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DCGI gives nod to market authorisation of Covaxin and Covishield vaccines

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Market Authorisation conditional to submission of ongoing clinical trial data and safety data of the vaccines

The Director Controller General of India (DCGI) has given nod to market authorisation of two COVID19 vaccines- Covaxin and Covishield, subject to certain conditions.

The Subject Expert Committee (SEC) of the Central Drugs Standard Control Organization (CDSCO) had recommended for upgradation of status for the vaccines from restricted use in emergency situations to grant of new drug permission with conditions in the adult population on 19th January 2022.

The market authorisation of two COVID-19 vaccines, Covaxin and Covishield, in the country by DCGI is subject to the conditions that firms shall submit data of overseas ongoing clinical trials of the product with due analysis on six monthly basis or as and when available, whichever is earlier.

The vaccine shall be supplied for programmatic setting and all vaccinations done within the country to be recorded on CoWIN platform and Adverse Event Following Immunization (AEFI), Adverse Event of Special Interest (AESI) shall continue to be monitored. The firms shall submit the safety data including AEFI and AESI with due analysis on six monthly basis or as and when available, whichever is earlier as per NDCT Rules, 2019.

“Conditional Market Authorisation” is a new category of market authorisation that has emerged during the current global pandemic of COVID-19. The approval pathways through this route are fast-tracked with certain conditions to enhance the access to certain pharmaceuticals for meeting the emerging needs of drugs or vaccines.