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# Govt seeks to raise drug manufacturing norms to global level

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**Mumbai:** The government is introducing the Drugs and Cosmetics (Amendment) Bill to amend the existing Act to consolidate provisions for clinical trials and regulate medical devices.

A recent notification by the Central Drugs Standard Control Organisation regarding the policy initiatives planned for 2015 includes the introduction of the Bill.

The initiatives include revision of good manufacturing practices (GMPs) 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.

## Booster dose

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The policy reforms talks about amendments in the Drugs and Cosmetics Rules, 1945 and strengthening of rules relating to quality control of drugs, cosmetics and medical devices, as well as introduction of provisions relating to phytopharmaceutical drugs (where active ingredients are made in plants) under the system of modern medicine.

It will also include simplification and rationalisation of various formats of applications and licences under the Drugs and Cosmetics Rules, 1945.

The initiatives will also take into account a review of the Drugs and Magic Remedies (Objectionable advertisement) Act, 1954 and propose amendments in the Act, wherever required. There will also be harmonisation of various recruitment rules for post in CDSCO and Central Drug Testing Laboratories.

"An IT-enabled system for online submission of clinical trial applications is being put in place in CDSCO through NIC. A plan for digitalisation of various activities of CDSCO as per recommendations of Cabinet Secretariat has been initiated," the notification said, adding that training institutes in the existing premises of National Institute of Biologicals, Noida will be set up. It also plans to evolve public private partnership model for engaging laboratories in private sector.

Bhavik Narsana, partner, Khaitan & Co, a legal consultant, said, "It would be a welcome move to amend the Drugs and Cosmetics Act and Rules and consolidate provisions related to clinical trials and medical devices. The legislative process will invite further public discussion and debate, and also prompt meaningful legislative changes. Changes to GMP standards could possibly be in response to the criticism of Indian manufacturing units' compliance standards. One would expect a greater level of harmonization between Indian and global standards."

The apex committee, in another notification by CDSCO, noted that its technical committee had deliberated upon 31 cases related to approval of clinical trials. Of, 15 cases related to global clinical trials (GCT) and clinical trials of NCEs.