

A Brief Review on Drug Regulatory Affair

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Submitted: 10-11-2023

Accepted: 20-11-2023

ABSTRACT:-

A regulatory issue is a unique synergy between the internal departments of the industry and the regulators, starting from the conceptualization of the product to be developed by the industry to the launch of that product. This is a very important and prominent feature of pharmaceutical product development. This chapter provides an overview of the importance of regulatory issues, although some aspects of the drug approval process are similar from country to country while others have some differences. This stress study expresses the approval process and regulatory requirements of the United States Food and Drug Administration (UDFDA), the European Medical Agency (EMA), and the Central Drug Standards Control Organization (CDSCO), as well as the Therapeutic Goods Agency (TGA) out of , Ministry of Health, Labor and Welfare (MHLW), National Food and Drug Administration (SFDA), Health Canada. This review presents the therapeutic advances and the main prospects for improvements and advances in cell therapies that we are currently encountering .This project focuses on the history, regulatory policies and administration of and related issues in various countries such as India, Japan, China, Europe, the United States, Australia, Brazil and Canada.

Keywords:- Regulatory Requirements, USFDA, CDSCO, TGA, MHLW, SFDA, EMA, ANVISA.

I. 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 coming 10 years. [16]

As the pharmaceutical industry around the world becomes more and more competitive, it realizes that the real fight for survival lies in getting the job done by understanding the policies associated with the various activities carried out in order to ensure that the process is regulated As one of the industries subject to strict regulation , the

pharmaceutical industry needs people more than ever who can deal comprehensively with regulatory issues. [10]

Regulatory affairs (RA), also known as government affairs, are a profession in regulated industries such as pharmaceuticals, medical devices, energy, and banking. Regulatory Cases (RA) also have a very special meaning in the healthcare industry (medicines, medical devices, organic functional foods). Most companies, whether large multinational pharmaceutical companies or small, innovative biotech companies, have specialized regulatory affairs (RA) departments. The success of a regulatory strategy depends less on regulations and more on how they are interpreted, applied and communicated within companies and to external parties.[4]

Pharmaceutical regulatory experts play a critical role in ensuring that all pharmaceutical products comply with industry regulations. [8]

Individuals working in pharmaceutical regulatory roles work not only in the initial use phase of a new or generic drug, but also in the approval and marketing phase, ensuring that all processes and products meet the required safety and efficiency standards [11]

Organizations such as the FDA also offer positions for those interested in working in the field. As biotechnology plays an increasing role in drug development and the pharmaceutical industry, more and more biotechnology regulatory bodies are addressing the issue. [7]

OBJECTIVE:-

The first and most important factor for the pharmaceutical industry has always been the time taken for the drug candidate to see the light of day, which is absolutely necessary for the success of the product and the pharmaceutical business Company. Therefore, effective management and monitoring of regulatory activities play a key role in business administration.

REGULATORY AUTHORITY IN DIFFERENT COUNTRIES USA :-

The Food and Drug Administration (FDA or USFDA) is a federal agency of the United States Department of Health and Human Services. USFDA was authorized by the United States Congress to enforce the Federal Food, Drug, and Cosmetic Act. The USFDA also enforces other laws such as: B. the Public Health Services Act and related regulations, many of which do not apply directly related to food or medication. USFDA is located at White Oak Maryland. The agency also has 223 field offices and 13 laboratories, including in all 50 states. In 2008, the USFDA began opening offices in other countries, including China, India, Chile, Belgium, and the United Kingdom.[13]

An agency within the U.S. Public Health Service, not directly related to food or drug USFDA has its headquarter at White Oak Mary 113

laboratories located throughout the 50 states. In 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 Drug Administration Act of 1906 was the starting point for the future creation of the Food and Drug Administration (FDA). Originally the Bureau of Chemistry served as the to regulate food safety, but in 1927 it was reorganized into the Bureau of Chemistry and Soils and the Food, Drug and Insecticide Agency. In 1930, the current Food and Drug Administration (FDA) came into effect following the retrenchment of the previous organization. Because FDA's roots date back to 1906-FDA still celebrates 1906 as its founding year. Since the above-mentioned Law official control over food and medicines has increased significantly. This Law also prescribed guidelines for safe use. To raise the regulatory bar, the federal government passed a law in classifying drugs as over-the-counter (OTC) drugs and prescription drugs, which was not previously in effect. According to this law, medicines intended to treat minor ailments such as indigestion and headaches can be classified as over-the-counter medicines and can be sold freely in pharmacies without a prescription. Medications for serious illnesses are prescription drugs (RXs). and dangerous number for self-medication. The statement was ordered to be placed on the label because "Attention: Federal law prohibits the dispensing of this drug without a prescription." This law Was known as the Durham-Humphrey Amendment of 1951, more

commonly known as the Statute of Limitations Amendment Act of 1951. Important changes took place with the Kefauver-Harris Drug Amendments of 1962. This follows the thalidomide tragedy in Western Europe. This law required new drugs to be supported by efficacy data and additional safety data, and in these changes the FDA required Good Manufacturing Practices (GMP) and marketing approval in advance.[2]

- **USFDA: -**

The United States Food and Drug Administration (FDA or USFDA) is a regulatory agency within the United States Department of Health and Human Services, one of the federal agencies of the United States. Headquarters Silver Spring, Maryland, United States. Established on June 24, 1938. The USFDA is responsible for protecting and promoting public health through regulations to monitor the safety of foods, tobacco products, dietary supplements, prescription and over-the-counter drugs (drugs). ,vaccinations. , biopharmaceutical products, blood transfusions, medical devices, electromagnetic radiation emitting devices (EREDs), veterinary products, and cosmetics.[18]

- **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 by inspecting and monitoring the safety of foods, tobacco products, caffeine products, dietary supplements, prescription and over-the-counter drugs (drugs), vaccines, biopharmaceuticals, blood transfusions, medical devices, devices , which emit electromagnetic radiation (ERED). Cosmetics, food and pet food.

Animal feed and veterinary products. The FDA's primary goal is to enforce the Federal Food, Drug, and Cosmetic Act (FD&C). Robert Califf is the current Commissioner as of February 17, 2022. The FDA has its unincorporated office in White Oak, Maryland. The agency also has 223 field offices and 13 laboratories in all 50 states, U.S. Virgin Islands and Puerto Rico. In 2008, FDA began deploying employees to other countries, including China, India, Costa Rica, and to Chile, Belgium, and the United Kingdom.[17]

- **EUROPIAN UNION:-**

The International Council for Harmonization (ICH), formerly the International Conference on Harmonization (ICH), held its inaugural sessions of the Assembly on October 23, 2015 and established the ICH as an international association, legal entity . Legal entity under Swiss law. This move builds on's 25 years of experience in successfully providing harmonized advice for the global development and regulation of pharmaceutical products, as well as long-standing recognition of the need for harmonization. Europe is on the way to developing a single market for medicines. . The success of in Europe has shown that harmonization is possible. At the same time, discussions took place between Europe, Japan and the United States about the possibility of Harmonization .However, it was not until the Conference of Drug Regulatory Authorities (ICDRA), held in Paris in 1989, that concrete action plans for were fleshed out. Soon after, the authorities contacted the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) to discuss , a joint regulatory and industry initiative for international harmonization of and ICH was born.[15],[20]



- **INDIA:-**

The Drugs and Cosmetics Act, 1940 and Rules, 1945 were made by the Parliament of India in to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Central Drugs Standard Control Organization (CDSCO) and the office of its head, the Drugs Controller General of India (DCGI) were established. In 1988, the Government of India added Schedule Y to the Drugs and Cosmetics Regulations, 1945. Appendix Y contains the clinical trial guidelines and requirements, which were revised to in 2005 to align with internationally accepted practices. If a company in India wants to manufacture/import a new drug , it has to apply for a license from the Licensing Authority (DCGI) by filling Form 44 and Form and providing details as per Schedule Y of the Drugs and Cosmetics Act.1940.and Rule 1945 [4].To demonstrate its efficacy and safety in the Indian population, it will conduct clinical trials as per the guidelines in Annex Y and submit a report of such clinical trials in the prescribed format,[14],[19]



Drug and Cosmetic Act 1940 and Rules

- **JAPAN:-**

Generic drug penetration in the country is expected to reach 60% by FY in 2017, followed by 70% by FY 2025. Therefore, generic drug manufacturers may see opportunities in Japanese markets. With expected higher demand for generic drugs, the country's major pharmaceutical companies are merging into joint ventures to meet this demand. Japan is the second largest pharmaceutical market after the USA and is a highly developed country. Japanese people have been found to consume different medications, with recently approved drugs being particularly common. Patient awareness is currently similar to that of Western countries. medications account for more than 20% of healthcare costs, with approximately medications accounting for nearly 50% of healthcare costs for elderly patients. To minimize this “drug processing delay,” the Japanese government encourages pharmaceutical companies to conduct concurrent clinical trials and include Japan in the global clinical trials.[19]



- **AUSTRALIA:-**

The Therapeutic Goods Administration (TGA) is part of the Health Products Regulatory Group (HPRG) of the Australian Department of Health, which was established in 1989. TGA, under the Therapeutic Goods Act of 1989 and the Therapeutic Goods Act of 1989. The Goods Regulations are responsible for the quality, safety, effectiveness and timely availability of medicines and medical devices in Australia. Prescription medication assessment is one of the many functions of the TGA. also regulates over-the-counter medicines, medical devices and nutritional and herbal products containing vitamins. New chemical substances and new applications that require expert advice are referred to as the Australian Drug Evaluation Committee (ADEC). ADEC can only make recommendations; TGA makes the final decision as to whether a medicine is registered for use in Australia. TGA also has responsibility for other medicines, including over-the-counter medicines, alternative medicines and medical devices. The medicines regulatory process in Australia is complex and resource intensive.[9]

- **CHINA:-**

The national drug regulatory authority in China was the State Food and Drug Administration (SFDA), which is under the Department of Drug Administration of the Ministry of Health. The SFDA is continually developing the, aware of its shortcomings and striving to bring its standards in line with those of the EU, USA and Japan. China's Regulatory Authority upholds intellectual property protection and is making further efforts to ensure clarity in regulations. China's regulator wants to focus on innovation and make progress in regulating medicines to ensure their safety and effective use. The SFDA emphasizes the development of innovative medicines as well as generic medicines (which are bioequivalent to these innovative medicines).[21]

China's drug regulatory agency SFDA was developed and modernized after the USFDA, which is under the supervision of the Ministry of Health. The SFDA was created to restructure and replace the state's Drug Administration (SDA). The SFDA is responsible for the registration and approval fees for drugs. The SFDA has 5 affiliated units that coordinate activities.[12],[3]

- **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,[5],[1]

- **CANADA:-**

In Canada, Health Canada is responsible for helping Canadians maintain the number and improve their health. Call to ensure quality healthcare services are available and work to reduce health risks. The Therapeutic Products Directorate (TPD) enforces the Food and Drug Regulations and Medical Device Regulations under the authority of the Food and Drug Administration (F&D) Act, which ensures that drugs and medical devices offered for sale in Canada, safe and effective and of high quality. TPD also administers the Drug and Medical Device Fee Regulation under the Financial Administration Act. Drugs are approved for sale in Canada after the drug review process is successfully completed. This process involves the review of a drug application by scientists from Health Canada's Health Products and Foods Branch (HPFB), and sometimes by external experts, to assess the safety, effectiveness and quality of the drug. natural health products such as vitamin and mineral preparations and herbal products that serve therapeutic purposes are considered medicinal products within the meaning of the Food and Beverages Act. However, these products are subject to the provisions of the Natural Health Regulations (NHPR) as Natural Health Products and are Natural Health Products. non-medical within the meaning of the R&D regulation.[6]

II. 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 healthcare 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 therefore of considerable economic importance for the company. Locally the FDA (Foods & Drugs Administration) is the main regulatory body governing and implementing the rules and regulations for the Drug & Pharma industry. The FDA 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 drugs 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 foreign country it is mandatory that he has to fulfill all the Statutory requirements laid by the regulatory authorities Of that country. Also, his product needs to be perfectly as per the specifications laid down by the concerned regulatory authority. Thus, in order to enter into trade with the foreign countries it is mandatory to get the necessary approvals and sanctions as per the formats given by local regulatory authorities. Ex. Approvals to be obtained from USFDA for USA, TGA.For Australia & New Zealand, MCA and MCM for UK & 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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