Central Drugs Standard Control Organisation

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Why is in news? CDSCO starts conducting joint inspections of identified Drug Manufacturing Units along with State Drugs Control Administration as per risk-based approach

The Central Drugs Standard Control Organisation (CDSCO) has started conducting joint inspections of identified Drug Manufacturing Units along with State Drugs Control Administration as per a **risk-based approach**.

This was started under the direction of Union Ministry of Health and Family Welfare. The Joint Inspections are being conducted all over the country as per the Standard Operating Procedures.

A Committee of two Joint Drugs Controllers has been constituted at CDSCO Head Quarters to monitor the process of inspection, reporting, and subsequent action so as to ensure compliance with the **Drugs and Cosmetics Act, 1940**, and the Rules thereunder.

The Union Health Ministry in a statement said, this will **ensure high standards of quality compliance with respect to drugs manufactured** in the country.

It said, an action plan for nationwide inspection of manufacturing units that are identified to be at risk of manufacturing not of standard quality drugs was made prior to carrying out inspections.

The objective of drug regulation is to **ensure the safety, efficacy, and quality of the drugs available in the country**.

Central Drugs Standard Control Organisation:

The Central Drugs Standard Control Organisation (CDSCO) is **India's national regulatory body for cosmetics , pharmaceuticals and medical devices** under the Drugs and Cosmetics Act.

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.

Under the **Drug and Cosmetics Act**, the regulation of manufacture, sale and distribution of Drugs is primarily the concern of the State authorities while the Central Authorities are responsible for approval of New Drugs, Clinical

Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs, coordination of the activities of State Drug Control Organisations and providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

Drug Controller General of India is responsible **for approval of licenses of specified categories of Drugs** such as blood and blood products, I. V. Fluids, Vaccine and Sera. Central Drugs Standard Control Organization **Head quarter is located at New Delhi** and functions under the Directorate General of Health Services.