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Novartis plants to start drug production soon

PRESS TRUST OF INDIA
New Delhi

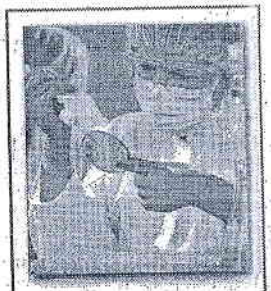
DRUG firm Novartis on Tuesday said it has taken remedial action at its two production units in western India which had received a warning letter from the USFDA and expects the manufacturing facility to return to normal functioning soon. Sandoz, the generic drug arm of the Swiss drug major, had received a caution letter from the US health regulator for violations of current good manufacturing practice (cGMP) norms at its two plants in Maharashtra.

"We have taken remedial action at the two plants in Kalwe and Turbhe which had received a warning letter from the USFDA and these units will soon be back to normal," Novartis India managing director and vice chairman, Ranjit Shahani told PTI on Tuesday.

On October 22, USFDA had issued a warning letter to the company's Sandoz Division concerning its Indian sites in Kalwe and Turbhe located in Maharashtra. The warning letter observations followed USFDA inspection at both sites in August 2014 and were related to deficiencies in current good manufacturing practice (cGMP) for finished pharmaceuticals. At Turbhe, Sandoz mainly produces active pharmaceutical ingredients and in Kalwe oral solid dosages or tablets are produced.

Meanwhile, speaking on the sidelines of an industry event, Novartis Pharma, global head of development, established medicines franchise, Lutz Hegemann said, "If India wants to develop to the same framework that we have in Europe, Switzerland or US, it is very important that the environment becomes highly predictable and that IPRs are clearly defined." If the whole data regulatory process becomes predictable in the long run, it makes investment in the country more sustainable, he added.

Shahani said the prime minister's recent statements on IPR had encouraged the Indian pharma industry. "We eagerly await translation of these into actionable items in the new IPR policy which is just being drafted out and also the rules being framed following that should provide fillip because we truly want to go from Make in India to invent in India.



By guidelines

- The USFDA had warned the company's Indian sites in Kalwe and Turbhe in Maharashtra
- The prime minister's recent statements on IPR had encouraged the Indian pharmaceutical industry
- The company has taken remidial action and hopes to resume production soon

Company