No. DCG (I)/Misc./2016 (113)

Central Drugs Standards Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare

FDA Bhavan, Kotla Road,
New Delhi-110002.
6th October, 2016

NOTICE

Central Drugs Standard Control Organisation is continuously engaged in streamlining various activities under the Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder:

2. The organization has already taken various important measures in recent months for streamlining the following activities:

(i) Import clearance through ICEGATE

(ii) Online submission and processing of following categories of applications through SUGAM portal:
- Import registration and licensing of drugs
- Import registration and licensing of medical devices
- Registration of Cosmetics
- Permit for import of drugs for personal use by patients
- Test Licence for import of small quantities of drugs for test and analysis
- Registration of Ethics Committee
- BA/ BE NOC for Export purpose
- Online Facility for payment of fee for various applications
- Online General Administration Module – Budget Information System

(iii) Risk Based Inspection of drug manufacturing facilities in the country based on check-list and evaluation tools developed for the purpose.

(iv) Imparting training to the regulatory officials of States and Centre through various training modules to improve the quality of services provided by the regulators.

3. Keeping in view the Government of India's policy to bring ease in doing business for making the "Make in India' concept a reality, CDSCO is in the process of revisiting the following regulatory provisions under the Drugs & Cosmetics Rules, 1945 to further improve the quality of services provided by the drug regulatory authorities of the States and Centre:

I. Validity of various licences/approvals granted under the Drugs & Cosmetics Rules, 1945 for manufacture for sale, sale and distribution of drugs and manufacture of cosmetics and approval of laboratories for test analysis of drugs is proposed to be perpetual unless otherwise suspended or cancelled by the Licensing Authority. However, there should be assessment of compliance with the conditions of licences/approvals at least once in 10 years.

II. Gap analysis and updation of GMP as prescribed in Schedule M to Drugs & Cosmetics Rules, 1945 to make it at par with WHO GMP guidelines.

All concerned are requested to provide their comments/suggestions/inputs on the above issues to CDSCO through email: dci@nic.in within two weeks i.e. latest by 21st October, 2016 so that a considered view can be taken in the matter.

(Dr. G. N. Singh)
Drugs Controller General (India)

1. All State/UT Drug Controllers
2. Pharma industry Associations

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PPS to AS (F&D), MoHFW/PPS to DGHS/PPS to JS (R), MoHFW