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Review

Role Of Regulatory Affairs In Marketing Of Pharmaceutical Products

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Abstract

The primary purpose of the rules governing medicinal products is to safeguard public health. However, this objective must be achieved by means which do not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community. The Marketing Authorisation Holder (MAH) of a medicinal product is responsible for the quality, efficacy and safety of its products. The marketing authorization procedure includes an assessment of a dossier, in which the future marketing authorization holder (MAH) evidences the safety, efficacy, and quality of the product. Furthermore, the indications, contraindications, dosage of the product, general classification for supply, as well as the package leaflet for the patient and proposed texts on the labelling of the medicinal products are assessed. The Summary of Product Characteristics (SPC) forms part of the marketing Authorization. It serves as the key source of information about the medicinal product for doctors and healthcare professionals. Generic medicines are those where patent protection has expired, and which may be produced by manufacturers other than the innovator company. Use of generic medicines has been increasing in recent years, primarily as a cost saving measure in healthcare provision. Generic medicines are typically 20 to 90% cheaper than originator equivalents. As the Pharmaceutical industry is expanding by leaps and bound no single country is capable of manufacturing all the drugs in required quantities at competing prices. Hence the Marketing Authorizations has become an essential part of Global Healthcare. Till sometime back Marketing Authorization procedures were country specific. The present study describes a brief review of Marketing Authorizations in various countries and regions around the world (WHO).

Keywords: Regulatory affairs (RA), Drug development, skills and abilities.

INTRODUCTION

Regulatory affairs (**RA**), also called **government affairs**, is a profession within regulated industries, such as pharmaceuticals, medical devices, cosmetics, agrochemicals (plant protection products and fertilizers),

energy, banking, telecom etc. Regulatory affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, biologics and functional foods).

Regulatory affairs professionals (aka regulatory professionals) usually have responsibility for the following general areas:

- Ensuring that their companies comply with all of the regulations and laws pertaining to their business.
- Working with federal, state, and local regulatory agencies and personnel on specific issues affecting their business, i.e., working with such agencies as the Food and Drug Administration or European Medicines Agency (pharmaceuticals and medical devices); The Department of Energy; or the Securities and Exchange Commission (banking).
- Advising their companies on the regulatory aspects and climate that would affect proposed activities. i.e. describing the "regulatory climate" around issues such as the promotion of prescription drugs and Sarbanes-Oxley compliance.[1]

The role of the regulatory affairs department

The regulatory affairs (RA) department of a pharmaceutical company is 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 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.[2]

Regulatory Affairs Importance

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Regulatory Affairs independently and as a profession have important positions to play in positively impacting medication policy, medication use and results as well as other aspects of medical proper care. In many instances this will be through cooperation with other wellness care professionals at a community stage. The following are the various actions that comprise the application of drug proper want to individuals. If performed, in whole or in part, they will result in added value to medication treatment by making a beneficial participation to the safe and affordable use of drugs, leading to beneficial results and improved medical proper care. Obtain and maintain medication records and relevant wellness details, if they do not already exist. This detail is essential to evaluate personalized medication treatment. Identify, evaluate and assess: Medication related problems, Symptoms described by patients, self-diagnosed conditions. The elements of drug proper take proper individual sufferers, taken together, explain comprehensive drug proper care, the delivery of which requires an ongoing, covenantal relationship between the pharmacologist and the affected person.[3]

The Responsibilities of the Regulatory Affairs Professionals[4]

The department of Regulatory Affairs is established to protect public health, by monitoring and controlling the safety and efficacy of drugs within several domains including pharmaceuticals, veterinary medicines, agrochemicals, cosmetics, medical devices, pesticides, and complementary medicines. The primary role of Regulatory Affairs is to provide strategic and technical advice to the pharmaceutical companies, right from drug development to the successful marketing of the product.

The Regulatory Affairs have the responsibility to keep the companies informed of the current government legislation, guidelines, regulatory intelligence, and customer practices. It also ensures that the company's drugs and products comply with the existing regulations and makes sure the entire product range is kept up to date with the changing legislative practices. They also inform about the legal and scientific restraints, limitations, and requirements regarding the product and help companies collect, collate, and evaluate scientific information generated by the R & D department.

An essential role of Regulatory Affairsprofessionals also includes formulating regulatory strategies for companies to submit appropriate regulatory documents for both international, domestic,and/or contract projects.For export and import, the RA advises them about the international legislation and guidelines. They help high-level company executives to coordinate, prepare, and review all documents and submissions given to regulatory authorities, ensuring that they are clear, consistent, and complete from the regulatory perspective.

In today's competitive environment, a proper conduct of the regulatory affairs activities is vital for the company's success and sustainability of its products. The regulatory affairs in the pharma industry is what provides physicians and other healthcare professionals with a comprehensive and accurate information about the quality, safety, and effectuality of the drug/product.

As the healthcare industry is growing tremendously, it is necessary for the healthcare professionals to be equipped with industry knowledge along with their academic/technical skills and abilities. In that sense, the Indore Institute of Pharmacy (IIP), one of the best PCI approved pharmacy colleges in Indore, Madhya Pradesh, offers quality education that caters to the very needs of the industry and prepares the students accordingly. Established in the year 2004, Indore Institute of Pharmacy ensures a high focus on quality healthcare and pharmaceutical education that enables the aspirants to become dynamic and competent professionals. Ever since inception, the Indore Institute has been creating a strong foundation in the Pharmacy domain, equipping students with comprehensive knowledge and understanding of the Profession of Pharmacy and preparing them for a successful career.

Table 1: Major Regulatory Authority Of Different Countries

Countries	Regulatory Authorities
India	• Central drug standard control organization • Ÿ Drug controller general of India(DCG)
US	Food and drug administration (USFDA)
UK	Medicine and health care products regulatory agencies (MHRA
Australia	Therapeutics good administration (TGA)
Japan	Japanese ministry of health, labour and welfare (MHLW)
Canada	Health Canada
Brazil	Agency Nacional degradation vigilancia sonotoria (ANVISA)
South Africa	Medicine control council (MCC)
Europe	European directorate for quality of medicine (EDQM) Ÿ European medicines evolution agencies(EMEA)

Role of Regulatory Affairs in Pharmaceuticals

Regulatory Affairs plays a key role in the pharmaceutical industry: from drug development to commercialization. Learn more about the roles and functions that RA teams can provide in the lifecycle management of your pharmaceutical product.

Regulatory Affairs plays a crucial role in the pharmaceutical industry, especially during drug development: a lengthy, complex, and extremely costly but necessary process.

Regulatory Affairs experts are involved in all phases of development, and even after drug approval and commercialization. They possess a unique combination of both scientific and management skills to achieve a commercially important goal within a drug development organization.

The Regulatory Affairs department provides strategic and technical advice at the highest level in such companies. In this way, they make a significant contribution, both commercially and scientifically, to the success of a development program and the company as a whole.

Many pharmaceutical companies are looking for external RA team members with specific expertise to ensure that products are developed, manufactured, and controlled at all levels of expected quality, safety, and efficacy. Experienced consultants to ensure all filing and submission goals are met, with high quality and within expected timelines.

Sounds familiar? This post will give you a better understanding of the role of Regulatory Affairs in the pharmaceutical industry at large and the functions that Regulatory Affairs teams can provide in the lifecycle management of your pharmaceutical product.

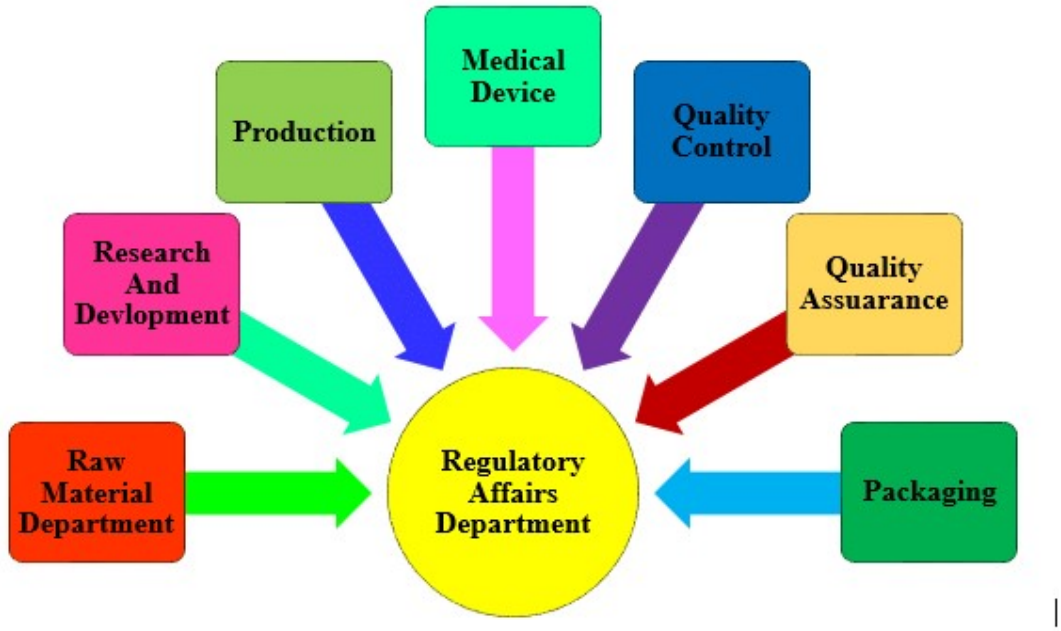

Fig 1: Pharmaceutical Regulatory Affairs

Lifecycle management: keeping your pharmaceutical product alive and kicking

Within the pharmaceutical industry, a strong lifecycle management strategy is important to ensure the successful and lasting commercialization of the pharmaceutical product. Lifecycle management will start early at the beginning of the discovery and R&D phase and will continue after the patent expiry of a product.The Regulatory Affairs team plays a key role throughout the product lifecycle to demonstrate the quality, control, conformity, safety, and efficacy of the product in the documentation submitted to the competent authorities for review and approval.

The role of Regulatory Affairs in Pharma throughout the lifecycle of a medicinal product

Once the drug discovery phase, during which potentially interesting compounds are tested for their non-clinical characteristics, the clinical phases (early to late phase) are initiated to further test the safety and efficacy of the drug candidate. After successful clinical trials, marketing approval for a medicinal product must be sought through the submission of a marketing authorization.

When the marketing authorization is granted by the competent authorities, commercialization of the medicinal product can begin, but through variation post-approval amendments will continue to be submitted by the regulatory affairs team, to ensure the dossier being approved by regulators is always updated.

In the next section, we will take a closer look at the different phases of the lifecycle of a drug and the role Regulatory Affairs plays throughout the pharmaceutical industry.

R&D – Clinical phase: setting up the right Clinical Development Strategy

Early in the development process, at the research stage, it is critical to get regulatory affairs involved to ensure that an appropriate Clinical Development Strategy is developed with the goal of a carefully planned series of clinical trials, ranging from first-in-human Phase I to Phase II "proof of concept" and crucial Phase III trials for registration purposes.

Clinical trials are expensive and can take many years to complete, and their outcome to demonstrate the drug candidate's efficacy is inherently uncertain. If a pharmaceutical company delays in completing or discontinuing a clinical trial of its drug candidates, the commercial prospects of the drug candidates will be harmed and the ability to generate revenue from any of these drug candidates will be delayed. The Clinical Trial

Application (CTA), the Investigational Medicinal Product Dossier (IMPD), which contains Chemical Manufacturing and Control (CMC) data, is a very important part of the CTA.

The regulatory affairs teams will develop the quality sections of the IMPD (CTD Modules 2.3 and 3) with a phase-appropriate level of detail. Although the EMA provides guidance to the industry on the expected content for an IMPD for chemical-based products, biological products, or ATMPs (Advanced Therapy Medicinal Products), an experienced CMC writer will need to provide the appropriate level of detail in the IMPD for the clinical phase in which the investigational product is currently at.

In the case of complex developments or innovative technologies, Regulatory Affairs experts will seek scientific advice from national competent authorities or EMA through a specific procedure to ensure that the development and future registration of the dossier proceed according to the agreed expectations of the regulators.

For some products for pediatric use, for the treatment of rare diseases (the prevalence of the condition in the EU should not exceed 5 in 10,000) or for products that may be designated as Advanced Therapy Medicinal Products (ATMPs), the regulatory team will ensure that the necessary applications are submitted to the competent authorities for either a pediatric investigation plan, an orphan designation or an ATMP classification.

Marketing Authorization Application

After a successful clinical phase, a company wants to obtain regulatory approval for the medicinal product, but the regulatory approval processes of the competent authorities are lengthy, time-consuming, and inherently unpredictable.

As a consequence, the role of an experienced regulatory affairs team in the approval process will be important to maintain the goal of timely commercialization of the product.

Knowing that a medicinal product may be marketed in the EU only when a Marketing Authorization has been issued by:

- the European Commission via Centralized Procedure (CP) or
- the competent authority of members states via National Procedure (NP), Mutual Recognition Procedure (MRP) or Decentralized Procedure (DCP)

when applying for the Marketing Authorization application, pharmaceutical companies have to decide on the submission strategy of the marketing authorization dossier.

The applicant must carefully consider all logistical and regulatory issues prior to submission. A key source for input and implementation throughout the decision-making process will be the regulatory affairs team, which will need to estimate

- the approval time based on the existing registration routes,
- the specific registration dossier requirements for each country,
- the mandatory registration route for certain products (Annex Medical Products to be Authorized by the Community),
- and the costs incurred in reimbursing the authorities for dossier evaluation and marketing authorization in the countries of interest.

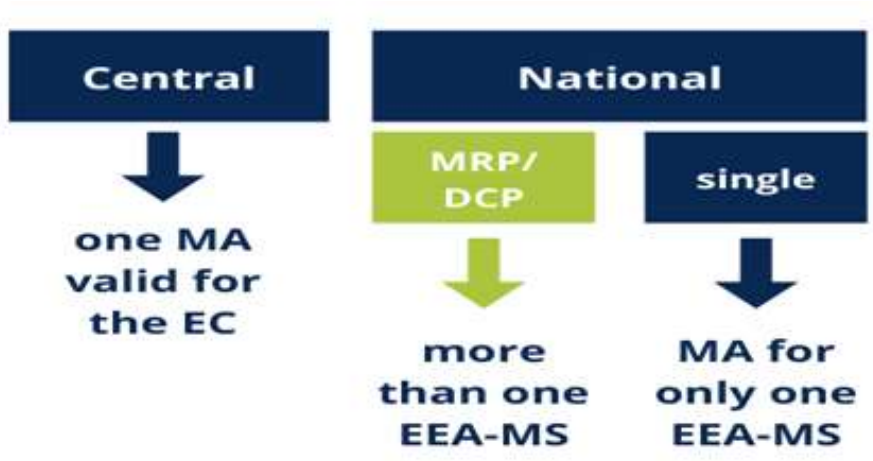

Fig 2: EU Procedures for a marketing authorization application

For the registration dossier, the CMC experts, the (non-)clinical experts together with the regulatory affairs offices ensure the compilation of a compliant CTD dossier which is submitted through the Common

European Submission Portal (CESP) on behalf of the pharmaceutical company in eCTD in any of the EU countries through the most appropriate registration procedure.

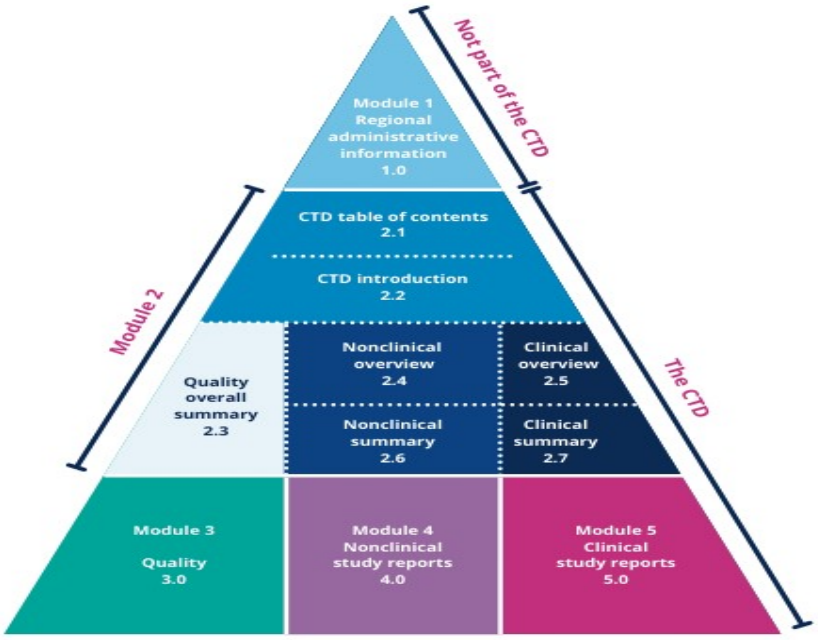

Fig 3: The Common Technical Document (CTD) is an internationally agreed upon format required by regulatory authorities for well-structured dossier applications for the registrations of medicinal products. The eCTD contains an electronic table of contents also referred to as a backbone that manages all the metadata for an application. This backbone is broken down into five modules. With the support of eCTD software, the regulatory affairs team ensures that the documents are placed appropriately into modules, which are graphically presented as the CTD Triangle.

Commercialization

After the competent authority grants marketing authorization, the product can be commercialized by the pharmaceutical company. The work of the regulatory team, however, is not slowing down. Post-approval changes will trigger the need for additional regulatory affairs work.

Variations to keep the marketing authorization up to date

Variations are all the changes made in the dossier of an authorized product after its initial registration. They may concern administrative changes, Quality changes, Safety/Efficacy changes, or Vigilance changes. The regulators foresee four types of variations: type IA, type IB, type II, and extensions of marketing authorizations (line extensions). Type IA variations are minor changes having only a minimal impact, or no impact at all, on the quality, safety, and/or efficacy of the medicinal product concerned.[5]

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. ASEAN is a model of a regional integration initiative undergoing dynamic development and changes. It has become one of the most successful regional groupings of developing nations, to promote cooperation, and trade in the face of wider international competition and economic upheavals. Since its inception four decades ago, ASEAN is now at a crucial stage in transforming itself from a regional Association into a dynamic, integrated economic Community. ASEAN's drug regulatory authorities and industry have worked very close regionally but also increasingly with global organizations to develop a number of harmonized documents. These are the common submission dossier known as the ASEAN Common Technical Dossier and the ASEAN Common Technical Requirements, which are steadily evolving. Largely they have been realized already, the next step will be to focus

on mutual recognition of pharmaceutical registrations and implementing a harmonized placement system. There is still much work to be carried out in the implementation. The future will show if this can be achieved by the versioned end goal of economic community in 2015. Already now ASEAN can be regarded as an example of having developed a successful pharmaceutical harmonization scheme. ASEAN is increasingly playing a major role in pharmaceutical industry.

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