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DRUG REGULATORY AGENCIES IN INDIA, USA, EUROPE AND JAPAN-A REVIEW

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ABSTRACT

Regulatory affairs in pharmaceutical industry aim at the protection of human health. People and government spent money on drugs because of the role they can play in saving lives, restoring health, preventing diseases and stopping epidemics. But, in order to do so, drug must be safe, effective and of good quality. Since the purpose of drug is to diagnose, prevent or treat diseases or ailments in humans, they are products intimately linked with the advances in research and regulation. The pharmaceutical industry, while pursuing an international market, is obliged to comply with national regulations. So, in this review article, an overview of few drug regulatory agencies of four countries: India, USA, Europe& Japan is covered. Regulatory agencies and organizations play a vital role to meet the requirements of legal procedures related to drug development process in a country. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate the drug development, licencing& registration.

INTRODUCTION

The regulatory agencies in few of the countries are as follows:

Sr.No	Country	Authority
1	USA	USFDA
2	UK	MHRA
3	Australia	TGA
4	India	CDSCO
5	CANADA	HEALTH CANADA
6	South Africa	MCC
7	Brazil	ANVISA
8	European Union	EMEA
9	China	SFDA
10	Nigeria	NAFDAC
11	NewZealand	MEDSAFE
12	Japan	MHLW
13	Zimbabwe	MCAZ
14	Switzerland	SWISSMEDIC
15	Korea	KFDA
16	Sri Lanka	MoH

World Health Organization (WHO), Pan American Health Organization (PAHO), World Trade Organization (WTO), International Conference on Harmonization (ICH), World Intellectual Property Organization (WIPO) are some of the international regulatory agencies and organizations which also play essential role inall aspects of pharmaceutical regulations related to drug product registration, manufacturing, distribution, price control, marketing, research and development, and intellectual property protection.

Drug regulation means to promote various activities to ensure the efficacy and safety, quality of drug. Pharmaceutical drugs are available from a large number of sources. People and Governments willing to spend money on drugs for many reasons so, it must be safe, effective and good quality and used appropriately. Therefore, effective drug regulation is required to ensure the safety, efficacy and quality of drugs as well as accuracy and appropriateness of the drug information available to the public.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 production, import, storage, distribution, sales and supply of drug must be regulated.

Effective regulation of drug requires a variety of functions:

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

Most importantly, the process of drug regulation.

The drug regulation consists of:

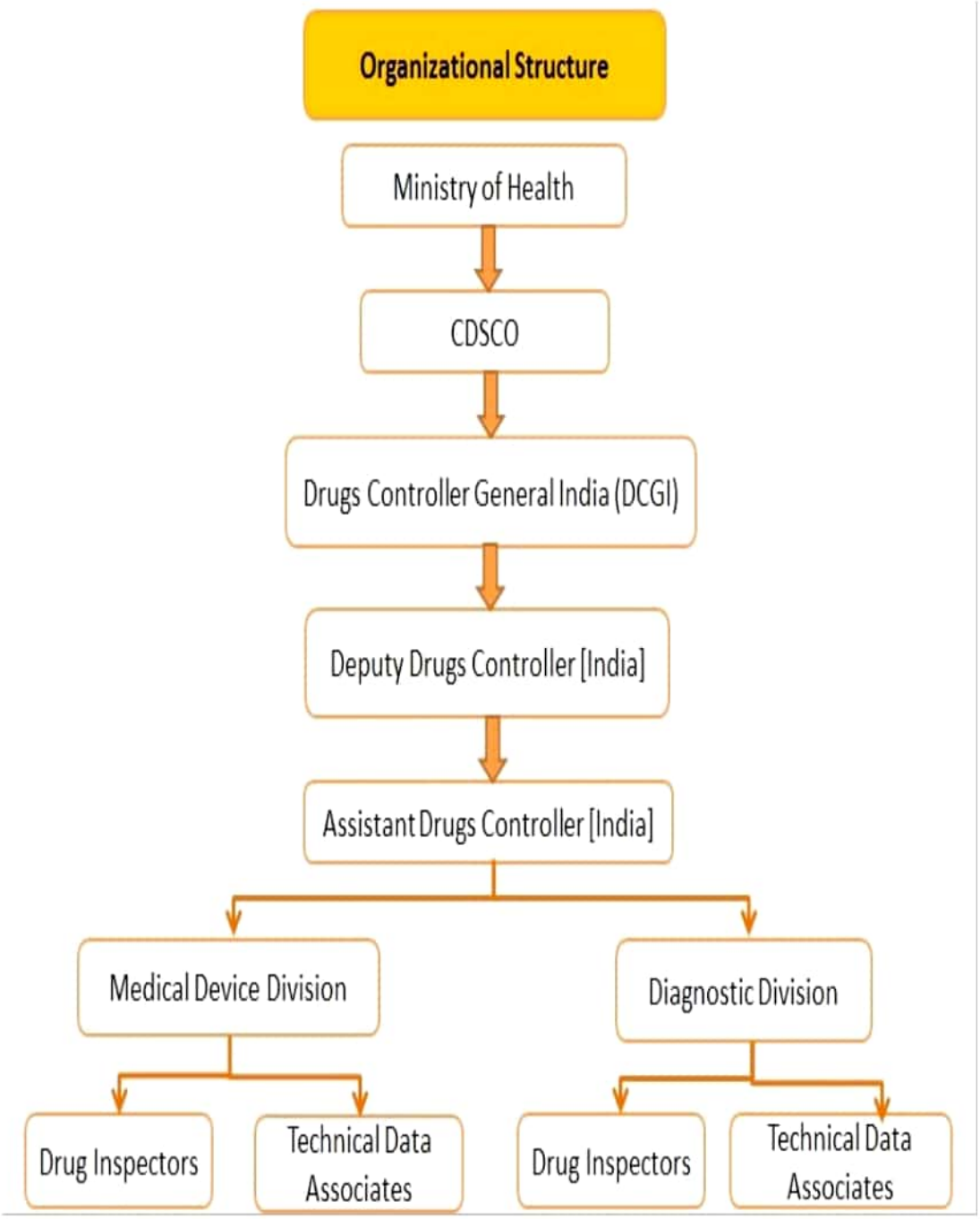
1. Drug Laws
2. Drug Regulatory Agencies
3. Drug Regulatory Boards
4. Quality Control
5. Drug Information Centres.

DRUG REGULATORY AGENCIES IN INDIA:

India has emerged as one of the leading markets for pharmaceutical products. Increase in the private healthcare infrastructure, widening rural markets, and inclusion of newer technologies have placed healthcare as an independent sector in India. With privatization of healthcare, the medical devices sector is growing too.

In order to regulate the import, manufacture, distribution and sale of drugs and cosmetics, the Drugs and Cosmetics Act, 1940 ("D&C, Act") was introduced in India in 1940. However, no separate regulation has been enacted for regulating the import, manufacture, distribution or sale of medical devices in India till date by the Government of India.

Drugs and Health is in concurrent list of Indian Constitution. It is governed by both Centre and State Governments under the Drugs & Cosmetics Act, 1940.



MAIN 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)

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 Licence 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-

In India, the Central Drugs Standard Control Organization ('CDSCO') is the 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. 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.

Headquartered in New Delhi, the CDSCO is India's main regulatory body for pharmaceuticals and medical devices and Within the CDSCO, the Drug Controller General of India (DCGI) is responsible for the regulation of pharmaceuticals and medical devices. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC). Licensing and classification of medical devices are handled by the Central Licensing Approval Authority (CLAA). The CLAA is also responsible for setting and enforcing safety standards, appointing notified bodies to oversee conformity assessment, conducting post-market surveillance and issuing warnings and recalls for adverse events.

The CDSCO establishes safety, efficacy, and quality standards for pharmaceuticals and medical devices. 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 is also divided into several zonal offices which do pre-licensing and post-licensing inspections, post-market surveillance, and recalls when necessary.

In addition to its regulatory functions, the CDSCO offers technical guidance, trains regulatory officials and analysts, and monitors adverse events. The CDSCO works with the World Health Organization to promote Good Manufacturing Practice (GMP) and international regulatory harmony.

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

18 members

1 Chairman (ex-officio)

1 Vice Chairman (ex-officio)

9 Member (ex-officio)

6 Member

1 Member Secretary (ex-officio)

ACTIVITIES AND RESPONSIBILITIES:

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

3. DRUG TECHNICAL ADVISORY BOARD (DTAB):

The Central Government constitute a Board (to be called the 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 NIHFW:

18 Members

10 ex-officio Members

5 Nominated Members

5 Elected Members

ACTIVITIES AND RESPONSIBILITIES:

It advices matter related to Drugs. The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election. The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure.

4. 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: Indian Pharmacopoeia Commission (IPC)

General Body 19 Members

Governing Body 10 Members

Scientific Body 23 Experts

CIPL Lab IPC Secretariat Indian Pharmacopoeia was prepared by Indian Pharmacopoeia Commission (IPC)

ACTIVITIES AND RESPONSIBILITIES:

Development of comprehensive monographs. Accord 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.

DRUG REGULATORY AGENCIES IN USA:

USFDA-

The Food and Drug Administration (FDA) National Institutes of Health (NIH) Centres for Disease Control and Prevention Department of Health and Human Services (DHHS) Fed World - US Government Information National Centre for Complementary and Alternative Medicine (NCCAM) National Centre for Infectious Diseases (NCID) National Library of Medicine National Science Foundation Office of Disease Prevention.

The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services. It consists of six product centres, one research centre, and two offices. FDA's responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions. Food and Drug Administration 10903 New Hampshire Ave Silver Spring, MD 20993-0002

The Food and Drug Modernization Act states that the FDA has 4 roles:

*To promote health by reviewing research and approving new products.

*To ensure foods and drugs are safe and properly labelled.

*To work with other nations to "reduce the burden of regulation".

*To cooperate with scientific experts and consumers to effectively carry out these obligations

The FDA is led by the Commissioner of Food and Drugs, who is appointed by the President and confirmed by the Senate.

FDA is responsible for Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labelled; Assuring human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective Protecting the public from electronic product radiation Assuring cosmetics and dietary supplements are safe and properly labelled Regulating tobacco products Advancing the public health by helping to speed product innovations Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health Initiation of a Recall. Includes voluntary, FDA requested, and FDA mandated.

FDA is responsible for: protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, and products that give off radiation regulating tobacco products advancing the public health by helping to speed product innovations helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.FDA is responsible for Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labelled; vaccines and other biological products and medical devices intended for human use are safe and effective .Protecting the public from electronic product radiation Assuring cosmetics and dietary supplements are safe and properly labelled Regulating tobacco products Advancing the public health by helping to speed product innovations Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health Initiation of a Recall. Includes voluntary, FDA requested, and FDA mandated.

DRUG REGULATORY AGENCIES IN EUROPE:

EMA:

EMA is a European agency for the evaluation of medicinal product. EMA was set up in 1995. From 1995 to 2004, EMA was known as European agency for the evaluation of medicinal product. The European Medicines Agency (EMA) is a decentralized body of the European Union, located in London Mission: to foster scientific excellence in evaluation and supervision of medicines.

ACTIVITIES OF EMA: Provides independent, science-based recommendations on the quality, safety and efficacy of medicines. Applies efficient and transparent evaluation procedures to help bring new medicines to the market. Implements measures for continuously supervising the quality, safety and efficacy of authorised medicines. Provides scientific advice to stimulate the development and improve the availability of innovative new medicines. Recommend safe limits for residues of veterinary medicines used in food-producing animals. Publishes impartial and comprehensible information about medicines and their use; develops best practice for medicines evaluation and supervision in Europe, and contributes alongside the Member States and the European Commission to the harmonisation of regulatory standards at the international level

European Directorate for the Quality of Medicines & Health Care the EDQM (Council of Europe) is a key European Organisation involved in Harmonisation & Co-ordination of Standardisation, Regulation & Quality Control of Medicines, Blood Transfusion, Organ Transplantation, Pharmaceuticals and Pharmaceutical Care. In 1996 The European Directorate for the Quality of Medicines (EDQM) is created.

EMA is a European agency for the evaluation of medicinal product. EMA was set up in 1995. From 1995 to 2004, EMA was known as European agency for the evaluation of medicinal product. The European Medicines Agency (EMA) is a decentralized body of the European Union, located in London Mission: to foster scientific excellence in evaluation and supervision of medicines.

office of executive director Executive director Legal service Senior medical officer Internal audit Information and communicate ion veterinary medicines and product data management Patient health protection Human medicines development and evaluation

DRUG REGULATORY AGENCIES IN JAPAN:

MHLW:

The Ministry of Health, Labour, and Welfare (MHLW) was established by a merger of the Ministry of Health and Welfare (MHW) and the Ministry of Labour, on January 6, 2001. The MHLW, which was originally established in 1938, has been in charge of the improvement and promotion of social welfare, social security and public health, and the new organization has the same tasks. It consists of the ministry proper, affiliated institutions, councils, local branches, and an external organization.

MHLW Social insurance agency Ministry proper Minister's secretariat Heath policy bureau Heath service bureau PFSB Social welfare & war victim's relief bureau Health and welfare bureau for elderly Equal employment children & family bureau Insurance bureau Pension bureau Director general for policy planning. Services for persons with disabilities Social Security: Pension systems that will ensure income in elderly age Long term insurance to provide nursing care services Public assistance systems that guarantee minimum standards

FUNCTION OF MHLW:

Public Hygiene: Appropriate medical services for diseases & injuries ensuring the safety of food, Water and medical supplies Research into health science in order to make technological advances Maternal and child health Job Security: Promotion of employment Employment of elderly people Employment of persons with disabilities Management of the employment insurance system

Human Resources Development : Promotion of human resources development that reacts to changes in the industrial system Encouragement of worker's skill development under their own initiative Development of skilled human resources that support industrial progress

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