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CURRENT TRENDS AND PERSPECTIVE IN PHARMACEUTICAL REGULATORY AFFAIRS

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ABSTRACT

Drug Regulatory Affairs ensures that pharmaceutical products meet stringent safety, efficacy, and quality standards before reaching patients, serving as a critical link between industry and regulatory bodies like India's Central Drugs Standard Control Organization (CDSCO) and global agencies such as the U.S. Food and Drug Administration (FDA). The increasing complexity of drug development, coupled with diverse regional regulations, poses challenges in achieving timely approvals while maintaining compliance. This research investigates strategies to streamline regulatory processes for new drug approvals in India, focusing on compliance with the New Drugs and Clinical Trials Rules, 2019, and alignment with international standards like those of the International Council for Harmonisation (ICH). The methodology involves a comparative analysis of regulatory frameworks, case studies of successful drug approvals, and interviews with regulatory professionals to identify bottlenecks and best practices. Findings reveal that harmonized documentation, early engagement with regulators, and adoption of digital submission platforms significantly reduce approval timelines. The study highlights the importance of Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) in ensuring product quality and regulatory acceptance. These strategies have practical applications in accelerating access to innovative therapies, particularly generics and biosimilars, in India's growing pharmaceutical market. The research also underscores the need for capacity building among regulatory professionals to navigate evolving guidelines. Future research should explore the integration of artificial intelligence in regulatory submissions and the impact of global harmonization on local markets. This work contributes to optimizing Drug Regulatory Affairs practices, enhancing India's role in global pharmaceutical innovation while prioritizing patient safety.

Keyword: CDSCO,FDA,ICH,GMP,GCP,MAA,INDA,GLP

INTRODUCTION

Regulatory Affairs is a pivotal discipline in the pharmaceutical, biotechnology, and medical device industries, serving as the cornerstone for ensuring that products comply with stringent regulatory requirements before they reach the market. This field acts as a bridge between companies developing healthcare products and regulatory authorities, such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Central Drugs Standard Control Organization (CDSCO) in India, and other global bodies. Regulatory Affairs professionals are responsible for navigating complex legal and scientific frameworks to secure approvals for product development, manufacturing, and marketing, thereby ensuring patient safety, product efficacy, and quality. This introduction outlines the role, significance, and evolving scope of Regulatory Affairs, with a focus on its relevance to pharmaceutical innovation and public health.The primary role of Regulatory Affairs is to facilitate the development and approval of safe and effective healthcare products. This involves preparing and submitting detailed documentation, such as Investigational New Drug (IND) applications, New Drug Applications (NDAs), or Marketing Authorization Applications (MAAs), to regulatory authorities. These submissions include comprehensive data on preclinical studies, clinical trials, manufacturing processes, and quality control measures. Regulatory professionals ensure compliance with standards like Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and Good Laboratory Practice (GLP), which are critical for maintaining product integrity. For instance, in India, the CDSCO oversees the approval of drugs and medical devices under the Drugs and Cosmetics Act, 1940, ensuring alignment with national and international guidelines. Regulatory Affairs also extends to post-market activities, such as adverse event reporting, product recalls, and compliance with labeling requirements, to safeguard public health after products are commercialized.The importance of Regulatory Affairs stems from its dual role in protecting consumers and enabling innovation. By enforcing rigorous standards, regulatory bodies prevent unsafe or ineffective products from entering the market, thus mitigating risks to patients. Simultaneously, Regulatory Affairs professionals expedite the approval process for novel therapies, ensuring timely access to life-saving treatments. For example, during the COVID-19 pandemic, regulatory agencies like the FDA and CDSCO implemented accelerated pathways, such as Emergency Use Authorizations (EUAs), to fast-track vaccine approvals without compromising safety. This balance between compliance and innovation is critical in a globalized pharmaceutical industry, where harmonized standards, such as those set by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), facilitate cross-border approvals.The scope of Regulatory Affairs is broad and dynamic, encompassing various stages of a product's lifecycle. In the development phase, professionals design clinical trial protocols to meet regulatory requirements, ensuring trials are ethically sound and scientifically robust. During manufacturing, they oversee compliance with GMP to guarantee consistent product quality. In the marketing phase, they ensure that product labeling, advertisements, and promotional materials adhere to regulatory guidelines. Additionally,the EMA operates under Regulation (EC) No 726/2004, emphasizing centralized procedures for certain drugs. In India, the CDSCO collaborates with state authorities and aligns with ICH guidelines to ensure global competitiveness. These frameworks require Regulatory Affairs professionals to possess a deep understanding of both scientific

principles and legal requirements, making the field interdisciplinary and challenging. Moreover, the rise of digital health technologies, such as medical apps and wearable devices, has expanded the scope of Regulatory Affairs to include new regulatory paradigms, such as the FDA's Digital Health Innovation Action Plan.The evolution of Regulatory Affairs is driven by advancements in science, technology, and globalization. The increasing complexity of biologics, personalized medicines, and gene therapies demands innovative regulatory approaches. For example, the development of mRNA vaccines has necessitated updates to regulatory guidelines to address novel platforms. Additionally, harmonization efforts, such as those by the ICH and World Health Organization (WHO), aim to standardize requirements across countries, reducing duplication and accelerating global access to medicines. Regulatory Affairs professionals must stay abreast of these changes, leveraging expertise in science, law, and communication to advocate for their organizations while upholding public health standards.In conclusion, Regulatory Affairs is an indispensable component of the pharmaceutical and healthcare industries, ensuring that products are safe, effective, and accessible. Its multifaceted role spans product development, regulatory compliance, and post-market surveillance, requiring professionals to navigate complex and evolving regulations. As the industry continues to innovate, Regulatory Affairs will play a critical role in shaping the future of healthcare by balancing regulatory rigor with the need for timely access to new therapies. This overview sets the stage for exploring specific regulatory challenges and strategies in the subsequent chapters of this thesis, particularly in the context of [insert your specific thesis focus, e.g., pharmaceutical development in India.

PLAN OF WORK

RATIONALE: -

In the first place, 'regulation' is the jurisdiction of human and communal conduct by dint of rules and precincts. The expression 'regulation' has 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 can 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: -

- To determine whether a regulatory function exists, how it is carried out and What financial and human

resources are available for its implementation

- To identify the strengths and weaknesses of drug regulation
- To propose strategies that can help policy-makers and implementers to improve drug regulation.
- To map the legal and organizational structures of drug regulation in selected countries

PLAN OF WORK:-

- Pharmaceutical regulatory affairs and its importance
- Regulatory department and professionals
- Different important regulatory acts
- A Comparative study on Drug Regulatory bodies In India,
- Explanation of some important terms in regulatory affairs

PHARMACEUTICAL REGULATORY AFFAIRS

Historical overview

During 1950s, multiple tragedies i.e. sulfanilamide elixir, vaccine tragedy and thalidomide tragedy have resulted in substantial increase of legislations for drug products quality, safety and efficacy. This has also resulted into stricter norms for Marketing Authorization (MA) and Good Manufacturing Practices (GMPs).

➢ AN OUTLOOK OF HISTORICAL DEVELOPMENT OF PHARMACEUTICAL INDUSTRIES AND DRUG REGULATORY AFFAIRS IN INDIA:-

INDIA

The drug industry in India was at very primitive stage till 20th Century. Most of the drugs were imported from foreign countries. Post First World War, the demand for drugs had increased enormously and that led to the cheap & substandard drugs into the market, as like in USA post Mexican American war.[12]

a) 1900-1960:- To control cheap drugs in market, Government passed the Poisons Act 1919. This Act regulates possession of substance or sale of substances as specified as poison. It also specifies the safe custody of the poisons, labelling and packaging of poisons, maximum quantity to be sold and inspection as well as examination of the poison sold by vendor during the year. The Poisons Act was followed by The Dangerous Drugs Act 1930. This act regulates the opium plant cultivation, manufacture and possession of opium, its import, export, tranship and sell of opium. The Narcotics and Psychotropic Substances Act was passed in 1985 which revoked the Dangerous Drugs Act 1930 and Opium Act, 1878.

- Following acts & rules were passed during this era:

• **Drugs and Cosmetics Act, 1940**: Regulate the import, manufacture, distribute and sale of drugs. This act covers allopathic, homeopathic, Unani and Sidha drugs.

• **Drugs and Cosmetics Rules, 1945:** The rules under the Drugs and Cosmetics Act regulate only manufacture of Ayurvedic drugs for sale, and not for consumption, use or possession.

• **Pharmacy Act, 1948:** This law was amended lastly in 1986 and it regulates the pharmacy profession of India.

• **Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955:** This rules control the drug advertisement in India.

• **Drugs Prices Control Order, 1955 (DPCO) (under the essential commodities Act):** DPCO was further amended in 1995. Under this rule, government may review and fix maximum sale price for bulk drugs as well as formulation.

b) 1960-1970:- The market share was dominated by multinational companies and very few Indian manufacturers were present. The Indian Pharmaceutical industry was in an early stage of growth. Focus for pure research and development was very

little due to lack of patent protection. Due to very high import dependency on drugs, the cost of drugs was very high as well as market availability was comparatively low.

c) 1970-1980:- Government took control for the medicines regulation and issued few acts and rules.

• **Indian Patent Act 1970:** It serves as the basis for patent protection in India. Based on this, only process and method of manufacture of Drug substance was allowed to get the patent. Product patent was not allowed under this act. Indian Patent Act of 1970 came into force from April 20, 1972. This new act replaced the Indian Patents and Designs Act of 1911.

• **Drug prices capped:** Drug Prices Control Order (DPCO) was introduced to control the high price against consumers.

• **Local companies begin to make an impact:** Since the product patent was allowed by Indian Patent Act 1970; local companies began manufacturing products/ drugs using different manufacturing process by reverse engineering. Due to this new drugs were available cheaply as well as many more substitute drugs were available in the market against costly imported new drugs. This has resulted in 1) increase the exports to countries like Russia, Africa, China, and South America. 2) Export of Bulk drug post patent expiry.

d) 1980-1990:- The industry has started investing in API process development and created production infrastructure. Government has also issued export incentives. The Narcotic Drugs and Psychotropic Substances Act, 1985 was issued which regulates the operation of narcotic drugs and substances.

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Act, 1985 was issued which regulates the operation of narcotic drugs and substances.

e) 1990-2000:- The pharmaceutical industry has observed a rapid expansion of domestic market and during same era globalisation happened. The companies have entered into research activity. India joined Paris Cooperation Treaty (PCT) in 1999 and implemented product patent effective from Jan 1, 2005.

f) 2000-2010:- This period is considered to be the Innovation and Research era. During these years, innovative research activity, patenting of the drugs formula, process, indication as well as merger of companies was started.

- **Patent Amendment Act 2005:** With this act, provision for Black Box Application made, as per that if patent application is filed before Jan 1, 2005, then under the transit provision of Trade Related aspects of Intellectual Property Rights (TRIPS), manufacturer can market this product post 2005 without infringing product patent, if manufacturer has made significant investment in manufacturing of the product, produced and marketed on or before Jan 1, 2005.

- **Compulsory Licenses:** Such licenses can be granted for manufacture and export of the drug products "to any country having insufficient or no manufacturing capacity, for the said product, to address public health problems". Herbal preparations having medicinal values can be patented under new amended law. Major regulatory changes in terms of marketing authorization process as well guidelines have come into effect. Few to name are as below:

- **Drugs and Cosmetics (First Amendment) Rules, 2011:** it mandates registration of Clinical Research Organization (CRO) for conducting Clinical Trials (CT). Schedule Y1 suggests requirements and guidelines for registration of Clinical Research Organizations.

- **Clinical Trial Registry:** India (CTRI): It has been set up by the ICMR's (Indian Council of Medical Research) National Institute of Medical Statistics (NIMS). India has developed on-line registry system and mandated registration of CRO before the enrolment of first patient for clinical trials. CRO needs to disclose mandatory items as mentioned under WHO International Clinical Trials Registry Platform (ICTRP) dataset.

- **Pharmacovigilance Programme of India (PvPI):** The Central Drugs Standard Control Organization (CDSCO) has launched Pharmacovigilance programme to assure drugs safety to Indian patients. This will help monitoring adverse drug reactions to Indian patients, as well as monitoring of benefit-risk ratio.

•Guidance documents: CDSCO has issued guidance for Industry for Fixed Dose Combinations (FDCs) registration as well as Guidance for preparation of Common

Technical Document for Import/manufacture and Marketing Approval of New drugs for Human Use (New Drug Application-NDA).

With this CDSCO has implemented system for preliminary scrutiny at the time of application receipt for

marketing approval of Fixed Dose Combinations (FDCs).

➢ Importance of regulatory affairs :-

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. Inadequate reporting of data may prevent a timely positive evaluation of a marketing application. A new drug may have cost many millions of Euros or dollars, pounds, to develop and even a three- month delay in bringing it to the market has considerable financial considerations. Even worse, failures to fully report all the available data or the release of product bearing incorrect labelling, may easily result in the need for a product re-call . Either occurrence may lead to the loss of several millions of units of sales, not to mention the resulting reduction in confidence of the investors, health professionals and patients. The Regulatory Affairs department is very often the first point of contact between the government authorities and the company. The attitudes and actions of the Regulatory Affairs professionals will condition the perceptions of the government officials to the company –for better, or for worse! Officials respond much better to a company whose representatives are scientifically accurate and knowledgeable than to one in which these qualities are absent.[4] The importance of the Regulatory Affairs function is such that senior Regulatory Affairs professionals are increasingly being appointed to boardroom positions, where they can advise upon and further influence the strategic decisions of their companies.[13.]

REGULATORY DEPARTMENT AND PROFESSIONALS

Today most companies, whether they are major multinational pharmaceutical corporations or small medium enterprises, innovate biotechnology companies, they all have specialist department of Regulatory affairs. Almost every company has this regulatory department to keep track on the legislations of countries where companies wish to market their product. This track includes collection and analysis of legal As well as scientific requirement for particular country to obtain and maintain marketing authorizations of health care products. Regulatory Affairs bring about a variety of disciplines and job responsibilities, which starts during the product development, its manufacture and continue till the product is widely available for use.

This department is responsible for knowing the regulatory requirements for getting new products approved. They know what commitments the company has made to the regulatory agencies where the product has been approved. They also submit annual reports and supplements to the agencies. Regulatory Affairs typically communicates with one of the Centers (e.g., Center for Drug Evaluation and Research) at the FDA headquarters, rather than the FDA local district offices. Gimps do not directly apply to Regulatory Affairs; however, they must understand and evaluate changes to drug manufacturing and testing activities to determine if and when the FDA must be notified. The Regulatory Affairs department will take part in the development of the product marketing concepts and is usually required to approve packaging and advertising before it is used commercially. Many companies operating in the high-technology health-care and related industries operate on a multinational basis and are very significant exporters. Their Regulatory Affairs departments must be aware of

the regulatory requirements in all the company's export markets.

Regulatory professionals plays a very important role in coordinating scientific endeavours with regulatory demands throughout the life of the product and helps the companies meet all the regulations and guidelines and in turn maximize the profits.[14] hence, a sound regulatory professionals with a right first time approach is necessity of all pharmaceutical companies.

As RA Professionals, they are often responsible for tracking changes in regulatory guidelines as they may occur.in order to do this, they must take the initiative to keep current on all the changes in regulations. Changes must be interpreted and

communicated to appropriate people in the company, including management. Management then determine what changes in company procedures and process may be required by stay in compliance.[1]

- **ROLES OF REGULATORY AFFAIRS PROFESSIONALS :-**

a) <u>Evaluation of MAA (Marketing Authorization Application)</u>

1. Evaluation of Marketing Authorization Application i.e. New Drugs Application, New Biologics Application, Medical Device and Cosmetics application, Generic Application, Clinical Trial Application, Variation Application, Drug Master Files for API, Excipients and Packaging Materials, Site Master File for GMP inspection

2. Issuance of Evaluation comments/ Exigencies to Manufacturers
3. Managing variation application, post approval changes and keeping record of annual update
4. Post Marketing Approval Management
5. Issuance of Marketing Authorization Approval, GMP, and GCP approval certificate
6. Managing MAA On-line and up-gradation towards common technical document format

b) <u>Input for guidelines and guidance documents</u>

1. Issuance of guidelines & guidance documents for Quality, Safety, Efficacy and Pricing Control as well as CTD for implementation
2. Collaboration with Global and Regional Harmonization units for exchange of technical knowledge, developing guidelines as well as allotting mutual recognition status for technical documents, GMP status and product approval
3. Part of foreign trade delegation to facilitate smooth management of Pharmaceutical business within countries and minimising barrier by reducing duplicate generation of Technical data and timeline for evaluation and approval by respecting each other regulatory framework

c) Inspection

1. Performing GMP Audit for Drug Manufacturing Site, GCP Audit for Clinical Study Site and Bio-equivalence Centre, and issuing certification confirming approval status

d) Support to Pharmaceutical Manufacturers

1. Supporting Manufacturer in defining drug development pathway during Pre-NDA meeting and providing comments / confirming development pathway

2. Time to time meeting with pharmaceutical manufacturers association to discuss ongoing challenges, technical issues, guidelines/ guidance documents discussion and future development

e) Monitoring Drug Safety and Efficacy

1. Monitoring Drug Safety by collecting Pharmacovigilance data and reviewing drugs in markets time to time by reviewing labels and taking appropriate action accordingly

2. Monitoring Clinical Trials as well as approving study results for next phase of study

3. Allowing speedy or fast track designation for essential drug to patient population.

DIFFERENT IMPORTANT REGULATORY ACTS

Most of India's pharmaceutical product policy is governed by the Drugs and Cosmetics Act (DCA). The DCA was first enacted in 1940 and has been amended many times since then.

All regulatory aspects related to import, manufacture, sale and advertisements of drugs in India are covered under three separate enactments, namely, Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics Rules 1945, The Pharmacy Act 1948 and the Drugs & Magic Remedies (Objectionable Advertisements) Act 1954.

Under the current Indian legal and regulatory regime, the manufacture, sale, import, exports and clinical research of drugs and cosmetics is governed by the following laws:-

-The Drugs and Cosmetics Act, 1940
-The Pharmacy Act, 1948
-The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
-The Narcotic Drugs and Psychotropic Substances Act, 1985
-The Medicinal and Toilet Preparations (Excise Duties) Act, 1956
-The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act).

- **Drug & Cosmetic Act**

1940 to 1945: India's parliament, under British rule, passed the Drug & Cosmetic Act of 1940, which led to the

Drugs & Cosmetics Rules of 1945, the central legislation that regulates India's drug and cosmetic import, manufacture, distribution and sale. This established the Central Drugs Standard Control Organization (CDSCO), and the office of its leader, the Drugs Controller General (India) (DCGI)[15]

It contains in detail the regulations divided in different schedules A to Y, Schedule I and Schedule II. Some very important schedules are as follows:

Schedule M of the Drugs and Cosmetics 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. Part I describes good manufacturing practices for premises and materials. Part II deals with requirements of equipments.

Schedule T of the Drugs and Cosmetics Act prescribes Good Manufacturing Practices (GMP) specifications for manufacture of Ayurvedic, Siddha and Unani medicines. It is divided in two parts. Part I deals with Good Manufacturing Practices, while Part II deals with list of machinery, equipment and minimum manufacturing premises required for their manufacture.

Schedule Y of the Drugs and Cosmetics Act specifies about the requirement and guidelines on clinical trials for import and manufacture of new drug. Additionally this act provides for construction and functioning of various regulatory bodies like Drug Technical Advisory Board, Drug consultative Committee, Central Drugs Laboratory etc.

- **Pharmacy Act 1948**

Pharmacy Act was enacted for the regulation of the profession and practice of pharmacy in the country. The Act has led to the formation of the Pharmacy Council of India (PCI) which regulates the functioning of pharmacy education institutions through state pharmacy councils. PCI is also the statutory body to register pharmacy graduates, thereby turning them eligible for practicing as community pharmacists.

- **Drugs & Magic Remedies (Objectionable Advertisements) Act 1954**

Drugs and Magic Remedies Act talks about controlling the advertisement of drugs in certain cases, to prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected therewith. State drug regulators are the enforcement agencies of D &MR Act.

- **The Narcotic Drugs and Psychotropic Substances Act, 1985**:

This is an Act to consolidate and amend the law relating to Narcotic Drugs, to make stringent provisions for the control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances and for matters connected therewith.

- **The Medicinal and Toilet Preparations (Excise Duties) Act, 1956**:

This act lay down the regulations for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol. It also specifies the manufacturing conditions to be maintained for such products.

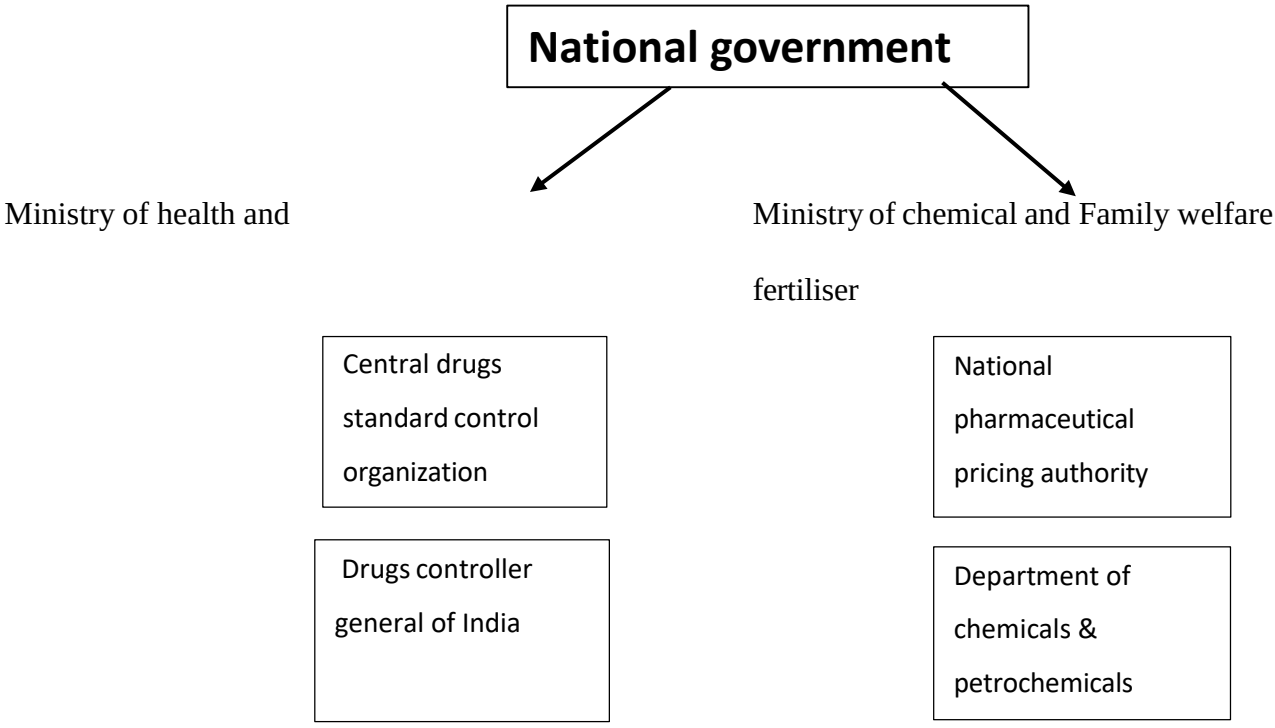
A COMPARATIVE STUDY ON DRUG REGULATORY BODIES IN INDIA

- **INDIA**

India's federal regulatory structure has been plagued by some of the classic problems of developing countries, including red tape and corruption. India has a federal form of government and the medical regulatory structure is divided between national and state authorities.[23] The principal national drug authority based in New Delhi is the Central Drug Standards Control Organization (CDSCO). CDSCO is controlled by the Drug Controller General India (DCGI). There are also 35 state-level Food and Drug Administrations, one for each of India's states and territories.[24]

The DCGI registers all imported drugs, new drugs, biological and drugs in selected categories. It also has responsibility for medical devices, clinical trials and quality standards.[25] The state FDAs register all other products, accredit manufacturing plants, and conduct the bulk of quality monitoring and inspections.

The Ministry of Health & Family Welfare and the Ministry of Chemicals and Fertilisers of the Government of India play a major role in regulating the pharmaceutical sector in the country. In India, state authorities are responsible for licensing a drug maker's research and manufacturing facilities. But the federal Central Drugs Standard Control Organization (CDSCO) and the drugs controller general of India (DCGI) have been responsible for approvals of preclinical and clinical trials, new drug applications, and the importation of drugs from abroad. But, problem lies in state authorities. India's state drug regulatory authorities (DRAs) often lack the staff to monitor their work. This staffing problem, combined with their relatively poor technical experience in such issues worsens the problem. The DRAs have been susceptible to influence by local political authorities, and thus unable to prevent illegal drug manufacturing and marketing activities.[26] Manufacturers that set up operation in states where regulatory oversight and enforcement are weakest can then market their drugs in the rest of the country.



Regulatory bodies in India

- **Ministry of Health & Family Welfare (Department of Health):**

- **Central Drugs Standard Control Organization (CDSCO)**

As an agency of the Department of Health, the CDSCO works both at the Central and the State level and is responsible for ensuring safety, efficacy and quality of drugs supplied to the public. The agency performs the above mentioned functions with the Drugs Controller General of India (DCGI) as the executive head.

- **Drugs Controller General of India (DCGI):**

The DCGI is an apex body in the pharmaceutical industry governing issues such as Approval/NOC for Clinical trials, Bioequivalence studies and Marketing permission in India. Along with it is also responsible for approval for Test License, Testing of Drugs, Registration for Import and Licensing, Export NOCs- Biological samples, Drugs, etc., Licensing of Blood Banks, r-DNA products, Vaccines and Medical Device, Amendment in Drugs And Cosmetics Acts and Rules from time to time

- **Ministry of Chemicals and Fertilisers:**

The Ministry of Chemicals & Fertilizers constitutes bodies such as the Department of Chemicals & Petrochemicals (DCP) and the National Pharmaceutical Pricing Authority (NPPA). These departments are entrusted with the responsibility of policy making, planning, development and regulations relating to Chemicals, Petrochemicals and Pharmaceuticals.

EXPLANATION OF SOME IMPORTANT TERMS IN REGULATORY AFFAIRS

- **Investigation of new drug application (INDA)**

It is an application which is filed with FDA to get approval for legally testing an experimental drug on human subjects in the USA.[38]

There are three IND types:

- **An Investigator INDA**- is submitted by a physician who both initiates and investigates, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.
- **Emergency use INDA**- Allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21 CFR, Sec. 312.23 or Sec. 312.34. It is also used for patients who do not meet the criteria of an existing study protocol, or if an approved study protocol does not exist.
- **Treatment IND**- is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

There are two IND categories:

-Commercial

-Research (non-commercial)

The IND application must contain information in three broad areas:

-Animal Pharmacology and Toxicology Studies

-Manufacturing Info

-Clinical Protocols and Investigator Information

- **New Drug Application (NDA) :**

The FDA defines it as "The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The data gathered during the animal studies and human clinical trials of an Investigational new drug become part of the NDA."[39]

The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:

-Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.

-Whether the drug's proposed labelling (package insert) is appropriate, and what it should contain.

-Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.

In simple terms - "NDA is an application which is filed with the FDA by a pharma company for getting approval for their newly discovered drug".

- **Abbreviated New Drug Application (ANDA):**

It is an application for a U.S. generic drug approval for an existing licensed medication or approved drug.

A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, Route of administration, quality, performance characteristics and intended use. All approved products, both innovator and generic, are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations.

- **Marketing authorisation application (MAA):**

It is an application (to the relevant authority) typically the UK's MHRA or the European Commission's Committee for Medicinal Products for Human Use (CHMP) to market a drug or medicine.

The U.S. Food and Drug Administration equivalent of marketing authorization application (MAA) is a New Drug Application (NDA).

- **Active Pharmaceutical Ingredient (API) (or Drug Substance):**

Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

- **Active Substance Master File (ASMF)/Drug Master File (DMF) :**

It is a document containing complete information on an Active Pharmaceutical Ingredient (API) or finished drug dosage form. It is known as European Drug Master File (EDMF) or Active Substance Master File (ASMF) and US-Drug Master file (US- DMF) in Europe and United States respectively.

The DMF contains factual and complete information on a drug product's chemistry, manufacture, stability, purity, impurity profile, packaging, and the cGMP status of any human drug product.

- **Current good Manufacturing Practice (cGMP) :**

These are practices and the systems required to be adapted in pharmaceutical manufacturing, quality control, quality system covering the manufacture and testing of pharmaceuticals or drugs including active pharmaceutical ingredients, diagnostics, foods, pharmaceutical products, and medical devices.

- **International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH):**

It is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of pharmaceutical product registration.

- **Good Clinical Practice (GCP):**

It is an international quality standard that is provided by International Conference on Harmonisation (ICH), that defines standards, which governments can transpose into regulations for clinical trials involving human subjects.

- **Good Laboratory Practice (GLP):**

It specifically refers to a quality system of management controls for research laboratories and organizations to try to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) safety and efficacy tests.

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.

SCOPE OF WORK: -

Locally the F.D.A. (Foods & Drugs Control Administration) is the main regulatory body governing and implementing the rules and regulations for the Drug & Pharma industry. The F.D.A. 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. 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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