

# The Central Drugs Standard Control Organisation (CDSCO)

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*Source: PIB & Ministry of Health & Family Welfare*

In order to bring all the **non-notified Medical Devices under the regulation**, Ministry of Health & Family Welfare, Govt. of India has prepared a road map and published draft rules in October 2019

## About CDSCO

- The Central Drugs Standard Control Organization (CDSCO) is the **Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act.**
- CDSCO under the Ministry of Health and Family Welfare regulates the safety, efficacy and quality of notified medical devices under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder.

## Functions of CDSCO

- Regulatory control over the import of drugs, approval of new drugs and clinical trials, meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB), approval of certain licenses as Central License Approving Authority is exercised by the CDSCO headquarters.
- **Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of New Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control**

**Organizations by providing expert advice with a view of bring about uniformity in the enforcement of the Drugs and Cosmetics Act.**

- Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.