also decided to intervene to address the latest issues raised by the US Food and Drug Administration (US FDA) at the Toansa factory of its Indian arm.

In response to an e-mail query by *Business Standard*, Daiichi Sankyo said it was assisting Ranbaxy in responding to Form 483 issued by US FDA, in which the regulator highlighted manufacturing violations at the Toansa (Punjab) factory, which manufactured active pharmaceutical ingredient (API). "We are supporting and focusing on this action as a matter of high priority," said Toshiya Kondo, senior director at Daiichi Sankyo. "For a further approach to solve a series of problems, we think we need a comprehensive policy after this."

Last week, Daiichi Sankyo, which acquired Ranbaxy in 2008, had announced its earnings were hit by ongoing events at its Indian arm. "We want to go back and prepare a more aggressive, more drastic response," Daiichi Sankyo Senior Executive Officer Manabu Sakai had reportedly said on Friday.

The Japanese company is likely to bring more Japanese

## CRISIS MANAGEMENT

Daiichi Sankyo is presently assisting Ranbaxy in responding to the Form 483 issued by the US FDA highlighting serious manufacturing violations at its Toansa (Punjab) factory, which manufactures APIs. The Japanese company is likely to bring in more of its people in the Indian factory to clean up the process and procedures on the ground.

executives to the Toansa factory to improve affairs there. Through the past year, many Japanese executives have already been inducted into Ranbaxy. It appears Daiichi Sankyo now plans to induct more foreign faces not only at Ranbaxy's top management level, but also at the middle and lower levels.

Daiichi declined to share the specific measures it would undertake as part of its business plans.

Experts and sources suggest the recent measures are steps towards Daiichi Sankyo taking total control of Ranbaxy in the near future. "There is a serious problem with the culture of the company and this has been going on for a long time. So far, Daiichi has trusted the Indian management, but that does not seem to have worked,"

said an official privy to developments at Ranbaxy. Significant and sustainable changes in processes and practices weren't possible without a change in culture, the executive added. "Daiichi, with its Japanese background, would certainly not like to tolerate this anymore."

While sources say Ranbaxy has recently informed the Drugs Controller General of India the recent violations at the company's Toansa factory are suspected to have been sabotaged by some of its disgruntled employees, experts say Daiichi Sankyo's action plan may include major human resources changes.

However, a few think Daiichi Sankyo may address the problems in a different way. "Though introducing Japanese executives can be a good temporary measure to implement corrective measures, in the long term, Daiichi Sankyo will have to face Indians. Therefore, the better option is to develop a cadre of Indian management and Indian teams whom it can trust with stringent controls," says Raveendra Chittoor, assistant professor of strategy at the Indian School of Business. Daiichi has to be careful about its strategy, as it shouldn't create mistrust by completely alienating Indian employees; Instead it should take employees into confidence and install best practices, Chittoor says.

*Chittoor*