Regular market approval granted for Covishield, Covaxin for use in adult population- Report

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The Drugs Controller General of India (DCGI) on Thursday granted regular market approval to Serum Institute of India's (SII's) Covishield and Bharat Biotech's Covaxin for use in the adult population subject to certain conditions, according to a PTI report.

The market authorisation for Covid-19 vaccines means that they can be authorised for use without reservation and conditions.

The approval was granted under the New Drugs and Clinical Trials Rules, 2019.

Under the conditions, the companies shall submit data of ongoing clinical trials and the Covid-19 vaccines to be supplied for programmatic setting. Adverse event following immunisation will continue to be monitored, the report said.

Recently, the National Pharmaceutical Pricing Authority (NPPA), DCGI, Drug regulators and senior officials of the Union Health Ministry conducted a meeting regarding fixing the prices of Covishield and Covaxin, but no final decision has been taken yet.

It is expected that the price of a Covid-19 vaccine dose will be fixed below ₹275 and additional service charges of ₹150 to make both the jabs affordable for all.

The DCGI approval came after the Subject Expert Committee (SEC) on Covid-19 of the Central Drugs Standard Control Organisation (CDSCO) on 19 January recommended granting regular market approval to Covishield and Covaxin for use in adult population subject to certain conditions.

Prakash Kumar Singh, Director, Government and Regulatory Affairs at SII, had submitted an application to the DCGI on 25 October last year seeking regular market authorisation for Covishield.

The DCGI had sought more data and documents from the Pune-based firm following which Singh recently had submitted a response along with more data and information.

"Such a large-scale vaccination with Covishield and containment of Covid-19 infection is in itself a testimony of the safety and efficacy of the vaccine," he had said.

In an application sent to the DCGI, V Krishna Mohan, whole-time director at the Hyderabad-based Bharat Biotech, submitted complete information regarding chemistry, manufacturing and controls, along with the pre-clinical and clinical data while seeking regular market authorisation for Covaxin.

Bharat Biotech International Limited (BBIL) took up the challenge to develop, produce and clinically evaluate a vaccine (Covaxin), from the SARS-CoV-2 strains isolated from Covid-19 patients in India, Mohan had said in the application.

Covaxin and Covishield were granted Emergency Use Authorisation (EUA) on 3 January.

With agency inputs