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SII APPLIES FOR FULL MARKET AUTHORISATION

Relevant for: Science & Technology | Topic: Biotechnology, Genetics & Health related developments

Serum Institute of India (SII) CEO Adar Poonawala on Friday said the vaccine major had applied to Indian authorities for full market authorisation of Covishield, stating supplies of the COVID-19 vaccine had exceeded 125 crore doses.

The SII had partnered with AstraZeneca for the supply of the vaccine to the Indian government, which in January this year granted emergency use authorisation in the country.

“Supplies of the COVISHIELD vaccine in India, have exceeded 1.25 billion doses. The Government of India now has enough data for full market authorisation, and therefore @SerumInstIndia has applied to the @CDSCO_INDIA_INF (DCGI) and @MoHFW_INDIA for this permission,” Mr. Poonawala said in a tweet tagging the Central Drugs Standard Control Organisation and the Union Health and Family Welfare Ministry.

Covishield and Covaxin were the first two vaccines approved by the Drugs Controller General of India (DCGI) in January this year, under emergency use authorisation against the pandemic.

Regulatory process

In case of full market authorisation, the vaccines need to undergo the standard regulatory process for reviewing the quality, safety and effectiveness of medical products. Earlier this week, Covovax, Corbevax, and Molnupiravir were granted emergency use authorisation in India.

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