Pharmaceutical Regulatory Agencies and Authorities

DRUG REGULATION:

- It is the control of drug use by International agreement and /or by regulatory authorities such as the US Food and Drug Administration(FDA), EMA, etc..,
- Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue guidelines for drug development, licensing, registration, manufacturing, marketing and labelling of pharmaceutical products.
- The scope, nature and practice of drug regulation, including priorities, standards, norms, enforcement strategies, resources available and the rigor of enforcement vary from country to country.

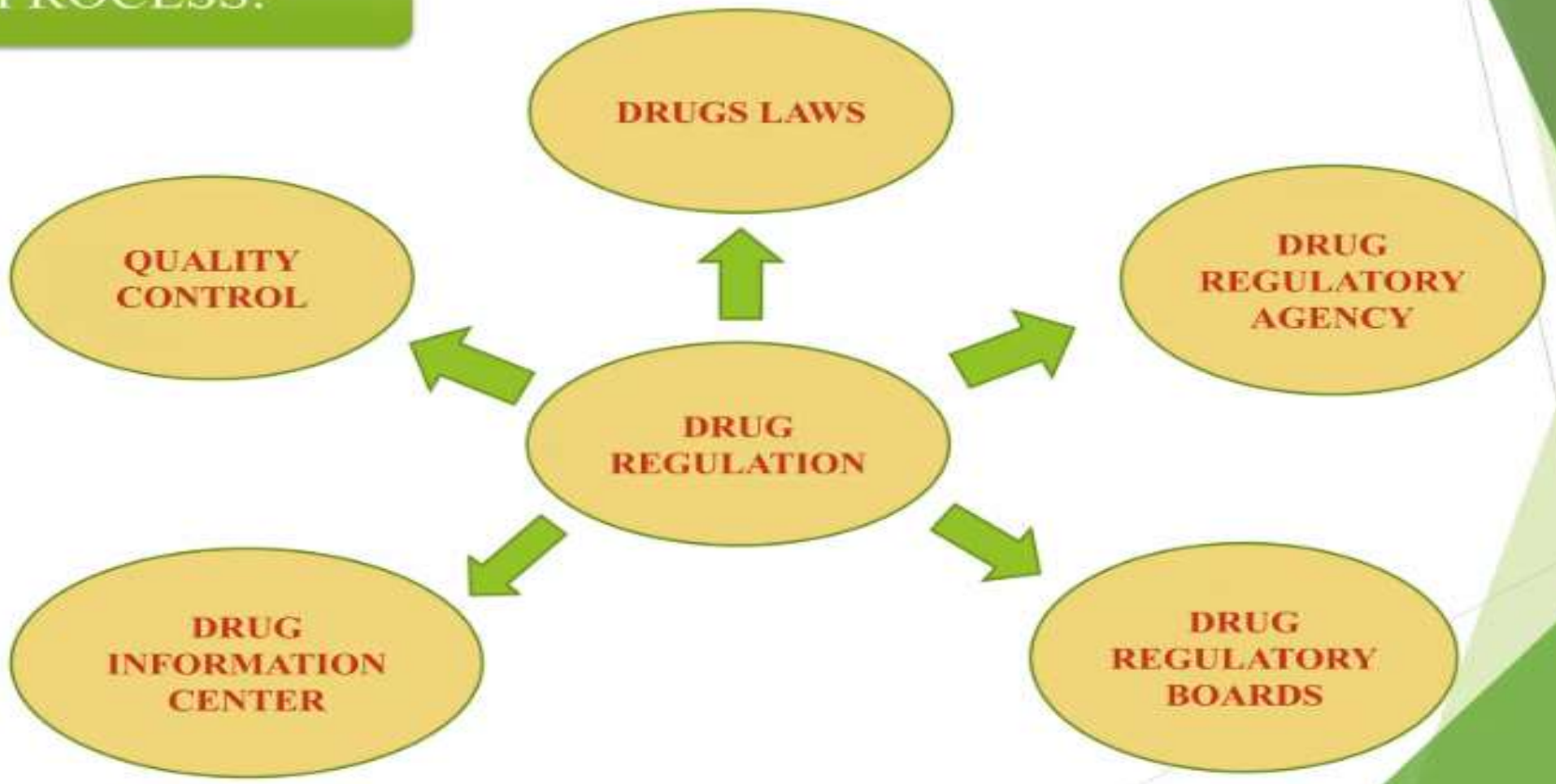
SOME OF THE INTERNATIONAL REGULATORY AGENCIES AND ORGANISATIONS:

- World Health Organization (WHO),
- Pan American Health Organization (PAHO),
- World Trade Organization (WTO),
- International Conference on Harmonization (ICH),
- World Intellectual Property Organization (WIPO),
- United States Food and Drug Administration (USFDA) etc.,

EFFECTIVE REGULATION OF DRUG REQUIRES A VARIETY OF FUNCTIONS:

- ❑ Guaranteeing the safety, efficacy and quality control of drugs.
- ❑ Licensing of premises, persons and practices.
- ❑ Inspection of manufacturing facilities and distribution channels.
- ❑ Product assessment and registration.
- ❑ Adverse drug reaction monitoring.
- ❑ Control of drug promotion and advertising

PROCESS:


DRUGS LAWS
QUALITY CONTROL
DRUG REGULATORY AGENCY
DRUG REGULATION
DRUG INFORMATION CENTER
DRUG REGULATORY BOARDS

DRUG REGULATORY AGENCIES IN INDIA:

MAIN BODIES:-

- Central Drug Standard Control Organization (CDSCO)
- Ministry of Health & Family Welfare (MHFW)
- Indian Council of Medical Research (ICMR)
- Drug Technical Advisory Board (DTAB)
- Central Drug Testing Laboratory (CDTL)
- National Pharmaceutical Pricing Authority (NPPA)

COMMON FUNCTIONS OF THESE MAIN BODIES:

- Functions undertaken by Central Government Statutory function laying down standards of drugs, cosmetics, diagnostics and devices.
- Laying down regulatory measures, amendments to Acts and Rules.
- To regulate market authorization of new drugs.
- To regulate clinical research in India to approve licenses to manufacture certain categories of drugs as Central License Approving Authority i.e. for Blood Banks, Large Volume Parenteral and Vaccines & Sera.
- To regulate the standards of imported drugs. Work relating to the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC). Testing of drugs by Central Drugs Labs.
- Publication of Indian Pharmacopoeia.

1. CDSCO

- Central Drugs Standard Control Organization ('CDSCO')
- Main regulatory body currently regulating import, sale and manufacture of medical devices which have been notified as drugs by virtue of Section 3(b)(IV) of the D&C Act. Headquartered in New Delhi, the CDSCO is India's main regulatory body for pharmaceuticals and medical devices

THE DRUG CONTROLLER GENERAL OF INDIA (DCGI)

Responsible for regulation of Pharmaceuticals and Medical devices.

DCGI-advised by DTAB(DRUD TECHNICAL ADVISORY BOARD)DCC(DRUG CONSULTATIVE COMMITTEE)

CENTRAL LICENSING APPROVAL AUTHORITY (CLAA) Responsible for setting and enforcing safety standards, appointing notified bodies to overseas conformity assessment, conducting post market surveillance and issuing warnings and recalls for adverse events. Lisensing of medical devices

RESPONSIBILITES:

- It establishes safety, efficacy, and quality standards for pharmaceuticals and medical devices.
- The CDSCO lays down standards of drugs, cosmetics, diagnostics and devices and issues licenses to drug manufacturers and importers.
- It also lays down regulatory measures, amendments to Acts and Rules and regulates market authorization of new drugs, clinical research in India and standards of imported drugs etc.
- It publishes and updates the Indian Pharmacopeia, a list of regulated pharmaceuticals and devices.
- For all drug and device applications, the CDSCO appoints notified bodies to perform conformity assessment procedures, including testing, in order to ensure compliance with their standards.
- The CDSCO offers technical guidance, trains regulatory officials and analysts, and monitors adverse events.

ZONAL OFFICES:

- North zone (Ghaziabad)
- West zone (Mumbai)
- South zone (Chennai)
- East zone (Kolkata)
- Some new offices at Hyderabad and Ahmedabad zone.

2. NATIONAL INSTITUTE OF HEALTH AND FAMILY WELFARE (NIHFW):

NIHFW is an Apex Technical Institute, funded by Ministry of Health and Family Welfare, for promotion of health and family welfare programmers in the country through education, training, research, evaluation, consultancy and specialized services.

The NIHFW was established on March 9, 1977 by a merger of the National Institute of Health Administration and Education (NIHAE) with the National Institute of Family Planning (NIFP).

List of Governing Body Members of NIHFW:

Totally 18 members are there;

- 1 Member Secretary (ex-officio)
- 1 Chairman (ex-officio)
- 6 Member
- 1 Vice Chairman (ex-officio)
- 9 Member (ex-officio)

ACTIVITIES AND RESPONSIBILITIES:

- Measuring weight of children to assess the nutritional status Assessment of diseases like level of anaemia.
- It is responsible for all governmental programs relating to family planning in India.
- Testing of food material like cooking salt for level iodine. To release fund on the advice of the Ministry.

3. DRUG TECHNICAL ADVISORY BOARD (DTAB):

The Central Government constitute a Board it was (Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of D&C, Act 1940.

List of Governing Body Members of DTAB:

- 5 Elected Members
- 5 Nominated Members
- 8 ex-officio Members

Totally 18 Members are there

Responsibility and Activity

The DTAB is responsible for advising the Central Government and State Government on technical matters related to drugs and cosmetics, ensuring safety and efficacy. Its activities include:

- Advising on policies for drug standards, safety, and efficacy.
- Evaluating the introduction of new drugs and their classification under different s chedules.
- Offering insights on updating or amending existing regulations and standards.
- Promoting research initiatives to enhance drug quality and safety.
- Mediating conflicts related to technical interpretations of the Act and rules

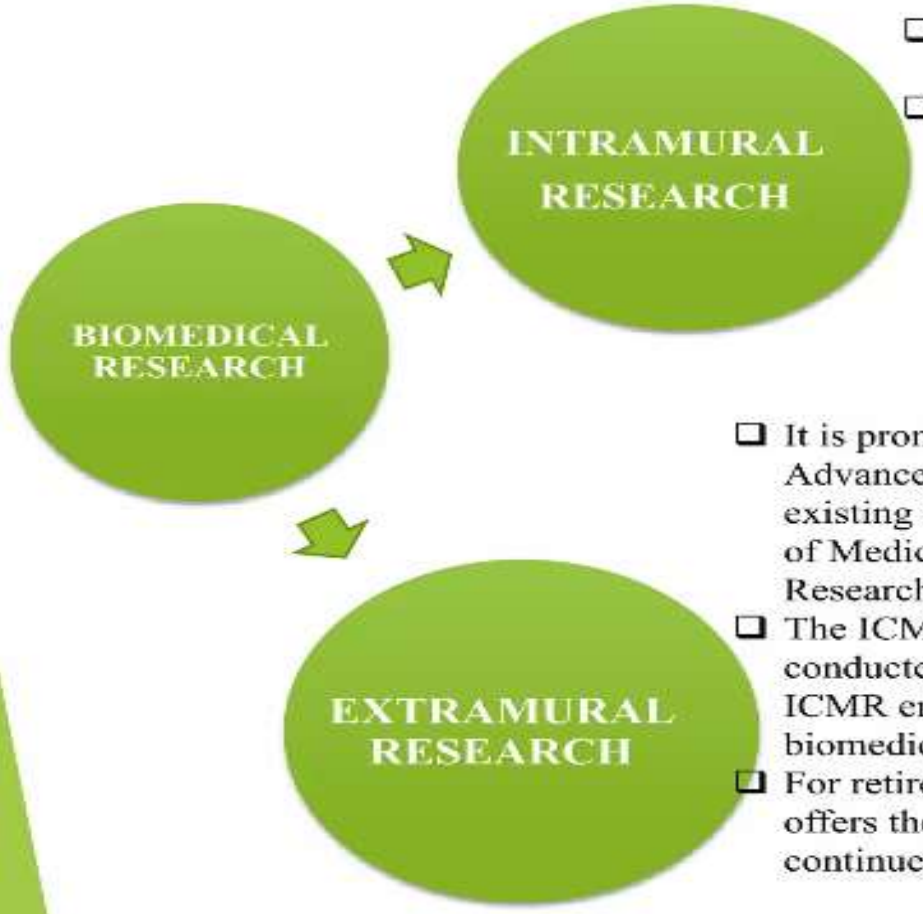
4.INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR):

- It was created in 1911 as IRFA (Indian Research Fund Association) and redesigned as ICMR in 1949 at Delhi.
- It is the one of the oldest medical research bodies in the world and funded by the government of India through the Ministry of Health and Family Welfare.

RESPONSIBILITIES:

The council promotes biomedical research in the country through,

1. Intramural research
2. Extramural research



- It is carried out through the council's 30 permanent research institutes.
- These institutes pursue specific area of research such as tuberculosis, leprosy, cholera, viral diseases including AIDS, malaria, kala-azar, vector control, nutrition, food and drug toxicology, reproduction, immunohematology, oncology and medical statistics

- It is promoted by ICMR by establishing centres for Advanced Research in different research areas around existing expertise and infrastructure in selected departments of Medical Colleges, Universities and other non ICMR Research Institutes.
- The ICMR funds task force studies. Open ended research is conducted on the basis of application for grants-in-aid. The ICMR encourages human resource development in biomedical research.
- For retired medical scientists and teachers, the council offers the position of Emeritus Scientist to enable them to continue or take up research on specific biomedical topics.

5.CENTRAL DRUG TESTING LABORATORY (CDTL):

The central drug laboratory, Kolkata is national statutory laboratory of the government of India for quality control of drug and cosmetic and established under the D&C act, 1940.

Oldest quality control laboratory of the drug control authorities in India.

Function under the director general of Health Services in the Ministry of Health and Family Welfare.

Composition:

ACTIVITIES AND RESPONSIBILITIES:

- Development of comprehensive monographs.
- According priority to monographs of drugs included in the national Essential Drug List and their dosage forms. Preparation of monograph for products that have normally been in the market for not less than 2 years.
- Collaborate with pharmacopoeias like the BP, USP, JP and International Pharmacopoeia with a view to harmonizing with global standards.