

Regulatory Requirements for Development and Filing of Generic Drugs Globally on Comprehensive Studies

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Introduction

The regulatory requirements of various countries of the world vary from each other. Therefore, it is challenging for the companies to develop a single drug that can be simultaneously submitted in all the countries for approval. The regulatory strategy for product development is essential to be established before the commencement of developmental work in order to avoid major surprises after the submission of the application [1]. The role of the regulatory authorities is to ensure the quality, safety, and efficacy of all medicines in circulation in their country. It not only includes the process of regulating and monitoring the drugs but also the process of manufacturing, distribution, and promotion it. One of the primary challenges for regulatory authority is to ensure that the pharmaceutical products are developed as per the regulatory requirement of that country. This process involves the assessment of critical parameters during product development.

The pharmaceutical industry in India has shown remarkable growth which in turn has risen the economy of India [2]. After the introduction of the product patent regime in India, there was a need for pharmaceutical companies both in India and abroad to explore newer markets. Indian pharma majors are entering new markets with global ambitions, mergers and acquisitions are in focus with a reason to enter a new market. For sustained growth over the next few decades, firms have to concentrate on generic drug products. Diseases that cannot be cured, diseases that have to be managed, provide great opportunities for generic drugs.

Due to the emerging regulatory needs of the pharmaceutical sector, the drug evaluation for the control of drug quality and trade has become highly sophisticated. Regulatory guidelines and standard tools provide a basis for the implementation of laws, whereas laws provide a legal basis for drug control. The world covers more than 100 countries, where most of them have established pharmaceutical legislations and regulatory requirements. For worldwide regulatory dossier submissions, it is a pre-requisite requirement to have a knowledge of country-specific guidelines and norms. Therefore, it is very important to analyze the differences and commonness between the regulatory requirements and pharmaceutical legislations of different countries of the world.

Generic drug development

To make a nonexclusive item, the formulator should know exhaustively the specific administrative necessities of each concerned nation where the medication is expected to be recorded. Nonexclusive medication item advancement utilizes an alternate methodology and technique contrasted with that used to foster a pioneer drug item containing another compound substance [3]. Conventional medication item makers should form a medication item that will have a similar restorative viability, wellbeing, and execution attributes as its marked partner.

Filing A Generic Drug Application

At the point when a dossier is prepared according to the administrative necessity of the separate country, it is submitted

to the administrative organization of that country [3]. Food and Drug Administration (FDA), European Medicines Agency (EMA), Pharmaceutical and Medical Devices Agency (PMDA), Therapeutic Goods Administration (TGA), Medicines Control Council (MCC), Tanzania Food and Drugs Authority (TFDA), Agência Nacional De Vigilância Sanitária (National Health Surveillance Agency) (ANVISA), Commonwealth Independent States (CIS), Department of Health (DOH), The Gulf Co-Operation Council (GCC).

Types of Submission Procedure

To market a generic medicinal product in European Economic Area (EEA) which consists of 27 member states and 3 EFTA countries, a marketing authorization has to be issued [4]. European medicines Agency (EMA formerly known as EMEA) regulates the medicinal products marketing authorization through various committees.

Conclusion

Although there is a continuous process of harmonization taking place all around the world, still we see a huge challenge, which is yet to be overcome by the Pharmaceutical industry in case of generic drug development and filing. This is due to the heterogeneity in the regulatory landscape of the various countries. Therefore, to meet these challenges, a lot of strategic planning is required before the development of any generic drug product.

References

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