

Received
Himanshu
Shukla
9599760063

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 Serum Institute of India Pvt. Ltd.,
212/2, Off. Soli Poonawalla Road,
Hadapsar, Pune, Maharashtra - 411028 (India).

Subject: Recommendations of the Signal Review Panel (SRP) related to ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) [COVISHIELD]- 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 including Summary of Product Characteristics (SmPC) of Vaxzevria (ChAdOX Astrazeneca Vaccine by global regulatory authorities such as UK-MHRA, European Medicines Agency (EMA), Health Canada and TGA, Australia, SRP has made recommendation on inclusion of the following rare adverse events in the SmPC of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) [COVISHIELD]:

- "Very Rare: Cranial (III or VII) nerve palsy following vaccination with COVISHIELD" in Section '4.8 Undesirable effects' of SmPC.
- "Very Rare/ Unknown: Guillain-Barré Syndrome (GBS) following vaccination with COVISHIELD" 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,


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

