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Review Article

An Overview Of Regulatory Affairs In Pharmaceutical Science

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ABSTRACT

Regulatory affairs in the pharmaceutical industry play an important role as the Pharmaceutical sector is rising very rapidly and there is a want of regulatory affairs professionals to provide the current needs of industries for the global competition. A regulatory affair is a profession which acts as the interface between pharmaceutical industries and government authorities across the world. The goal of the regulatory affairs professional is the protection of human health, ensuring safety, efficacy, and quality of drugs, ensuring appropriateness and accuracy of product information. This present article discusses the evolution of Regulatory Affairs, its role in the pharmaceutical industry and its involvement for the implementation of regulatory guidelines which improve the growth of the industry.

INTRODUCTION

Regulatory Affairs [RA], also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries [pharmaceuticals], medical devices, Biologics and functional foods [1]. pharmaceutical regulatory affairs, as a profession and as a profession, have an important role to play in influencing over-the-counter medication politics, medication use and outcomes as well as other aspects of medical care. In many cases, this will be done at the community level with other health care professionals. The following are the various actions that can be applied to drug users. If done, in whole or in part, it will add to the value of drug therapies, making them a safe and affordable use of medications, leading to beneficial results already exist[2] The success of regulatory strategy is less depend on regulation than on how they are interpreted, applied .and communicated within companies and to outside constituents. Pharmacy affairs professionals play an essential role in a ensuring all pharmaceutical product comply with regulation governing the industry [3] A science of developing new tools, standards and approaches to assess the

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safety, efficacy, quality and performance of regulated products All medicines must meet three criteria: be of good quality, safe and effective. The judgments about medicines quality, safety and efficacy should be based on solid science.[4] A regulatory affair [RA] is a career which acts because the interface between the pharmaceutical industry and drug regulatory government internationally. it's far mainly involved inside the registration of drug products in the respective international locations prior to their marketing. The modern Pharmaceutical industry is well prepared, systematic and compliant to global regulatory standards for the producing of Chemical and organic drugs for human and veterinary intake in addition to scientific gadgets, conventional natural products and cosmetics. The Regulatory Affairs department is an important part of the organizational shape of pharmaceutical companies. Internally it it liaises on the interface of drug improvement, manufacturing, advertising and marketing and clinical studies. . Regulatory Affairs is actively concerned in each degree of improvement of latest medicine and the publish-advertising sports with authorized medicinal merchandise [5]

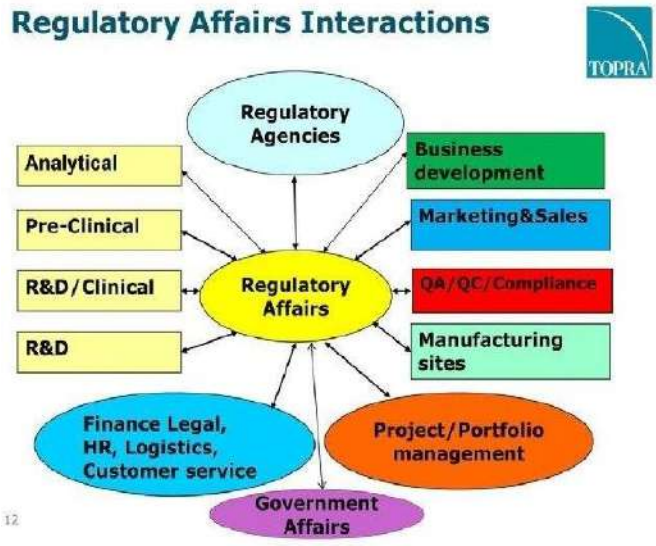

fig:1 Roles or interaction of RA

OBJECTIVES OF REGULATORY AFFAIRS

The present study describes a brief review of various regulatory bodies of major developed and developing countries around the world and the scope and challenges of such pharmaceutical regulatory organizations in delivery of safe and effective healthcare products. The main objective of regulatory affairs is to provide the basis for the assurance of high quality of food products which can increase consumer's interest for ensuring the efficacy, quality, and safety.

1. Roles of Regulatory Affairs Professional in Health Authorities as well as Pharmaceutical Industry
2. Pharmaceutical Legislations
3. Clinical Trials.
4. Roles of Regulatory Affairs Professional in Health Authority in Health Authorities as well as Pharmaceutical Industry.
5. Regulatory Affairs Network in Pharmaceutical Industry.
6. Indian Pharmaceutical Industry & Drug Regulations development in different Era.
7. Major Rules and Act of India
8. Drug Regulatory Affairs and Global, Regional and National Regulatory Network. [5]

Historical overview of regulatory affairs :

Drug regulation structure in existence today-drug laws ,drug regulatory agencies, drug evaluation boards, QC laboratories, drug information centers, and etc-have developed over time. In such developments began centuries ago; in others , they are relatively recent, having started only in the 1990s.[3]

Importance Of Regulatory Affairs:

The time to arrive at the market in today's computing environment is essential for a product and therefore the success of the company. Hence, it has substantial economic value for the company for its actions in the field of RA. The importance of the RA function means that senior "RA professionals" are progressively being selected to

positions of the board room, where they may advise & affect their companies‟ strategic decisions. Regulation is a binding directive from an agency to explain how the law may be interpreted and complied. If the rules are not followed, the warning letter published may result in a portion of the FDA website that is not a positive idea for a pharmaceutical firm. A new drug may involve a huge investment in its development and thus a few months delay in reaching it to the market may require enormous financial consideration. In worst cases, failure to completely provide all relevant data or to disclose the inaccurate labelling of the product might simply lead to the recall of the product. Either of these issues could result in the loss of several million sales units, and most importantly the decrease in confidence of the investor, patients as well as health professionals. RA is the initial point of connection between the government agency and the corporation [7]

Why regulatory affairs? The development of drug laws and drug regulations :

For an understanding of drug laws worldwide. Some basic facts must be understood and borne in mind. Typically drug laws are regulations after the fact –their development being triggerd by unwanted and sometimes disastrous events. Information and knowledge on the use of medicinal products increase exponentially; thus, drug laws are proliferative at an ever-growing place. [8]

Scope Of Regulatory Affairs Professional In Industries

Regulatory affairs professionals are employed in industry, government regulatory authorities and academics. The wide range of regulatory professionals includes in these areas:

- Pharmaceuticals
- Medical devices
- In vitro diagnostic
- Biologics and biotechnology
- Nutritional Projects
- Cosmectics
- Veterinary products[9

What is regulatory affairs ?

Regulatory affairs broadly define it one most consider every interaction company can have with a regulatory authority, be that authority national , state/provincial ,or local. then consider in every internal department or individual that might need something form, or need to provide something to a, regulatory affairs .then consider the entire life cycle of a product, from conception to marketing [the perhaps, eventual removal] and every type of product is regulated [10]

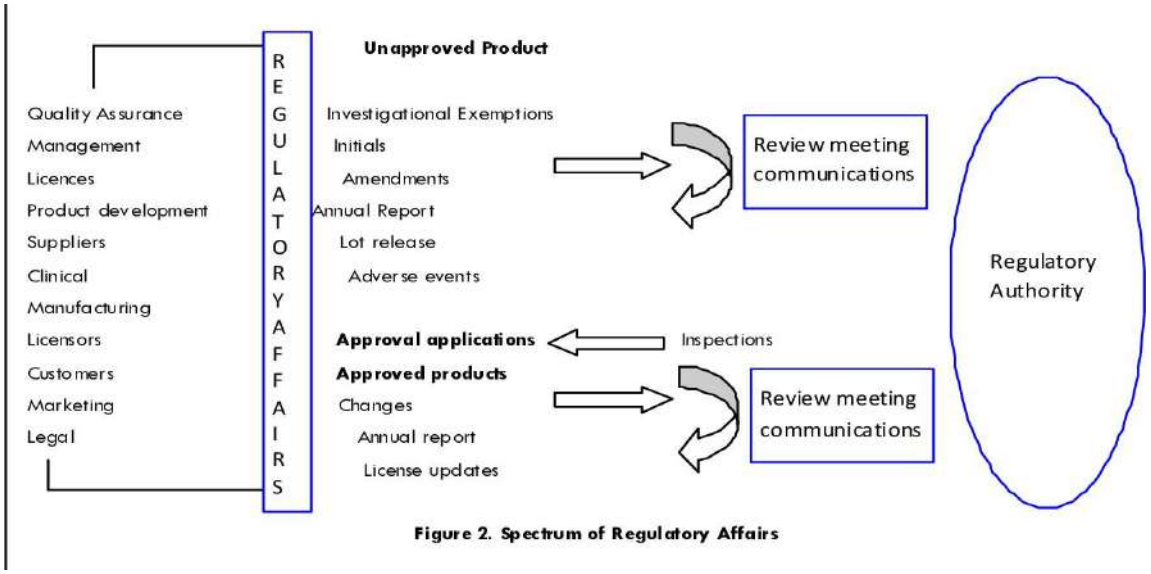

Figure 2. Spectrum of Regulatory Affairs

Regulatory affairs is a profession developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines, and by the companies responsible for the discovery, testing, manufacture and marketing of these products wanting to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare. A new class of professionals emerged to handle these regulatory matters for companies.As discipline, regulatory affairs covers a broad range of specific skills and occupations. Under the best of circumstances, it is composed of a group of people who act as a liaison between the potentially conflicting worlds of government, industry, and consumers to help make sure that marketed products are safe and effective when used as advertised. People who work in regulatory affairs negotiate the interaction between the regulators [the government], the regulated [industry], and the market [consumers] to get good products to the market and to keep them there while preventing bad products from being sold.[12]

THE ROLE OF THE REGULATORY AFFAIRS DEPARTMENT

The regulatory affairs [RA] department of a pharmaceutical company responsible for obtaining approval for new pharmaceutical products and ensuring that approval is maintained for as long as the company wants to keep the product on the market. It serves as the interface between the regulatory authority and the project team, and is the channel of communication with the regulatory authority as the project proceeds, aiming to ensure that the project plan correctly anticipates what the regulatory authority will require before approving the product. It is the responsibility of RA to keep abreast of current legislation, guidelines and other regulatory intelligence. Such rules and guidelines often allow some flexibility, and the regulatory authority as the project proceeds, aiming to ensure that the project plan correctly anticipates what the regulatory authority will require before approving the product. It is the responsibility of RA to keep abreast of current legislation, guidelines and other regulatory intelligence. Such rules and guidelines often allow some flexibility, and the regulatory authorities expect companies to take responsibility for deciding how they should be interpreted. The RA department plays an important role in giving advice to the project team on how best to interpret the rules. During the development process sound working relations with authorities are essential, e.g. to discuss such issues as divergence from guidelines, the clinical study programme, and formulation development. Most companies assess and prioritize new projects based on an intended Target Product Profile TPP. The RA professional plays a key role in advising on what will be realistic prescribing information label for the intended product. As a member of the project team RA also contributes to designing of the development programme. The RA department reviews all documentation from a regulatory perspective, ensuring that it is clear, consistent and complete, and that its conclusions are explicit. The department also drafts the core prescribing information that is the basis for global approval, and will later provide the platform for marketing. The documentation includes clinical trials applications, as well as regulatory submissions for new products and for changes to approved products. The latter is a major task and accounts for about half of the work of the RA department.

An important proactive task of the RA is to provide input when legislative changes are being discussed and proposed. In the ICH environment there is a greater possibility to exert influence at an early stage.[13]

Fig 3 : Approval process of drug substance

Regulatory Authorities –

Public health being the prime concern, it is necessary that the drug/drug product available for human/veterinary use and medical devices must not only be effective but also be safe for the intended use. To ensure this, various territorial regulatory bodies came into existence. Major regulatory agencies include World Health Organization [WHO], United States Food and Drug Administration [USFDA, United States], European Medicines Agency [EMA, European Union], Medicines and Healthcare Products Regulatory Agency [MHRA, UK], Therapeutic Goods Administration[TGA, Australia], Health Canada [Canada], Pharmaceuticals and Medical Devices Agency (PMDA, Japan) and Central Drugs Standard Control Organization [CDSCO, India]. It was observed that regulatory guidelines differ with respect to territorial requirements; this demanded the need for universal harmonisation. Thus, The International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use [ICH] was founded in 1990 by united efforts of the United States, Europe and Japan to bring together different regulatory bodies globally and set ICH Guidelines for pharmaceutical drug product development. Since its inception, the ICH has evolved gradually with a mission to attain better harmonisation towards development and registration of medicines with a higher degree of safety, efficacy and quality worldwide. Although ICH has harmonised the drug regulatory aspects worldwide, the regional regulatory bodies continue to play a pivotal role in drug approvals across the territory.[15]

Mission Of Regulating Bodies:

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. FDA also plays a significant role in the Nation's counterterrorism capability. [16]

REGIONAL REGULATORY BODIES:

Table :1 Regional regulating bodies.

Sr.no	Countries	Regulating bodies
1	Australia	Therapeutic Goods Administration [TGA]
2	Brazil	Agencia Nacional de Vigiloncia Sanitaria [ANVISA] National Health Surveillance Agency
3	Canada	Health Canada

4	China	State Food and Drug Administration
5	Denmark	Danish Medicines Agency
6	Europe	European Medicines Agency [EMEA]
7	India	Central Drug Standard Control Organization [CDSCO]
8	Italy	Italian Medicines Agency [AIFA]
9	Ireland	Irish Medicines Board
10	Japan	Ministry of Health, Labour and Welfare [MHLW]
11	Malaysia	National Pharmaceutical Control Bureau
12	New Zealand	Med safe - Medicines and Medical Devices Safety
13	Netherland	Authority
14	Nigeria	Medicines Evaluation Board
15	Singapore	Centre for Pharmaceutical Administration Health
16	South Africa	Sciences Authority
17	Switzerland	Medicines Control Council [MCC]
18	Thailand	Swissmedic , Swiss Agency for Therapeutic Products
19	USA	Thailand Food and Drug Administration
20	United Kingdom	Food and Drug Administration [FDA]
21	Germany	Medicines
22	Sri Lanka	Agency [MHRA]
23	Uganda	Federal Institute of health and Medical Devices

International Regulating Bodies :

Many of the countries don‟t have their own regulating bodies or the improper regulated agencies so they follow the global guidelines. Majority of the Gulf countries don‟t have their Kuwait, Oman, Saudi Arabia etc., so they adopt the most suitable guidelines according to the region. [17]

Table:2 international regulatory bodies.

Regulatory bodies	Year of establishment	Headquarters
World	1948	Geneva, Switzerland
World	1995	Geneva, Switzerland
International conference	1990	Belgium, Europe
Pan American health organization [PAHO]	1902	Washington D.C USA
World intellectual property organization [WIPO]	1967	Geneva, Switzerland

Pharmaceutical Drug Regulatory Affair:

Regulatory Affairs is a comparatively new profession which has developed from the desire of governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines .The companies manufacture and marketing these products must ensure that they supply Quality products to public for their health and welfare. Now most of the companies have specialist departments of Regulatory Affairs professionals. 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 noted. The companies responsible for the discovery, testing, manufacture and marketing of these products also

want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare.[18]

Needs of regulatory affairs in pharmacy circulum:

The pharmaceutical biotechnology and medical device research and development industries are among the most highly regulated industries in the country. As India is growing very rapidly in pharmaceutical sector, there is a need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory affairs.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 guidelines 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, which are capable of handling issues related to regulatory affairs in a comprehensive manner.[19]

Responsibilities of the regulatory department:

The Regulatory Affairs professional's job is to keep track of the ever- changing legislation in all the regions in which the company wishes to distribute its products. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating. They give strategic and technical advice at the highest level in their companies, Right from the beginning of the development of a product, making an important contribution both commercially and scientifically to the success of a development program and the company as a whole.

- Some of the responsibilities of the regulatory department are the following:
- Study and interpret the rules
- Constantly check the legislation and monitor any updates
- Ensure the registration and compliance of products on the market with the legislation of the territory
- Evaluate product registrability in countries of distribution
- Prepare and update technical dossiers and product regulatory documentation
- Prepare registration documents and carry out all the necessary actions to complete the registration of products abroad
- Mediate between authority needs and company needs
- Revise artworks and promotional materials from a regulatory point of view.
- As it can be imagined, the regulatory department is essential in the creation process of a new product, since it allows to understand the characteristics that the product can have, and the process needed to be able to have the product on the market in the shortest possible time, being in contact with all company departments to allow the registration of the product on the market and the distribution of the product. The role of the regulatory is equally fundamental during the whole life cycle of the product when it is important to analyze variations that are needed on the products and their dossier and to implement the needed activities in order to allow the compliance of the product following changes of the normative. Thus, the RA department has multiple responsibilities and areas of expertise and is a connection point between different company dimensions. Its role is in constant transformation and has a much more

dynamic nature than one might think at first.[20]

Regulatory affairs education:

The person is in the regulatory affairs must be familiar with all the guidelines He should have detailed understanding of a particular regulatory document which has been drafted company Such people are the primary communication link between the and worldwide regulatory agencies such as USFDAI [United States Food and Drug Administration] and European Union of Drug Regulatory Affairs [EUDRA] A number of organizations such as the Regulatory Affairs Professional Society [RAPS], the Drug Information Association [DIA] the Food and Drug Law Institute [FDLI] and international organizations such as the European Society of Regulatory Affairs play a vital role in providing relevant information Commercial traming companies such as Parexel-Barett and the Pharmaceutical Education and Research insumite [PERI conduct meetings professionals. [19] on the regulatory as which would be help to the professionals.[19]

Drug Approval procedure in different countries:

For approval of new drug different countries have to follow different regulatory requirements. For marketing authorization application [MAA] a solitary administrative methodology is material to different nations is just about a troublesome assignment. Thusly it is important to know about administrative necessity for MAA of every nation. It is difficult to go for a single regulatory approach for approval of a new drug in different countries therefore. each country has its own regulatory requirements which have to be satisfied to approve a new drug in that particular country. Hence there is a need for gaining awareness on regulatory issues of various countries. Firstly, when a lead molecule is identified for a target disease, it should be optimized. After the discovery of a drug, pre-clinical trials are conducted on animals to ensure safety and efficacy. An application should be submitted to competent authority of a concerned country to get permission for conducting clinical studies. Clinical trials are performed in four phases to assure safety, efficacy and then the drug dose is optimized in humans. A Marketing Authorization Application [MAA] is then submitted, which is approved by the competent authority, if the drug satisfies the requirements of safety and efficacy and proves that its benefits outweigh its risks. New Drug Application [NDA] is an application which is submitted to the individual regulatory authority for authorization to market a new drug i.e. innovative product. To gain this permission a sponsor submits preclinical and clinical test data for analysing the drug information, description of manufacturing trials. Different phases of clinical trials Pre-clinical study Phase I - Clinical trial Phase II - Exploratory trial Phase III- Confirmatory trial Phase IV - Post marketing trial This assessment confirms that adequate data and information have been submitted in each area to justify “filing” the application. [21]

Table 3. Regulatory bodies in different countries

Country	Regulatory body
India	Central Drug Standard Control Organization [CDSCO]
USA	Food and Drug Administration [FDA]
Europe	European Medicines Agency [EMEA]
Canada	Health Canada Ministry
Japan	Ministry of Health, Labour & Welfare[MHLW]

Regulatory approval & submission procedure in india:

The Drug and Cosmetic Act 1940 and Rules 1945 were passed 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 [India]

[DCGI] was established. In 1988, the Indian government added Schedule Y to the Drug and Cosmetics Rules 1945. 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. The changes includes, establishing definitions for Phase I–IV trials and clear responsibilities for investigators and sponsors. The clinical trials were further divided into two categories in 2006. In one category [category A] clinical trials can be conducted in other markets with competent and mature regulatory systems whereas the remaining ones fall in to another category [category B] Other than A. Clinical trials of category A [approved in the U.S.,Britain, Switzerland, Australia, Canada, Germany, South Africa, Japan and European Union] are eligible for fast tracking in India, and are likely to be approved within eight weeks. The clinical trials of category B are under more scrutiny, and approve within 16 to 18 weeks. An application to conduct clinical trials in India should be submitted along with the data of chemistry, manufacturing, control and animal studies to DCGI. The date regarding the trial protocol, investigator's brochures, and informed consent documents should also be attached. A copy of the application must be submitted to the ethical committee and the clinical trials are conducted only after approval of DCGI and ethical committee. To determine the maximum tolerated dose in humans, adverse reactions, etc. on healthy human volunteers, Phase I clinical trials are conducted. The therapeutic uses and effective dose ranges are determined in Phase II trials in 10-12 patients at each dose level . The confirmatory trialsPhase III are conducted to generate data regarding the efficacy and safety of the drug in ~ 100 patients in [3- 4 centers] to confirm efficacy and safety claims. Phase III trials should be conducted on a minimum of 500 patients spread across 10-15 centers, if the new drug substance is not marketed in any other country. The new drug registration [using form number 44 along with full preclinical and clinical testing information] is applied after the completion of clinical trials. The comprehensive information on the marketing status of the drug in other countries is also required other than the information on safety and efficacy. The information regarding the prescription, samples and testing protocols, product monograph, labels, and cartons must also be submitted.[22]

Drug Approval Process in India:

The Drug and Cosmetic Act 1940 and Rules 1945 were announced by the India's parliament to direct the import, production, circulation and offer of medications and cosmetics. The Central Drugs Standard Control Organization [CDSCO] and the office of its leader, the Drugs Controller General [DCGI] was established. The clinical trials can be registered in the Clinical Trials Registry of India [CTRI] giving details of the clinical trials and the subjects involved in the trials. The rules to be followed under The Drugs and Cosmetics Rules 1945 are: 1. Rule 122 - A: Application for permission to import new drug 2. Rule 122- B: application for approval to manufacture new drug other than the drugs specified under Schedule C and C. 3. Rule 122 - D: Permission to import or manufacture fixed dose combination. 4. Rule 122 - DA: Application for permission to conduct clinical trials for New Drug/Investigational New Drug. 5. Rule 122 - DAB: Compensation in the case of injury or death during the clinical trials. The applicant submits the application to the ethical .the clinical trials are conducted only after approval of DCGI and ethical committee. To determine the maximum tolerated dose in humans, adverse reactions, etc. on healthy human volunteers, Phase I clinical preliminaries are performed. All clinical trial from phase I to phase IV are performed. The new drug registration is applied only after the completion of clinical trials.

The information regarding the clinical trial as well as prescription, samples and testing protocols, product monograph, labels, and cartons must also be submitted. The application can be reviewed by DCGI in a Range of about 12-18 months.[21]

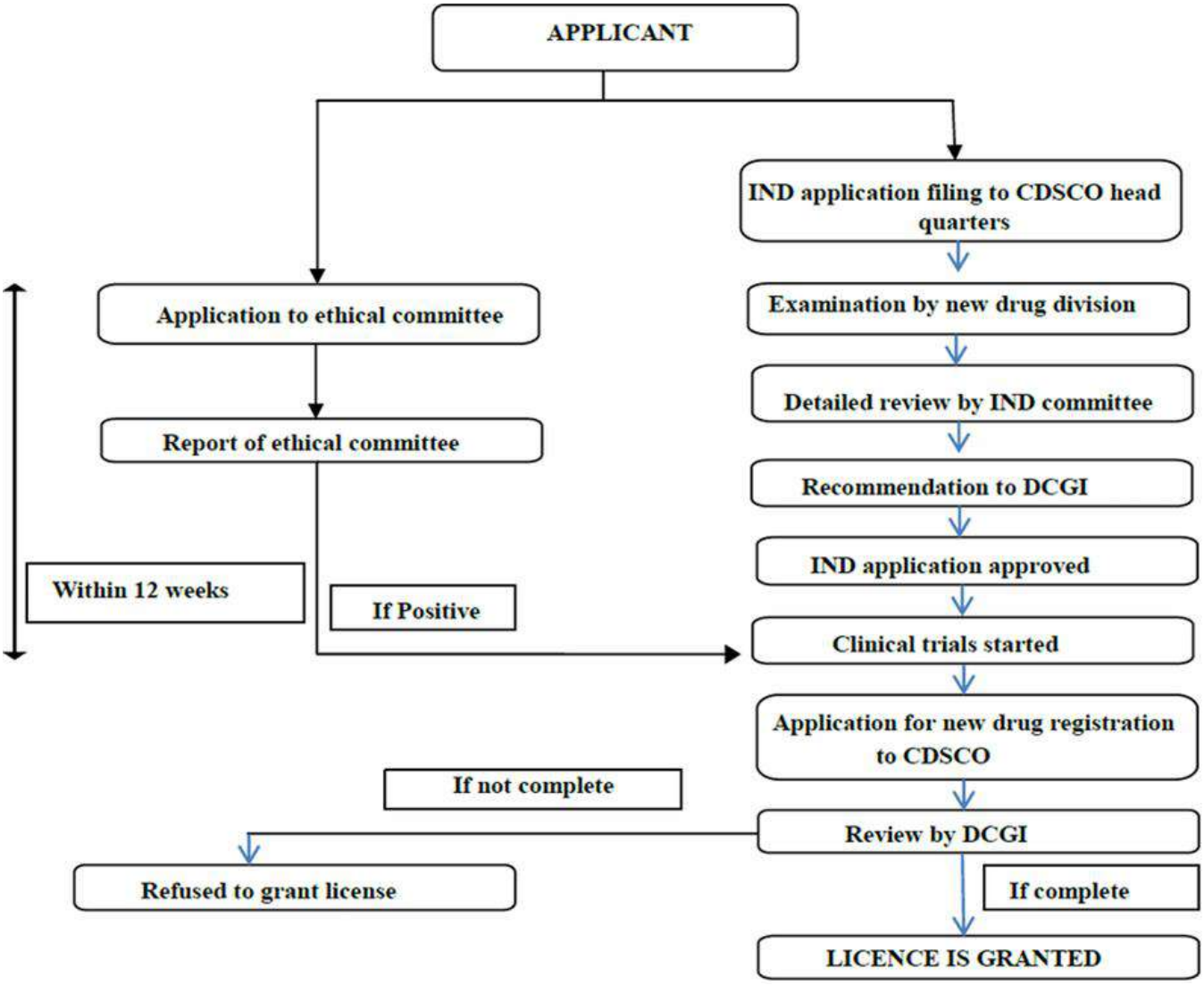

Figure 4: Drug approval procedure in India

Drug Approval Process in United States:

The United States has believably the world‟s most stringent standards for approving new drugs. Drug approval standards in the United States are considered by many to be the most demanding in the world. The FDA is responsible for promoting and protecting public health. FDA‟s new drug approval process is accomplished in two phases: Clinical Trials [CT] and New Drug Application [NDA] approval. The new drug product is controlled through a new drug application [NDA]. Currently such applications are accepted for review in eCTD format. The major concern about NDA is that the product shall be safety and effective. Only after submission of investigational new drug [IND] application FDA approval process begins. The US Drug Law and Regulations United States Pharmacopoeia [USP] were started in 1820 to set standards for strength and purity of drugs. Major milestones in the evolution of US drug law are:

- Food and Drugs Act [1906]: It requires that the drugs must meet official standards of strength and purity.

- Federal Food, Drug and Cosmetic Act [1938]: It was enacted after sulfanilamide tragedy, to prove the safety of a drug before being marketed.
- Kefauver- Harris Amendment [1962]: It was passed after the thalidomide disaster. It requires the manufacturers to prove that drug is safe and effective. All the firms should send adverse effect reports to FDA.
- Orphan Drug Act [1973]: This allows tax deductions for drug companies to develop orphan drugs.
- Generic drug enforcement Act [1992]: It deals with convictions related to ANDA approvals
- FDA Modernization Act [1997]: It contains some changes in Federal Food, Drug and Cosmetic Act regarding collection and assessment of user fees and accelerated approval processes.[21]

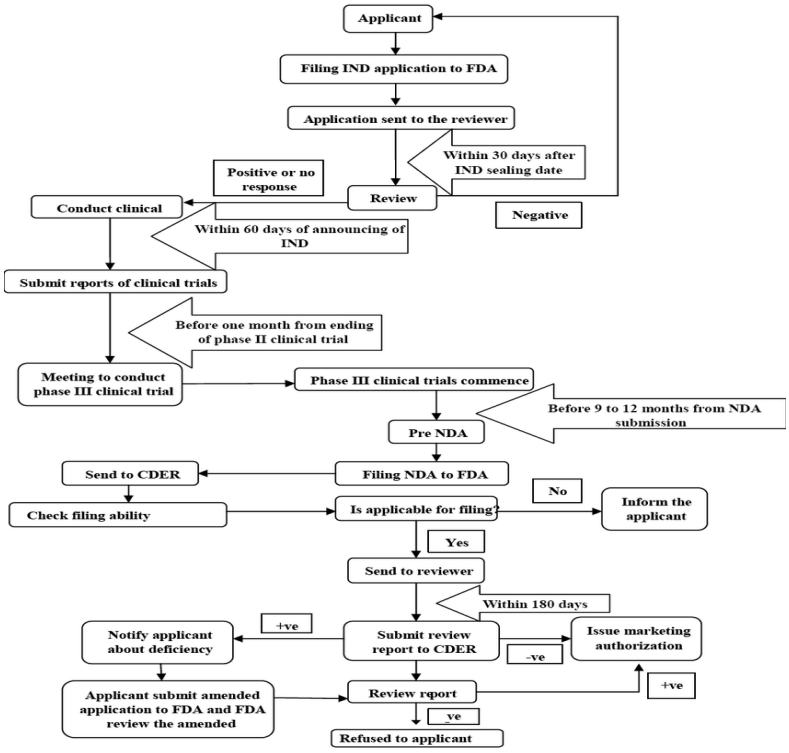

Figure 5: Drug Approval process in USA

New drugs approved in India within period of 1 year:

1. Application in Form-44 duly signed, by the competent authority with name and designation
2. Treasury Challan of Rs. 25000/- as per Drugs & Cosmetic Rules.
3. Undertaking by the Principal Investigator [PI] as per appendix VII of schedule "Y" of Drugs and Cosmetic Rules.
4. A copy of the approval of the BE study centre from CDSCO.
5. Sponsor‟s Authorization letter duly signed by the competent authority on their letterhead.
6. The study protocols.
7. Clinical study data and published report of pharmacokinetic and pharmacodynamic study carried out in healthy volunteers data published in reputed journals.
8. Package literature on the international product.
9. Complete Certificate of Analysis of same batches [both test & reference formulations] to be used in the BE study.

10. In the case of multiple doses BE study adequate supporting safety data should be submitted.
11. In the case of Injectable preparation the subacute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.
12. Depending on the nature of the drug like cytotoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.[25]

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.

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