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ROLE OF REGULATORY AFFAIRS IN PHARMACEUTICAL COMPANY: AN OVERVIEW

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ABSTRACT Pharmaceutical drug regulatory affairs covers different registration parameter of pharmaceutical product .As it is the new profession which was developed from the desired of all over the world to protect the public health by providing good quality of medicine including safety and efficacy in the area of not only pharmacy but also in the area of the veterinary medicine, medical device, insecticides , pesticides, agrochemical, cosmetic and complementary medicine .It also made the interface between the pharmaceutical company and the regulatory agencies . It is also responsible for maintaining the appropriateness and accuracy of the product information. And its main role to act as an liaison with regulatory agencies , providing expertise and regulatory intelligence in translating regulatory requirement into practical workable plan , advising the company on regulatory aspects and climate that would affect their proposed activities.

KEYWORDS : Regulatory affairs, registration, pharmacy, accuracy, liaision, affect

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]. Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals [2].

As it is heart of all about Collecting, Analyzing and Communicating the Risks and Benefits of health care products to regulatory agencies and public all over the world. It is also a science of developing new tools, standards and approaches to assess the 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.

The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents [3]. Pharma regulatory affairs professionals play an essential role in ensuring all pharmaceutical products comply with regulations governing the industry [4]. Those working in pharma regulatory affairs jobs not only work in the initial application phase for a new or generic drug, but also in the licensing and marketing stages – making sure all operations and products meet required safety and efficacy standards. Professionals must combine knowledge of the business, legal and pharmaceutical industries to determine if regulations are being followed and in many cases form the link between pharma companies and regulatory authorities, such as the Food and Drugs Agency (FDA) and the European Union [5].

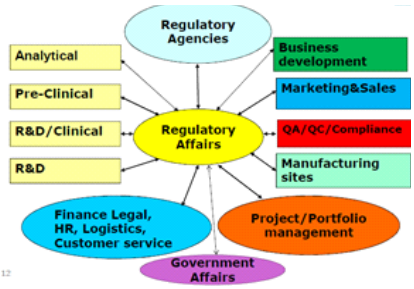

FIG- 1 Roles or interactions of RA

WHY NEED TO REGULATE

- All substances are poisons; there is none which is not a poison. The right dose differentiates a poison and a remedy
- To ensure quality, safety and efficacy of drug products in order to assure the continued protection of Public Health.
- No drug product is completely safe or efficacious in all circumstances, but there is a moral, as well as legal, expectation that appropriate steps are taken to assure optimal quality, safety and efficacy by the Producers concerned. *Benefit versus Risk*.

PHARMACEUTICAL DRUG REGULATORY AFFAIRS

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 [6].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 notified. 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. The Regulatory Affairs (RA) departments must be aware of the regulatory requirements in all the company's export markets [7].

REGULATORY AFFAIRS PROFESSION

The pharmaceutical research and development process of bringing a new drug to the market takes many years; it is therefore essential that the process be managed effectively from beginning to end in order to meet the regulatory requirements and permit a favorable evaluation of efficacy and safety in the shortest possible time [8]. The drug regulatory affairs (DRA) professional plays an important role in every phase of this process, from developing regulatory strategies following the discovery of a new chemical entity to planning post-marketing activities.

In this position, the DRA professional must possess a proficient scientific background (B.Sc, M.Sc., Ph.D., M.D. B. Pharm, M.Pharm or

Pharm.D.) and have acquired a thorough knowledge of Indian regulations as well as international regulations [9].

The DRA professional must actively participate in discussions and coordinate team activities to obtain all the necessary documentation and then assess it for completeness and accuracy. Therefore, an effective DRA professional must exhibit the organizational and interpersonal skills of a "team player" and also be thorough and detail oriented.

CHALLENGE TO REGULATORY AFFAIRS PROFEESION

Regulatory affairs include complete dynamics:

- Multi –dimensional
- Knowledge in science and technology
- Prolific communication skill
- Deal with people with diverse background, skills, culture, and personalities
- Deal with conflicting loyalties, motivations, social and ethicals, responsibilities

  Case in point: submission of a dossier

  During submission of a dossier a regulatory affair would be:
- Guided by various regulatory guidance
- Receiving input from various department within the firm about process capabilities and product attribute specification
- Receiving advice from peers about easy way to get approvals
- Receiving motivation from the management through incentives for achieving speedy approvals

PRODUCT LIFE CYCLE - REGULATORY AFFAIRS PERSPECTIVE

The role of regulatory affairs – development phase

– Ensuring that the legislative requirements are met
- Arrange for Scientific Advice - authorities
- Advice on development studies to demonstrate safety, quality and efficacy

– Set up regulatory strategy
– Participate in cross-functional project teams
– Ensure application of guidelines
– Preparation of submission of application to conduct clinical trials
– Managing the preparation of the regulatory submission
- Minimize time to market (every day counts!)
- Advice on a global development plan

– Optimize submission strategies
- Efficiency in dossier preparation

– Format, document re-uses
– Electronic submissions
– Internal company relationships, project management
– Review high-level documents/reports
- Interact with commercial side of business such as pricing and reimbursement

The role of regulatory affairs – approval phase

- Check progress of evaluation and anticipate questions
- Clarify raised questions, plan response and strategies with other departments
- Plan and manage agency meetings/hearings
- Negotiate approval and Product Information with agencies

The role of regulatory affairs – post approval phase

– Compliance
- Submission of variations/amendments

– Renewals
– Pharmacovigilance
– Product information review
– New indications / new formulations
- Regulatory input to development plans!

– Regulatory Intelligence
- What does the future hold?

THE VARIOUS ROLES WITHIN REGULATORY AFFAIRS

- Project management
- Submission management
- Maintenance management
- CMC specialist
- Pre-clinical/Clinical specialist
- Labeling expert
- Regulatory intelligence
- Global versus local Regulatory Affairs

REPORTING OF REGULATORY AFFAIRS

- Medical Director
- Research & Development Director
- Quality Management Director
- Commercial Director
- Managing Director or chief executive officer

ORGANIZATIONAL STRUCTURE OF REGULATORY AFFAIRS

Not unified across the companies and is changing

- Global regulatory affairs
- Regional regulatory affairs
- Local regulatory affairs
- Manufacturing site regulatory affairs
- Drug Agency regulatory affairs

The structure will depend on size, type and culture of the company and the personalities involved

REGULATORY STRATEGY

- Planning of regulatory affairs
- Planning of addressing critical development issues, which is dynamic and changes during the process
- Plan of how to register a product in the global market (to be in line with corporate, business and strategy of RA unit and projects)
- Plan how to balance time & cost & human resources

Strategy is only as good as the analysis behind it

MAJOR REGULATORY AUTHORITY OF DIFFERENT COUNTRIES

S.NO	COUNTRIES	REGULATORY AUTHORITIES
1	India	• Central drug standard control organization • Drug controller general of India(DCG)
2	US	Food and drug administration (USFDA)
3	UK	Medicine and health care products regulatory agencies (MHRA)
4	Australia	Therapeutics good administration (TGA)
5	Japan	Japanese ministry of health, labour and welfare (MHLW)
6	Canada	Health Canada
7	Brazil	Agency Nacional degradation vigilancia sonotoria (ANVISA)
8	South Africa	Medicine control council (MCC)
9	Europe	• European directorate for quality of medicine (EDQM) • European medicines evolution agencies (EMEA)

EXPECPTION FROM THE REGULATORY AFFAIRS AGENCIES

- To ensure that a dossier results in a SmPC (Summary for the prescribers Package leaflet – Information for the patient) that results in sales
- To ensure that the regulators are the first supportive customers for the product
- Networking, regulatory intelligence
- The integration of regulatory into the discovery and development process

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.

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[10].

Regulation is a binding instruction issued by an agency that tells how to interpret and comply with a law. Failures to follow the regulations may end up in the *"issued warning letter"* section of the FDA website, which is not a good for a Pharma company.

RESPOSIBILITIES OF REGULATORY AFFAIRS AGENCIES

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[11].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 [12].

Some of the responsibilities of Regulatory Affairs Department

- Ensuring that their companies comply with all of the system policy and laws pertaining to their business.
- 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 or European Medicines Agency.
- Advising their companies on the regulatory aspects and climate that would affect proposed actions
- I.e. describing the "regulatory climate" in the region of issues such as the endorsement of prescription drugs.
- Coordinate, prepare and review all appropriate documents for example dossier and submit them to regulatory authorities within a specified time frame in conjugation with the organization.
- Prepare and review of SOPs related to regulatory affairs. Review of BMR, MFR, change control and other relevant documents[13].
- Respond to queries as they arise, and ensure that registration/ approval are granted without delay [14].
- Impart training to R&D, Pilot plant, ADl and regulatory affairs.
- Have a duty to provide physicians and other healthcare professionals with accurate and complete information about the quality, safety and effectiveness of the product.

RECENT ADVANCEMENT IN DRUG REGULATORY AFFAIRS

Recently, the Govt. of India has constituted a few autonomous bodies to gauge the standards of profession of Pharmacy & grade the colleges accordingly so that the students, parents, employers and funding agencies have a valid & reliable rating of the various Pharmacy colleges in the country.[15]

These are:

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

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