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ASIA EDITION

Ranbaxy controversy: What have been the highlights?

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On **May 13, 2013**, Indian drug major Ranbaxy pleaded guilty to charges related to drug safety. The company admitted to have sold drugs that did not adhere to the good manufacturing practices (GMP) set by the US FDA Further, Ranbaxy confessed to have made intentionally false statements to the investigators to boost sales in the US. The fines and forfeitures came up to $500 million, an amount that the company claimed to have kept aside in 2011 itself, in anticipation of the settlement.

The controversy began in **2006**, when the US FDA issued a warning letter to Ranbaxy for deviations from standard GMP at its Paonta Sahib manufacturing plant in India's Northern state, Himachal Pradesh. Furthermore, in **2008**, FDA officials halted the US importation of 30 drugs that were produced at two of Ranbaxy's manufacturing units. Following this, a former Ranbaxy executive-turned-whistleblower, Mr Dinesh Thakur, alerted the US authorities about the forgery and adulteration taking place within the firm.

It was also during this time that Japanese firm Daiichi Sankyo (on **June 11, 2008**) acquired a majority stake in the domestic major for over $3 billion (Rs 150 billion). Daiichi currently holds 63.9 percent stake in Ranbaxy.

Even as the probe continued, the US Department of Justice (DOJ) placed Ranbaxy under a consent decree in **2012**, prohibiting the company from selling drugs manufactured at some of its Indian plants in the US, until their quality could be verified.

The drama surrounding the controversy intensified on **May 23, 2013**, when Daiichi Sankyo said that it "believes that certain former shareholders of Ranbaxy concealed and misrepresented critical information concerning the US Department Of Justice and US FDA investigations."

The former shareholders and owners of Ranbaxy, the Singh family, reacted strongly to Daiichi's comments Mr Malvinder Singh, said in a statement that, "The comments made by Daiichi Sankyo regarding concealment and misrepresentation are false and baseless. Daiichi Sankyo purchased the Singh family's interests in Ranbaxy in 2008 after a long negotiation process, as is typical of deals of this magnitude, and after conducting full due diligence on the affairs of Ranbaxy."

Even as Daiichi plans to recover the $500 million that it paid in fines from the company's former promoters, Ranbaxy stocks have taken a beating since the settlement was made. On the closing of May 24, 2013, Ranbaxy stocks, which trade under the symbol RBXZF in US-based NASDAQ, recorded prices of $8.45 and also recorded stock value of $7.80 (Rs390.30) per share in the Bombay Stock Exchange.

Meanwhile, the Indian health ministry has ordered the Drugs Control General of India (DCGI) to examine all the dossiers and drug applications on the basis of which approvals had been granted to Ranbaxy. "The regulator will evaluate all documents to see whether there has been any compromise in safety, quality, efficacy, or even in submitting data for seeking approvals," a statement from the ministry said.

The Ranbaxy issue has threatened to complicate things for the other drug manufacturers from India, who currently hold a strong foothold in the US. India has the largest number of US FDA approved manufacturing plants outside of the US and the country's top five pharmaceutical companies contribute to 50 percent of the US market revenue. India, which gained popularity for cost effective, high quality drugs, today exports generics worth over $300 million in over 200 key markets in the US, Europe, Asia and Africa.

Will the Ranbaxy controversy hamper the growth of other Indian firms in the US? Let us know what you think in the comments section below.