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Role of Regulatory Affairs in Marketing Pharmaceutical Products

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Abstract: ***Regulatory affairs (RA) plays very important role in pharmaceutical sectors, which have the responsibility for getting approval for new products arriving in the market As it is providing good quality of drug including safety and effectivity in the space of not only solely pharmacy however co - jointly in the area of the veterinary medicine. Regulatory affairs are rewarding, intellectually stimulating and extremely regarded profession among pharmaceutical companies. The role of regulatory affairs is to develop and do a regulatory system to create certain sure that the collective efforts of the drug development team leads to product that's planning to is approve by international regulators. Regulatory affairs behaves as the link between the regulatory authority and the project team, and is the passage for communication with the regulatory authority because it move forwards, target to providing that project arrange properly predicts what the regulatory authority would require before approving the product.***

Keywords: Marketing, Pharmaceutical

1. Introduction

Food and Drug administration (FDA) needs Pharmaceutical Corporation to come up with and supply all the knowledge deemed necessary to evaluate a given drug, medicine, biologic or device with respect to two prospective safety and efficacy. All these information is used by the agency to decide whether the product should be on the market and if so, how it should be marketed and sold. The other name of regulatory affairs is (RA) Government affairs may be a profession at a interval regulated industries like pharmaceuticals, medical devices, energy and banking. Regulatory affairs have to very specific meaning because it is connected or regarding to the healthcare industries. This includes pharmaceuticals, medical devices, biological and functional foods. [1] Regulatory affairs acts as the interface between the pharmaceutical industry and drug regulatory authorities across the world. Regulatory affairs mainly involved in the registration of drug products in the respective countries prior to their marketing. A new drug moiety can cost several million of rupees or dollars and any blunder causes to greater impact on company status. As medicines play a very huge role in human life so, there must be regulations for drug ensuring their not only quality, safety but also efficacy. The regulatory affairs professional is that the just one who is totally to blame for holding merchandise in compliance and maintaining all the records regarding to healthcare system. One of the vital role of regulatory specialist is to ensure that the all information regarding drugs has been correctly established to the patient covering labeling also. Even a small mistake in regulation can cause the product to be recall and leads to loss of several millions of the money. [2]

The RA professional plays a key role in advising on what will be label (realistic prescribing information) for the intended product. The RA professional's reviews all documentation from a regulatory perspective, ensuring that department also drafts the core prescribing information that is the basis for global approval and will later provide the platform for marketing. The RA records or documentation includes clinical trials applications, as well as regulatory submission for new product moiety and also for changes to approval products.

What are regulatory affairs?

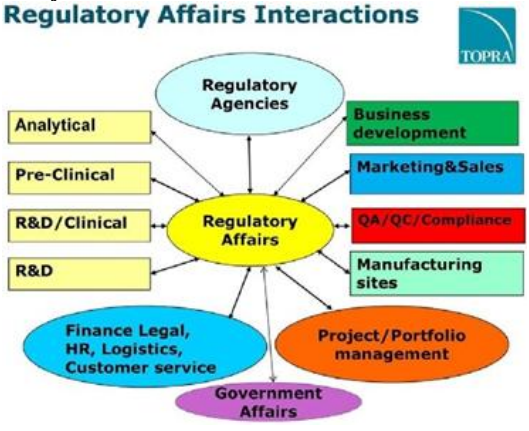
We can outline Regulatory affairs as, it's a comparatively a replacement profession that developed from a need of state to shied a public health to protect by controlling the safety and efficacy of a drug product in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines.

Regulatory affairs in the pharmaceuticals industry may be defined as "The interface between the pharmaceutical company and the regulatory agencies across the world." [3]

The regulatory affairs department is a very important part of the structure of pharmaceutical companies. Internally it liaises at the interphase of drug development, manufacturing, promoting and clinical research. outwardly it's the key interface between the corporate and therefore regulatory authorities. In another words RA is,

- A dynamic and challenging profession
- Gives strategic and technical advice for product development.
- Contributes commercially and scientifically to the success of a development programmes and company.
- Ensures public health by to controlling, safety and efficacy of products.

Regulatory Bodies in the World



Country	Regulatory Body
USA	Food and Drug administration (FDA)
UK	Medicines and Healthcare products regulatory agency (MHRA)
Australia	Therapeutic Goods administration (TGA)
India	Central Drug Standard Control Organization (CDSCO)
Canada	Health Canada
Europe	European Medicines Agency (EMEA)
Japan	Ministry of health, Labour and Welfare

The current pharmaceutical trade is well organized, systematic and compliant to international restrictive standards for producing of chemical and biological medicine for human and veterinary consumption moreover as medical devices, ancient flavourer merchandise and cosmetics. [4]

Why need to regulate

- Drugs are not ordinary consumer products.
- All substances are poisons, there's none which isn't a poison. The right dose of drug differentiates a poison and a correct remedy.
- To ensure quality, safety and efficacy of a drug / medicine in order to assure the continued protection of public health.
- Not a single drug product is completely safe or efficacious in all circumstances, but there is a moral, as well as legal, expectation that appropriates steps are taken to assure optimal quality, safety and efficacy by the drug product concerned. Benefit versus risk. [5]

Objectives of Regulatory Affairs

The major three objectives of regulatory affairs are;

- Role of regulatory affairs professional in health authorities as well as pharmaceutical industry.
- Pharmaceutical legislations.
- Clinical trials

The present study on Regulatory affairs 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 organization in delivery of safe and effective healthcare products. [6]

Role of Regulatory Affairs in Pharmaceutical Industry

Role of regulatory affairs,

a) Development Phase

- Arrange for scientific recommendation – authorities
- Recommendation on development studies to demonstrate safety, quality and efficacy.
- A group up regulatory strategy
- Ensure application of guidelines
- participate in cross functional project teams
- Managing the preparation of the regulatory submission
- Minimize time to market
- Advice on a global development plan
- Optimizes submission strategies
- Efficiency in dossier preparation
- format, document - uses
- Electronic submission
- Internal company relationships, project management
- Review high – level documents
- Interact with commercial side of business such as pricing and reimbursement

b) Approval Phase

- Check progress of evaluation and anticipate questions.
- raised or clarify raised questions, plan response and strategies with other departments agencies
- plan and manage agency meetings.
- negotiate approval and product information with agencies

c) Post Approval Phase

- Submission of variations
- Renewals
- Pharmacovigilance
- Product information review
- New indications / new information
- Regulatory input to development plans
- Focus on what does the future hold regarding to drug product

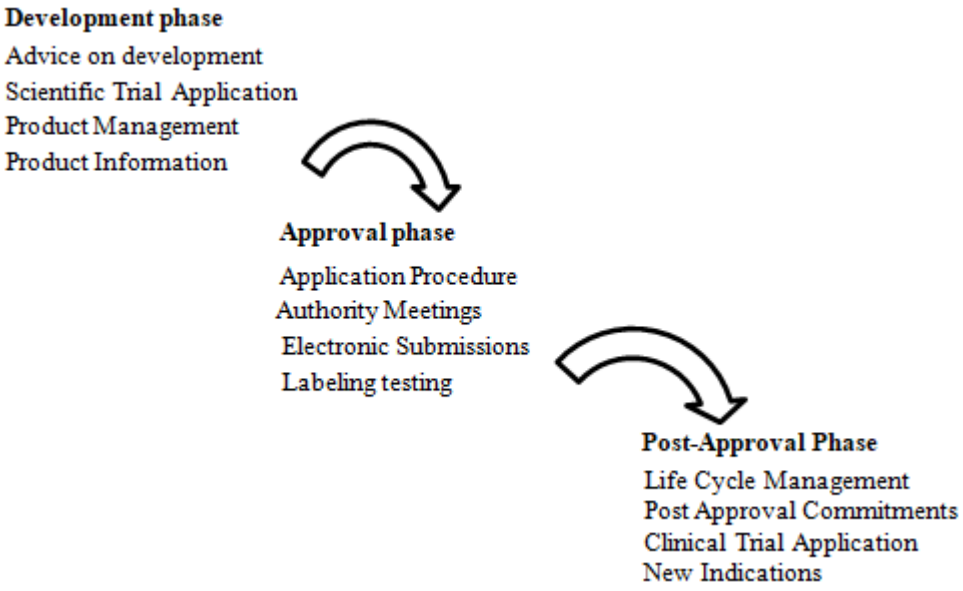
Involvement of R. A. In different sectors

Currently totally different countries ought to follow different regulatory requirements needs for approval of latest drug. For promoting authorization application (MAA) a one regulatory approach is applicable to varied countries is almost a tough task. Thus it's necessary to own information regarding regulatory requirement for MAA of every country. [7]

Different phases of clinical trials

1) Pre - clinical study – Mice, Rat, Rabbit, Monkeys.
2) Phase I –Human pharmacological trial - estimation of safety and tolerability
3) Phase II – preliminary clinical trial – estimation of effective and short term side effects.
4) Phase III – confirming trial – confirmation of therapeutic advantages
5) Phase IV – post promoting trial - studies done when drug approval [8, 9, 10]

Product Life Cycle and Regulatory Affairs Perspective



When the action taken is either an approvable or a not approvable, then the regulatory provides applicant with an opportunity to meet with agency and discuss the deficiency. [11, 12]

1) Involvement of Regulatory Affairs in Pharmaceutical Industry

Regulatory affairs professionals provides military science associated sensible steerage to R and D production, QC department etc. Just aid the drawn of the progress of a product, making main benefaction both together economically and scientifically to the triumph of a evolution theme and company as a entirely. It takes time of about up to 15 years to evaluate and to put a new pharmaceutical product and many issues may stand up in the process of scientific progress and because of an altering regulatory habitat. Regulatory professionals help out the company to keep out of issues originated by immaterial documentation, unsuitable scientific reasoning or improved presentation of records.

2) Involvement of Regulatory Affairs in Product Management

The key role of R. A. professional is very larger than the registration of drug products, they advice companies both strategically and technically at the pick their role starts right from development of a drug product to making, marketing and post marketing strategies. Their advice at all stages both in terms of legal and technical requirement help companies save a lot of time and money in developing the product and marketing the same. For countries that don't have their on rules the globe World Health Organization tips on health matters. [13] And World Trade Organization on trade regulations between nations is followed. [14]

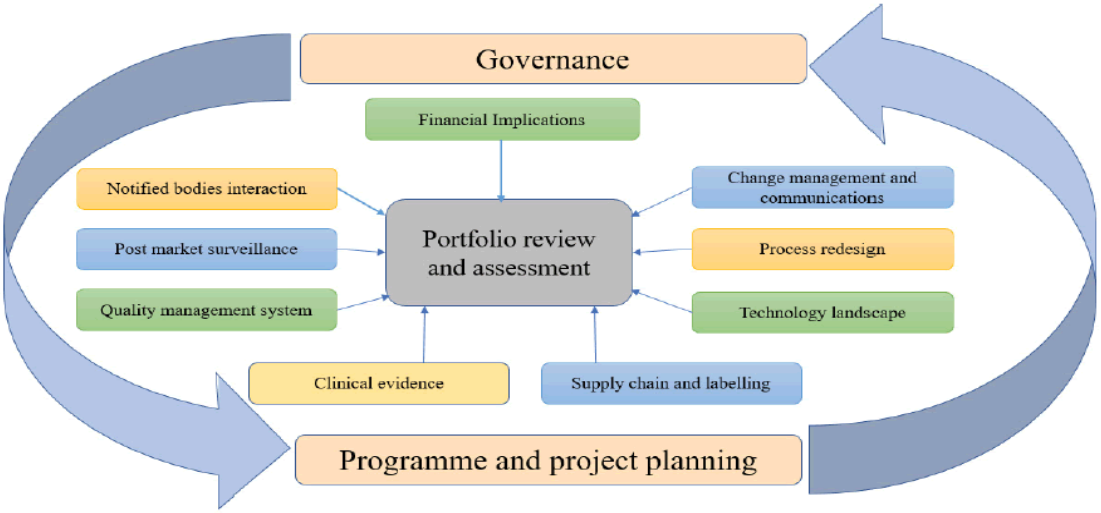


Figure 4. Portfolio review and assessment.

3) Involvement of regulatory affairs in R and D

The regulatory affairs staff work in an association with marketing and R and D to develop, original products that take authority of recently developed high - tech and regulatory progresses to speed up the time to market. Accompanied by new products assumed to add on notable outcomes to the company`s core, slight drop in time to market equalize to major material obtain in outcome and yield. Recruiting modifiable clinical trial planned, relinquishing fast approval by regulatory authorities and

eschewing hazards in processes can speed up development of new product and suggest lessening expensive mistakes and time lags. [15]

Scope of Regulatory Affairs Professional in Industries

Regulatory affairs professionals are utilized in industry. Government regulatory authorities are and academics. The wide range of regulatory professionals includes in the following sectors:

- Pharmaceuticals
- Medical devices
- In - vitro diagnostics
- Biologics and biotechnology
- Nutritional products
- cosmetics
- veterinary products

The regulation of medical products has been increasing since early twentieth century. Regulatory agencies are being established in an ever increasing range of states across the globe. Those who have established are reorganizing their systems and attempting to harmonize with organizations of alternative countries.

The pharmaceutical, biotechnology and medical devices are among the foremost extremely regulated industries within the world. Regulatory affairs (RA) professionals are utilized in pharmaceutical industry. The Indian pharmaceutical industry is one of the fastest growing industries in India, and it is expected to grow at a higher rate in coming 10 years. It is valued at $8.0 billion approximately and ranks 4thin terms of volume and 13th in terms of value globally. [16]

All companies engaged in R and D worth its salt has an individual RA department to aid them in new product development. The clinical analysis research industry, that provides opportunities for RA professionals, is additionally growing at associate alone rate.

Responsibilities of Regulatory Affairs Agencies

The Regulatory affairs professionals work is to keep track of the ever changing legislation in all regions in which the company wishes to distribute its products. They also advice on the legal and scientific restraints and requirements, and collect, collate, and measure the scientific knowledge that their analyses and development colleagues are generating. [17] They give strategic and technical advice at the highest level in their companies, right from the beginning of the development of a product, creating a very important contribution each commercially and scientifically to the success of a development program and the company as a whole. [18]

Some of the responsibilities of regulatory affairs department are:

- Ensuring that their companies comply with all of the system policy and laws pertaining to their business.
- Advising their companies on the regulatory aspects and climate that would affect proposed actions. i. e. describing the " regulatory climate" within the region of problems equivalent to the endorsement of prescription drugs.
- Working with federal, state, and local regulatory agencies and staff on specific issues distressing their commerce. i. e. working with agencies as the food and drug administration European Medicines Agency.
- Coordinate, prepare and review all appropriate documents for example dossier and submit them to regulatory authorities inside a given time frame in conjugation with the organization.
- Prepare and review of SOPs related to regulatory affairs. review of BMR, MFR, change management and alternative relevant documents. [19]
- Respond to queries as they arise, and ensure that registration / approval are granted without delay. [20]
- Impart training to R and D, pilot plant, ADI and regulatory affairs.
- Have a duty to provide physicians and other health care professionals with accurate and complete information about the quality, safety, and effectivenessof the products.
- Working with confederate, state and provincial agencies and staff on particular problems influencing their business.
- Counsel companies on the regulatory features and region that would influence their suggested activities.
- In marketing arrangements their main responsibilities concerns construction and presentation of registration data to regulatory agencies and convey out all communication to acquire and continue marketing authorization (MA) for the products united.
- They need to keep track on almost altering laws in all countries where the companies is focusing to market their product.
- They play a crucial part in marketing easier the economical development of new health products and mechanization via product circuition.

Challenges

1) To promote public health and protect the public from harmful and dubious drugs.
2) To determine proper legalization covering all products with a medical claim and everyone relevant pharmaceutical activities, whether or not disburse by the public or nonpublic sector.
3) To increase worldwide regulatory growth to ensure safety of people. [21]

Importance of Regulatory Affairs (RA)

In today`s competitive atmosphere the reduction of the time taken to succeed in the market is important to a product and therefore the company`s success. The correct conduct of its regulatory affairs activities is therefore of considerable economic importance for the company.

The importance of the regulatory affairs functions is such that senior regulatory affairs professionals are increasingly being appointed to boardroom positions, where they can advice upon and further influence the strategic decisions of their companies. [22]

Regulation is a binding instruction issued by an agency that tells how to interpret and comply with a law. Failures to follow the laws could find yourself within the "issued

warning letter "section of the FDA website, which isn't a decent for a drug company.

Recent Advancement in Drug Regulative Affairs

Recently, the Govt. of India has constituted a few autonomous bodies to gauge the standards of profession of pharmacy and grade the colleges accordingly so that the students, parents, employers and funding agencies have a valid and reliable rating of the various pharmacy colleges in the country. [23]

These are:

1) National Board of Accreditation (NBA) under the aegis of all India Council for Technical Education.
2) National Assessment Accreditation Council (NAAC) by the University Grants Commission.

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