Regulatory authorities and agencies

Overview of Regulatory authorities and agencies of (Organization structure and types of applications):

India

United States

European Union

Australia

Japan

Canada

Background

Regulatory affairs in the pharmaceutical industry focus on safeguarding human health. People and governments invest in medications due to their crucial role in saving lives, restoring health, preventing diseases, and halting epidemics. However, for drugs to fulfill these roles, they must be safe, effective, and of high quality. Because drugs are intended to diagnose, prevent, or treat human diseases or conditions, they are closely connected to advancements in research and regulation. The pharmaceutical industry, while targeting global markets, must adhere to national regulations. This review article provides an overview of several drug regulatory agencies in four countries: India, the USA, Europe, and Japan. Regulatory agencies and organizations are essential in ensuring compliance with legal procedures related to the drug development process within a country. Each country has its own regulatory authority responsible for enforcing rules and regulations and issuing guidelines to oversee drug development, licensing, and registration.

Sr. No	Country	Authority
1	India	CDSCO
2	USA	USFDA
3	European Union	EMEA
4	Australia	TGA
5	Japan	MHLW
6	CANADA	HEALTH CANADA

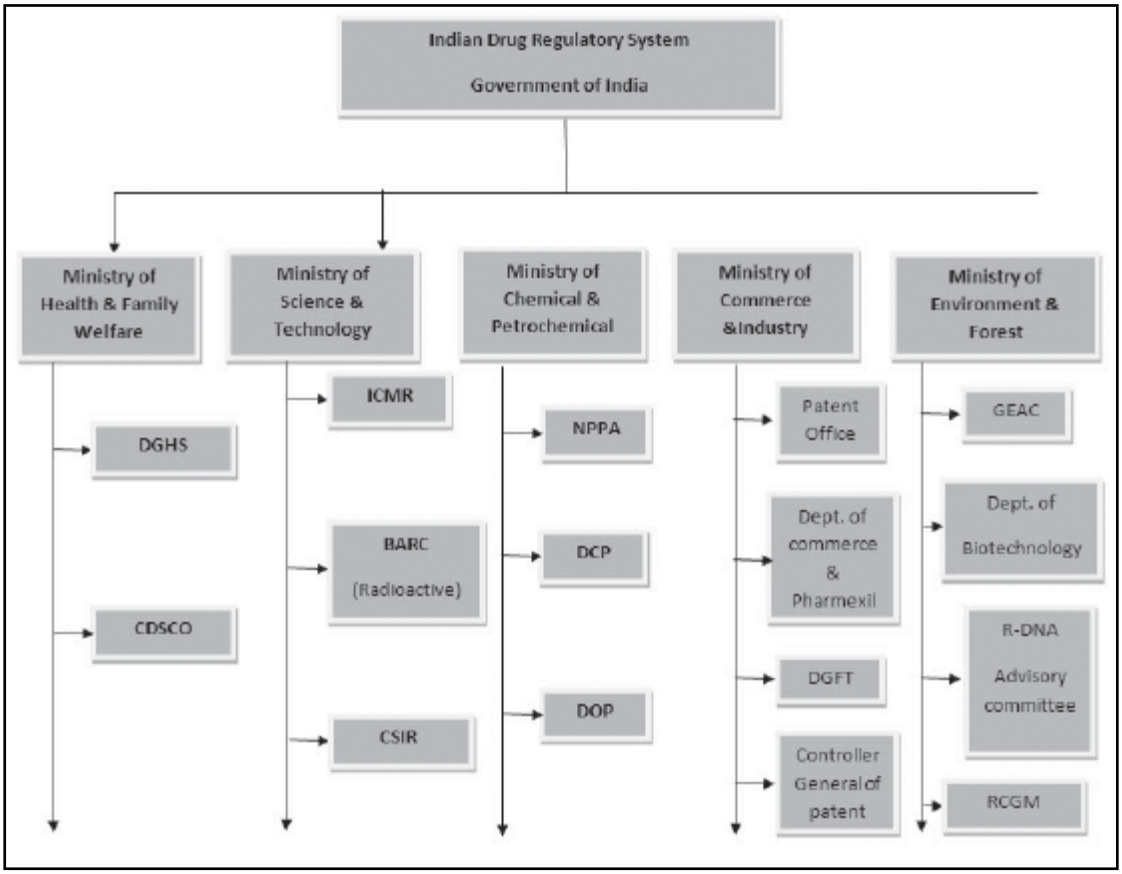
Drug Regulatory Agencies in India

India has become a significant market for pharmaceutical products. The expansion of private healthcare infrastructure, the growing accessibility of rural markets, and the adoption of new technologies have established healthcare as an independent sector in India. Alongside the privatization of healthcare, the medical devices sector is also experiencing growth.

To regulate the import, manufacture, distribution, and sale of drugs and cosmetics, India introduced the Drugs and Cosmetics Act, 1940 ("D&C Act"). However, there is currently no separate regulation for the import, manufacture, distribution, or sale of medical devices in India. The regulation of drugs and health falls under the concurrent list of the Indian Constitution, meaning it is overseen by both the central and state governments under the Drugs & Cosmetics Act, 1940.

Main Regulatory Bodies:

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



Roles and Responsibilities of the Central Government

1. Establishing standards for drugs, cosmetics, diagnostics, and medical devices.
2. Implementing regulatory measures and making amendments to relevant laws and rules.
3. Regulating the market authorization of new drugs.
4. Overseeing clinical research within India.

5. Granting manufacturing licenses for specific categories of drugs, such as those for blood banks, large volume parenterals, vaccines, and sera, as the Central License Approving Authority.
6. Ensuring the standards of imported drugs.
7. Managing the activities related to the Drugs Technical Advisory Board (DTAB) and the Drugs Consultative Committee (DCC).
8. Conducting drug testing through Central Drugs Laboratories.
9. Publishing the Indian Pharmacopoeia.

Central Drugs Standard Control Organization (CDSCO)

In India, the Central Drugs Standard Control Organization (CDSCO) serves as the primary regulatory authority overseeing the import, sale, and manufacture of medical devices categorized as drugs under Section 3(b) (IV) of the Drugs and Cosmetics (D&C) Act. The CDSCO is responsible for setting standards for drugs, cosmetics, diagnostics, and devices, and it issues licenses to drug manufacturers and importers. It also formulates regulatory measures, proposes amendments to the Act and Rules, and oversees market authorization of new drugs, clinical research in India, and standards for imported drugs.

Based in New Delhi, the CDSCO is the principal regulatory body for pharmaceuticals and medical devices in India. Within the organization, the Drug Controller General of India (DCGI) oversees the regulation of pharmaceuticals and medical devices, with guidance from the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC). The Central Licensing Approval Authority (CLAA) manages the licensing and classification of medical devices, sets and enforces safety standards, appoints notified bodies for conformity assessment, conducts post-market surveillance, and issues warnings and recalls for adverse events.

The CDSCO establishes safety, efficacy, and quality standards for pharmaceuticals and medical devices and publishes the Indian Pharmacopeia, which lists regulated pharmaceuticals and devices. Notified bodies are appointed by the CDSCO to perform conformity assessment procedures, including testing, to ensure compliance with standards. Additionally, the CDSCO has several zonal offices that conduct pre-licensing and post-licensing inspections, post-market surveillance, and recalls when necessary.

Beyond its regulatory duties, the CDSCO provides technical guidance, trains regulatory officials and analysts, and monitors adverse events. The organization collaborates with the

World Health Organization (WHO) to promote Good Manufacturing Practice (GMP) and international regulatory harmonization.

National Institute of Health and Family Welfare (NIHFW)

The National Institute of Health and Family Welfare (NIHFW) is a premier technical institute funded by the Ministry of Health and Family Welfare. Its mission is to advance health and family welfare initiatives across the country through education, training, research, evaluation, consultancy, and specialized services. Formed on March 9, 1977, the NIHFW was created by merging the National Institute of Health Administration and Education (NIHAE) with the National Institute of Family Planning (NIFP).

Governing Body Members of NIHFW

- **Total Members:** 18
    - 1 Chairman (ex-officio)
    - 1 Vice Chairman (ex-officio)
    - 9 Members (ex-officio)
    - 6 Members
    - 1 Member Secretary (ex-officio)

Activities and Responsibilities

- **Nutritional Status Assessment:** Measuring children's weight to evaluate their nutritional health.
- **Disease Assessment:** Evaluating the prevalence of diseases such as anemia.
- **Food Material Testing:** Checking cooking salt for iodine levels.
- **Fund Disbursement:** Allocating funds as advised by the Ministry.
- **Program Implementation:** Overseeing all government programs related to family planning in India.

Drug Technical Advisory Board (DTAB)

The Central Government has established the Drugs Technical Advisory Board (DTAB) to provide advice to both the Central and State Governments on technical issues related to the administration of the Drugs and Cosmetics Act, 1940.

Governing Body Members of DTAB

- **Total Members:** 18
    - 10 ex-officio Members
    - 5 Nominated Members
    - 5 Elected Members

Activities and Responsibilities

- **Advisory Role:** The Board advises on matters related to drugs.
- **Term of Office:** Nominated and elected members serve for three years and can be re-nominated or re-elected.
- **Procedure Regulation:** The Board can create bye-laws, with Central Government approval, to set a quorum and regulate its procedures.

Central Drug Testing Laboratory (CDTL)

The Central Drug Laboratory in Kolkata is the national statutory laboratory for the quality control of drugs and cosmetics, established under the Drugs and Cosmetics Act, 1940. It is the oldest quality control laboratory for drug control authorities in India and operates under the Director General of Health Services within the Ministry of Health and Family Welfare.

Composition

- **Indian Pharmacopoeia Commission (IPC)**
    - General Body: 19 Members
    - Governing Body: 10 Members
    - Scientific Body: 23 Experts
    - CIPL Lab
    - IPC Secretariat

Activities and Responsibilities

- **Monograph Development:** Creating comprehensive monographs, prioritizing drugs listed in the national Essential Drug List and their dosage forms.
- **Market Analysis:** Preparing monographs for products that have been available in the market for at least two years.
- **Global Collaboration:** Working with other pharmacopoeias like the British Pharmacopoeia (BP), United States Pharmacopeia (USP), Japanese Pharmacopoeia (JP), and International Pharmacopoeia to harmonize standards globally.

Drug regulatory agencies in USA

The FDA, part of the U.S. Department of Health and Human Services, operates multiple centers, including product centers, a research center, and various offices. Its jurisdiction spans across all 50 states, the District of Columbia, and U.S. territories. The agency's mandate, outlined by the Food and Drug Modernization Act, includes promoting health through research review and product approval, ensuring the safety and accurate labeling of foods and drugs, collaborating internationally to streamline regulatory processes, and partnering with scientific experts and consumers to fulfill its responsibilities effectively.

The FDA, overseen by the Commissioner of Food and Drugs appointed by the President and confirmed by the Senate, plays a crucial role in safeguarding public health through various responsibilities. These include ensuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, biological products, and medical devices. Additionally, the FDA regulates our nation’s food supply, cosmetics, dietary supplements, and products emitting radiation. It also oversees tobacco products and facilitates public health advancements by accelerating product innovations. Moreover, the FDA provides the public with accurate, science-based information necessary for the safe use of medicines, devices, and foods to enhance health outcomes. The FDA also initiates recalls, which can be voluntary, requested by the FDA, or mandated by the FDA.

Drug regulatory agencies in Europe

The European Medicines Agency (EMA) is an agency of the European Union responsible for evaluating medicinal products. Established in 1995, it was initially known as the European Agency for the Evaluation of Medicinal Products until 2004. Located in London, its mission is to promote scientific excellence in the evaluation and supervision of medicines.

The European Medicines Agency (EMA) engages in various activities to ensure the quality, safety, and efficacy of medicines. It provides independent, science-based recommendations on medicines, facilitates transparent evaluation procedures for new medicines, and continuously monitors authorized medicines for quality, safety, and efficacy. EMA also offers scientific advice to support the development and availability of innovative medicines, establishes safe residue limits for veterinary medicines used in food-producing animals, and publishes unbiased information on medicines and their use.

Additionally, EMA develops best practices for medicines evaluation and supervision in Europe, collaborates with Member States and the European Commission to standardize regulatory practices globally, and supports harmonization efforts. The agency's office

includes departments such as the Executive Director's Office, Legal Services, Medical Officers, Internal Audit, Veterinary Medicines and Product Data Management, Patient Health Protection, and Human Medicines Development and Evaluation.

The European Directorate for the Quality of Medicines & Health Care (EDQM), established in 1996 under the Council of Europe, plays a crucial role in harmonizing and coordinating the standardization, regulation, and quality control of medicines, blood transfusions, organ transplantation, pharmaceuticals, and pharmaceutical care across Europe.

Drug regulatory agencies in japan

The Ministry of Health, Labour, and Welfare (MHLW) was formed on January 6, 2001, through the merger of the Ministry of Health and Welfare (MHW) and the Ministry of Labour. Originally established in 1938, MHLW's responsibilities include enhancing social welfare, managing social security, and promoting public health, which continue under its current structure. The ministry comprises various entities such as its core department, affiliated institutions, councils, local branches, and external organizations.

MHLW's functions encompass overseeing social insurance, health policies, and services for the elderly, as well as managing pension systems and disability services to ensure income security and public assistance. Additionally, it focuses on public hygiene by providing medical services, ensuring food and water safety, and advancing health sciences. Job security initiatives include promoting employment, particularly for the elderly and persons with disabilities, and managing the employment insurance system. Furthermore, MHLW emphasizes human resources development to support industrial progress through skill development and adapting to changes in the industrial landscape.

Regulatory process for drug in Canada

The diagram illustrates the regulatory pathway for drugs in Canada, divided into pre-market and post-market phases. Pre-market activities commence with pre-clinical studies, followed by clinical trials. Upon completion, the drug undergoes regulatory product submission and subsequent review. The culmination of this process is the market authorization decision, leading to public access.

In the post-market phase, surveillance, inspection, and investigation ensure ongoing monitoring and safety after the drug is accessible to the public.

Regarding cosmetic products, all cosmetics sold in Canada must adhere to safety standards under the Food and Drugs Act and Cosmetic Regulations. Cosmetics encompass substances

used for cleansing, improving, or altering the complexion, skin, hair, or teeth, including deodorants and perfumes. They must be manufactured, packed, and stored in sanitary conditions, and their ingredients must be disclosed to Health Canada by the manufacturer or importer. This requirement applies to cosmetics used in professional esthetic services, institutional settings, and those sold through craft sales or home-based businesses.

1. **Cosmetic**: Any substance or combination used to clean, enhance, or change the complexion, skin, hair, or teeth, including deodorants and perfumes.
2. **Drug**: Any substance or combination used for diagnosing, treating, preventing, or mitigating diseases, disorders, or abnormal physical conditions in humans or animals, or for restoring, correcting, or modifying organic functions, or for disinfecting premises where food is handled.
3. **Natural Health Product**: A subset of drugs consisting of medicinal ingredients of natural origin, including substances listed in Schedule 1, combinations thereof, homeopathic medicines, or traditional medicines used for diagnosing, treating, preventing, or mitigating diseases, disorders, or abnormal physical conditions in humans, or for restoring, correcting, or modifying organic functions to maintain or promote health.
4. **Personal Care Product (PCP)**: Substance or mixture categorized under cosmetics, drugs, or natural health products in Canada.
5. **Product at the Cosmetic-Drug Interface (PCDI)**: Subset of personal care products that are difficult to classify as either a drug or cosmetic under the Food and Drugs Act.

Regulatory programs within Health Canada that oversee personal care products include:

- **NHPD**: Natural Health Products Directorate
- **PSD**: Product Safety Directorate
- **TPD**: Therapeutic Products Directorate

- **Manufacturer Responsibility:** Manufacturers bear full responsibility for ensuring the safety of their products.
- **Market Control:** Authorities regulate the entry of cosmetics into the market.
- **Distribution Freedom:** Products can be sold through any distribution channel.
- **Notification Requirement:** Mandatory notification of product name, function, and detailed ingredient lists within 10 days of market placement.

- **Labeling Requirements:** Mandatory metric quantity labeling; non-metric labels are allowed as supplements. Non-Canadian addresses are acceptable for manufacturer or dealer identification.
- **Cosmetic Notification Form (CNF):** Requires specific product details such as manufacturer information, cosmetic function, form, ingredients, and ingredient concentrations. Submission is free and protected under privacy laws.
- **Compliance:** Submission of CNF does not equate to approval; manufacturers must ensure compliance with all regulatory requirements.
- **Concerns and Compliance:** Health Canada notifies manufacturers of any issues with submitted notifications. Non-compliance may lead to regulatory action.

Examples of cosmetics include soaps, moisturizers, makeup products, and tooth whiteners, while products like sunscreens, acne treatments, and insect repellents are classified differently and have distinct regulatory requirements.

Label information must include product identity, net quantity, manufacturer details, hazard warnings, and ingredient lists, with resources available for additional labeling requirements.

Natural health products

Natural health products (NHPs) encompass naturally occurring substances used to enhance or maintain good health. They are derived from plants, animals, microorganisms, and marine sources, and are available in various forms such as tablets, capsules, tinctures, creams, and drops. Often referred to as complementary or alternative medicines, NHPs include vitamins, minerals, herbal remedies, homeopathic medicines, traditional medicines like traditional Chinese and Ayurvedic practices, probiotics, amino acids, and essential fatty acids.

Product authorization

In Canada, NHPs must undergo rigorous evaluation to ensure they are safe, effective, and of high quality before they can be licensed for sale. Products that meet these standards are identified by an eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) displayed on their labels. This designation signifies approval by Health Canada based on comprehensive assessments of safety, efficacy, and quality, including adherence to specific labeling, packaging, and manufacturing practices.

To obtain product and site licenses, manufacturers must provide detailed information about their products, including medicinal ingredients, dosage, potency, non-medicinal ingredients, and recommended uses. Health Canada evaluates this information to issue licenses, ensuring

that NHPs meet stringent regulatory requirements and are safe for consumers when used as directed. The presence of an NPN or DIN-HM on the label confirms compliance with Health Canada's standards and approval for legal sale in Canada.

Labeling requirements for Natural Health Products (NHPs) in Canada are designed to ensure consumers can make informed and safe choices. Here are the specific details that must be included on NHP labels:

1. **Product Name:** Clearly identifiable name of the NHP.
2. **Product License Number:** Eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) indicating Health Canada approval.
3. **Quantity of Product:** Amount of product contained in the bottle or package.
4. **Medicinal and Non-Medicinal Ingredients:** Complete list of all ingredients used, distinguishing between active medicinal ingredients and non-medicinal components.
5. **Recommended Use:** Detailed information on how to use the product, including intended purpose or health claim, route of administration (e.g., oral, topical), and dosage instructions.
6. **Cautionary Statements:** Statements advising consumers of potential risks, precautions, and interactions associated with the product.
7. **Warnings and Contraindications:** Information on situations where the product should not be used due to potential adverse effects or interactions.
8. **Possible Adverse Reactions:** Notification of any known or possible adverse reactions associated with the product.
9. **Special Storage Conditions:** Instructions on how to store the product to maintain its stability and effectiveness.

These labeling requirements ensure that NHPs sold in Canada provide clear and accurate information, helping consumers use these products safely and effectively.