Shree H. N. Shukla Institute of Pharmaceutical Education and Research, Rajkot

B. Pharm
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Subject Name: Industrial Pharmacy-II
Subject Code: BP702TT

CHAPTER -5 INDIAN REGULATORY REQUIREMENTS

SYLLABUS: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

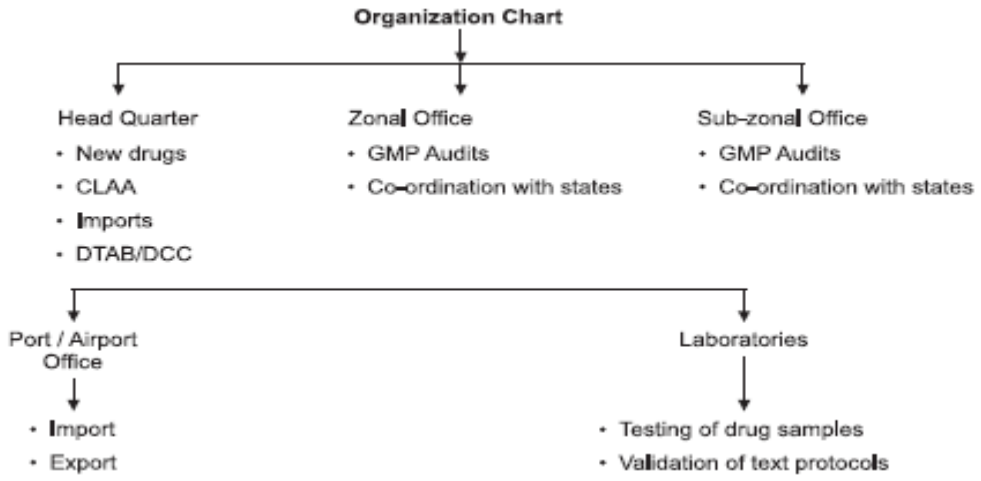
Syllabus Topic: Introduction

The Central Drug Standard Control Organization (CDSCO) regulates drugs, cosmetics, diagnostics and devices in India. It is headed by the Drug Controller General of India (DCGI), responsible for safety, efficiency and quality standards for pharmaceuticals and medical device and publisher of the Indian Pharmacopoeia. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Commission (DCC). State Government is responsible for licensing, approvals, inspection and recalls of drugs manufactured within their domain. India is main regulatory body for regulation of pharmaceuticals and medical devices and the Drug Controller General of India (DCGI) is responsible for the regulation of pharmaceuticals and medical devices. The CDSCO works with the World Health Organization to promote Good Manufacturing Practice (GMP) and international regulatory harmony. The organization responsible for approved issuance of license for various categories of drugs such as blood and blood products, I.V. fluids, vaccines, sera etc., either manufacturing in India or imported. It regulates the manufacturing, sale, distribution of drugs through the state authorize and register manufacturing, sale and distribution of drugs.

Syllabus Topic: Central Drug Standard Control Organization (CDSCO)

The CDSCO is the main regulatory body for regulation of pharmaceuticals, medical devices and clinical trials. The head office of CDSCO is located in New Delhi and it is functioning under the Control of Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.

Drug Controller General of India (DCGI): He/She is responsible for approval of new drugs, medical devices and clinical Trials to be conducted in India. The person who is appointed by the Central Government under the DCGI the state drug control organization will be functioning. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC).



Zonal Office: Mumbai, Kolkata, Chennai, Ghaziabad, Ahmadabad, Hyderabad. These centers are involved in GMP audits and inspection of manufacturing units of large volume, parental, sera, vaccine and blood products.

Sub-zonal Office: Chandigarh, Jammu, Bangalore. These centers are coordinated with state drug control authorities under their jurisdiction for uniform standard of inspection and enforcement.

❖ **Central Drugs Testing Laboratories:**

1. Central Drugs Laboratory, Kolkata.

2. Central Drugs Testing Laboratory, Mumbai.

3. Central Drugs Testing Laboratory, Chennai.

4. Central Drugs Laboratory, Kasauli.

5. Regional Drugs Testing Laboratory, Guwahati.

6. Regional Drugs Testing Laboratory, Chandigarh.

These laboratories are responsible for quality control of Drugs and Cosmetics in India.

❖ **Functions of CDSCO:**

1. Approval of new drugs and clinical trials.

2. Import Registration and Licensing.

3. Licensing of Blood banks, LVPS, Vaccines, Pie-DNA products and some medical devices and diagnostic agents.

4. Amendment to D and C Act and Rules.

5. Banning of drugs and cosmetics.

6. Grant to Test license, Personal License, NOC'S for export.

7. Testing of drugs by Central Labs.

8. Publication of Indian Pharmacopoeia.

9. Monitoring adverse drug reactions.

10. Guidance on technical matter.

Syllabus Topic: State Drugs Control Organization

❖ **Functions of State Licensing Authorities**:

1. Licensing of drug testing laboratories.

2. Approval of drug formulation for manufacture.

3. Monitoring of quality of Drugs and Cosmetics, manufactured by respective state and those marketed in the state.

4. Investigation and prosecution in respect of contravention of legal provision.

5. Administrative actions.

6. Pre and post licensing inspection.

7. Recall of substandard drugs.

Syllabus Topic: Approval of New Drug

1. The drug approval process varies from one country to another.

2. In some countries, only a single body regulates the drugs and it is responsible for all regulatory tasks such as approval of new drugs.

3. New drug will not be imported, except under permission granted by the Licensing Authority, accomplished by fifty thousand rupees.

4. The licensing authority, after being satisfied that the drug if permitted to be imported as raw material (bulk drug substance) or a finished permutation will be effective and safe for use in the country may issue import permission.

5. For new drug discovered in other countries, phase-I trials are not usually allowed to be initiated in India.

- **Approval for Clinical Trials:**

1. Approval for clinical trials and application to conduct clinical trials in India should be submitted along with the date of chemistry, manufacturing, control and animal studies to DCGI.

2. The data regarding the trail protocol investigators brochures and informed consent documents should also be attached.

3. A copy of the application must be submitted to the ethical committee and the clinical trials are conducted only the after approval of DCGI and ethical committee.

- **Approval of Clinical trials, Import and Manufacture of New Drugs:**

Requirements and Guidelines:

Schedule Y

Rule 122A – Permission to import new drug.

Rule 112B – Permission to manufacture new drug.

Rule 122DA – Definition of clinical trials.

Rule 122E – Definition of new Drugs.

1. New substance having therapeutic indication.

2. Modified on new claims, new route of administration for already approved drug.

3. Fixed dose combination.