The **Central Drugs Standard Control Organisation** (**CDSCO**) is India's national regulatory body for cosmetics, pharmaceuticals and medical devices. It serves a similar function to the Food and Drug Administration (FDA) of the United States or the European Medicines Agency of the European Union. The Indian government has announced its plan to bring all medical devices, including implants and contraceptives under a review of the Central Drugs and Standard Control Organisation (CDSCO).

Within the CDSCO, the Drug Controller General of India (DCGI) regulates pharmaceutical and medical devices and is positioning within the Ministry of Health and Family Welfare. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC). Divided into zonal offices, each one carries out pre-licensing and post-licensing inspections, post-market surveillance, and drug recalls (where necessary). Manufacturers who deal with the authority required to name an Authorized Indian Representative (AIR) to represent them in all dealings with the CDSCO in India.

Divisions

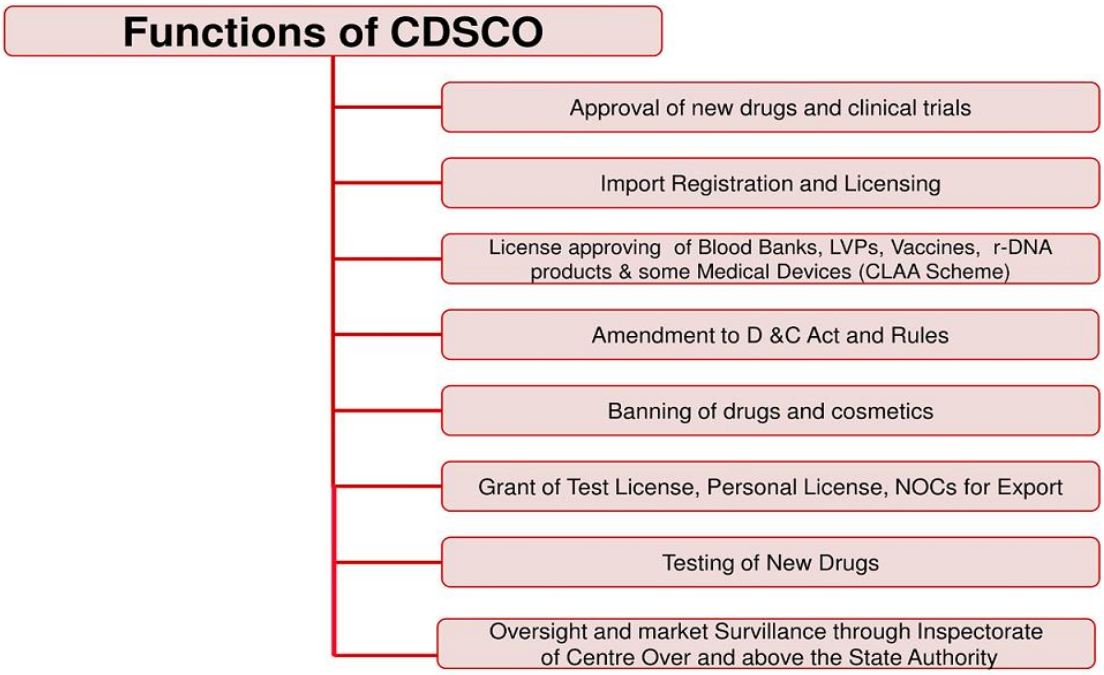
Central Drugs Standard Control Organization has 8 divisions:

- BA/BE
- New Drugs
- Medical Device & Diagnostics
- DCC-DTAB
- Import & Registration
- Biological
- Cosmetics
- Clinical Trials

Function of CDSCO

The figure summarizes the major functions of the Central Drugs Standard Control Organization (CDSCO). CDSCO is responsible for approving new drugs and granting permission for clinical trials to ensure that medicines entering the Indian market are safe and effective. It manages the import registration and licensing of drugs and medical devices coming from other countries. The organization also approves licenses for blood banks, large volume parenterals, vaccines, r-DNA products, and selected medical devices under the CLAA scheme. CDSCO plays a key role in amending the Drugs and Cosmetics Act and

associated rules to keep regulations updated. It has the authority to ban drugs and cosmetics that are unsafe or harmful for public use. The organization also issues test licenses, personal licenses, and No-Objection Certificates (NOCs) for the export of pharmaceutical products. Additionally, CDSCO is involved in the testing of new drugs before they are marketed. Finally, it conducts national-level oversight and market surveillance through central inspectorates, working beyond state authorities to ensure the quality, safety, and compliance of drugs and medical devices across the country.



1. Approval of new drugs and clinical trials

CDSCO evaluates and approves new drugs before they can be sold in India. It also reviews and authorizes clinical trial applications to ensure that studies are conducted ethically, safely, and based on proper scientific standards.

2. Import Registration and Licensing

Any drug or medical device manufactured outside India must be registered and licensed through CDSCO before being imported. This ensures that only quality and legally compliant products enter the Indian market.

3. License approving of Blood Banks, LVPs, Vaccines, r-DNA products & some Medical Devices (CLAA Scheme)

CDSCO grants licenses for critical facilities and products such as:

- Blood banks
- Large Volume Parenterals (IV fluids)
- Vaccines
- Recombinant DNA products
- Certain medical devices

These facilities are regulated under the **CLAA (Central Licensing Approval Authority) Scheme** to ensure national-level quality control.

4. Amendment to D&C Act and Rules

CDSCO also updates and amends the **Drugs and Cosmetics Act, 1940** and its rules when needed. This keeps Indian drug regulation aligned with current technology, safety standards, and global practices.

5. Banning of drugs and cosmetics

If a drug or cosmetic is found to be unsafe, harmful, misbranded, or of poor quality, CDSCO has the authority to ban its manufacturing, sale, distribution, or import to protect public health.

6.Grant of Test License, Personal License, NOCs for Export

CDSCO issues:

- **Test licenses** for research or product evaluation
- **Personal licenses** for importing small quantities of medicines
- **No Objection Certificates (NOCs)** for exporting drugs abroad

This supports research and international trade while maintaining regulatory control.

7. Testing of New Drugs

CDSCO conducts or oversees laboratory testing and analysis of new drugs to verify their:

- Quality
- Safety
- Efficacy

This helps prevent substandard products from reaching patients.

8. Oversight and market surveillance through Inspectorate of Centre over and above State Authority

In addition to state drug inspectors, CDSCO has central-level inspectors who:

- Monitor product quality in the market
- Inspect manufacturing facilities
- Enforce regulatory compliance

This ensures uniform national drug safety standards across India.

DRUGS AND MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENTS) ACT, 1954

The **Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954**, is an Act of the Parliament of India that controls the advertising of drugs in India. It prohibits advertisements of drugs and remedies that claim to have magical properties and makes doing so a cognizable offence.

Overview

The act defines "magic remedy" as any talisman, mantra, amulet, or other object claimed to have miraculous powers to cure, diagnose, prevent, or mitigate a disease in humans or animals. It also includes such devices claimed to have power to influence structure or function of an organ in humans or animals.

The law prohibits the advertising of drugs and remedies for

- inducing miscarriage or preventing conception in women
- improving or maintaining the capacity for sexual pleasure
- correcting menstrual disorders
- curing, diagnosing, or preventing any disease or condition mentioned in an included schedule

The act stated that the schedule may be changed later to include more diseases for which there are no accepted remedies or for which timely consultation with a registered medical practitioner (as defined under the Indian Medical Degrees Act, 1916 or Indian Medical Councils Act, 1956; includes other state laws too) is required. The act stated that the Central government must make these changes in

consultation with the Drugs Technical Advisory Board and Ayurveda and Unani practitioners, if necessary.[1]

The penalty carries a maximum sentence of 6 months imprisonment with or without fine on the first conviction. The term may be up to a year in case of any subsequent conviction. All company members will be deemed guilty if the convicted party is a company.

Criticism and future amendments

The law is rarely enforced, and several such products are freely available to the public. It is considered severely outdated as 14 of the diseases on the list are now curable, and newer diseases like AIDS are not on the list. Some advertisements of these categories also appear on cable television channels with little repercussions. Proposed amendments to this law have also raised questions regarding the status of traditional medicine systems like Yoga and Ayurveda concerning modern medicine.