

DCGI allows Natco Pharma to launch generic hepatitis-C drug Harvoni

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NEW DELHI: The Drug Controller General of India (DCGI) on Tuesday allowed Natco Pharma to launch the generic version of US-based Gilead Sciences Inc's hepatitis-C drug Harvoni in India. With this, Natco has become the second Indian drug maker to get DCGI nod for generic Harvoni in India. Last week, the India drug regulator had approved Hetero Drugs Ltd's copycat version of Harvoni.

Harvoni, the fixed-dose combination of ledipasvir-sofosbuvir of 90mg and 400mg, respectively, is an improved version of Gilead's hepatitis-C drug Sovaldi or sofosbuvir. Natco plans to launch this combination drug immediately under its brand name Hepcinat LP and through its strategic partners in India, a statement from the company said.

Ledipasvir+sofosbuvir is a two-drug fixed-dose combination product that contains 90

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mg of Ledipasvir and 400 mg of Sofosbuvir in a single tablet, and sold globally by Gilead Sciences Inc under its brand Harvoni.

It is indicated for the treatment of Chronic Hepatitis C (CHC) genotype one infection in adults. "This single-tablet regimen is the first of its kind to offer significantly higher cure rates in Genotype-1 CHC infection compared to conventional therapies", the company added.

Regulatory/ company