CDSCO

Central Drugs Standard Control Organization

All about CDSCO License

About CDSCO

The Central Drugs Standard Control Organization (CDSCO) is India's national regulatory authority for drugs, cosmetics, and medical devices. It operates under the Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India. CDSCO is responsible for ensuring the safety, efficacy, and quality of pharmaceutical products, cosmetics, and medical devices available in India.

Products Covered Under CDSCO

A wide range of different products covered under CDSCO license:

Drugs and Pharmaceuticals:

- Allopathic drugs (e.g., antibiotics, painkillers)
- Vaccines and biological products
- Blood products
- Gene therapy products

Medical Devices:

- Diagnostic equipment
- Surgical instruments
- Implants and prosthetics

Cosmetics:

- Skin care products
- Hair care products
- Makeup products

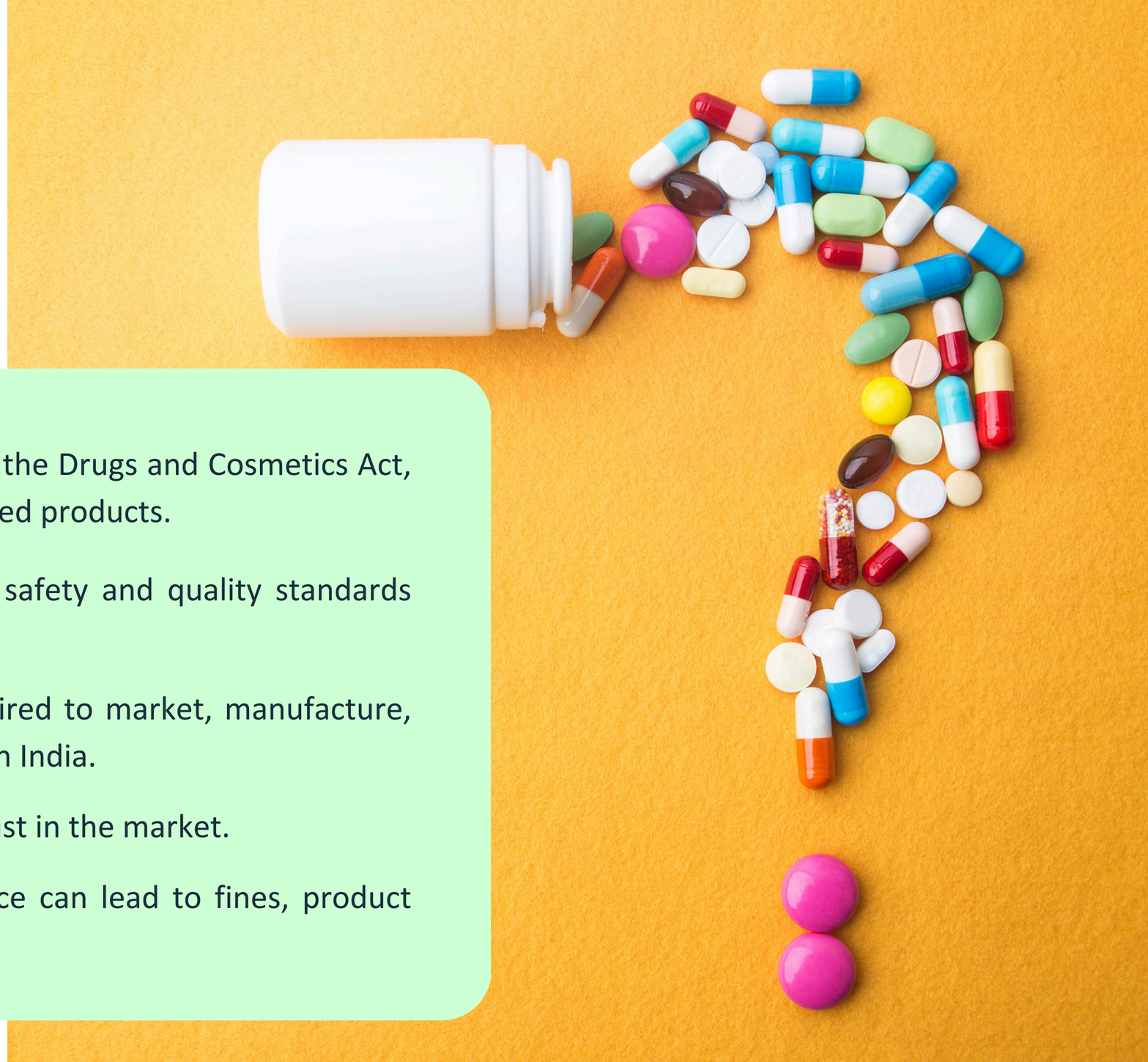
Imported Products:

- Drugs, Cosmetics and medical devices brought into India must be registered and approved by CDSCO.

New Drugs and Investigational Products:

- New drug approvals
- Clinical trial regulation
- Investigational new drugs (INDs)

Why is a Cosmetics License Important?



- **Legal Compliance:** It is mandatory under the Drugs and Cosmetics Act, 1940, to have a CDSCO license for regulated products.
- **Product Safety:** Ensures products meet safety and quality standards for public use.
- **Market Access:** A CDSCO license is required to market, manufacture, import, or distribute regulated products in India.
- **Consumer Trust:** Builds credibility and trust in the market.
- **Prevents Legal Penalties:** Non-compliance can lead to fines, product recalls, or criminal prosecution.

Documents Required for CDSCO License

The documentation varies depending on the product category but generally includes:

For Drugs

- Application form (e.g., Form 44 for new drugs)
- Product specifications and stability studies
- Manufacturing site details and GMP certificate
- Clinical trial data, if applicable

For Medical Devices

- Application form (e.g., Form MD-14)
- Device Master File (DMF) and Technical File
- Test reports and clinical evaluation report
- ISO 13485 certificate for Quality Management Systems

For Cosmetics

- Form COS-1 or COS-2
- List of ingredients with percentages
- Safety data sheets for raw materials
- Manufacturing site details

Procedure for CDSCO License

1

Identify whether you need a license for import, manufacture, or distribution.

2

Create an account on the Sugam online portal.

3

- Fill out the appropriate form (e.g., Form MD-14 for medical devices or Form 44 for drugs).
- Upload the required documents.

4

Pay the applicable government fees online.

5

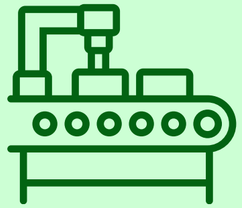
- The application undergoes scrutiny by the regulatory authority.
- Inspections may be conducted for manufacturing facilities.

6

If all conditions are satisfied, the CDSCO issues the license.

When is a Cosmetics License Required?

A cosmetics license is required in the following scenarios:

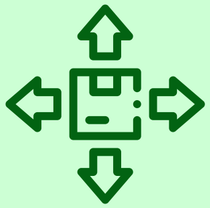


Manufacturing

If you are manufacturing cosmetics locally, you need a license from the respective state authority.

Importing

If you intend to import finished cosmetic products from other countries.



Distribution and Sale

While wholesalers and retailers do not need a cosmetics license, they must ensure the products they sell comply with regulatory requirements.

Validity and Renewal of CDSCO License

- **Validity:** Typically, CDSCO licenses are valid for 5 years, although this can vary depending on the specific product or license type.
- **Renewal:**

1. Apply for renewal before the expiry of the license.
2. Submit updated documents and pay the renewal fees.
3. The process is usually simpler than the initial application, provided there are no compliance issues.

Thank You

Get Connected

Call- +91-9718925753

Email- greenyokoramaelectric2103@gmail.com

Visit- www.gyellp.com

Address-

1st Floor, Unit No 105, Pearl Business Park, Neta Ji Subhash Place, Pitampura, New Delhi - 110034