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"REVIEW ON STRATEGY, ROLE AND DYNAMICS IN DRUG REGULATORY AFFAIRS"

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ABSTRACT

Pharmaceutical drug regulatory affairs cover 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.

Key words :

Regulatory affairs,
Pharmaceutical industries,
World regulatory bodies.

Introduction:

Regulatory Affairs (RA) is a profession within the health care industry namely, Pharmaceutical, Medical Device, Biologics, & Functional Food.

Regulatory Affairs is a 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. It is a profession within regulated industries. Regulatory affairs also have a very specific meaning within the healthcare industries.

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..

RA profession at its heart is all about Collecting, Analyzing and Communicating the Risks and Benefits of health care products to regulatory agencies and public all over the world.

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices etc. This department is responsible for understanding the regulatory requirements for getting new /generic products approved.

HISTORICAL OVERVIEW

During 1950's, 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.

Due to rapid increase in laws, regulations and guidelines for reporting safety, efficacy and quality of new medicinal products, necessity for expert regulatory professional arises tremendously.

None of the drug manufacturing marketing units are able to launch drug in market until and unless respective health authority (national 7 international) give green signal in writing.

Without fulfilling requirements of law of land, it is practically impossible to have drug products in market.

Almost two decades before, drug regulatory affairs was least known / needed by pharmaceutical industry. lt was in very nascent stage where registration executives were working under export department.

However, the situation has changed drastically where fully fledged Global Regulatory Affairs department become mandatory to define drug development, approval and marketing strategy.

Hence, the scope of Drug regulatory affairs has become vast and experts are needed in health authorities and pharmaceutical industry at various levels and departments.

At the same time, the regulation pertaining to Pharmacovigilance Companies to monitor new drugs safety aspects throughout the life cycle of product.

Requirements mandates In this scenario, the role of regulatory expert is very critical and important for deciding the entry strategy into various national and international markets.

ROLE OF REGULATORY AFFAIRS DEPARTMENT

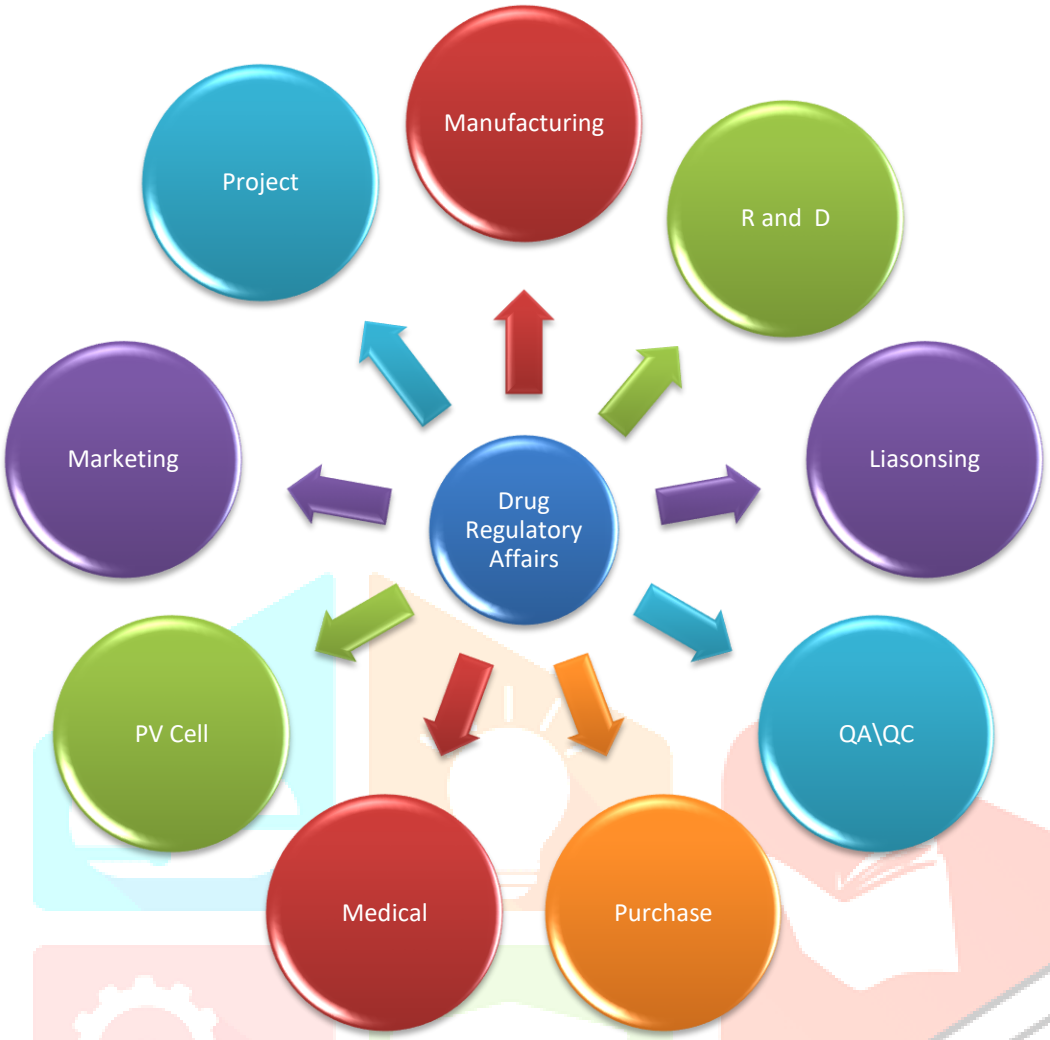
1. Ensuring that their companies comply with all of the system policy and laws pertaining to their business.

2. Working with federal, state, and local regulatory agencies and working with agencies as the Food and Drug Administration or European Medicines Agency (pharmaceuticals and medical devices).

3. 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.

Role of Regulatory Affairs Professionals In Health Authorities (HA): A) Evaluation of MAA: 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.

Drug regulatory Affairs [DRA] Network in Pharmaceutical Industry



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 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.

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.

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.

MAJOR REGULATORY AUTHORITY OF DIFFERENT COUNTRIES

SR .NO	COUNTRIES	REGULATORY AUTHORITIES
1	India	Central drug standard control organization
2	US	Food and drug administration (USFDA)
3	Australia	Therapeutics good administration (TGA
4	Japan	Japanese ministry of health, labor and welfare (MHLW)
5	South Africa	Medicine control council
6	Canada	Health Canada
7	UK	Medicine and health products regulatory agencies
8	Europe	European medicines evolution agencies

Challenges :

The major challenges of these regulatory bodies are

- To promote public health and protect the public from harmful and dubious drugs,
- To establish proper legalization covering all products with a medicinal claim and all relevant pharmaceutical activities, whether carried out by the public or the private sector.
- To increase worldwide regulatory growth to ensure safety of people.

THE DRUG REGULATORY AFFAIRS PROFESSIONAL RESPONSIBILITY

- 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.

- The main responsibility of the DRA professional within a pharmaceutical company is to secure approval of drug submissions from Health Therapeutic Products Program (TPP) and to ensure

- regulatory compliance of marketed and investigational drugs with the Food and Drug Act and Regulations and TPP Guidelines/Policies.

- 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.

- They are responsible for the presentation of registration documents to regulatory agencies, and carry out all the subsequent negotiations necessary to obtain and maintain marketing authorization for the products concerned. 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.

- It also helps the company to avoid problems caused by badly kept records, in appropriate scientific thinking or poor presentation of data.

Global Importance of Drug Regulatory Affairs

In this Global competitive environment the reduction of the time taken by a product to reach the market is critical parameter and hence the company's success relies on that. The proper control maintain of its Regulatory Affairs activities is therefore of considerable economic importance for the company. Wrong or inadequate reporting of data may prevent a timely positive evaluation of a marketing application. A new drug requires many millions of dollars to develop it and even a single day delay in bringing it to the market has considerable financial considerations. Even worse, failures to fully report all the required data or the product release of with incorrect labeling, may result in a product recall. 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.

A good Regulatory Affairs professional will have a 'right first time' approach and will play a very important part in coordinating scientific Endeavour with regulatory demands throughout the life of the product, helping to maximize the cost-effective use of the company's resources. The Regulatory Affairs department is the first point of contact between the Ministry of Health /Government departments and the company.

Emerging Trends Affecting Regulatory Strategy:

- Strong growth in Emerging Markets
- Acquisition and licensing opportunities
- Biologics and Biosimilars market expansion
- Aging populations
- New product development strategies
- Rare diseases
- Quality aspects in entire supply chain
- ICH expansion
- Collaboration among regulatory agencies

Conclusion :

It can be concluded that there is a wide variation globally in the way products are registered and even in the type and amount of registration data required. Countries having stringent regulations accordingly require similar technical expertise. Due to the variability, it is impractical to get global marketing approval at same time and launch in all the regions at one go. Hence, one should carefully understand and define the clear regulatory strategy by looking at the target regions different patent terms and its extension, various application possibilities, data requirements, potential timeline for marketing launch in different regions.

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