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DRUG REGULATORY AFFAIRS: AN INSIGHTS ON REGULATORYAUTHORITIES OF VARIOUS COUNTRIES

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India.

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ABSTRACT

Current constrain of Regulatory Affairs reveals diverse countries need to follow different regulatory requirements for Marketing Authorization Application (MAA) approval of new drugs. Every country has its own regulatory authority which is responsible to enforce the rule sand regulations and issue the guidelines to regulate the marketing of the drugs. Once a lead drug molecule has been discovered, non clinical studies of a drug should be conducted to efficacy and safety. Then, clinical trials can be performed, after an application is submitted to competent authority of the concerned country. The three phases of clinical trials are conducted as per the protocol. The competent authority reviews an application submitted to get approval for marketing the drug and approves it if satisfied that the drug supports quality, safety and efficacy concerns. Even after the approval of new drug, government should monitor its safety by post marketing surveillance which is considered as Phase IV. Though certain aspects of drug approval process are similar among different countries, some differences do occur. In this present exertion study expresses the drug approval process and regulatory requirements according to US Food and Drug Administration (UDFDA), European Medical Agency (EMA) and Central Drug Standard Control Organization (CDSCO), Therapeutic Goods Administration (TGA), Ministry of Health, Labor and Welfare (MHLW), State Food and Drug Administration (SFDA), Health Canada. This review out lines advances in therapy and the mains pot light for the improvement and advance of cell therapies that are being confronted today. This project focuses on history, regulatory policy and administration, and related issues with respect to different countries like India, Japan, China, Europe, US, Australia, Brazil and Canada.

KEYPOINTS: Regulatory Requirements:-USFDA, CDSCO, TGA, MHLW, SFDA, EMA,

ANVISA.

INTRODUCTION

The Indian pharmaceutical industry is one of the fastest growing industries in India, With a compounded annual growth rate (CAGR) Of over 13 % in last 5 years and it is expected to grow at a higher rate in more becoming 10 years.[1] As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive these are realizing that the real battle of survival lies in executing the work by understanding the guide lines related to various activities carried out to give an assurance that the process is under regulation .Pharmaceutical Industry, being one of the highly regulated industries, is in immense need of people than ever before Who are capable of handling issues related to regulatory affairs in a comprehensive manner.[2] Regulatory Affairs (RA), also called as Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. A regulatory affair (RA) also has a very specific meaning within the health care industries (pharmaceuticals, medical devices, Biologic sand functional foods). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of regulatory affairs (RA) professionals. The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents.[3] Pharma regulatory affairs professionals play an essential role in ensuring all pharmaceutical products comply with regulations governing the industry.[4] Those working in pharma regulatory affairs jobs not only work in the initial application phase for a new or generic drug, but also in the licensing and marketing stages — making sure all operations and products meet required safety and efficacy standards.[5]

Organisations such as the FDA also provide roles for those interested in working in the field. As biotechnology plays increasing role within drug development and the pharmaceutical industry, growing numbers of biotech regulatory affairs positions are copening up.[6]

LITERATURE SURVEY

“A regulation may be defined as any instrument by which governments, their subsidiary bodies, and supranational bodies (such as the EU or the WTO) set requirements on citizens and businesses that have legal force. The term may thus encompass a wide range of instruments: from primary laws and secondary regulations to implement primary laws, subordinate rules, administrative formalities and decisions that give effect to higher level

regulations (for example, the allocation of permits), and standards. Regulations may emanate from non-governmental or self-regulatory bodies to which governments have delegated regulatory powers."[7]

Presents a powerful and clear taxonomy of regulatory tools of government within which we can start to understand the complex nature of regulatory environments. It is this frame work we use to help unpack the regulatory tool environment.

1. **Economic Regulation:-** This form of regulation is one requiring intervention in markets to safeguard and protect the public interest as a result of market failure (Stigler1971; OECD2001, 2010).This occurs when the price mechanism that regulates supply and demand will not be sufficient to deliver politically desired outcomes equitably and efficiently. Here, natural monopolies and external costs such as environmental externalities are the most prominent types of market failure. The most common interventions by government may be to introduce taxes or outcome conditioned payments, create missing markets (such as markets in pollution), break-up or regulate monopolies (or punish collusion), improve information flows, or take over provision of public goods or essential services that otherwise would be under-provided.
2. **Transactional regulation:- This** is becoming increasingly significant in the extensive use of privatisation and contractuallisati on in the delivery of public policy. In the Localism Act (2011) for example, they are seen as key mechanisms of delivering the public interest. Freiberg (2010) defines this as "regulation that occurs through the direct interaction between parties via a contract, grant agreement or other financial arrangement under which the parties have a right to enter into the arrangement or negotiate its terms"
3. **Authorization as Regulation**:-This form of regulation is perhaps the old estandisseen as a token of trust to enable citizens to get on with their daily lives (Freiberg 2010). This is designed to protect the public interest by the state authorising particular activities, premises or products through a range of tools associated with licensing permission, registration, certification, accreditation and litigation.
4. **Structural Regulation**:- Structural regulation refers to tools that are designed to produce regulatory outcomes by removing or limiting choice and structuring behavior in such away that people have no choice at all but to act in accordance with the desired regulatory pattern or face sanctions. Here, the focus is then on designing the regulatory environment in which people operate. This has close linkages with legal regulation.

5. Informational regulation:- Information is an indirect tool of regulation in enabling people to make improved decisions. For example, disclosure (e.g. fat content in food)and performance indicators (e.g. number of planning applications approved) all both part of an increasing and popular regulatory trend as regulatory support tools which provide a mechanism to help people reach particular decisions or policy directions (e.g. a Strategic Environmental Assessment supports the analysis of options for a particular plan, policy or programme – ensuring that environmental factors can be properly weighed in the final considerations).

6. Legal regulation:-Legal regulation reflects the traditional view of regulation as legislation. However, it is evident that regulation is far more than law, but law is a major form of regulation because it is a system of rules backed by sanctions. These work with structural regulation as Levers of control which favour the use of standards (for example, emission, product controls, process and equipment standards), planning and building controls (referred to as Building Regulations). Standards seek to ensure that minimum requirements are complied with as a means of regulating performance across a particular sector for example or area. Whilst standards do provide 'adequate' solutions, they are often constrained to limiting 'negative' aspects of a particularly activity rather than promoting good practice. They can also direct behaviour in a restricted way based on their intended primary function. For example, building regulations, with their focus on safety, have been criticised for a lack of emphasis on quality.

7. Use of Ecosystem Approach and Ecosystem services:-There is significant interest in the potential role of ecosystem services within regulatory tools. The incorporation of the ecosystem approach and ecosystem services into policy, for example the UK's Natural Environment White Paper, EU Biodiversity Strategy and the International Convention on Biological Diversity ,represents a vanguard of efforts to increase consideration of these issues within governmental actions and ultimately within regulation. As a result, they are becoming integrated into regulatory tools (Baker et al. in press).The break down into supporting, regulating, provisioning and cultural ecosystem services means that the environment can be more effectively incorporated into decision-making and this taxonomy helps improve the value component which has suffered under market failure conditions in decision-making.[8]

OBJECTIVE

RATIONALE

In the first place, 'regulation' is the jurisdiction of human and communal conduct by dint of

rules and precincts. The expression regulation' not been quite novel to industries like pharmaceuticals and biotechnology. The code of practice and laws that preside over the pharma business were taken on board in interest of shielding the consuming populace by struggling to supply drugs of uniform or reliable quality, efficacy and safety. Interestingly the prominence of the regulation and regulatory affairs professional are the intention of this article.

Industries like pharma, biologics, food and medical equipment earl be uncertain if the new products and methods are not tested and checked for functionality with great vigilance before being publicised. The first and foremost factor for the pharma sector has been always in the time and occupied by the drug candidate to see the light of the day which is very in-dispensable for the product's success and for the pharma companies. Therefore, effective administration and superintendence of regulatory affairs actions plays a crucial job towards economy of the corporation.

STUDY OBJECTIVES

1. To determine whether a regulatory function exists, how it is carried out and what financial and human resources are available for its implementation.
2. To identify the strengths and weaknesses of drug regulation.
3. To pro pose strategies that can help policy maker sand implementers to improve drug regulation.
4. To map the legal and organizational structures of drug regulation in selected countries.

PLAN OF WORK

PLANOFWORK

- Pharmaceutical regulatory affairs and its importance.
- Regulatory department and professionals.
- Different important regulatory acts.
- Regulatory authorities of different countries.
- A Comparative study on Drug Regulatory bodies In India, US,
- European Union (EU) and Japan.
- Explanation of some important terms in regulatory affairs.

REGULATORY AUTHORITY IN DIFFERENT COUNTRIES

USA

The Food and Drug Administration (FDA or U.S.FDA) is a federal agency of the United States Department of Health and Human Services. The U.S. FDA was empowered by the United States Congress to enforce the Federal Food, Drug, and Cosmetic Act. U.S.FDA also enforces other laws such as; Public Health Service Act and associated regulations, many of which are not directly related to food or drugs. The U.S.FDA has its headquarter at White Oak Mary land. The agency also has 223 field offices and 13 laboratories located throughout the 50 states. In 2008, the U.S.FDA started opening offices in foreign countries including; China, India, Chile, Belgium, and the United Kingdom.[9]

An agency within the U.S. Public Health Service, which is a part of the Department of Health and Human Services Agency monitors the manufacture, import, transport, storage and sale of Medicines, medical devices. biological products & radiation-emitting devices. The Federal Food and Drugs Act 1906 was starting point for eventual creation of Food and Drug Administration (FDA). Originally The Bureau of Chemistry was used to regulate food safety, however in 1927, it was reorganized into the Bureau of Chemistry and Soils and Food, Drug and Insecticide Administration. In 1930, the current Food and Drug Administration (FDA)came into effect after shortening of earlier organization. Since the root of FDA was bom in1906, FDA still celebrates 1906 as its establishment year. From the above act, regulatory control on food and drug has increased drastically. However Sulfanilamide Elixir tragedyraisedconcernaboutthesafetyofdrugproducts. In 1938, more than 100 people were died due to diethylene glycol (highly toxic solvent) utilized for mixing Sulfanilamide drug. Consequently, the law was enacted as Food, Drug and Cosmetic Act of 1938 too verse safety of medicine. With this law, pre-marketing approval of all new drugs was made mandatory and proof for scientific safety study was asked by FDA. This law also mandated the directions for safe use. Raising the bar of regulation, federal government issued a law for categorizing medicines as Over-The-Counter (OTC) drugs and Prescription drugs which was not in place earlier. As per this law, medicines for minor ailments i.e. indigestion, headache can be fall under OTC drugs and freely sold at pharmacy store without prescription. Major ailments drugs are "Prescription Only (RX)" and unsafe for self-medication. It was mandated to put statement a labelling as "Caution- Federal Law prohibits dispensing without a prescription". This law was known as Durham-Humphrey Amendment of 1951, best known as Prescription Amendment Act of 1951. Milestone changes happened on the basis of

Kefauver-Harris Drug Amendments 1962 This was the after effect of Thalidomide tragedy in Western Europe. As per this law, new drugs were required to be supported with efficacy as well as greater safety data, Good Manufacturing Practices (GMPs) and prior Marketing Authorization Approval was mandated by FDA in these amendments.[10] Drug regulations evolved rampantly in last five decades and many laws came into effect which resulted into organized regulatory structure of FDA. The agency grew from single chemist from United Stated Agriculture Department (USAD) to approximately 9100 employees of varied category i.e. physicians, pharmacologists, chemists, microbiologists, pharmacists, veterinarian and law yers. Currently, agency is responsible for protecting the public health by assuring the safety, effectiveness and security of human and veterinary drugs. It regulates over 1 trillion dollars worth of products in New Human Drug, Biologics, Biologics, Complex Medical Devices, Food and Colour Additives, Infant formulas and Animal Drugs.

USFDA

The U. S. Food and Drug Administration (FDA or USFDA) is a regulatory agency within the U. S. department of health and human services, one of the united states federal executive departments. Headquarter - Silver Spring, maryland, united states. established-24 June 1938. The USFDA is responsible for protecting and promoting public health through the regulation supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products and cosmetics.[11]

MISSION

To promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner. With respect to such products, protect the public health by ensuring that the food are safe, Whole some, sanitary, and properly labelled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labelled, and public health and safety are protected from the electronic product radiation. Participates through appropriate process with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.[12]

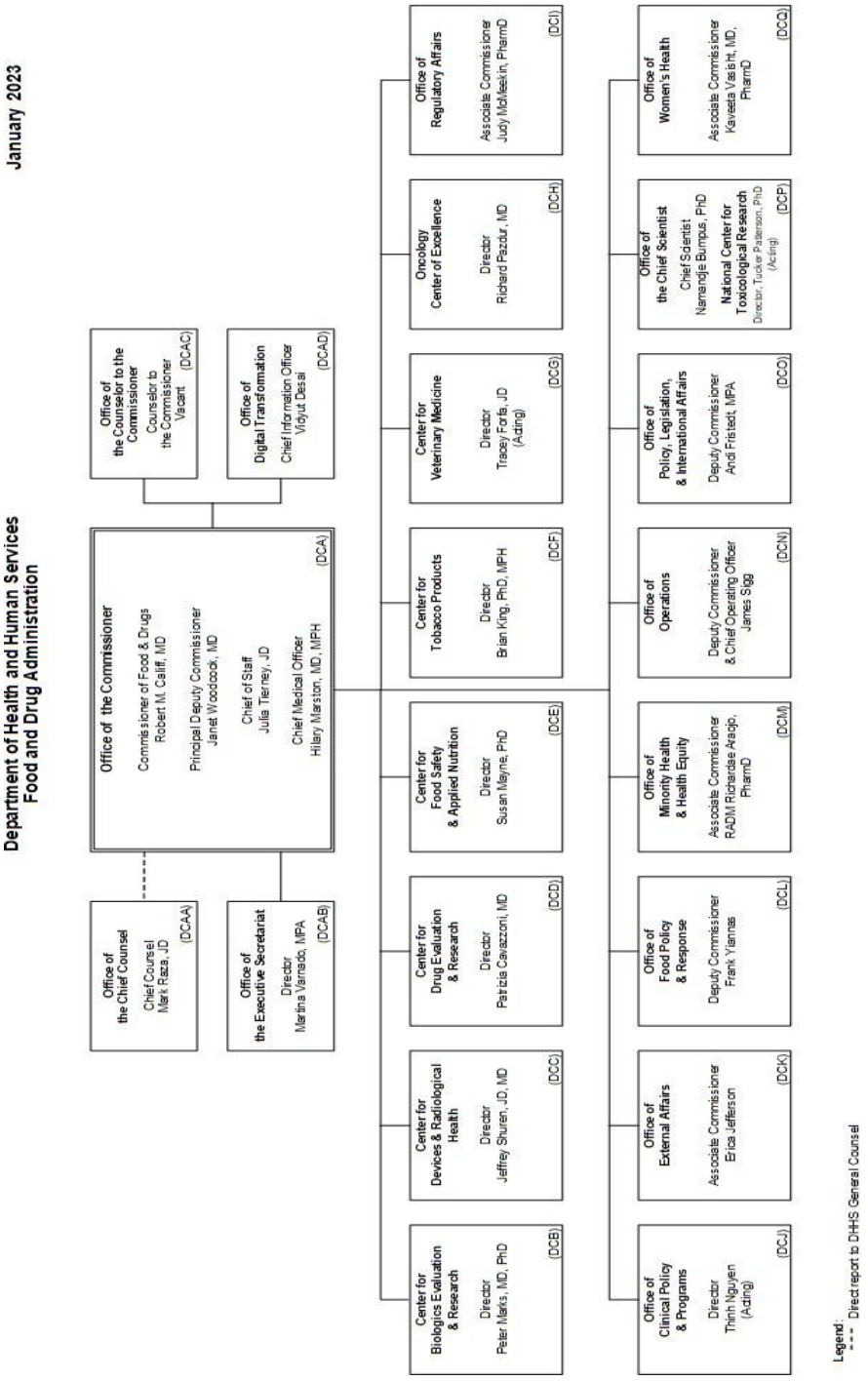
US-FDA Organization Structure

The US 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.

1. The Office of the Commissioner (OC)
2. The Center for Drug Evolution and Research(CDER)
3. The Center for Biologics Evolution and Research (CBER)
4. The Center for Foods Safety and Applied Nutrition (CFSAN)
5. The Center for Devices and Radiological Health(CDRH)
6. The Center for Veterinary Medicine (CVM)
7. The National Center for Toxicological Research (NCTR)
8. The Office of Regulatory Affairs (ORA)

The U.S. FDA consists of employees drawn from a wealth of science and public health professions biologists, physicians, chemists, biomedical engineers, toxicologists, pharmacologists, veterinarians, and specialists in public health education and communication.

U.S. FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics, and products that emit radiation.[13,14]



US-FDA Guidelines

Part of title21CFR

Part of 58: Good laboratory practice for nonclinical laboratory studies. Part of 101:-Food labelling.

Part of 110:- Current good manufacturing practice in manufacturing, packing, or holding human food.

Part of 201:- Labelling.

Part of 312:- Investigational new drug application.

Part Of 314:-Applications for FDA approval to market new drug.

Part of 328:- Over - the – counter drug products intended for oralingestion that contain alcohol.

Part of 331:- Antacid products for over-the-counter (OTC) human use.

Part of 341:-Cold, cough, allergy, bronchodilator, and antiasthmatic drug products forover-the-counter human used.

Part of 600:-Biological products: general. Part of 820:- Quality system regulation.

Part of 892:-Radiology devices.

Part of 1392:-Registration of manufacturers, distributors, importers and exporter so flist.[15]

Europianunion

The International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation (ICH) held the inaugural Assembly meetings on 23 October 2015 establishing ICH as an international association, a legal entity under Swiss law. This step built upon a 25-year track record of successful delivery of harmonised guidelines for global pharmaceutical development as well as their regulation, and a longer standing recognition of the need to harmonise. Europe moved towards the development of a single market for pharmaceuticals. The success achieved in Europe demonstrated that harmonisation was feasible. At the same time there were discussions between Europe, Japan and the US on possibilities for harmonisation. It was, however, at the WHO Conference of Drug Regulatory Authorities (ICDRA), in Paris, in 1989, that specific plans for action began to materialise. So on after wards, the authorities approached International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) to discuss a joint regulatory-industry initiative on international harmonisation, and ICH was conceived.[16,17]

FUNCTIONS

1. To make recommendations towards achieving greater harmonisation in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration and the maintenance of such registrations;
2. To maintain a forum for a constructive dialogue on scientific issues between regulatory authorities and the pharmaceutical industry on the harmonisation of the technical requirements for pharmaceutical products;
3. To contribute to the protection of public health in the interest of patients from an

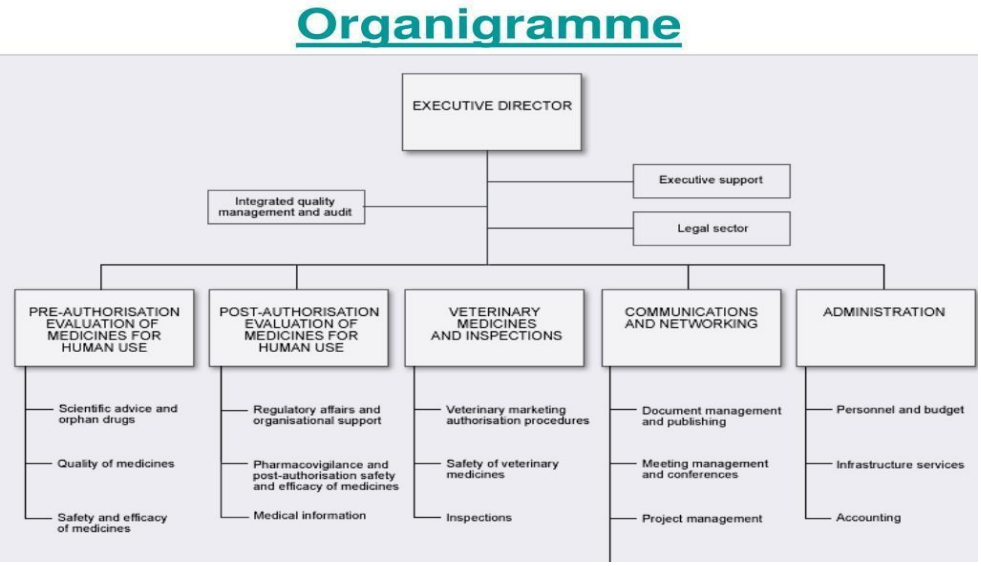
international perspective;

4. To monitor and update harmonised technical requirements leading to a greater mutual acceptance of research and development data;
5. To avoid divergent future requirements through harmonisation of selected topics needed as a result of therapeutic advances and the development of new technologies for the production of medicinal products;
6. To facilitate the adoption of new or improved technical research and development approaches which update or replace current practices;
7. To encourage the adequate implementation and integration of common standards through the dissemination of, the communication of information about and coordination of trainingon, harmonised guidelines and their use;
8. And to develop policy for the ICH Medical Dictionary for Regulatory Activities Terminology (Med DRA) whilst ensuring the scientific and technical maintenance, development and dissemination of Med DRA as a standardised dictionary which facilitates hesaring of regulatory information internationally for medicinal products used by humans.

GUIDELINES

- Quality Guideline: Harmonisation achievements in the Quality area include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk management.
- Safety Guidelines: ICH has produced a comprehensive set of safety Guidelines to uncover potential risks like carcinogenicity, genotoxicity and reprotoxicity. A recent breakthrough has been a non-clinical testing strategy for assessing the QT interval prolongation liability: the single most important cause of drug withdrawals in recent years.
- Efficacy Guideline: The work carried out by ICH under the Efficacy heading is concerned with the design, conduct, safety and reporting of clinical trials. It also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics /genomics techniques to produce better targeted medicines.
- Multidisciplinary Guideline: Those are the cross-cutting topics which do not fit uniquely into one of the Quality, Safety and Efficacy categories. It includes the ICH medical terminology (Med DRA), the Common Technical Document (CTD) and the development of Electronic Standards for the Transfer of Regulatory Information.[18]

Organization



INDIA

The Drug and Cosmetic Act 1940 and Rules 1945 were proclaimed by the India's parliament to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Central Drugs Standard Control Organization (CDSCO) and the office of its leader, the Drugs Controller General (DCGI) was established. In 1988, the Indian government added Schedule Y to the Drug and Cosmetics Rules1945. Schedule Y provides the guidelines and requirements for clinical trials, which was further revised in 2005 to bring it at par with internationally accepted procedure .When a company in India wants to manufacture/import a new drug it has to apply to seek permission from the licensing authority (DCGI) by filing in Form 44 also submitting the data as given in Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945.[4] In order to prove its efficacy and safety in Indian population it has to conduct clinical trials in accordance with the guide lines specified in Schedule Y and submit the report of such clinical trials in specified format.[19,20]

CDSCO

The Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and also has six zonal offices, four sub zonal offices, thirteen. Port office sand seven laboratories spread across the country. The Drugs & Cosmetics Act, 1940 and rules 1945 haveen trusted various responsibilities to central & state regulators for regulation of drugs & cosmetics. It envisages uniform implementation of the provisions of the Act &

Rules made there under for ensuring the safety, right sand well being of the patients by regulating the drug sand cosmetics.[21] CDSCO is constantly thriving upon to bring out trasparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country. Under the Drug sand Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the equaily of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expertad vice with a view of bring about the uniformity in then for cement of the Drugs and Cosmetics Act. Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.[22]

Vision:-To Protect and Promote public health in India.

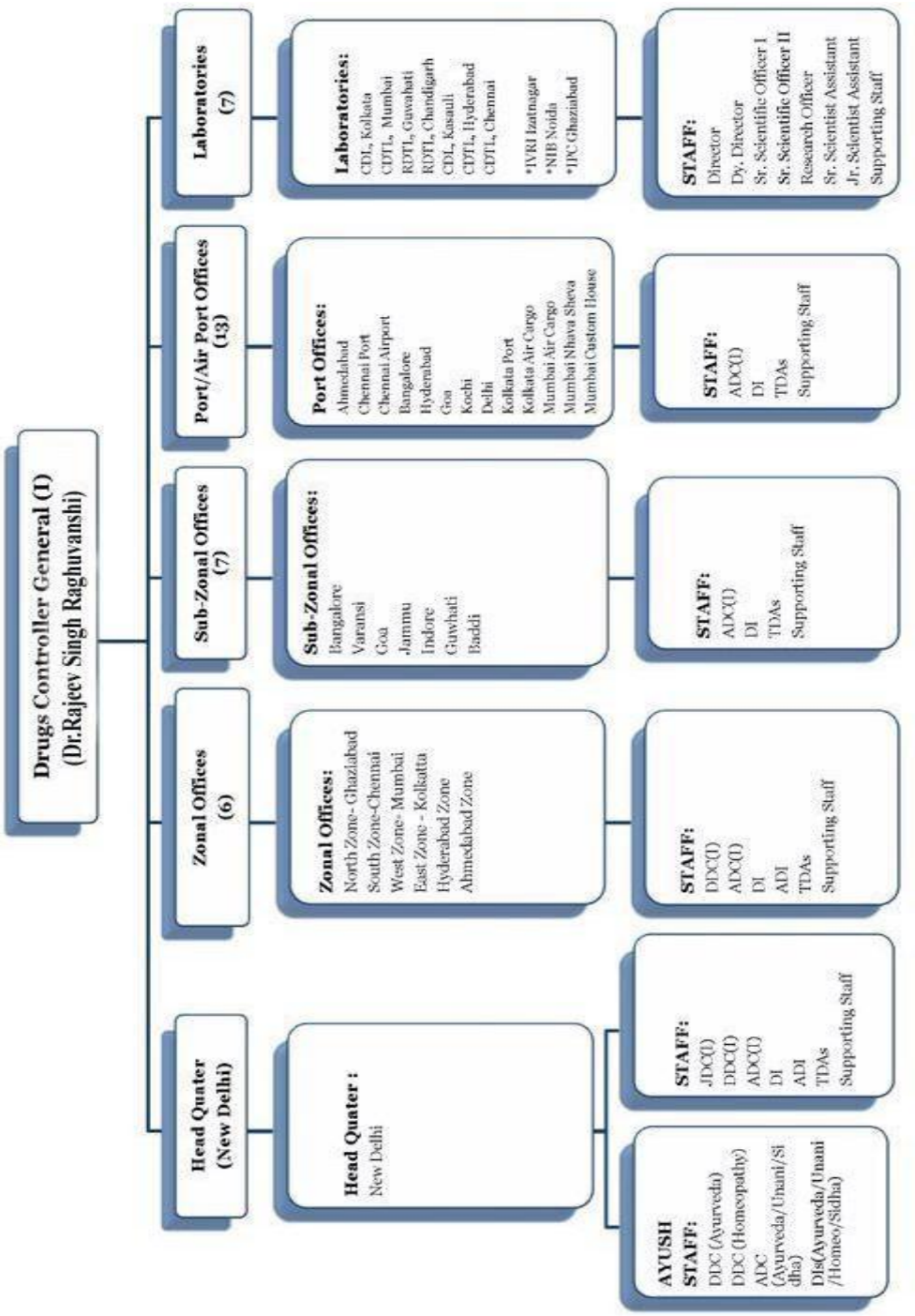
Mission:-To safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.

Function and duties

1. Scrutiny of the Bills of entry with a view to ensure that the imported drugs comply with the provisions of Chapter III of the Drugs & Cosmetic Act and Rules there under and Drugs and Magic Remedies (Objectionable Advertisements) Act and Rules & Narcotic Drugs and Psychotropic Substances Act (NDPS) & Rules there under and any other law for the time being in force.
2. To check the shipping bills for export for compliance of Drugs & Cosmetics Act and keep control under Narcotic Drugs and Psychotropic Substances Act & Rules.
3. In the case of Narcotic Drugs and Psychotropic Substances Act & Rules, a certificate issued by Narcotics commissioner must be checked for import / export and details furnished to Drugs Controller General (India) through the Deputy Drugs controller (India) of the respective Zones.
4. To ensure that no New Drug is imported into the country unless its import permitted by the Drugs Licensing Authority under Rules (Rules 122 A & 30-AA).
5. To ensure that small quantities of drugs imported for Test, Examination and Analysis or clinical trials or for personal use are duly covered by Test License (11or 11-A) or Permit Licenseas (12 B) as the case may be.
6. Maintenance of Statistics data regarding imports /export fall Drugs/ cosmetics/ medical

devices and submit the same on monthly basis to the Deputy Drugs Controller (India) of the respective zones and to other authorities as and when required. (7) Co-ordination with the Commissioner of Customs –The Port Officers should have enough knowledge of the relevant portions for Customs Act and DGFT policies.

7. Import of raw materials under Advance Licenses/100% EOU cases must being mated to the concerned State Drugs Controller to examine proper post-import check with a copy marked to the DDC(I) of the concerned Zone.
8. Assist members of the trade with the information required.
9. Preparation and forwarding of Quarterly and Annual Reports.
10. Examination of post parcels couriers for import and export of drugs, cosmetics and medical devices.
11. Coordination with the customs and other investigating agencies for the matters of violation of import/export under intimation to the DDC (I) of the concerned zone.
12. To examine there-import /re-export consignment as per the procedures.
13. To draw samples from import/export and re-import consignment as per laid down procedures.
14. To examine unclaimed / seized cargo when referred by customs and offer opinion as per procedure laid down.
15. In case of drugs and cosmetics of not of standard quality /spurious, to be informed to all the port offices directly with a copy marked to the Deputy Drugs controller of the concerned zone.



DCGI

Drugs Controller General of India (DCGI) is the head of department of the Central Drugs Standard Control Organization of the Government of India responsible for approval of licences of specified categories of drugs such as blood and blood products, IV fluids, vaccines, and sera in India. Drugs Controller General of India, comes under the Ministry of Health & Family Welfare. DCGI also sets standards for manufacturing, sales, import, and distribution of drugs in India.

Function

1. Preparation and maintenance of national reference standard.
2. To bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.
3. Training of Drug Analysts deputed by State Drug Control Laboratories and other Institutions.
4. Analysis of Cosmetics received as survey samples from CDSCO (central drug standard control organization).

Indian Regulations & Guidelines

- CDSCO Central Drugs Standard Control Organization (CDSCO), Ministry of Health& Family Welfare, Government of India provides general information about drug regulatory requirements in India.
- NPPA Drugs (Price Control) Order 1995 and other orders enforced by National Pharmaceutical Pricing Authority (NPPA), Government of India. View the list of drug sunder price control here…..
- D & C Act, 1940 The Drugs & Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs in India.
- Schedule M Schedule of the D & C Act specifies the general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs.
- Schedule T Schedule T of the D & C Act prescribes GMP specifications for manufacture of Ayurvedic, Siddha and Unani medicines.
- Schedule Y The clinical trials legislative requirements are guided by specifications of Schedule Y of The D & C Act.
- G C P guidelines The Ministry of Health, along with Drugs Controller General of India (DCGI) and Indian Council for Medical Research (ICMR) has come out with draft guide lines for research in human subjects. These GCP guidelines are essentially based on Declaration of Helsinki, WHO guidelines and ICH requirements for good clinical practice.
- The Pharmacy Act, 1948 The Pharmacy Act, 1948 is meant to regulate the profession of Pharmacy in India.
- The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 provides to control the advertisements regarding drugs; it prohibits the advertising of remedies alleged to possess

magic qualities.

- The Narcotic Drugs and Psychotropic Substances Act, 1985 The Narcotic Drugs and Psychotropic Substances Act, 1985 is an act concerned with control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.[23]

JAPAN

The generic drug penetration in the country is expected to reach 60% in fiscal 2017, followed by 70% in fiscal 2025. Thus, generic drug companies could see opportunities in the Japanese markets. With the higher expected demand for generics, big pharma companies in the country are coming together to form joint ventures to cater to this demand. Japan is the second largest pharmaceutical market behind the United States and a highly developed country. It has been discovered that Japanese people are using multiple drugs with an especially high use of recently approved drugs. The patient awareness is now similar to that in the Western countries. Medicinal products represent over 20% of healthcare costs with about almost 50% in elderly patients. Therefore Japan becomes more and more attractive for the pharmaceutical industry. One of the biggest hurdles for the government is the "drug lag" problem due to the obligation to perform clinical bridging studies in Japan hand since clinical data obtained in non-Japanese trials such as EU and US studies cannot solely be used to obtain market approval in Japan. To minimize this "drug lag" the Japanese government is encouraging pharmaceutical companies to conduct simultaneous clinical development and include Japan in global clinical trials.[24]

MHLW

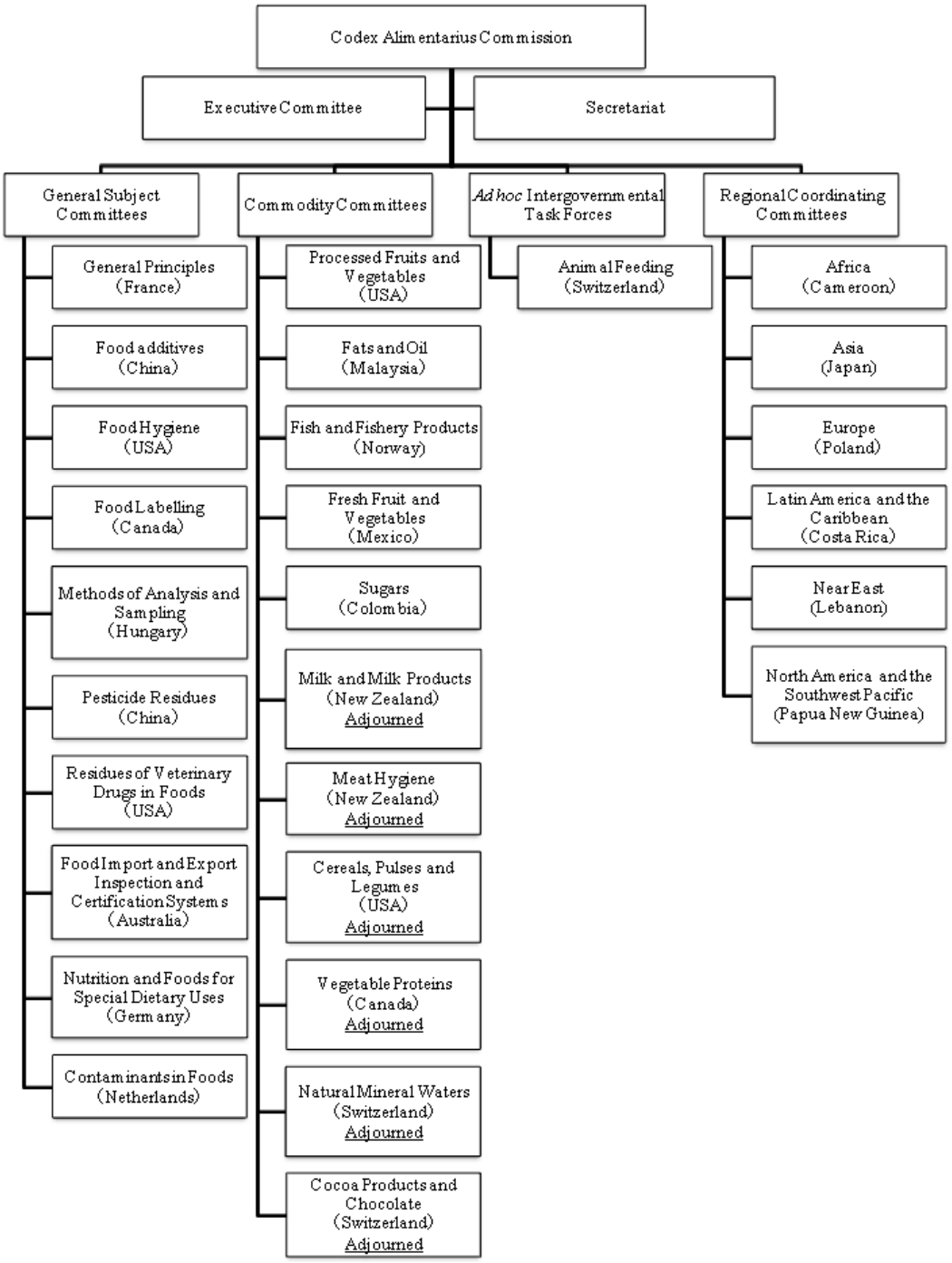
The Ministry of Health, Labor and Welfare (MHLW) is regulatory authority of the pharmaceutical regulatory affairs in Japan. Formal approvals and licenses are required to marketing drugs in Japan which are obtained from the MHLW. One of the 11 bureaus of the MHLW is the Pharmaceutical and Food Safety Bureau (PFSB). This bureau handles clinical studies, approval reviews and post-marketing safety measures.

Functions of MHLW

- To give a marketing approval.
- To issue a license for marketing authorization holder.
- To issue a manufacturer license.

Japan provides a public medical insurance system, which is carried on as a social insurance system covering all citizens. Through this insurance system, about 30% of the nation's medical expenses are covered by public funds, and all prices for medicine, including medical compensation for doctors and prices for new drugs are substantially controlled by the Japanese government. The Japanese government determines prices reimbursed by public medical insurance for each of preparations and standards of all drugs prescribed by doctors. There imbursement price of each drug is reviewed every two years and almost all reimbursement prices of drugs are reduced, including those of new drugs immediately after their release on to the market. On the other hand, among major advanced nations, only Japan has a system in which the prices of new drugs immediately after their release onto the market are reduced through political action. Japan has made significant progres in reforming and modernizing its drug and medical device approval process in recent years. Although approval times continue to lag behind those of other developed countries, the government has set ambitious goals and the PMDA and MHLW have made marked improvements. These gains, along with Japan's position as the world's second largest medical market, continue to make Japan a desirable place for foreign pharmaceutical companies and medical devices makers to do business.[25]

Organization Chart of Codex Alimentarius Commission



Guidelines

1. The principal investigator shall endeavor to secure the reliability of research and when carrying out research which involves invasiveness (not including minor invasiveness) and intervention, shall per form monitoring and as nesessary, audit, in accordance with the specifications pre scribed in there search protocol approved by the chief executive of there search implementing entity.
2. The principal investigator shall offer necessary instruction and management to those

engaged in monitoring or audit to ensure that such monitoring and audit will be appropriately carried out in accordance with the specifications prescribed in the research protocol approved by the chief executive of there search implementing entity.

3. The principal investigator shall not appoint those engaged in implementing 50 and monitoring of the research, which is subject to the audit, to execute such audit.
4. Those engaged in monitoring shall report to the principal investigator concerning results of the said monitoring. In addition, those engaged in audit shall report to the principal investigator and the chief executive of there search implementing entity concerning results of the said audit.
5. Those engaged in monitoring and those engaged in audit shall not disclose, without justifiable reason, any information obtained while performing their duties. The same shall apply even after they cease to been gaged the duties.
6. The chief executive of research implementing entity shall support the execution of monitoring and audit pursuant to the provisions of above and take relevant measures for the execution of such monitoring and audit.[26]

Australia

The Therapeutic Goods Administration (TGA) is part of the Health Products Regulation Group (HPRG) in the Australian Government Department of Health established in 1989. The TGA, through the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations, s responsible or the quality, safety, efficacy, and timely availability of drugs and medical devices in Australia. Prescription drug evaluation is one of many TGA functions. The TGA also regulates non prescription drugs, medical devices, and vitamin, nutritional and herbal products. New chemical entities and applications which require expert advice are referred to as the Australian Drug Evaluation Committee (ADEC). The ADEC can only make recommendations; the TGA makes the final decision to register a drug for use in Australia TGA is also responsible for other medications, including OTC medicines, alternative medicines, and medical devices. The drug regulation process in Australia is complex and resource-intensive.[27] TGA is accountable in terms of the quality, safety, and efficacy of drugs made available in Australia. This accountability includes an acceptance of a balance between safety and efficacy. As there is no such thing as a totally safe drug, and thus appropriate process must recognize the risk/benefit ratio of any particular drug. This requires a detailed evaluation of the data supplied by the company sponsoring an application. A drug may come to the attention of the TGA when a marketing application is received or when a

Australian clinical trial is being planned. For clinical trials, the sponsoring company submit preliminary data for evaluation to the TGA (CTX scheme) or notify the TGA (CT scheme) that the trial has been approved by an Institutional Ethics Committee (IEC).[28]

TGA

The TGA is responsible for conducting assessment and monitoring activities to ensure that therapeutic goods available in Australia are of acceptable standards. Established on 15 February 1991. The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods. They carry out arrange of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances. TGA regulates the quality, supply and advertising of medicines, pathology devices, medical.

Devices, blood products and most other therapeutic. any items that claim to have a therapeutic effect, are involved in the administration of medication, or are otherwise covered by the Therapeutic Goods Act 1989, the Therapeutic Goods Regulations 1990, or a ministerial order, must be approved by the TGA and registered in the Australian Register of Therapeutic Goods. The TGA also includes seven specialized statutory ommittees, which the agency can call upon for assistance on technical or scientific issues. Four other committees also exist to give guidance on annual influenza vaccines, industry consultation matters, and the Therapeutic Goods Advertising Code.[29]

Objective of TGA

1. To provide a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines and ensure the quality, safety and performance of medical devices.
2. Essentially therapeutic goods must been tered on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia.

Role of the TGA

The TGA carries out an overall control through five main processes

1. Pre-market evaluation and approval of registered product in tended for supply in Australia.
2. Development, maintenance and monitoring of the systems for listing of medicines.

3. Licensing of manufacturers in accordance with international standards of GMPs.

TGA structure

The TGA' s offices are grouped into following core groups.

1. TGA Executives.
2. Market Authorization Group (MAG).
3. Monitoring and Compliance Group (MCG).
4. Regulatory Support Group.
5. Office of Regulatory Integrity (ORI).

Organizational Structure of TGA

Health Products Regulation Group Executives are Deputy Secretary, Chief Medical Principal Legal and Policy Adviser, First Assistant Secretary Regulatory Practice and vision First Assistant Secretary, Medicines Regulation Division, First Assistant Medical Devices and Product Quality Division.

1. Medicines Regulation Division: The Medicines Regulation Division evaluates applications to approve new medicines for supply in Australia. The division is also responsible for monitoring medicines approved for supply in Australia after they are on the market. The division also includes

i. Prescription Medicines Authorization: Responsible for evaluating new medicines, leading to an approval or rejection decision.
ii. Complementary and OTC Medicines: Responsible for regulating OTC medicines as well as complementary medicines, which include traditional and herbal medicines, and vitamin and mineral supplements.
iii. Scientific Evaluation: Responsible for approving applications to market biological and generic medicines in Australia. The branch also provides scientific advice to support the decisions made by the Medicines Regulation Division, in particular evaluating the toxicological and pharmaceutical chemistry aspects of therapeutic products and provide expertise in the biological sciences.
iv. Pharmacovigilance and Special Access Branch: Oversight of medicines and vaccines to ensure they maintain an appropriate level of quality, safety, and efficacy followings the entry into the Australian market place. The branch also evaluates and authorizes certain clinical trials and special access arrangements for all types of therapeutic products.[30]

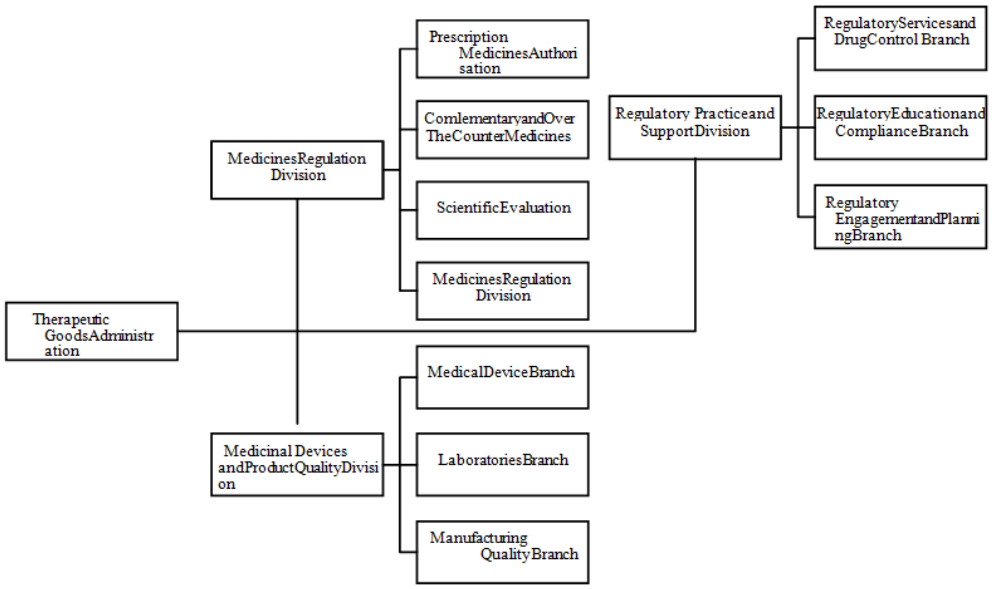
2. Medical Devices and Product Quality Division: The Medical Devices and Product Quality

Division monitor's medical devices approved for supply in Australia and works to ensure Australian and international therapeutic goods manufacturers meet specified standards. The Division includes:

i. Medical Devices Branch: Responsible for evaluating medical devices, including in vitro diagnostic tests, and monitoring them throughout their lifecycle to ensure they continue to meet an appropriate level of quality, safety, and performance.

ii. Laboratories Branch: Responsible for conducting laboratory testing, quality assessment, and test procedure development in scientific disciplines such as microbiology, immunebiology, molecular biology, biochemistry, chemistry, and biomaterials engineering. The branch also contributes to post-market monitoring and the evaluation of a range of therapeutic products for market authorization.

iii. Manufacturing Quality Branch: Responsible for ensuring manufacturers of medicines, as well as blood, tissue, and cellular therapies, meet appropriate quality Australia and a broad as well as the provision of clearances for facilities where standards. This involves both the physical inspection of manufacturing facilities in stable in sections have been carried out by comparable overseas regulators.[31]



China

The National Drug regulatory authority of China was state food and Drug administration (SFDA) which is under the control of ministry of health's department of Drug administration. The SFDA was founded by the Chinese ministry of health in March 1998, the SFDA was

previously known as state pharmaceutical administration of China, SFDA mainly oversees the Drug manufacturing, trading and registrations. The implementation of a single Drug regulatory authority was important step to direct foreign access; the SFDA also contains affiliated departments which plays a key role in Drug regulatory administration. The SFDA is uninterruptedly evolving by knowing its deficiency and it is trying to keep its standards according to the standards of EU, USA, and Japan Chinese regulatory authority is maintaining its protection of intellectual property, and also making its more efforts on regulatory clarity, Chinese regulatory authority is striving for emphasis on innovation, and to start progressing on Drug regulation, to ensure Safety and effective usage, SFDA is giving importance for developing innovative Drugs as well as generic Drugs (which are bioequivalent to that of innovator Drugs).[32]

The Chinese Drug regulatory authority SFDA was developed and modernized after the USFDA which is under the supervised control of ministry of health, the SFDA was established to restructure and replace state Drug administration (SDA), and the SFDA is an in charge for all Drug registrations and approvals. The SFDA has 5 affiliated units to coordinate the activities.[33]

Regulations

1. Study and formulate policies and development plans for the securities and futures markets; draft the relevant laws and regulations on the securities and futures markets as well as put forward suggestions for formulation or modification of the said laws and regulations; and work out the relevant rules, regulations and measures for the securities and futures markets
2. Exercise a vertical administration over the domestic securities and futures regulatory institutions and conduct a unified supervision over the securities and futures markets; and perform a regulatory supervision over the managements and the managerial officials of the relevant securities companies;
3. Supervise the issuance, listing, trading, custody and settlement of stocks, convertible bonds, bonds of securities companies, and bonds and other securities under the charge of CSRC as assigned by the State Council; supervise the securities investment bonds; approve the listing of corporate bonds; and supervise the trading of the listed treasury bond sand corporate bonds;
4. Supervise the securities market behaviors of the listed companies and their share holders

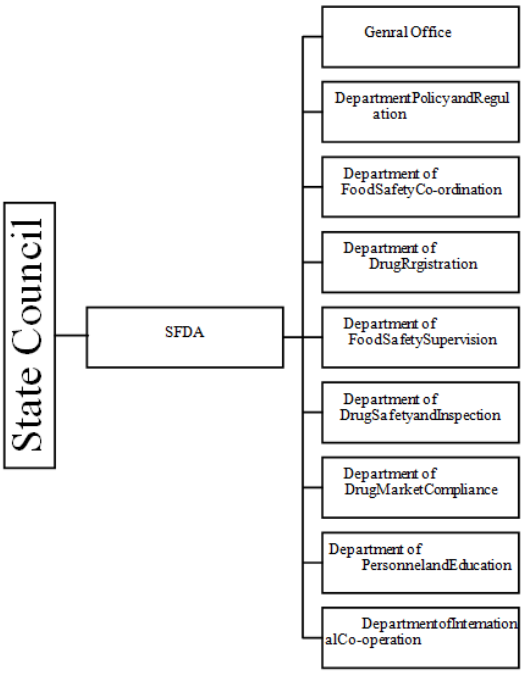
who shall fulfill the relevant obligations according to the relevant laws and regulations

5. Supervise the listing, trading and settlement of domestic contract-based futures; and monitor the overseas futures businesses of the domestic institutions in accordance with the relevant regulations
6. Supervise the securities and futures exchanges as well as their senior managerial personnel in accordance with the relevant regulations; and supervise the securities and futures associations in the capacity of a competent authority;
7. Supervise the securities and futures business institutions, securities investment fund management companies, securities depository and clearing corporations, futures clearing institutions, securities and futures investment consulting institutions, and securities credit rating institutions; examine and approve the qualifications of fund custodian institutions, and supervise their fund custody businesses; formulate and implement measures on the qualifications of senior management for the relevant institutions; and guide the Securities Association of China and the Futures Associations of China in the administration of the qualifications of the personnel engaged in securities and futures businesses;
8. Supervise the direct or indirect issuance and listing of shares overseas by domestic enterprises as well as the listing of convertible bonds by the companies listed overseas; supervise the establishment of securities and futures institutions overseas by domestic securities and futures business institutions; and supervise the establishment of securities and futures institutions in China by overseas institutions for securities and futures businesses;
9. Supervise the communication of the securities and futures information; and take charge of the management of the statistics and information resources for the securities and futures markets;
10. Work with the relevant authorities in the examination and approval of the qualifications of the accounting firms, the asset evaluation institutions and their personnel for securities and futures intermediary businesses; and supervise the law firms, the lawyers and the eligible accounting firms, the asset appraisal institutions and their personnel in their securities and futures business activities;
11. Investigate and penalize the activities in violation of the relevant securities and futures laws and regulations;
12. Administer the foreign exchanges and international cooperation affairs of the securities and future sector in the capacity of a competent authority
13. Perform other duties as assigned by the State Council.

Guidelines

A bunch of new guidance and guidelines has been published since the regulatory reform

- 2015.01 Multi-Regional Clinical Trial (Pilot)
- 2015.07 Announcement of Self-inspection on the Clinical Trial Data
- 2015.07 Adverse Drug Reaction Reporting and Monitoring
- 2016.02 Priority Review & Approval Procedure
- 2016.03 New Chemical Drug Registration Classification
- 2016.06 Biostatistics Principles for Clinical Trials
- 2016.06 Communications for Drug Development and Technical Evaluation (Trial)
- 2016.07 Electronic Data Capture for Clinical Trials
- 2016.07 Data Management Planning and Reporting of Statistical Analysis
- 2017.01 General Considerations to Clinical Trials for Drug
- 2017.05 Regulatory Data Protection (Draft for Public Comment)



BRAZIL

The Brazilian Health Surveillance Agency, commonly known as ANVISA, abbreviated from Portuguese "Agencia Nacional de Vigilancia Sanitaria," is the food and drug regulatory agency in Brazil. ANVISA was created in 1999 and is linked to the Ministry of Health. It is characterized by its administrative independence, financial autonomy, and the stability of its directors. In the federal public regulatory structure, the agency is connected to the Ministry of

Health. ANVISA's primary goal is to protect and promote public health, by exercising health surveillance over products and services, including processes, ingredients, and technologies that pose any health risks.

Mission:- "To protect and promote health, ensuring the hygiene and safety of products and service sand taking part in developing access to it."

The National Health Surveillance Agency was established in 1999 by president Fernando Henrique Cardoso.

Linked to the Ministry of Health, the agency coordinates:

- The National Sanitary Surveillance System.
- The National Program of Blood and Blood Products.
- The National Program of Prevention and Control of Hospital Infections.
- ANVISA is responsible for
- Monitoring drug prices
- Prices of medical devices
- Control and inspection of smoking products
- Technical support in granting of patents by the National Institute of Industrial Property.
- Protection of the health of the population by exercising sanitary control over production
- Marketing of products and services subject to sanitary surveillance, controlling ports airports and borders
- linked to the Brazilian Ministry of Foreign Affairs and foreign institutions over matters concerning international aspects of sanitary surveillance.[41]

ANVISA is a part of NSSS .National System of Sanitary Surveillance (NSSS) is an organization of Brazil whose responsibility is:-

– To keep a watch over certain professional activities
– To put as top to charlatanism
– To inspect ships, cemeteries and places where food was on sale to the public.

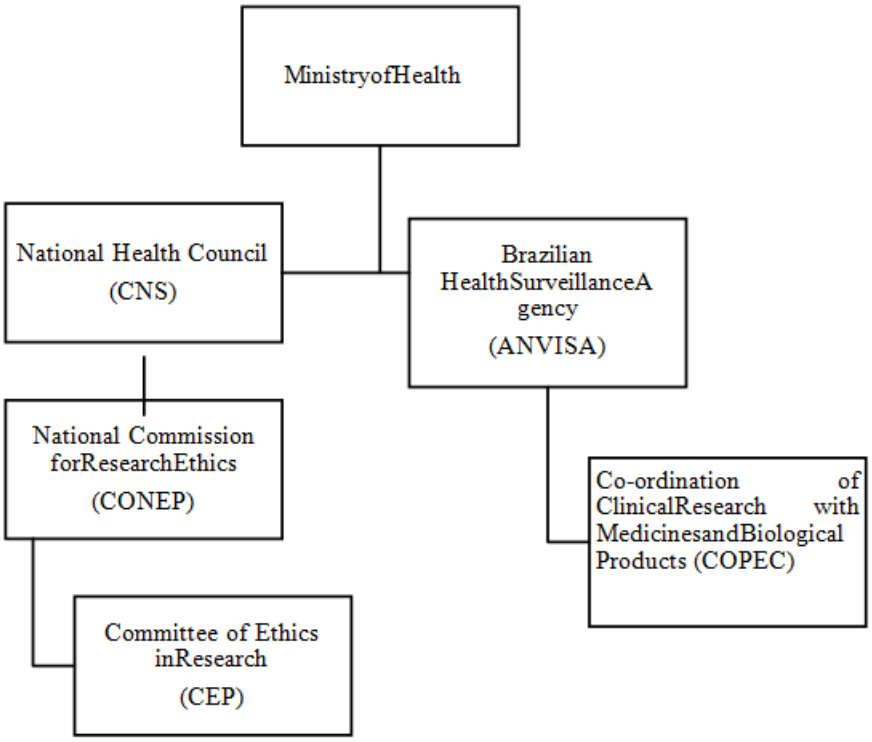
ANVISA's vision is to achieve legitimation in society as an integral part of the Brazilian Unified Health System, via a nimble, modern, transparent, and domestic and international bench mark in health surveillance and regulation. ANVISA's mission is "to protect and promote public health and to intervene in the risks caused by the production and use of products regulated by health surveillance. This mission must be carried out in coordination

with states, municipalities and the Federal District, according to the Brazilian Unified Health System principles, to improve the quality of life of the population." The agency is also responsible for health control in ports ,air ports ,and borders, as well as for establishing relations with the Ministry of International Affairs and with foreign organisms and institutions to deal with international affairs regarding health surveillance. ANVISA was accepted as a new regulatory member of the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). As part of the objective to extend itsglobaloutreach,ICH,inNovember2016, welcomedANVISAfrom BrazilandtheMinistryofFoodandDrugSafety(MFDS)fromSouthKoreaasthefirstnewregulatory Members,togetherwiththeBiotechnologyInnovationOrganization(BIO)asanewindustryassociat ionMember.Therearenow 13 members and 22 observers.

In Brazil, it is required that all Active Pharmaceutical Ingredients (APIs) and drug products manufactured or imported are registered with the agency. The regulatory system though established but yet is quite complex. The drug registration is valid for five years and may be revalidated for equal and successive periods of time. Their regulatory requirements and guidelines are written in the format called "resolution". As a new ICH member, ANVISA strives to revise many of their resolutions and bring them up-to-date, especially those topics that have corresponding ICH guidelines. However, many of these updated guidelines contain higher level of details with concrete structure, thus making it difficult to embrace the risk-based approached as compared to the original ICH countries. Below are some examples of recent distributed resolutions.

Responsibilities

ANVISA is responsible for drug registration and licensure of pharmaceutical laboratories and other companies inside the pharmaceutical production flow. The agency is also responsible for establishing regulations applicable to clinical trials (with regards to drugs Chemistry, Manufacturing, and Control (CMC) and subject safety). In conjunction with the Health Ministry and other ministries members, ANVISA works with the Chamber of Drug Market Regulation (CMED) to regulate drug pricing. Ethical human clinical trials are in turn regulated by an Ethics Committee (EC) linked to the Health Ministry. ANVISA controls a broad diversity of health-related areas



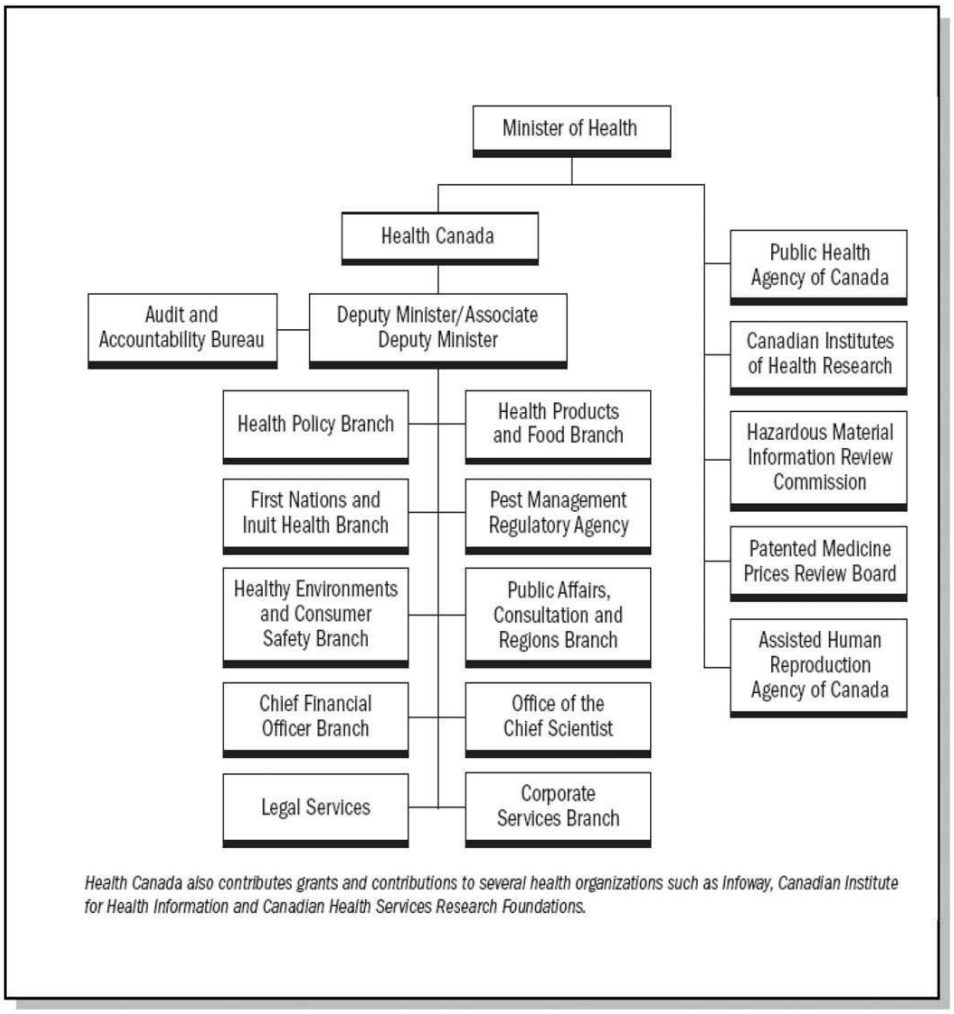
CANADA

In Canada, Health Canada is responsible for helping Canadians to maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks The Therapeutic Products Directorate (TPD) applies the Food and Drug Regulations and the Medical Devices Regulations under the authority of the Food and Drugs F&D) Act to ensure that the pharmaceutical drugs and medical devices offered for sale in Canada are safe, effective, and of high quality. The TPD also administers fee regulations for drug and medical devices under the authority of the Financial Administration Act. Drugs are authorized for sale in Canada once they have successfully gone through the drug review process. This process is the means by which a drug application is reviewed by scientists in the Health Products and Food Branch (HPFB) of Health Canada, and on occasion, out side experts, to assess the safety, efficacy and quality of a drug. Through out the process, the safety and well being of Canadians is the paramount concern. Drugs in Canada include both prescription and non prescription pharmaceuticals: biologically-derived products such as vaccines, blood-derived products product through biotechnology. tissues and organs; disinfectants: and radiopharmaceuticals According to the F&D Act a drug includes any substance or mixture of substances manufactured sold or represented for use in the diagnosis, treatment. mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings

or animals; restoring, correcting or modifying organic functions in human beings or animals or disinfection in premises in which food is manufactured, prepared or kept. Natural health products, such as vitamin and mineral supplements and herbal products for which therapeutic aims are made are also considered drugs at the level of the F&D Act however, these products are regulated as natural health products under the Natural Health Products Regulations (NHPR) and not as drugs under the F&D Regulations Health Canada is the Department of the Government of Canada responsible for the country's federal health policy, overseen by the Minister of Health as a part of their Health Port folio. Originally it was created as the Department of Health in 1919.

Health Canada today was formed in 1993 from the former Health and Welfare Canada department established in 1944. 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. These organizations help to ensure compliance with federal law in a variety of healthcare, agricultural, and pharmaceutical activities. This responsibility also involves extensive collaboration with various other federal and provincial level organizations in order to ensure the safety of foo health, and pharmaceutical products including the regulation of health research and pharmaceutical manufacturing/testing facilities Health Canada's leadership consists of The Minister of Health, Deputy Minister, and Associate Deputy Minister. It has 13 me branches along with their different offices, and bureaus fall under the jurisdiction of Health Canada. In their responsibility of maintaining and improving the health of Canadians, the Minister of Health is supported by the Health Portfolio, which comprises Health Canada well as Public Health Agency of Canada, Canadian Institutes of Health Research the Patented Medicine Prices Review Board: and the Canadian Food Inspection Agency.

Organization



FOOD AND DRUG ADMINISTRATION

FOOD AND DRUG ADMINISTRATION (FDA)

The United States Food and Drug Administration (FDA or US FDA) is a federal agency of the Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, caffeine products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, 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). Robert 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.[47]

Food and Drug Administration **Agency overview**	
Formed	June 30, 1906; 116 years ago
Preceding agencies	Food, Drug, and Insecticide Administration (July 1927to July1930) Bureau of Chemistry, USDA (July1901 through July 1927)Division of Chemistry, USDA(established1862)
Jurisdiction	Federal government of the United States
Headquarters	White Oak Campus10903 New Hampshire Avenue Silver Spring, Maryland
Employees	18,000(2022)
Annual budget	US$6.5billion (2022)
Agency executives	Robert Califf, Commissioner Janet Wood cock, Principal Deputy Commissioner
Parent agency	Department of Health and Human Services
Child agencies	➢ Center for Biologics Evaluation and Research ➢ Center for Devices and Radiological Health ➢ Center for Drug Evaluation and Research ➢ Center for Food Safety and Applied Nutrition ➢ Center for Tobacco Products ➢ Center for Veterinary Medicine National ➢ Center For Toxicological Research ➢ Office of Criminal Investigation ➢ Office of Regulatory Affairs

Vision

FDA is dedicated to world-class excellence as a science-based regulatory agency with a public health mission. aim to provide effective and innovative leadership—both domestically and internationally—to protect health, prevent illness, prolong life, and promote wellness.

Mission

FDA is charged with protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, cosmetics, and radiation-emitting products; and regulating tobacco products. Specifically, FDA is responsible for advancing the public health by: Helping to speed innovations that make medicines and foods safer and more effective; Providing the public with the accurate, science-based information they need to use medicines and foods to improve their health; Regulating the manufacture, marketing, and distribution of tobacco products to protect the public and reduce tobacco use and ensuring the security of the supply of foods and medical products.

History of the Food and Drug Administration

Up until the 20th century, there were few federal laws regulating the contents and sale of domestically produced food and pharmaceuticals, with one exception being the short-lived Vaccine Act of 1813. Under Harvey Washington Wiley, appointed chief chemist in 1883, the Division began conducting research into the adulteration and misbranding of food and drugs on the American market. In June 1906, President Theodore Roosevelt signed into law the Pure Food and Drug Act of 1906, also known as the "Wiley Act" after its chief advocate. The Act prohibited, under penalty of seizure of goods, the interstate transport of food that had been "adulterated. The Act applied similar penalties to the interstate marketing of "adulterated" drugs, in which the "standard of strength, quality, or purity" of the active ingredient was not either stated clearly on the label or listed in the United States Pharmacopeia or the National Formulary. The responsibility for examining food and drugs for such "adulteration" or "misbranding" was given to Wiley's USDA Bureau of Chemistry. When the FDA requested Endo Pharmaceuticals on June 8, 2017, to remove oxymorphone hydrochloride from the market, it was the first such request in FDA history.

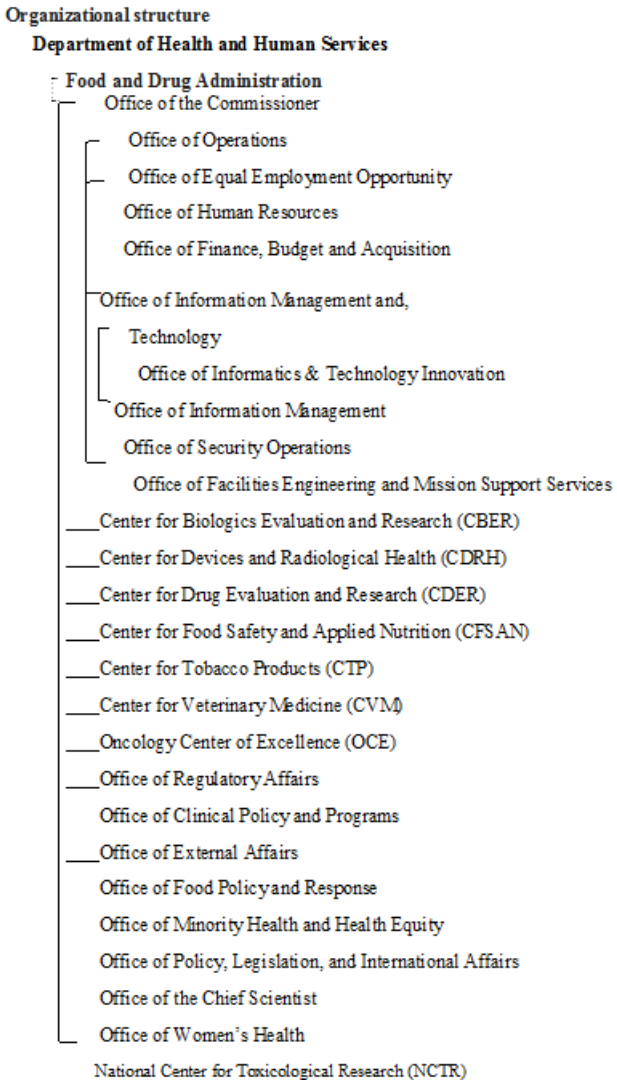
Location

Headquarters

FDA headquarters facilities are currently located in Montgomery County and Prince George’s County, Maryland.

Office of Regulatory Affairs

The Office of Regulatory Affairs is considered the agency’s “eyes and ears,” conducting the vast majority of the FDA’s work in the field. Its employees, known as Consumer Safety Officers, or more commonly known simply as investigators, inspect production and warehousing facilities, investigate complaints, illnesses, or outbreaks, and review documentation in the case of medical devices, drugs, biological products, and other items where it may be difficult to conduct a physical examination or take a physical sample of the product. The Office of Regulatory Affairs is divided into five regions, which are further divided into 20 districts. Districts are based roughly on the geographic divisions of the Federal court system. Each district comprises a main district office and a number of Resident Posts.



Scope and funding

As of 2021, the FDA had responsibility for overseeing $2.7 trillion in food, medical, and tobacco products. Some 54% of its budget derives from the federal government, and 46% is covered by industry user fees for FDA services. For example, pharmaceutical firms pay fees to expedite drug reviews. According to Forbes, the pharmaceutical firms provide 75% of the FDA's drug review budget.

Science and research programs

The FDA carries out research and development activities to develop technology and standards that support its regulatory role, with the objective of resolving scientific and technical challenges before they become impediments. The FDA's research efforts include the areas of biologics, medical devices, drugs, women's health, toxicology, food safety and applied nutrition, and veterinary medicine.

Data management

The FDA has collected a large amount of data through the decades. The Open FDA project was created to enable easy access of the data for the public and was officially launched in June 2014.

Regulator programs:-1.Emergency approvals (EUA)

Emergency Use Authorization (EUA) is a mechanism that was created to facilitate the availability and use of medical countermeasures, including vaccines and personal protective equipment, during public health emergencies such as the Zika virus epidemic, the Ebola virus epidemic and the COVID-19 pandemic.

2. Regulations

The programs for safety regulation vary widely by the type of product, its potential risks, and the regulatory powers granted to the agency. For example, the FDA regulates almost every facet of prescription drugs, including testing, manufacturing, labeling, advertising, marketing, efficacy, and safety. Inspection observations are documented on Form 483.

3. Food and dietary supplements

a) Regulation of food and dietary supplements by the U. S. Food and Drug Administration

The regulation of food and dietary supplements by the Food and Drug Administration is governed by various statutes enacted by the United States Congress and interpreted by the FDA. Pursuant to the Federal Food, Drug, and Cosmetic Act and accompanying legislation , the FDA has authority to oversee the quality of substances sold as food in the United States, and to monitor claims made in the labeling of both the composition and the health benefits of foods.

b) "FDA-Approved" vs. "FDA-Accepted in Food Processing"

The FDA does not approve applied coatings used in the food processing industry. The FDA does have a set of regulations that cover the formulation, manufacturing, and use of non stick coatings. Hence, materials like Polytetrafluoroethylene (Teflon) are not, and can not be, considered as FDA Approved, rather, they are "FDA Compliant" or "FDA Acceptable".

4. Medical counter measures (MCMs)

Medical countermeasures (MCMs) are products such as biologics and pharmaceutical drugs that can protect from or treat the health effects of a chemical, biological, radiological, or nuclear (CBRN) attack. The FDA runs a program called the "FDA Medical Countermeasures

Initiative" (MCMi), with programs funded by the federal government. It helps support "partner" agencies and organisations prepare for public health emergencies that could require MCMs

5. Medications

The Center for Drug Evaluation and Research uses different requirements for the three main drug product types: new drugs, generic drugs, and over-the-counter drugs. A drug is considered "new" if it is made by a different manufacturer, uses different excipients or inactive ingredients, is used for a different purpose, or undergoes any substantial change.

6. New medications

New drugs receive extensive scrutiny before FDA approval in a process called a new drug application (NDA). Under the Trump administration, the agency has worked to make the drug approval process go faster. New drugs are available only by prescription by default. A change to over-the-counter (OTC) status is a separate process, and the drug must be approved through an NDA first. A drug that is approved is said to be "safe and effective when used as directed"

7. Generic drugs

Generic drugs are chemical and therapeutic equivalents of name-brand drugs, normally whose patents have expired. Approved generic drugs should have the same dosage, safety, effectiveness, strength, stability, and quality, as well as route of administration. For a pharmaceutical company to gain approval to produce a generic drug, the FDA requires scientific evidence that the generic drug is interchangeable with or therapeutically equivalent to the originally approved drug. This is called an Abbreviated New Drug Application (ANDA). As of 2012, 80% of all FDA approved drugs are available in generic form.[citation needed]

9. Over-the-counter drugs

Over-the-counter (OTC) are drugs like aspirin that do not require a doctor's prescription. The FDA has a list of approximately 800 such approved ingredients that are combined in various ways to create more than 100,000 OTC drug products. Many OTC drug ingredients had been previously approved prescription drugs now deemed safe enough for use without a medical practitioner's supervision like ibuprofen

10. Corona virus (COVID-19) testing

During the corona virus pandemic, FDA granted emergency use authorization for personal protective equipment (PPE), in vitro diagnostic equipment, ventilators and other medical devices. On March 18, 2020, FDA inspectors postponed most foreign facility inspections and

all domestic routine surveillance facility inspectors. In contrast, the USFDA's Food Safety and Inspection Service (FSIS) Continued inspections of meatpacking plants, which resulted in 145 FSIS field employees who tested positive for COVID-19,and there who died.

11. Vaccines, blood and tissue products, and biotechnology

The Center for Biologics Evaluation and Research is the branch of the FDA responsible for ensuring the safety and efficacy of biological therapeutic agents. These include blood and blood products, vaccines, allergenics, cell and tissue-based products, and gene therapy products. New biologics are required to go through a premarket approval process called a Biologics License Application (BLA), similar to that for drugs.

12. Cosmetics

Cosmetics are regulated by the Center for Food Safety and Applied Nutrition, the same branch of the FDA that regulates food. However, all colour additives must be specifically FDA approved before manufacturers can include them in cosmetic products sold in the U.S. The FDA regulates cosmetics labelling, and cosmetics that have not been safety tested must bear a warning to that effect.

13. Veterinary products

The Center for Veterinary Medicine (CVM) is a center of the FDA that regulates food additives and drugs that are given to animals. CVM regulates animal drugs, animal food including pet animal, and animal medical devices. CVM does not regulate vaccines for animals; these are handled by the United States Department of Agriculture.

14. International Cooperation:- In February 2011, President Barack Obama and Canadian Prime Minister Stephen Harper issued a "Declaration on a Shared Vision for Perimeter Security and Economic Competitiveness" and announced the creation of the Canada-United States Regulatory Cooperation Council (RCC) "to increase regulatory transparency and coordinatin between the two countries.

CONCLUSION

Many in the Regulatory Affairs Profession believe the New Approach to regulation Will eventually be adopted for all healthcare products as it represents the best model for delivering new health care advances to market in a reasonable time With acceptable safety.

Regulatory Affairs department is constantly evolving and growing and is the one Which is

least impacted during the Acquisition and Merger, and also during recession. Regulatory Affairs departments are growing within companies. Due to the changing resources necessary to fulfill the regulatory requirements, some companies also choose to outsource or out task regulatory affairs to external service providers.

In today's competitive environment the reduction of the time taken to reach the market is critical to a product's and hence the company's success. The proper conduct Of its Regulatory Affairs activities is there fore Of considerable economic importance for the company.

SCOPE OF WORK

Locally the F.D.A. (Foods & Drugs Control Administration) is the main regulatory body governing and implementing the rule sand regulations for the Drug & Pharma industry .The F.D.X has State branches and sub-branches all over the country. With globalization process reaching out to India, the geographical barriers have become obsolete. Any country will have to Compete and trade globally in order to progress and survive in the years to come .The major drug and Pharma-Companies have realized this fact and have stepped into the global area of competitive trade. If an Indian manufacturer wants to sell his drug or formulation to a foreigncountryitismandatorythathehastofulfillallthe Statutoryrequirementslaidby there gulatoryauthoritiesOfthatcountry.Also,his product needs to be perfectly as pert he specifications laid down by the concerned regulatory authority. Thus, in order to enter in to trade with the foreign countries it is mandatory to get the necessary approvals and sanctions as per the formats given by local regulatory authorities. E.g. Approvals to be obtained from U.S.F.D.A. for U.S.A, T.G.A. for Australia & New Zealand ,M.C.A and M.C.M. for U.K. & European countries and ICH guidelines going to be uniform for international levels.

Since, the business involved is worth multibillion dollars; this branch has assumed Tremendous significance and is bound to grow enormously, in the Post-GATT era. Many big players in the drugs & Pharma field has already established separate Regulatory Affairs Departments in their companies. Regulatory experts are thus in great demand. Since, the field is highly technical Pharmacy professionals again fit in these positions.

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