

POLICY INITIATIVES PLANNED FOR 2015

A.

POLICY REFORMS

i. Amendments in the Act and Rules

1. Introduction of the Drugs and Cosmetics (Amendment) Bill to amend the Drugs and Cosmetics Act, 1940 for upgradation and introduction of provisions for clinical trials and regulation of medical devices.
2. Amendments in the Drugs and Cosmetics Rules, 1945 in the light of new provisions to be incorporated under the Drugs and Cosmetics Act, 1940 and strengthening of rules relating to quality control of drugs, cosmetics and medical devices.
3. Introduction of provisions relating to Phytopharmaceutical drugs under the system of modern medicine.
4. Simplification and rationalization of various formats of applications and licences under the Drugs and Cosmetics Rules, 1945.
5. Revision of Good Manufacturing Practices for drugs as well as medical devices under the Drugs and Cosmetics Rules, 1945 to update the requirements to make them at par with the International requirements.

ii. Drugs and Magic Remedies (Objectionable advertisement) Act, 1954

Review of the Drugs and Magic Remedies (Objectionable advertisement) Act, 1954 and propose amendments in the Act, wherever required.

iii. Harmonization of recruitment rules

Harmonization of various recruitment rules for post in CDSCO and Central Drug Testing Laboratories.

iv. E-governance

1. An IT-enabled system for online submission of Clinical Trial applications is being put in place in CDSCO through NIC.

2. A plan for Digitalization of various activities of CDSCO as per recommendations of Cabinet Secretariat has been initiated.
- v. Publication of revised National List of Essential Medicines as NLEM, 2015.
- vi. Finalization of Accreditation Standards for Clinical Trials for Ethics Committee, Investigator and Clinical Trials.
- vii. Evolving of Public Private Partnership model for engaging laboratories in private sector.
- viii. Setting up of training institutes in the existing premises of National Institute of Biologicals, Noida.