F. No. VAC-11014(17)/4/2026-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Vaccine Division)

FDA Bhawan, Kotla Road,
New Delhi-110002

CIRCULAR

24 JUN 2026

Sub: Submission of Post Approval Changes Applications of Registration Certificate and Import Licence of Human Vaccines and Anti-sera through SUGAM Portal – Reg.

In order to streamline the regulatory submission procedure, the submission of applications for **Post Approval Changes in Registration Certificate and Import Licence of Human Vaccines and Anti-sera** shall be made functional in the online system of SUGAM Portal (www.cdscoonline.gov.in).

Thereby, all applicants seeking approval of such Post Approval Changes shall now apply through the SUGAM online portal in the **other section checklist module of Post approval changes** which are already applicable for post approval changes as per CDSCO Guidance for Industry- Post Approval Changes in Biological Products: Quality, Safety and Efficacy Documents"- Document No. PAC/2024 Version –1.2.

Submission of applications in hard copy through CRU or by e-mail will not be accepted for processing from 01st July 2026.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To,

1. All stakeholders through CDSCO Website
2. State/UT Licensing Authorities (For information and necessary action)
3. CDAC Team