REGULATORY SYSTEM FOR MANUFACTURING, IMPORT AND NEW DRUG APPROVAL IN INDIA

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THE DRUGS AND COSMETICS ACT & RULES

- The **Drugs and Cosmetics Act, 1940** is an Act of the Parliament of India which regulate import, manufacture, distribution and sale of drugs including vaccines and cosmetics
- This act was originally known as the Drugs Act and was passed in 1940. It came into force from April 1947. In 1964, the act was amended to include Ayurveda and Unani drugs
- The primary objective of the act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to stated quality standards
- The Drugs and Cosmetics Rules, 1945 contains provisions for classification of drugs under given schedules and there are guidelines for the storage, sale, display and prescription of each schedule
- Schedule (organized plan for matters to be attended to) are from A to Y
- Total 168 Rules divided in to 19 Parts from I –XIX as per the different subjects pertaining to drugs

REGULATORY AUTHORITY

Ministry of Health & Family Welfare

Director General of Health Services

DCGI- Drugs Controller General (India)
(CDSCO & IPC)

CDL/CDTL
(ICMR &ICAR)
Govt. Drug Testing Laboratories
&
State Drug Regulatory Authority

MINISTRY OF HEALTH & FAMILY WELFARE

- Central Drugs Standard Control Organization(CDSCO)
- Drugs Technical Advisory Board (DTAB)
- Drugs Consultative Committee (DCC)
- Indian Pharmacopoeia Commission (IPC)
- Central Drugs Laboratories (CDLs)
- (IVRI & CCSNIAH are CDL for veterinary biologicals)

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

- Central Drugs Authority for regulating the quality of drugs including vaccines manufactured & marketed in the country
- Headed by the Drugs Controller General (India), the statutory licensing authority for manufacture, sale and distribution of drugs and also for import of drugs

Activities

- ✓ Approval of new drugs and clinical trials
- ✓ Import Registration and Licensing
- ✓ License for Blood Banks, Vaccines, r-DNA products, Medical Devices etc
- ✓ Amendment to D &C Act and Rules
- ✓ Banning of drugs and cosmetics
- ✓ Testing of new drugs
- ✓ Grant of Test License, Personal License, NOCs for Export

The Drugs Technical Advisory Board (DTAB)

Apex body to advise DCG(I) on technical matters arising out in the implementation & administration of D&C Act and to carry out the other functions assigned to it by the Act

The Board consist of the following members

- ✓The Director General of Health Services, Chairman
- ✓ The Drugs Controller General (India), Member Secretary
- ✓ The Director of the Central Drugs Laboratory, Calcutta
- ✓ The Director of the Central Research Institute, Kasauli
- ✓ The Director of the IVRI, Izatnagar
- ✓ The President of the Medical Council of India
- ✓ The President of the Pharmacy Council of India
- ✓ The Director of the Central Drug Research Institute, Lucknow
- ✓ Two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government
- ✓ Other elected members

The Drugs Consultative Committee (DCC)

- The Central Government may constitute an advisory committee to be called the Drugs Consultative Committee to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout in the administration of this Act

- Consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned

- DCC shall meet as and when required and shall have power to regulate its own procedure

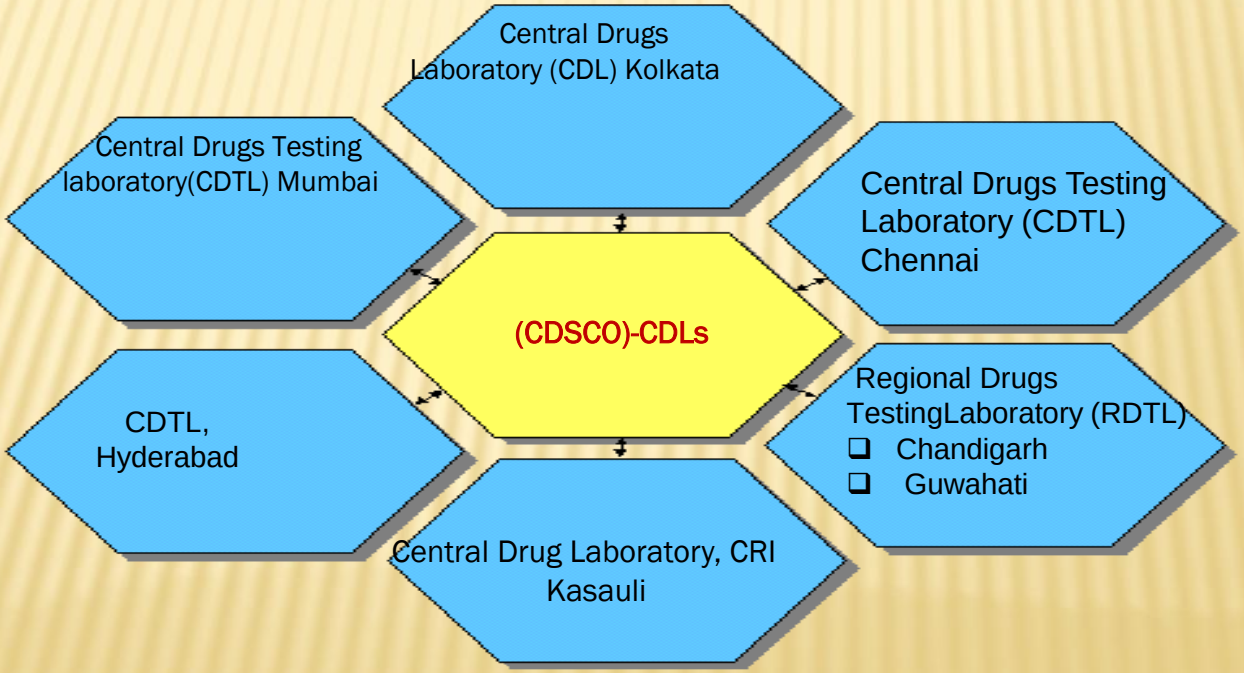
Central Drugs Laboratories (CDL)

- Established under the Indian Drugs & Cosmetics Act, 1940.
- Seven CDLs under control of CDSCO (DGHS) & others under ICAR (IVRI), DAHDF & ICMR institutes

Statutory Functions:

(a) Analytical quality control of majority of the imported and other Drugs

(b) Acting as an Appellate authority in matters of disputes relating to quality after consultation with the DTAB



Indian Pharmacopoeia Commission

- **Indian Pharmacopoeia Commission** is an autonomous institution of the Ministry of Health and Family Welfare which sets standards for all drugs that are manufactured, sold and consumed in India
- Headed by the Secretary cum Scientific Director
- To develop comprehensive monographs having standards for drugs to be included in the IP and to keep them updated by revision on a regular basis
- The IPC is advised & guided by
  - ✓ Governing body
  - ✓ General body
  - ✓ Executive committee
  - ✓ Scientific body
  - ✓ Expert committees
  - ✓ Working group
  - ✓ National consultative committee (NCC)
- The Secretary, MH & FW is the chairman of the Governing and General body.
- The primary responsibility of the scientific body is to provide guidelines for standards development related to the Indian Pharmacopoeia with the assistance of its expert committee

REGULATORY- FUNCTIONS OF STATE GOVERNMENTS

- Statutory Functions
- a) Licensing of drug manufacturing and sales establishment
- b) Licensing of drug testing laboratories.
- c) Approval of drug formulations for manufacture.
- d) Monitoring of quality of Drugs & Cosmetics,manufactured by respective state units and those marketed in the state
- e) Investigation and prosecution in respect of contravention of legal provision
- f) Administrative actions
- g) Pre- and post- licensing inspection.
- h) Recall of sub-standard drugs

DRUG LICENSING

Approval by CDSCO for Veterinary Drugs and vaccines:

- **i) Vaccines and drugs**
- a) Manufacture
- b) Import
- **ii) Schedule drugs**
- a) Manufacture
- b) Import
- **iii) New Drugs**

REGULATORY

- Applications for import, manufacturing and marketing of vaccines and drugs are submitted in the CDSCO.
- Permission for import/manufacture for veterinary drugs and vaccines are granted in consultation with Department of Animal Husbandry & Dairying, Ministry of Fisheries, Animal Husbandry & Dairying

REGULATORY

- Process for granting permission for import:
- a) the import of vaccines and drugs are permitted based on the following:
- i) Essentiality and desirability of the vaccine virus strains /bacterial strains in India.
- ii) safety, quality and existing study on the vaccine to be provided by the firm.
- iii) the vaccines should be approved for marketing in the exporting country.

REGULATORY

iv) if new vaccines or new strain to be imported there is need to conduct clinical trial and to prove that pathogen is circulating in the country.

iv) Clinical trial is conducted in the country's veterinary Colleges and Institutions.

v) After clinical trial import permission are granted for new vaccines.

vi) Name of the countries where the vaccines and drugs to be registered/approved to be provided.

MANUFACTURING APPROVAL PROCESS

- If Active Pharmaceutical Ingredients (API) is not available in the country , CDSCO gives approval for import.
- Manufacturing permission for test batches is also approved by CDSCO
- Clinical trial protocol for manufacturing veterinary drugs and vaccines to be approved by the DAHD.
- Report of clinical trial to be submitted to CDSCO
- DAHD further examines clinical trial report.
- Final manufacturing license is issued by CDSCO on recommendation of DAHD.
- The manufacturer obtains GMP certificate from CDSCO.

REQUIREMENT FOR APPROVAL OF NEW DRUG

- Chemical and pharmaceutical information
- Animal Pharmacology data
- Animal Toxicology data
- Clinical pharmacology data
- For new drug substances clinical trials are required to be carried out from Phase I to Phase III before permission to market the drug in India is granted

THANK YOU