DCGI full form is **Drugs Controller General of India (DCGI**). DGCI heads the Central Drugs Standard Control Organization (CDSCO) department. The department comes under the Government of India. The DCGI is responsible for approving licenses for specified drug categories in India. The DCGI also lays down the requisite standards and quality for drugs. It regards the selling, importing, manufacturing, and distributing drugs in India. The DCGI aims to bring uniformity in enforcing the Drugs and Cosmetics Act.

Drug Controller General of India (DCGI)

The Drugs Controller General of India (DCGI) leads the Central Drugs Standard Control Organization (CDSCO). This organisation comes under the Ministry of Health and Family Welfare (MoHFW). They derive their powers from the Drugs and Cosmetics Act of 1940.

It is a critical post in terms of the health sector in India. It is essential in making regulatory approval for drugs and vaccines in India. The DCGI played a crucial role in approving the COVID vaccines recently.

Title	Description
Current DCGI (2023)	Dr Rajeev Singh Raghuvanshi
Ministry Concerned	Ministry of Health and Family Welfare
Act	Drugs and Cosmetics Act, 1940

Responsibilities of the DCGI

The DCGI is responsible for multiple works in the health sector. The DCGI also lays down the requisite standards and quality for drugs. It regards the selling, importing, manufacturing, and distributing drugs in India. It also regulates medical and pharmaceutical standards. The DCGI is also the appellate authority to decide upon the quality of the drug.

- It prepares and maintains the requisite reference standard for drugs.
- The DCGI ensures uniformity in implementing the Drugs and Cosmetics Act of 1940.
- The DCGI conducts the training in this field. It trains the Drug Analysts of the State Drug Control Laboratories and the related Institutions.
- The DCGI also analyses cosmetics as survey samples. It is received from the Central Drugs Standard Control Organization.

- The DCGI is also the central licensing authority under the Medical Device Rules 2017. It handles the licensing of the medical devices that fall under this Act's ambit.
- It also approves the drugs under the Drugs and Cosmetics Act.
- The DCGI handles the conduction of clinical trials. The DCGI also sets standards for drugs.
- The DCGI also ensures quality control over drugs imported into the country.
- It coordinates the activities of various state drug control organizations.
- It is responsible for registering foreign manufacturers. These makers trade drugs and medical devices whose products are imported into India.
- It is responsible for granting licenses to import drugs. It is used by Government hospitals or Medical Institutions for their patients' use.
- It recommends banning harmful or sub-therapeutic drugs. It does so under section 26A of the Drugs and Cosmetics Act.

Governance of DCGI

The governance of the DCGI involves the appointment of a qualified individual to lead the organization and oversee its functions. Here are some key points about the governance of DCGI:

- The government appoints a person to the position of Drug Controller General of India. The appointment is made based on the individual's qualifications and expertise in the field of drug regulation.
- As of 1st February 2023, Dr. Rajeev Singh Raghuvanshi is serving as the Drug Controller General of India. Prior to him, Dr. VG Somani held the position.
- The DCGI heads the Central Drugs Standard Control Organization (CDSCO), which is the Indian drug regulatory body. Their responsibilities include ensuring the quality of drugs and cosmetics sold in the country, approving new drugs, and regulating clinical trials.

When DCGI Approval is Needed

- Importing medical devices into India
- Launching new high-risk medical devices

- Conducting clinical investigations
- Changing design of an approved device (for major changes)

Importing Medical Devices into India

Any medical device that is manufactured outside India must get approval from CDSCO/DCGI before it can be imported and sold in the country. This ensures that only safe, tested, and clinically proven devices enter the Indian market.

Key requirements:

- Import license (Form MD-15)
- Regulatory documents such as:
    - Free Sale Certificate from the country of origin
    - ISO 13485 certificate
    - Technical manuals and testing reports
- Details of packaging, labelling, and shelf life

Without this approval, importing and selling the device is not legally allowed.

Launching New High-Risk Medical Devices

High-risk medical devices (Class C and D) such as stents, heart valves, ventilators, infusion pumps, etc., need strict regulatory control.

Before they can be marketed in India, the manufacturer must:

- Submit scientific and technical data
- Share safety and clinical performance evidence
- Receive approval from DCGI

This process ensures that devices posing higher risk to patients have proven:

- Safety
- Effectiveness
- Quality

Only after DCGI approval can these devices be launched commercially in India.

Conducting Clinical Investigations

If a new medical device does not have sufficient previous clinical data or is being introduced in India for the first time, clinical investigations (trials) may be required.

These studies are conducted on patients to verify:

- Safety
- Performance
- Clinical benefit

Before starting the trial, manufacturers must:

- Apply to DCGI
- Submit clinical investigation protocols
- Get ethics committee approval

After successful clinical investigation, the results are submitted to DCGI for final approval of the device.

Changing Design of an Approved Device (Major Changes)

Even after a medical device is approved, any major change in design, materials, manufacturing process, or intended use must be re-approved by DCGI.

Examples of major changes:

- Changing the device material
- New electronic components
- Modified software for critical functions
- Change in intended use (e.g., from adult use to pediatric use)

Reason:
Major changes can affect device function, safety, or clinical performance, so DCGI must verify the updated design before the device can be sold again.