F. No. D.21013/230/2016-DC
CENTRAL DRUGS STANDARD CONTROL ORGANISATION
DIRECTORATE GENERAL OF HEALTH SERVICES

FDA Bhawan, Kotla Road,
New Delhi
2nd December, 2016

NOTICE

Under the ongoing e-Governance project of CDSCO, most of its mandated functions are currently being performed online. Since the system has been in place for some time now, it has been felt desirable to elicit response from various stakeholders about the extent of relief/facilities this system has actually generated. Further, to bring out improvement in functioning of various regulatory activities at CDSCO, it has been decided to elicit response from stakeholders. The response may thus be furnished on following points:-

(i) Processing and approval of applications through online system i.e. Sugam;

(ii) Risk based inspections started in the country;

(iii) NRA assessment through WHO for different functions like
- National Regulatory System.
- Regulatory Inspection
- Process of Registration and marketing approval.
- Lot release by CDL, Kasauli etc.

(iv) Skill development exercise started by CDSCO by imparting training to CDSCO regulators, State regulators and laboratory officials;

(v) DCG(I) Cell for addressing Grievance/Complaints;

(vi) Amendment in :
- D&C Act & Rules.
- Medical Device Rules
- Cosmetics
- Clinical Trial

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2. The response in question may please be furnished within 03 weeks of this Notice having been posted on CDSCO's website at www.cdsco.nic.in .

(S.K. Tanwar)
DDA (D)

To

(i) All State/ UT Drug Controllers.
(ii) All Pharma Associations
(iii) Others Stakeholders

Copy to:-

(i) PPS to JS (KLS).
(ii) Staff of DCG (I).
(iii) Director (Admn.)
(iv) Guard file.