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A REVIEW ON ROLE OF REGULATORY AFFAIRS IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

The Regulatory affairs in the pharmaceutical industry play an crucial 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. Regulatory affairs (RA) professionals play vital roles in a pharmaceutical industry because it is concern about the healthcare product lifecycle, it provides strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare products to individuals around the world. The pharmaceutical companies accountable for the discovery, testing, clinical trials, production, 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. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies.

KEYWORDS: Regulatory affairs, Pharmaceutical industries, Pharmacy College, Regulatory education.

INTRODUCTION

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, is in immense need of people than ever before who are capable of handling issues related to regulatory affairs in a comprehensive manner.

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. A regulatory affair (RA) also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of regulatory affairs (RA) professionals. 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.

Figure 1: shows the various role of DRA department.

Pharma regulatory affairs professionals play an essential role in ensuring all pharmaceutical products comply with regulations governing the industry. 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. Regulatory affairs jobs in the UK and further afield are generally within the pharmaceutical, chemicals, biotechnology, medical devices and cosmetics industries. Organisations such as the FDA also provide roles for those interested in working in the field. As biotechnology plays an increasing role within drug development and the pharmaceutical industry, growing numbers of biotech regulatory affairs positions are opening up. Inspection of biotechnology facilities requires a high level of technical knowledge due to the ever-advancing systems being used.

Pharmaceutical Drug Regulatory Affairs

The person 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.[7] 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 Table1. Major Regulatory Authorities of Different Country when the FDA must be notified.[8] 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.[9] 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 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. Their Regulatory Affairs (RA) departments must be aware of the regulatory requirements in all the company's export markets.[10] As an added complication, despite recent international efforts towards harmonization of requirements, the regulations laid down by different governments. Therefore, great care has to be taken in drawing up efficient and economical research and development programs whose results may be used as widely as possible. Regulatory Affairs professionals, with their detailed knowledge of the regulations and guidelines, are frequently called in to advice on such matters.

OBJECTIVES OF REGULATORY AFFAIRS

- How and why the pharmaceutical industry and drug regulations have developed in USA
- Major Regulations of USA
- Framework of EU and its regulatory
- "The Rules Governing Medicinal Products in the European Union"
- Pharmaceutical Legislations of EU
- Indian Pharmaceutical Industry & Drug Regulations development in different Era
- Types of Marketing Authorization Procedure in EU Market

- Major Rules and Act of India
- Roles of Regulatory Affairs Professional in Health Authorities as well as Pharmaceutical Industry

PARAMETER OF REGULATORY AFFAIRS

- Design =Development Plan
- Co-ordination= Writing/reviewing, supervising
- Construction= Assembling & Submission Management
- Testing= Where are the weaknesses
- Drug regulations
- National Laws (e.g. UK - Medicines Act, US- CFR)
- Regional Laws (EC directives)
- National and Regional Guidelines
- International Guidelines (ICH)

EVOLUTION OF REGULATORY AFFAIRS

During the 1950s, many tragedies happened due to the misjudgement of the personnel during manufacture and some intentional addition of adulteration of substances into the pharmaceutical product, which has lead to the death of the patients. After so many incidents, the regulatory bodies introduced the new laws and guidelines which improve the quality, safety and efficacy of the products. This has also resulted in stricter norms for Marketing Authorization (MA) and Good Manufacturing Practices (GMPs).

Regulatory bodies in the world

Table 1: Different regulatory bodies in the world.[1,2]

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 (MHLW)
Brazil	Agencia national de vigiloncia sanitaria (ANVISA) national health surveillance agency
China	State food and drug administration
Denmark	Danish medicines agency
Italy	Italian medicines agency (AIFA)

Ireland	Irish medicines board
Malaysia	National pharmaceutical control bureau
New Zealand	Med safe-medicines and medical device safety authority
Netherlands	Medicines evaluation board
Nigeria	National agency for food and drug administration and control (NAFDAC)
Singapore	Centre for pharmaceutical administration health sciences authority
South Africa	Medicines control council (MCC)
Switzerland	Swissmedic, Swiss agency for therapeutic products
Thailand	Thailand food and drug administration
Germany	Federal institute of health and medical devices
Sri Lanka	Cosmetics, devices and drugs regulatory authority of sri lanka
Uganda	Uganda national council for science and technology (UNCST)
Ukraine	Ministry of health

Table 2: International regulatory bodies.[2]

Regulatory body	Headquarters
World health organization (WHO)	Geneva, Switzerland
World trade organization (WTO)	Geneva, Switzerland
International conference on harmonization (ICH)	Belgium, Europe
Pan American health organization (PAHO)	Washington D.C. USA
World intellectual property organization (WIPO)	Geneva, Switzerland

SCOPE OF REGULATORY AFFAIRS PROFESIONAL IN INDUSTRIES

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

- Pharmaceuticals
- Medical Devices
- In –vitro diagnostics
- Biological and biotechnology
- Nutritional products
- Cosmetics
- Veterinary products

REGULATORY EDUCATION

The personnel in the regulatory affairs should have a good knowledge of all documents related to the respective country guidelines. Regulatory affairs personnel should be well known about the WHO, ICH, GMP, and other regulatory documents which have to be revised and submitted. These people are the primary communication barrier between the pharmaceutical companies and worldwide regulatory bodies such as USFDA and the European Union, etc.

HISTORICAL OVERVIEW OF REGULATORY AFFAIRS

During 1950s, multiple tragedies i.e. sulphanilamide elixir, vaccine tragedy and thalidomide tragedy must 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).

PHARMACEUTICAL DRUG REGULATORY AFFAIRS

This department is up to the mark of knowing the regulatory requirements for getting new products approved. They know what commitments the corporate has made to the regulatory agencies where the merchandise 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, instead of the FDA local district offices. Gimps don't directly apply to Regulatory Affairs; however[1], they need to grasp and evaluate changes to drug manufacturing and testing activities to work out if and when the FDA must be notified. Regulatory Affairs may be a comparatively new profession which has developed from the requirement of governments to safeguard public health, by controlling the protection and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines.[2-4] The companies in command of the invension, testing, manufacture and marketing of those products also want to verify that they provide products that are safe and make a worthwhile contribution to public health and welfare. Regulatory[5] Affairs professionals, with their detailed knowledge of the regulations and guidelines, are frequently called in to advice on such matters.

IMPORTANCE OF REGULATORY AFFAIR

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 labeling, may easily result in the need for a product recall.[11-13] 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.[14] The Regulatory Affairs department is very often the first point of contact between the government authorities and the company.

REGULATORY AFFAIRS IN PRODUCT MANAGEMENT

The key role of RA professional is broader than registration of products, they advise companies both strategically and technically at the highest level. Their role begins right from development of a product to making, marketing and post marketing strategies. Their advice at all stages both in terms of legal and technical requirements help companies save a lot of time and money in developing the product and marketing the same. For countries that do not have their on regulations the World Health Organization guidelines on health matters and World Trade Organization on trade regulations between nations is followed.[14-16]

REGULATORY AFFAIRS IN CLINICAL TRIALS

The RA professional is the primary link between the company and worldwide regulatory agencies such as US Food and Drug Administration (USFDA & Center for Devices and Radiological Health) Medicines and Healthcare Products Regulatory Agency, United Kingdom, (UKMCA), Therapeutic Goods Administration, Australia European Medicines Agency, Organization of Economic Collaboration and Development (OECD) and Health Canada. He also communicates and interprets the seemingly endless mace of laws, regulations and guidelines to the other departments of the company. The RA personnel develops strategies to overcome delays and presents finding of clinical trials to the regulatory bodies so as to get quick clearance thus reducing the time for approval of new molecules. At its core, the RA professional facilitates the collection, analysis and communication about the risks and benefits of health products to the regulatory agencies, medical and health systems and the public. Operationally RA is responsible for assuring that government obligation, market driven demands and evolving scientific conventions are understood and addressed by various stakeholders.[14-16]

REGULATORY AFFAIRS IN R&D

The regulatory affairs personnel work hand in hand with marketing and R&D to develop, innovative products that take advantage of new technological and regulatory developments to accelerate time to market. With new products expected to add significant revenues to the company's bottom lines, small decreases in time to market equate to large material gains in revenue and profit. Employing adaptive clinical trial strategies, obtaining quick approval

from regulatory authorities and avoiding pitfalls in processes can accelerate development of new products and help to reduce costly errors and time lags.[14-16]

WORKING OF REGULATORY AFFAIRS INFORMATION

Regulatory is the interface between the company/sponsor and the outside world the regulatory department is a focal point of information, both incoming and outgoing. In order to practice regulatory and succeed, both in objective public measures (e.g., approvals) and internal ones (e.g., recognition and reward), etc.

GATHERING INFORMATION

All the information should be ethical proper documentation any opportunity to see, hears, or talks with a regulator, a more experienced drug development expert, a colleague, or a sworn enemy is an opportunity to gather information. There should be no need to go over published sources of information, both commercial and governmental.[11-13]

COMMUNICATING INFORMATION

The easiest way information is to share and communicate is non-critical information. The main issue with such information is getting to the right audience without boring them into forgetting that they're getting useful data. Most companies subscribe to news updates or have internal regulatory information updates through email. One suggestion is to make them playful and user friendly, using popular Web pages as guides. The difficult information to communicate is critical information. This could mean anything vital to the success or failure of a project, specific and important feedback from the FDA. The first thing to do is document the information carefully, so that we can fully understand it and its implications. Then think of those individuals who are that combination of "need to know" and "know who else needs to know." At a small industry it should be done by CEO or the president but in a larger companies, the head of clinical, a project manager, should be handled.[11-13]

Need of regulatory affairs

Drug development and commercialization is highly regulated path to drug registration marketing approval is paved with good intension but can be complicated things change constantly. Regulatory bodies deal in the area of regulatory law, secondary legislation, administrative law and rule making (codifying and enforcing rules and regulation and imposing supervision or overnight for the benefit of public at large). The existence of independent regulatory agencies is justified by complexity of certain regulatory and

supervisory tasks that require expertise, the need for rapid implementation of public authority in certain sectors and drawbacks of political interfernces.[2]

India is growing very rapidly in pharmaceutical sector; there is need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory affairs professional are link between pharmaceutical industries and worldwide regulatory agencies. They are required to be well versed in the regulations, laws, guidelines and guidance of the regulatory agencies. There is growing need to incorporate the current requirement of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with latest developments to serve the industries.[1]

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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