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Ranbaxy gets US FDA nod for Diovan generic

Company will also enjoy 180 days of exclusive marketing rights for the drug in the American market

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Ranbaxy Laboratories has received the US Food and Drug Administration (US FDA)'s approval to sell a generic version of Novartis's hypertension medicine Diovan, sources say. The company will enjoy 180 days of exclusive marketing rights for the drug in the American market, it is learnt.

"The company will launch the drug at the earliest," a company executive said, indicating the generic version was likely to enter the American market within the next few days.

The launch of the Diovan generic has been pending since September 2012, when Novartis lost patent protection in this regard. It is expected the launch of the generic will give a significant boost to Ranbaxy's revenue, under pressure for a long time.

In the absence of competition from generics, Novartis clocked about $3.4 billion of sales from this drug globally. Estimates by market analysts show if Ranbaxy launches the drug at a discount of 40-50 per cent, it might earn about $200 million during the six-month exclusivity period.

The US FDA approval marks a positive for Ranbaxy. The company, recently acquired from Japan's Daiichi Sankyo by domestic drug maker Sun Pharmaceutical in a $4-billion transaction, has been in the midst of woes at its largest drug market, the US. Currently, four key Ranbaxy facilities in India are barred from supplying products to the US, owing to violation of manufacturing norms.

Following the untoward developments at its facilities, many of the company's key products awaiting US FDA approval were stuck with the regulator. While Ranbaxy's US-based Ohm Laboratories is allowed to manufacture for that market, sources say it is possible the company has tied up with a third party for sourcing active pharmaceutical ingredient (API), as its primary API plant in Toansa is has been barred from supplying products by US FDA.

Company