

X-11026/03/17-BD

**Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General India
(Biological Division)**

**FDA Bhawan, Kotla Road,
New Delhi – 110002, India**

Dated: 06 FEB 2017

NOTICE

You are aware that Central Drugs Standard Control Organization (CDSCO) in pursuance of the implementation of e-Governance has launched various online services through the portal "SUGAM". The development of software for filling following online applications for Human Vaccines has been completed and its robustness was tested by the industry users in several iterations.

1. Clinical Trial applications for Human Vaccines
2. Marketing Authorization application for Human Vaccines
3. Registration Certificate for Human Vaccines
4. Import license for Human Vaccines

The module has already been made live since 30.01.2017 and applications can be filed online henceforth. Applicants desiring to file applications for obtaining above mentioned permissions are requested to register on the portal as per the prescribed procedure.

Further it is decided that the applications for obtaining above mentioned permission to be mandatorily filed online through SUGAM w.e.f. 04.02.2017. However, the applicants shall continue to submit hardcopies even after 04.02.2017, till such time it is indicated otherwise.


(Dr. G.N. Singh)

Drugs Controller General (I)

To:

All Human vaccine manufacturers/importers/CRO's

Cc:

1. PPS to DGHS, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi
2. PPS to AS, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi
3. PPS to JS (R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi
4. Guard File