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Ranbaxy Paonta Sahib may have seen 6–10 exits: Sources

Move comes within weeks after the firm's API-making facility in Punjab was barred from supplying to the American market

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New Delhi, 24 February

Drug maker Ranbaxy Laboratories is learnt to have seen the exit of 6-10 employees at its Paonta Sahib (Himachal Pradesh) factory. This comes within weeks of the company's active pharmaceutical ingredient (API)-making facility in Toansa (Punjab) being barred from supplying to the American market. During an inspection of the facility, the US regulatory authorities had found serious violations of and deviations from good manufacturing norms.

While it was not clear whether these employees left on their own or were asked to go, an email query to Ranbaxy regarding the exits of employees at its Paonta Sahib factory did not elicit any response.

A source said following the latest enforcements and induction of Japanese executives at Ranbaxy factories, the company had adopted a near-zero-tolerance attitude, adding stringent measures had been put in place. While most see the development as "a much required corrective action", some, including many employees, say it is part of Ranbaxy's strategy to weed out those who might have been negligent in duty. "The Ranbaxy management has engaged consultants to identify people who are not useful to the company," an employee at the company's research and development centre in Gurgaon told *Business Standard*.

A source said Daiichi Sankyo, Ranbaxy's parent company, had put in place tough quality-control measures. Production has fallen and new approvals are pending, with four Ranbaxy facilities under the US Food and Drug Administration (FDA) scanner. The four Ranbaxy facilities banned from supplying medicines to the US include three key formulation-manufacturing units in Paonta Sahib, Dewas (Madhya Pradesh)and Mohali (Punjab). The API factory in Toansa was the last to be barred from supplying drugs to the US.

The source quoted earlier said the company's Paonta Sahib facility continued to supply to other markets such as the EU and Australia.

Ranbaxy's factory at Paonta Sahib (including the Bata Mandi unit), which initially received a warning letter from the US FDA in 2006, came under an 'import alert' in September 2008, months after Daiichi Sankyo signed its initial agreement to acquire Ranbaxy from its previous promoters. In February 2009, the FDA invoked its application integrity policy against the Paonta Sahib facility to address falsified data generated from the plant. The regulator also halted approvals of any applications from the plant. The application integrity policy is invoked when a company's actions put to doubt the integrity of data in drug applications.

Experts say Ranbaxy's latest observation on negligence in duty might help it send the right signals. However, the company needs to be cautious, as it must not demotivate employees at large, they add. "At this stage, the company needs to take some stringent measures to send the signal that quality and compliance is essential. However, it should not overdo it and must keep some mid-level core employees in confidence because it cannot run factories with Japanese staff alone; it will need local people to work with them and, therefore, it must secure trust and goodwill among them," said Raveendra Chittoor, assistant professor of strategy, Indian School of Business.

CHANGING TIMES, MENDING WAYS

2006: US FDA issues warning letter to Ranbaxy's Paonta Sahib facility

2007: Whistle-blower's lawsuit alleges the company defrauded Federal programmes

Jun 2008: Daiichi Sankyo acquired majority stake in Ranbaxy

Sep 2008: US FDA imposes import alert on Ranbaxy's facilities at Paonta Sahib and Batamandi (Himachal Pradesh) and Dewas (in Madhya Pradesh) and bans 30 drugs

Nov 2008: Daiichi Sankyo concludes Ranbaxy buyout

Feb 2009: US FDA invokes Application of Integrity Policy against Ranbaxy's Paonta Sahib plant and halts pending applications

May 2009: Malvinder Mohan Singh steps down as CEO and MD of Ranbaxy

Dec 2011: Ranbaxy signs a consent decree with the US authorities to take corrective actions at Paonta Sahib, Batamandi, Dewas and Gloversville (New York)

May 2012: Ranbaxy hires two US-based consultants to advise it on remedial work to be done at its manufacturing units in India

May 13, 2013: Criminal charges filed; Ranbaxy agrees to pay a fine of $500 million

May-July: Ranbaxy witness exit of some employees

Sep 2013: US FDA bans Ranbaxy's newly commissioned formulation making facility in Mohali (Punjab)

Nov 2013: Executives from Japanese parent Daiichi Sankyo inducted in various factories

Jan 2014: US FDA bans Ranbaxy's main API manufacturing factory in Toansa (Punjab)

Feb 2014: US FDA Commissioner Margaret Hamburg visits India and meets pharma company CEOs including Ranbaxy head Arun Sawhney

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