

SRP - COVAXIN

F. No. X-11026/11/2023-BD  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Biological Division)

FDA Bhawan, Kotla Road,  
New Delhi- 110002.

Dated:

03 FEB 2023

To

M/s Bharat Biotech International Limited,  
Genome valley, Shameerpet Mandal,  
Hyderabad Telangana (India) - 500078

**Subject:** Recommendations of the Signal Review Panel (SRP) related to Whole Virion, Inactivated Coronavirus (SARS-CoV-2) Vaccine) [COVAXIN]- regarding.

**References:** Recommendations of the Signal Review Panel (SRP) related to COVID 19 Vaccines received to this office from Immunization division vide email dated 25.01.2023

Sir,

With reference to the subject cited above, this is to inform that the Signal Review Panel (SRP) for vaccines under Immunization Division of MoHFW has been set up to assess information on potential vaccine safety signals (routine and COVID-19 vaccines) using AEFI surveillance database.

Based on the evaluation of the AEFI related data and published medical literature SRP has made recommendation on inclusion of the following rare adverse events in the SmPC of Whole Virion, Inactivated Coronavirus (SARS-CoV-2) Vaccine) [COVAXIN]:

- "Unknown frequency: Guillain-Barré Syndrome (GBS) following vaccination with COVAXIN "in Section '4.8 Undesirable effects' of SmPC."

This is being communicated to you to update the SmPC & Prescribing Information (PI) as per recommendations of SRP and submit the same to this Directorate.

Yours faithfully,

Recd  
Anil Kumar  
6/2/23  
92713933134

VG  
(Dr. V. G. Somani)  
Drugs Controller General (India)  
Dr. V. G. Somani