File No. 7-5/2015/misc./034(e-Governance)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological- Vaccine Division)

FDA Bhawan, Kotla Road
New Delhi 110 002
Dated: 26 OCT 2023

CIRCULAR

Subject: Online Applications for Post Approval Changes (PAC) w.r.t Clinical Trial Permission in Form CT-06 and Post Marketing Surveillance (PMS) Study for Human Vaccines and Anti-sera – Reg.

In order to streamline the regulatory submission procedure, the submission of applications for Post Approval Changes (PAC) w.r.t Clinical Trial Permission in Form CT-06 and Approval for Protocol / Report of Post Marketing Surveillance (PMS) Study for Human Vaccines & Anti-sera is functional now through Online System of SUGAM Portal **(www.cdscoonline.gov.in)** under "Post Approval Changes".

All applicants seeking above mentioned PAC shall apply though online portal as per the checklist in the module.

The facility of offline submission of applications in hard copy will not be available for processing from 01.11.2023.

(Dr.Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

To,

1. All Stakeholders through CDSCO website.
2. All Zonal / Sub-Zonal Offices of CDSCO.
3. CRU Section of CDSCO (HQ)
4. CDAC Team.