CDSCO

Vaccine and anti-sera post-approval changes move to SUGAM

A CDSCO circular of June 24, 2026 moves post-approval change applications for human vaccine and anti-sera registration certificates and import licences to SUGAM.

THE CENTRAL DRUGS Standard Control Organization (CDSCO), Vaccine Division, under the Directorate General of Health Services, issued a circular under F. No. VAC-11014(17)/4/2026-eoffice, stamped June 24, 2026. It is signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India). Its subject is the submission of Post Approval Changes applications of Registration Certificate and Import Licence of Human Vaccines and Anti-sera through the SUGAM Portal. It is addressed to all stakeholders through the CDSCO website, to State/UT Licensing Authorities for information and necessary action, and to the CDAC Team. CDSCO lists the same file under both its circulars and its public notices.

KEY FACTS

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To streamline the regulatory submission procedure, the circular says the submission of applications for Post Approval Changes in the Registration Certificate and Import Licence of Human Vaccines and Anti-sera "shall be made functional" in the online system of the SUGAM Portal (www.cdscoonline.gov.in). All applicants seeking approval of such changes shall now apply through SUGAM, in the "other section checklist module of Post approval changes". The circular describes that module as already applicable "for post approval changes as per" CDSCO's "Guidance for Industry- Post Approval Changes in Biological Products: Quality, Safety and Efficacy Documents", Document No. PAC/2024 Version 1.2.

From July 1, 2026, applications submitted in hard copy through CRU or by email will not be accepted for processing. The circular gives no separate date for when the SUGAM module opens; it says applicants "shall now apply" through it.

The circular does not say what happens to post approval change applications filed in hard copy or by email before July 1, 2026, and it gives no transition period for them. It does not say who the applicants are; it refers to "all applicants seeking approval of such Post Approval Changes". It does not list which changes it covers, pointing instead to the PAC/2024 guidance, and it sets no fee.

Issued by	Central Drugs Standard Control Organization, Vaccine Division (Directorate General of Health Services)
Document	Circular, F. No. VAC-11014(17)/4/2026-eoffice
Dated	June 24, 2026
Signed by	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India)
Applies to	Applications for Post Approval Changes in the Registration Certificate and Import Licence of Human Vaccines and Anti-sera

Where to file	SUGAM Portal (www.cdscoonline.gov.in), in the other section checklist module of Post approval changes
Guidance referred to	CDSCO Guidance for Industry- Post Approval Changes in Biological Products: Quality, Safety and Efficacy Documents, Document No. PAC/2024 Version 1.2
Takes effect	July 1, 2026, for the end of hard copy and email applications
No longer accepted for processing	Applications in hard copy through CRU or by email
Pending applications	Not addressed
Addressed to	All stakeholders through CDSCO Website; State/UT Licensing Authorities (for information and necessary action); CDAC Team
Listed by CDSCO	Under Circulars and under Public Notices, both dated June 24, 2026; the two files are identical

The circular (PDF, 477 KB)

Source: CDSCO's own copy.

Checked against the official copy on October 28, 2026.

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