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DRUG REGULATORY AGENCIES IN INDIA AND U. S. A.

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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 aliments in humans, they are productsintimately 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 drugs regulatory agencies of four countries: India, USA, Europe & Japan is covered. Regulatory agencies and organizations play a vital role to meed the requirements of legal procedures related to drug development process in a country. Every country has its own regulatory autority,which is responsible to enforce the rules and regulatons and issue the guidelines to regulate the drugs development, licencing & registration.

KEYWORDS: Regulatory affairs in pharmaceutical industry aim at the protection of human health.

AIM AND OBJECTIVE

Aim

- To Study Regulatory Agencies in India and U.S.A.

Objective

- We study major worldwide agencies

- We study about CDSCO(central drug standard control organization)
- We study about FDA (food and drug administration)
- Ensuring the safety, efficacy,and quality of pharmaceutical in the Indian market.
- Regulate the approval process for new drug,including clinical trials oversight.
- Monitor and control the manufacturing,import, and distribution of drugs.
- Enforce standard to prevent the production and sale of substandard or counterfeit medication.
- Facilitate innovation by providing a regulatory framework for the pharmaceuticalindustry.
- Safeguard public health by regulating the development,testing,and approval of drugs.
- Establish and enforce quality standards for drug manufacturing processes.
- Oversee clinical trials to ensure ethical pratices and reliable data.
- Monitor the safety of marketed drugs through post market surveillance.
- Provide accurate information to healthcare professional and the public about drug safety and efficacy.

INTRODUCTION

REGULATORY AGENCIES

A regulatory agency or regulatory body, is a government authority that is responsible for exercising autonomous dominion over some area of human activity in a licensing and regulating capacity. 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 in all aspects of pharmaceutical regulations related to drug product registration, manufacturing, distribution, price control, marketing, research and development, and intellectual property protection.

Functions of Regulatory Agencies

1. Guaranteeing the safety, efficacy and quality of drug.
2. Licensing of premises, persons and practices.
3. Inspection of manufacturing facilities and distribution channels.
4. Product assessment and registration. - Adverse drug reaction monitoring.
5. Quality control.
6. Control of drug promotion and advertising. Most importantly, process drug regulation

Major Regulatory Agencies World Wide

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.

India	Central Drug Standard Control Organization (CDSCO)
USA	Food and Drug Administration (FDA)
China	State Food and Drug Administration
Germany	Federal Institute for Drugs and Medical Devices
South Africa	Medicines Control Council
Australia	Therapeutic Goods Administration (TGA)
Canada	Health Canada
Europe	European Medicines Agency (EMA)
Japan	Ministry of Health, Labour & Welfare (MHLW)
New Zealand	Med safe-Medicines Medical Devices Safety Authority
UK	Medicines and Healthcare products Regulatory Agency (MHRA)
Korea	Korea Food & Drug Administration (KFDA)

1. USA - Food and Drug Administration (FDA)

The United States Food and Drug Administration (FDA or USFDA) is a federal agencyof the Department of Health and Human Services.

The FDA is led by the Commissioner of Food and Drugs, appointed by the Presidentwith the advice and consent of the Senate.

USFDA was formed in July 30, 1906.

2. INDIA- Central Drugs Standard Control Organisation (CDSCO)

The Central Drugs Standard Control Organisation (CDSCO) is India's national regulatory body for cosmetics, pharmaceuticals and medical devices. The Drug Controller General of India (DCGI) regulates pharmaceutical and medical devices and is positioning within the Ministry of Health and Family Welfare. The DCGI is advisedby the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee(DCC).

3. AUSTRALIA - Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration (TGA) is the medicine and therapeutic regulatory agency of the Australian Government. The TGA regulates the quality,supply and advertising

of medicines, pathology devices, medical devices, blood products and most other therapeutics. TGA was formed in the year 1989.

4. CANADA- Health Canada

Health Canada is the department of the Government of Canada responsible for national health policy. The department itself is also responsible for numerous federal health- related agencies, including the Canadian Food Inspection Agency (CFIA) and the Public Health Agency of Canada (PHAC), among others. Originally created as the "Department of Health" in 1919—in the wake of the Spanish flu crisis,what is known as *Health Canada* today was formed in 1993 from the former Health and Welfare Canada department (established in 1944).

5. EUROPE- European Medicines Agency (EMA)

The European Medicines Agency (EMA) is an agency of the European Union (EU) in charge of the evaluation and supervision of medicinal products. Prior to 2004, it was known as the European Agency for the Evaluation of Medicinal Products or EuropeanMedicines Evaluation Agency (EMEA). The EMA was founded in 1 January 1995.

6. JAPAN - Ministry of Health, Labour & Welfare (MHLW)

The Ministry of Health, Labour and Welfare is a cabinet level ministry of the Japanese government. The ministry provides services on health, labour and welfare. It was formed with the merger of the former Ministry of Health and Welfare and the Ministry ofLabour.

7. NEW ZEALAND- Med safe - Medicines and Medical Devices SafetyAuthority

Med safe, the New Zealand Medicines and Medical Devices Safety Authority, is the medical regulatory body run by the New Zealand Ministry of Health, administering the Medicines Act 1981 and Medicines Regulations 1984.

8. CHINA- State Food and Drug Administration

The National Medical Products Administration (NMPA, formerly the China Food and Drug Administration, or CFDA) was founded on the basis of the former State Food and Drug Administration (SFDA). CFDA was formed in the year 1950.

9. South Africa- Medicines Control Council

The Medicines Control Council (MCC) is a statutory body that regulates the performance of clinical trials and registration of medicines and medical devices for use in specific diseases.

The MCC is responsible to ensure that all clinical trials of both non-registered medicines and new indications of registered medicines comply with the necessary requirements for safety, quality and efficacy.

10. Germany- Federal Institute for Drugs and Medical Devices

The Federal Institute for Drugs and Medical Devices is the medical device regulatoryauthority in Germany. Functioning as an independent body within the Federal Ministry of Health, it deals with the authorization of drugs of medical devices on thebasis of the German Medicines Act (AMG), monitors legal trade of narcotics, and evaluates the potential risk posed by medical devices.

LITERATURE REVIEW

1. Mankar et al (2014)

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 drugs 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.

2. Shri R. S et al(2020)

Drugs play a major role in saving lives, maintaining health, preventing diseases, stopping epidemics and in improving economy of a country. Therefore, people, government, pharmaceutical industries and research institutes spend money on drugs. However, in order to do so, drug must be safe, effective and of good quality. This means the development, production, importation, exportation, and distribution of drugs are regulated to ensure that they meet prescribed standards. For effective regulation of pharmaceutical products, governments establish strong National Regulatory Authorities (NRAs), to assure that medicines are regulated effectively thereby protecting and promoting public health.

Pharmaceutical regulations across the globe play a vital role in guaranteeing the safety, quality and efficacy of the drugs. Pharmaceutical regulatory agency is accountable to enforce the regulations and issue guidelines for drug development, licensing, registration, producing, labelling, storage, marketing, distribution, pricing ofdrugs, import and post marketing studies of pharmaceutical products.

Pharmaceutical industries, while pursuing an international market, must comply with pharmaceutical regulations of other countries, which have different regulatory requirements. A single regulatory approach for Marketing Authorization Application (MAA) of a drug product applicable to different countries is difficult. Therefore, Common Technical Document (CTD) was developed to provide a common format for submission of applications electronically for registration of pharmaceuticals. In this review article, an overview of pharmaceutical regulatory agencies of three countries: India, USA and Europe covered.

3. Harsha et al (2017)

Regulatory affairs (RA) professionals play critical roles in a pharmaceutical industry because it is concern about the healthcare product lifecycle, it provides strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare products to individuals around the world. The role of regulatory affairs is to develop and execute a regulatory strategy to ensure that the collective efforts of the drug development team results in a product that is approvable by global regulators but is also differentiated from the competition in some way and also is to ensure that the company's activities, from non-clinical research through to advertising and promotion, are conducted in accordance with the regulations and guidelines established by regulatory authorities. Regulatory Affairs is an attractive career choice for graduate students from a scientific background who enjoy communication and team work, are comfortable with multi-tasking and are eager to expand their knowledge in the wide realms of the pharmaceutical world.

Regulatory Affairs is a rewarding, intellectually stimulating and highly regarded profession within pharmaceutical companies.

DRUG REGULATORY AGENCIES IN INDIA

Fig 1: Central Drug Standard Control Organization CDSCO.

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

1. Central Drug Standard Control Organization (CDSCO)
2. Ministry of Health & Family Welfare (MHFW)
3. Indian Council of Medical Research (ICMR)
4. Indian Pharmaceutical Association (IPA)
5. Drug Technical Advisory Board (DTAB) & Drug Consultative Committee (DCC)
6. Central Drug Testing Laboratory (CDTL)
7. Indian Pharmacopoeia Commission (IPC)
8. 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. **Central Drug Standard Control Organization (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 regulatesmarket 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 markets 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 Pharmacopoeia, 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 prelicensing 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.

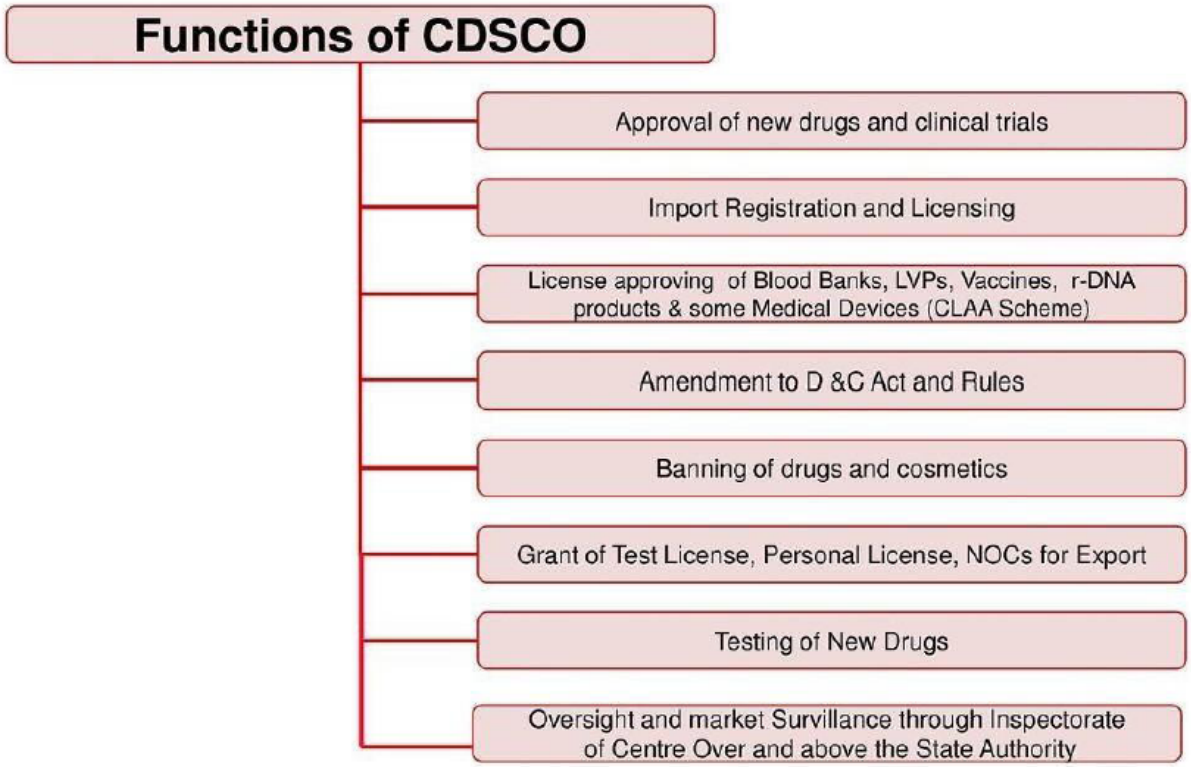

Fig. 2: Flow chart of Functions of CDSCO.

2. Ministry of Health & Family Welfare (MHFW)

Fig. 3: Ministry of health and family welfare.

- 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).

3. List of Governing Body Members of NIHFW

1. 18 members
2. 1 Chairman (ex-officio)
3. 1 Vice Chairman (ex-officio)
4. 9 Member (ex-officio)
5. 6 Member
6. 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 fundon the advice of the Ministry. It is responsible for all governmental programs relating to family planning in India.

4. Indian Council of Medical Research (ICMR)

Fig. 4: Indian Council Of Medical Research.

The Indian Council of Medical Research (ICMR), the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest and largest medical research bodies in the world.

The ICMR is funded by the Government of India through the Department of Health Research, Ministry of Health and Family Welfare.[2][3] In 2007 the organization establishedthe Clinical Trials Registry - India, which is India's national registry for clinical trials.

ICMR's 26 national institutes address themselves to research on specific health topics like tuberculosis, leprosy, cholera and diarrhoeal diseases, viral diseases including AIDS, malaria, kala-azar, vector control, nutrition, food & drug toxicology, reproduction, immuno-haematology, oncology, medical statistics, etc. Its 6 regional medical research centres address themselves to regional health problems.

Activities

Extramural research 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.

ICMR's Viral Research and Diagnostic Laboratories (VRDL) for diagnosis of the viral and other infectious diseases is gradually evolving and is proposed to be the largest network of laboratories for timely identification of viruses and other agents causing morbidity significant at public health level and specific agents causing epidemics and/or potential agents for bioterrorism and undertake research for identification of emerging and newer genetically active/ modified agents.

5. Indian Pharmaceutical Association (IPA)

Fig. 5: The Indian Pharmaceutical Association (IpA).

Connecting The Pharmacists and Pharmaceutical Scientists of India The Indian Pharmaceutical Association (IPA) is the National body representing over 1 million pharmacists and pharmaceutical scientists from Industry, Academia, Regulatory, Hospital and Community Pharmacy and work to meet the India's health care needs. IPA is a non-governmental organization that has been in official relations with the FIP and WHO. IPA is member of Drug Technical Advisory Board (DTAB), Ministry of Health and Family Welfare, Government of India. IPA has been awarded "Best Professional Organisation Award -2015" by Indian Association Congress.

IPA is recognised as the leader of pharmacy at National level. IPA continue to expand its presence, within pharmacy and pharmaceutical sciences and influence through partnerships with some of the world's leading health, policymaking, education and science institutions.

6. Drug Technical Advisory Board (DTAB) &Drug Consultative Committee (DCC)

Fig. 6: DTAB-DCC Committee.

The Central Government constitute a Board called the Drugs Technical Advisory Board (DTAB) to advise the Central Government and the State Governments on technical matters arising out the administration of this Act and to carry out the other functions assigned to it by this Act.

The Board shall consist of the following members, namely.

(i) the Director General of Health Services, ex officio, who shall be Chairman;
(ii) the Drugs Controller, India, ex officio;
(iii) the Director of the Central Drugs Laboratory, Calcutta, ex officio;
(iv) the Director of the Central Research Institute, Kasauli, ex office;
(v) the Director of the Indian Veterinary Research Institute, Itanagar, ex officio;
(vi) the President of the Medical Council of India, ex officio;
(vii) the President of the Pharmacy Council of India, ex officio;
(viii) the Director of the Central Drug Research Institute, Lucknow, ex officio;
(ix) two persons to be nominated by the Central Government from among persons who arein charge of drugs control in the States;
(x) one person, to be elected by the Executive Committee of the Pharmacy Council ofIndia, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto;
(xi) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university ora college affiliated thereto;
(xii) one person to be nominated by the Central Government from the pharmaceutical industry;

(xiii) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

(xiv) one person to be elected by the Central Council of the Indian Medical Association;

(xv) one person to be elected by the Council of the Indian Pharmaceutical Association;

(xvi) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government.]

Functionalities

1. Co-ordinate the DTAB meetings under the Chairmanship of Director General of Health Services (DGHS) to advise the Central Government and the State Governments on technical matters arising out of the administration of the Drugs and Cosmetics Act, 1940 andto carry out the other functions assigned to it by this Act.

2. Co-ordinate the DCC meetings under the Chairmanship of Drugs Controller General (India) to advise the Central Government, the State Governments and DTAB on any other matter tending to secure uniformity throughout India in the administration of the Drugs and Cosmetics Act, 1940.

3. Initiate the amendments in the Drugs and Cosmetics Rules, 1945 as per the recommendations of DTAB and co-ordinate with Ministry of Health & Family Welfare (MOHFW) for draft and final Gazette Notifications.

4. Examination, compilation and consideration of comments/suggestions/objectionsreceived with respect to draft Gazette Notification / Public Notices / Circulars etc.

5. Co-ordinate the constitution of sub-committees recommended in DTAB and DCC meetings and further follow-up for their reports.

6. Co-ordinate the stake holders' meetings with respect to amendments of Drugs and Cosmetics Rules, as per recommendations from MOHFW whenever required.

7. Central Drugs Testing Laboratory (CDTL)

There are seven Central Drug Testing Laboratories under CDSCO. These are at Kolkata, Mumbai, Chennai, Guwahati, Chandigarh, Kasauli and Hyderabad. The Central Drug Laboratory, Kolkata is the appellate laboratory for testing of drugs and is NABL accredited for Chemical and Biological Testing. The Central Drug Testing Laboratory, Mumbai is a statutory Laboratory involved in testing of samples of Drugs from the ports, new drugs and oral contraceptive pills. It is an appellate laboratory for copper T-intrauterine contraceptive device and tubal rings. The Central Drugs Testing Laboratory, Chennai is an appellate

Laboratory for condoms and is NABL accredited for both chemical and mechanical sections. The Regional Drugs Testing Laboratory, Guwahati tests the samples of drugs received especially from States in the East Zone and is NABL accredited for both chemical Zone and biological testing. The Regional Drug Testing Laboratory, Chandigarh is NABL Accredited Laboratory as per ISO/IEC 17025:2005 having Chemical, Instrumentation and Microbiological testing. Laboratory is involved in the analysis of Drugs & Cosmetic samples received from the Drugs Inspectors of CDSCO and O/o Assist. Drugs Controller (India), IGI Airport, Delhi.

8. Indian Pharmacopoeia Commission (IPC)

Indian Pharmacopoeia Commission (IPC) 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. The set of standards are published under the title Indian. Pharmacopoeia (IP) which has been modelled on and historically follows from the BritishPharmacopoeia. The standards that are in effect since 1 December 2010, are the Indian Pharmacopoeia 2010 (IP 2010). The Pharmacopoeia 2014 was released by Health. Minister Ghulam Nabi Azad on 4 November 2013.[5] The Pharmacopoeia 2018 was releasedby Secretary, Ministry of Health & Family Welfare, Government of India.

9. National Pharmaceutical Pricing Authority (NPPA)

The National Pharmaceutical Pricing Authority (NPPA) is a government regulatory agency that controls the prices of pharmaceutical drugs in India. National Pharmaceutical Pricing Authority (NPPA) was constituted vide Government of India Resolution dated 29th August 1997 as an attached office of the Department of Pharmaceuticals (DP), Ministry of Chemicals and Fertilizers as an independent Regulator for pricing of drugs and to ensure availability and accessibility of medicines at affordable prices.

Functions of NPPA

- To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.
- To deal with all legal matters arising out of the decisions of the Authority.
- To monitor the availability of drugs, identify shortages, if any, and take remedialsteps.
- To collect/ maintain data on production, exports and imports, market share of individual companies, the profitability of companies etc, for bulk drugs and formulations.
- To undertake and sponsor relevant studies in respect of the pricing of drugs/

pharmaceuticals.

- To recruit/ appoint the officers and other staff members of the Authority, as per rules and procedures laid down by the Government.
- To render advice to the Central Government on changes/ revisions in drug policy.
- To help the Central Government in parliamentary matters relating to the drugpricing.

APPLICATION SUBMITTED TO CDSCO

1. Investigational New Drugs Application (IND)

It's an application filled to the FDA in order to start clinical trials in humans if the drug was found to be safe from the reports of Preclinical trials.

2. New Drug Application (NDA)

If the clinical studies confirm that a new drug is relatively safe and effective, and will not pose unreasonable risks to patients, the manufacture files a New Drug Application (NDA), the actual request to manufacture and sell the drug in the United States.

3. Abbreviated New Drug Application (ANDA)

An ANDA is submitted to the FDA for the review and approval of a generic drug product. ANDAs are regulated by FDA's Office of Generic Drugs (OGD) and are considered abbreviated, as they generally are not required to include pre-clinical (animal) and clinical (human) data to establish safety and effectiveness.

4. Import Drug Licence

Any dealer importing the products for the manufacturing of drugs or is engaged in thebusiness of importing drugs in India shall obtain this license.

5. Loan Drug Licence

Licence issued to an applicant or business that does not own the manufacturing unit but uses the manufacturing facilities of another licensee.

6. Multi Drug Licence

Multi-Drug license is acquired by the entity operating in more than one state having multiple units.

7. Retail Drug License

This license is obtained by retailers engaged in the business of pharmaceuticals, stand-alone

pharmacists, etc. by applying to the State Pharmacy Council.

8. Wholesale Drug License

Wholesalers doing the business of pharmaceuticals shall obtain wholesale drug license from the central drugs standard control organization. Wholesale drug license specifies certain minimum requirement on the person applying for this license such as: -Degree and diploma inpharmacy.

9. Restricted Drug License

The license for restricted sale of drugs other than those specified in schedule C, C1 and X are issued in the form.

UNITED STATES OF AMERICA

The United States Food and Drug Administration (FDA or USFDA) is a federal agency of the Department of Health and Human Services.

The FDA is led by the Commissioner of Food and Drugs, appointed by the President with the advice and consent of the Senate. The Commissioner reports to the Secretary of Health and Human Services. Robert M. Califf is the current commissioner, as of 17 February 2022.

The FDA has its headquarters in unincorporated White Oak, Maryland. The agency also has 223 field offices and 13 laboratories located throughout the 50 states, the United States Virgin Islands, and Puerto Rico. In 2008, the FDA began to post employees to foreign countries, including China, India, Costa Rica, Chile, Belgium, and the United Kingdom.

The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-thecounter pharmaceutical drugs (medications), vaccines, biopharmaceuticals blood transformation, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.

The FDA's primary focus is enforcement of the Federal Food, Drug, and Cosmetic Act (FD&C), but the agency also enforces other laws, notably Section 361 of the Public Health Service Act, as well as associated regulations. Much of this regulatory-enforcement work is not directly related to food or drugs, but involves such things as regulating lasers, cellular phones, and condoms, as well as control of disease in contexts varying from household pets

to human sperm donated for use in assisted reproduction**.**

ORGANIZATIONAL STRUCTURE OF USFDA

Department of Health and Human Services

- Food and Drug Administration
- Office of the Commissioner
- Office of Operations
- Office of Equal Employment Opportunity
- Office of Human Resources
- Office of Finance, Budget and Acquisition
- Office of Information Management and Technology
- Office of Informatics & Technology Innovation
- Office of Information Management
- Office of Security Operations
- Office of Facilities Engineering and Mission SupportServices
- Centre for Biologics Evaluation and Research (CBER)
- Centre for Devices and Radiological Health (CDRH)
- Centre for Drug Evaluation and Research (CDER)
- Centre for Food Safety and Applied Nutrition (CFSAN)
- Centre for Tobacco Products (CTP)
- Centre for Veterinary Medicine (CVM)
- Oncology Centre of Excellence (OCE)
- Office of Regulatory Affairs
- Office of Clinical Policy and Programs
- Office of External Affairs
- Office of Food Policy and Response
- Office of Minority Health and Health Equity
- Office of Policy, Legislation, and International Affairs
- Office of the Chief Scientist
- Office of Women's Health
- National Centre for Toxicological Research (NCTR)

1. Commissioner of Food and Drugs

The United States Commissioner of Food and Drugs is the head of the Food and Drug

Administration (FDA), an agency of the United States Department of Health and Human Services. The commissioner is appointed by the president of the United States and must be confirmed by the Senate. The commissioner reports to the Secretary of Health and Human Services.

2. Center for Biologics Evaluation and Research (CBER)

CBER is the Centre within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. CBER protects and advances the public health by ensuring that biological products are safe and effective and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products.

3. Center for Devices and Radiological Health (CDRH)

The Centre for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiationemitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providingindustry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

4. Centre for Drug Evaluation and Research (CDER)

The Centre for Drug Evaluation and Research (CDER) performs an essential public healthtask by making sure that safe and effective drugs are available to improve the health of people in the United States.

As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines. For example, fluoride toothpaste, antiperspirants, dandruff shampoosand sunscreens are all considered drugs.

5. Centre for Food Safety and Applied Nutrition (CFSAN)

The Centre for Food Safety and Applied Nutrition, known as CFSAN, is one of six product oriented centres, in addition to a nationwide field force, that carry out the mission of the Food

and Drug Administration (FDA). FDA is a scientific regulatory agency responsible for the safety of the nation's domestically produced and imported foods, cosmetics, drugs, biologics, medical devices, and radio-logical products.

The Centre provides services to consumers, domestic and foreign industry and other outside groups regarding field programs; agency administrative tasks; scientific analysis and support; and policy, planning and handling of critical issues related to food and cosmetics.

6. Centre for Tobacco Products (CTP)

The Centre for Tobacco Products (CTP) was established by the United States Food and Drug Administration as a result of the Family Smoking Prevention and Tobacco Control Act signed by President Obama in June 2009. The FDA centre was responsible for the implementation of the Family Smoking Prevention and Tobacco Control Act.

The smoking prevention and tobacco law established regulatory controls for tobacco products.

- Setting performance standards for tobacco products.
- Reviewing premarket applications for new and modified risk of tobacco product.
- Requirement of warning labels for tobacco products.
- Enforcing advertising and promotion restrictions for tobacco products.

7. Centre for Veterinary Medicine (CVM)

The Centre for Veterinary Medicine (CVM) is a branch of the U.S. Food and Drug Administration (FDA) that regulates the manufacture and distribution of food, food additives, and drugs that will be given to animals. These include animals from which human foods are derived, as well as food additives and drugs for pets or companion animals. CVM is responsible for regulating drugs, devices, and food additives given to, or used on, over one hundred million companion animals, plus millions of poultry, cattle, swine, and minor animal species. Minor animal species include animals other than cattle, swine, chickens, turkeys, horses, dogs, and cats.

CVM monitors the safety of animal foods and medications. Much of the centre's work focuses on animal medications used in food animals to ensure that significant drug residues are not present in the meat or other products from these animals.

8. Oncology Centre of Excellence (OCE)

The Oncology Centre of Excellence (OCE) was authorized by the 21st Century Cures Act of

2016 and established on January 19, 2017. The Centre unites experts across the FDA to conduct expedited review of medical products for oncologic and hematologic malignancies. The OCE also leads a variety of research and educational outreach projects and programs to advance the development and regulation of medical products for patients with cancer.

9. National Centre for Toxicological Research (NCTR)

The National Centre for Toxicological Research (NCTR) is the branch of the United States Food and Drug Administration which conducts research to define biological mechanisms of action underlying the toxicity of products regulated by the FDA. Dr. William Shakespeare, Jr. has been the NCTR Director since 2005.

The FDA toxicological research facility is geographically adjacent to the Pine Bluff Arsenal, and was once an integrated part of the installation. The U.S. Army used the facility for biological warfare research and chemical weapons development until 1969, when President Richard Nixon signed an executive order banning such research from federal facilities, and the Army subsequently transferred operation of the site to the FDA.[3] The NCTR was established by executive order in 1971.

APPLICATION SUBMITTED TO USFDA

1. Investigational New Drugs Application (IND)

It's an application filled to the FDA in order to start clinical trials in humans if the drug was found to be safe from the reports of Preclinical trials.

2. New Drug Application (NDA)

If the clinical studies confirm that a new drug is relatively safe and effective, and will notpose unreasonable risks to patients, the manufacture files a New Drug Application (NDA), the actual request to manufacture and sell the drug in the United States.

3. Abbreviated New Drug Application (ANDA)

An ANDA is submitted to the FDA for the review and approval of a generic drug product. ANDAs are regulated by FDA's Office of Generic Drugs (OGD) and are considered abbreviated, as they generally are not required to include pre- clinical (animal) and clinical (human) data to establish safety and effectiveness.

4. Biologic License Application (BLA)

Biological products are approved for marketing under the provision of the Public Health

Service (PHS) Act.

The Act requires a firm that manufacturing a biologic for sale in interstate commerce to hold a licence for the product.

A biologic licence application is a submission that contains specific information on the manufacturing process, chemistry, pharmacology, clinical pharmacology, and the medical effects of the biologic product.

If the application approved by the USFDA then a licence is issued allowing the firm to market the products.

Examples of biologic product are vaccines, blood and blood products, cellular and gene therapy products, allergenic, etc.

SUMMARY

Drug Regulatory Agencies in pharmaceutical industry and company its aim to protects the 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 isto diagnose, prevent or treat diseases or ailments in humans, they are products intimately linked with the advances in research and regulation.

Drugs play a major role in saving lives, maintaining health, preventing diseases, stopping epidemics and in improving economy of a country. Therefore, people, government, pharmaceutical industries and research institutes spend money on drugs. However, in order to do so, drug must be safe, effective and of good quality.

The pharmaceutical industry, while pursuing an international market, is obliged to complywith national regulations. So, in this project report, an overview of few drugs regulatory agencies of four countries: India and USA are 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.

CONCLUSION

Here, I have come to the end of the project on the topic "Drugs Regulatory Agencies Indiaand USA''.

The regulatory agencies in india, represented by the central drugs standard control organization (CDSCO), and the united states, through the food and drug administration (FDA), respectively, play pivotal roles ensuring the safety, efficacy, and quality of pharmaceuticals within there jurisdictions. This agencies serve as guardians of public health, imploying comprehensive regulatory frame work to oversee various aspects of the drug development and distribution process.

similarly, the FDA in the united states operates with mission to protect and promate the public health by ensuring the safety American consumers. the FDA's multifaceted approach involves rigorous evaluation of drug submissions, enforcement of stringent manufacturing practices (GMP),and continuous monitoring of drug safety once products are on the market.the agency plays a crucial roles in disseminating accurate information to healthcare professionals and the public,empowering individuals to make informed decisions about the healthcare.

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