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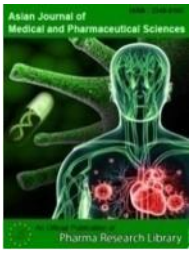

Research Article

A study on marketing and authorization of pharmaceutical Packaging materials in USA, UK, CANADA and INDIA

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Abstract

Medicine is the science and art of healing. It encompasses a variety of health care practices evolved to maintain and restore health by the prevention and treatment of illness 1. Innovations in medical technology - starting from the ancients and till date – have produced numerous appliances and instruments that have been essential in diagnosis, treatment, prevention and rehabilitation, apart from pharmaceuticals. Modern medicine requires and utilizes numerous such instruments that can be used to uplift the health standards. Medical devices are evolved from medical technology. Medical devices need to be of adequate quality and safety to bring public health benefits without harming patients, health care workers or the community. Countries and jurisdictions have different policies and plans in relation to the personal and population-based health care goals within their societies. Major biopharmaceutical companies are required to determine the regulatory strategy that can speed up the drug approval process. India has issued new clinical trials rules to expedite new drug approvals. The clinical trial approval process was reformed to speed up the drug approval processes for prescription and orphan drugs. India's regulatory authority, the CDSCO, has taken steps to improve transparency and accountability and promote ethical and scientific clinical research and development of new drugs. This resulted in high number of waivers for local phase 3 clinical trials and new conditional approval pathway for new drugs already approved and licensed by health authorities in the US, UK, Canada, and India.

Keywords: Medicine, biopharmaceutical companies, regulatory strategy, clinical trials, drug approval processes.

Article Info

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Contents

1. Introduction

Medical device" as per Drugs and Cosmetics Act[2] means an instrument, apparatus, appliance, implant, material or another article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may be assisted in its intended function by such means for one or more of the specific purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder
- Diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability
- Investigation, replacement or modification or support of the anatomy or of a physiologicalprocess
- Supporting or sustaining life
- Disinfection of medical devices
- Control of conception

The market potential for medical devices is very high when compared to pharmaceuticals. The global market for medical products and hospital supplies is over $220 billion (2009). As like pharmaceuticals, medical devices to have regulatory issues during the development of the product. The four phases of development such as research, development, regulatory and post market studies play a vital role in getting a device into the market[1-4]. The project mainly deals with the regulations for the approval, manufacture, import and marketing of medical devices in India and regulated markets. The core area will be dealing with the type of submissions to regulatory authorities, types of approvals, crucial factors involved in classification of medical devices, clinical trial related issues and comprehensive data for approvals. The project also deals with GHTF (global harmonization task force) an international body that frames guidelines for medical devices which are accepted globally. GHTF plays a major role in framing guidance documents which are accepted globally. It prevents the trade barrier and allows safe access to medical devices in different parts of the world.

2. Methodology

Food Safety and Standards Authority of India, herein referred to as, FSSAI, has introduced an Amendment; Food Safety and Standards (Advertising and Claims) Second Amendment Regulations, 2022, herein referred to as, FSSA Standards (Advertising and Claims) Second Amendment Regulations, 2022. It aims at providing fairness in claims and advertisements of food products and make food businesses accountable for such claims/advertisements so as to protect consumer interests. Specific guidelines are to be followed by Food Businesses in aspects of labelling, declarations, servings, display panels, schedules, nutritional values, nutrition comparative claims, additives, sodium elements, etc. This is developed to build transparency for consumers and accountability on the part of the FBOs (Food Business Operators).

Aim

The study aims to assess the marketing and authorization of pharmaceutical marketing materials in USA,UK, Canada and India.

Objectives

- To study the regulatory approval stages of drugs in authorization of pharmaceutical marketing materials in USA, UK, Canada and India.

3. Results and Discussion

Generally, the drug approval process to be composed mainly in the two steps, application to conduct clinical trial and application to the regulatory authority for marketing authorization of drug. The new drug approval process of different countries is similar in some of the aspects where as it differs in some aspects. In most of the counties, sponsor firstly files an application to conduct clinical trial, and only after the approval by the regulatory authority, the applicant conducts the clinical studies and further submits an application to the regulatory authority for marketing authorization of drug. In all countries, information submitted to regulatory authorities regarding the quality, safety and efficacy of drug is same; however, the time, fees and review process of clinical trials and marketing authorization application different. For the purpose of harmonisation, the International Conference on Harmonisation (ICH) has taken major steps for recommendations in the uniform interpretation and application of technical guidelines and requirements[5-9].

Through The International Conference on Harmonization (ICH) process, the Common Technical Document (CTD) guidance has been developed for Japan, European Union, and United States. Hence, India also follows the same. This step will ultimately reduce the need to duplicate work carried out during the research and development of new drugs. Therefore, harmonization of drug approval processes either by ICH or WHO may be initiated at global level. The regulatory agency for INDIA and US is a single agency i.e. CDSCO and USFDA respectively, whereas in EU, there are three regulatory agencies, they are EMEA, CHMP and NATIONAL HEALTH AGENCY. Europe also has multiple regulatory procedures when compared to US and INDIA. The approval time in all the countries is almost the same i.e., 12 to 18 months. The fee for the new drug approval in US is very high when compared to EUROPE and INDIA. Conclusion The Drug approvals in the India, Europe & US are the most thought due in the world. The primary purpose of the rules governing medicinal products in India, Europe & US is to safeguard public health. It is the role of public regulatory authorities to ensure that pharmaceutical companies comply with regulations. There are legislations that require drugs to be developed, tested, trailed, and

manufactured in accordance to the guidelines so that they are safe and patient's well-being is protected[10-12].

The new drug approval process in India falls under the 2019 new rules. New clinical trial regulations have also been implemented to expedite registration of orphan-designated and innovative medicines. The new rules and regulations apply to all types of new drugs, INDs for human use, clinical trials, bioavailability/bioequivalence (BA/BE) studies, and ethics committees, which has further streamlined the approval process. The drug approval process involves two steps – application to the regulatory authority to conduct a clinical trial and application for marketing authorization of drug.

Regulatory Approach in the US

In the US, a generic drug product must be shown to be therapeutically equivalent to a designated RLD. Therapeutically equivalent drug products have the same clinical efficacy and safety profiles when administered to patients under conditions specified in the labeling, and thus can be substituted for each other without any adjustment in dose or other additional monitoring. To obtain approval of a generic drug product, an Abbreviated New Drug Application (ANDA) submitted to the US Food and Drug Administration (FDA) Office of Generic Drugs (OGD) should contain data demonstrating pharmaceutical equivalence [per 21 CFR 320.1 (c)] and bioequivalence (BE) [per 21 CFR 320.1 (e)] of the proposed generic product to the designated RLD.

Drug approval process in Canada

Drugs are authorized for sale in Canada once they have successfully gone through the drug review process. This process is the means by which a drug application is reviewed by scientists in the Health Products and Food Branch (HPFB) of Health Canada, and on occasion, outside experts, to assess the safety, efficacy and quality of a drug.

Drug approval process in UK

The medicines regulatory environment is undergoing a period of significant evolution, partly in response to the changing environment in which it operates. Advances in science and technology have led to the development of new types of product, with increasing numbers of biopharmaceuticals; biosimilar medicines; advanced therapies (gene therapy, cell therapy, tissue therapy); more personalized treatments and precision medicine; greater convergence between medicines and medical devices; and more combination products – products composed of a combination of a drug or biological product and a device – and products that sit on the borderline between medicines and other sectors, such as food, cosmetics and biocides. The diversity and complexity of products have never been greater. The industries producing pharmaceuticals and medical devices are increasingly global in nature, developing products for global markets.

Drug approval process in India

Since India's CDSCO implemented the 2019 New Drugs and Clinical Trials Rules (2019 new rules),[1] the drug approval process has been faster and a greater number of innovative medicines and orphan-designated medicines for rare diseases are now available. Under the new rules, clinical trials may be abbreviated for the approval of orphan-designated medicines. Sponsors of orphan drugs can apply to the CDSCO for an expedited review process, waiving the requirement for local clinical trials in recognition of significant unmet medical needs. Under the 2019 new rules, applicants may apply to the licensing authority for an expedited review process in which the evidence of clinical safety and efficacy has been established even if the drug has not completed all the normal clinical phases[13-14]. This will accelerate the application review and the clearance process to initiate a clinical trial as well as facilitate earlier entry of effective new drugs to the market and reduce the costs associated with development. These new provisions aim to encourage more indigenous research and development for diseases affecting patients in India.[1] In addition, the flexibility and expedited processes will help position India as one of the major markets in Asia for pharmaceutical companies to market their drugs.[2] India is well suited as a venue for this plan. It is a developing country, with a population of approximately 1.4 billion, about 17.7% of the world's population,[3] and there is considerable untapped research and manufacturing potential. In addition, many medical needs for serious diseases such as diabetes, cancer, tuberculosis, and AIDS are unmet, creating a demand for therapies. For example, the government has implemented a national strategic plan for rapidly reducing tuberculosis-related morbidity and mortality in India by 2025. The plan is facilitated by supportive government policies integrated into the four strategic pillars of "detect, treat, prevent, and build. In India, a sponsor may apply to the licensing authority for an expedited review of new drugs developed for use in a disaster or for defense in an extraordinary situation (e.g., war or radiation exposure) when specific, rapid preventive and treatment strategies are required in circumstances in which a real-world clinical trial may not be possible.[1] Permission for the manufacture of a new drug may be granted if the following conditions are satisfied: Preclinical data makes a case for claimed efficacy[15].

4. Conclusion

Asia-Pacific regulatory systems are diverse and can be challenging to access and navigate without an awareness of recent developments. The Indian Ministry of Health and Family Welfare Authority has streamlined the drug approval process so that patients with serious and/or unmet medical needs can access safe and efficacious drugs without unnecessary delay[60]. The recent regulatory agency developments were implemented to enhance efficiencies and flexibility and include the regulatory pathway, CMC regulatory requirements, collaborative initiatives with

international regulators, exemptions, and clinical trial reforms to expedite the drug approval processes for prescription and orphan-designated medicines. Industry data and real-life case studies help to determine the optimal registration strategy with an understanding of the regulations in determining the most efficient strategy to obtain approval.

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