

Suspension of supply of COVID-19 vaccine (COVAXIN®)

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Today, WHO confirmed the suspension of supply of Covaxin (Bharat Biotech) through UN procurement agencies, and recommended that countries using the vaccine take action as appropriate.

The suspension is in response to the outcome of a WHO inspection on 14–22 March 2022, and the need to conduct process and facility upgrade to address recently identified deficiencies in good manufacturing practices (GMP).

Bharat Biotech has committed to addressing the GMP deficiencies and is developing a corrective and preventive action plan for submission to the Drugs Controller General of India (DCGI) and WHO. In the interim and as a precautionary measure, the company has indicated that it will suspend production of Covaxin for export. As a consequence, supply will be interrupted for the foreseeable future.

The risk assessment to date does not indicate change in the risk–benefit ratio. The data, available to WHO, indicate the vaccine is effective and no safety concerns exist.

For continuation of vaccination with alternative sources of COVID-19 vaccines, countries should refer to the respective SAGE recommendation: <u>Considerations for the Assessment of COVID-19</u>
<u>Vaccines for Listing by WHO</u>

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