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DRUG REGISTRATION PROCESS FOLLOWED IN TANZANIA

J. Manoj Krishna*, D. Nagarjuna Reddy, M. V. Nagabhushanam, Brahmaiah Bonthagarala and G. Ramakrishna

Department of Pharmaceutical Management and Regulatory Affairs, Hindu College of Pharmacy, Amaravathi Road, Guntur, Andhra Pradesh, India-522002.

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***Corresponding Author**
J. Manoj Krishna
Department of Pharmaceutical Management and Regulatory Affairs, Hindu College of Pharmacy, Amaravathi Road, Guntur, Andhra Pradesh, India-522002.

ABSTRACT

The Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and Cosmetics Act, 2003 with the mission of protecting and promoting public health by ensuring quality, safety and effectiveness of food, drugs, cosmetics and medical devices. In view of unique nature of pharmaceutical products and its raw materials, the Tanzania Food, Drugs and Cosmetics Act, 2003 provides for control of importation and exportation of pharmaceutical products or any substance used for the manufacture of pharmaceuticals. The law requires that any person dealing with importation of the products must be registered by TFDA and the imported pharmaceutical products must also be registered or approved by the Authority. These are the fundamental requirements for authorizing importation of pharmaceutical products and raw materials into the Tanzanian market. The guidelines are therefore reviewed in order to cope with the new developments in terms of requirements for importing or exporting pharmaceutical products and raw materials. The reviewed guidelines currently entitled as "Guidelines for Importation and Exportation of Pharmaceutical Products and Raw Materials, 2011" provides for guidance on the information and documentation required in an application submitted to TFDA by an importer or exporter of pharmaceutical products and raw materials.

KEYWORDS: Tanzania Food and Drugs Authority (TFDA), Drug Registration Process, Pharmaceutical Products.

1. INTRODUCTION

Tanzania, formerly known as Tanganyika. In 1964, Tanganyika united with the Island of Zanzibar form the United Republic of Tanzania, the largest of the East African countries and sadly one of the poorest countries in the world.[1]

Tanzania is located east of Africa's Great Lakes north of Mozambique and south of Kenya, it has a coastline at the Indian Ocean in east. The nation is bordered by six other African countries: Burundi, the Democratic Republic of the Congo, Malawi, Rwanda, Uganda, and Zambia, it also shares maritime borders with the Comoros and the Seychelles. It has shorelines at three of the Great Lakes: Lake Victoria, Lake Tanganyika and Lake Nyassa (LakeMalawi).[2] Tanzania has a population of 50.1 million people, capital is Dodoma, largest city, chief port, major economic and transportation hub and de facto capital is Dar es Salaam. Spoken languages are Swahili and English (both official), Arabic (widely spoken in Zanzibar).

Tanzania is mountainous and densely forested in the northeast, where Mount Kilimanjaro is located. Three of Africa's Great Lakes are partly within Tanzania. To the north and west lie Lake Victoria, Africa's largest lake, and Lake Tanganyika, the continent's deepest lake, known for its unique species of fish. The eastern shore is hot and humid, with the Zanzibar Archipelago just offshore. The Kalambo water falls in the southwestern region of Rukwa are the second highest uninterrupted fall in Africa and are located near the southeastern shore of Lake Tanganyika on the border with Zambia. The Menai Bay Conservation Area is Zanzibar's largest marine protected area. Over 100 different languages are spoken in Tanzania, making it the most linguistically diverse country in East Africa. Among the languages spoken in Tanzania are all four of Africa's language families: Bantu, Cushitic, Nilotic, and Khoisan. Swahili and English are Tanzania's official languages.

2. Scope

Tanzania is an emerging market; the pharmaceutical market is valued at over US$250 million, and is growing at an annual rate of around 16.5% and is expected to reach approximately US$550 billion in 2020. Currently, the market is highly dependent on imports, which account for around 75% of the total pharmaceutical market. The procedures and approval requirements of new drugs, variations, import, export and disposal have been set up by the TFDA, which help in maintaining quality of the drug products that are imported as well being produced locally.

3. Objective

To understand the approval process and registration process in Tanzania.

- To gain the depth knowledge of the approval process in Tanzania.
- To study about dossier submission of the drug in the country.
- And, to gain knowledge about the variations requirements of that particular drug.

4. Plan of Work

The research was carried out by the following stages:

Stage 1: Literature Review

Stage 2: Understanding the Process of Registration in Tanzania.

Stage 3: Common Technical Documents Review

Stage 4: Studying the Guidance for registration process.

Stage 5: Studying the Guidance for variation process.

5. METHODOLOGY

The Procedure for Drug Registration process in Tanzania includes the detailed review and analyze the following:

Medicines are only authorized to circulate in the market after being registered. The Tanzania Food and Drugs Authority (TFDA) has been mandated by the Ministry of Health and Social Welfare (MOHSW) to ensure quality, safety and efficacy of medicines. Since about 70% of medicines are imported from abroad, registration process contribute to the availability of quality, safe and efficacious medicinal products in the country. In this regard the registration process needs to be effective and should avoid unnecessary delays in order to increase the variety of medicines registered in the country.[14]

Tanzania is an emerging market; the pharmaceutical market is valued at over US$250 million, and is growing at an annual rate of around 16.5% and is expected to reach approximately US$550 billion in 2020. Currently, the market is highly dependent on imports, which account for around 75% of the total pharmaceutical market. The procedures and approval requirements of new drugs, variations, import, export and disposal have been set up by the TFDA, which help in maintaining quality of the drug products that are imported as well being produced.[15] The economics of pharmaceutical supply in Tanzania. Tanzania offers the prospect of a rapidly expanding market for the multinational pharmaceutical industry. However, this market has been to a large extent developed by the intense promotional activities of the drug companies themselves. In addition to normal marketing

methods, these companies indulge in techniques which would be neither acceptable nor legal in developed countries. As a result, expensive proprietary drugs are overpurchased and overprescribed, mainly in the large urban hospitals, with consequent deprivation of other health care facilities, particularly those for the rural peasants who form the majority of the population. The activities of the multinational pharmaceutical companies in the Third World are therefore an important component in the continuing underdevelopment of health in these nations.[16]

Regulations followed by Tanzania was reviewed and analyzed from Tanzania Food and Drug Authority website.

1. The registration process in Tanzania is followed according to the guidelines of "Guidelines on Submission of Documentation for Registration of Human Medicinal Products"
2. Variations process in Tanzania is followed according to the guidelines of Application guidelines for variations of registered human medicinal products.

Any changes to registered products (variations) may involve administrative and/or more substantial changes and are subject to approval by TFDA. Procedures for the implementation of the different types of variations need to be set out in order to facilitate the task of both Marketing Authorization Holders and TFDA and to guarantee that variations to the medicinal product do not give rise to public health concerns.

3. Fees and terms are reviewed according to TFDA Annual sheets of 2013-15.

6. CONCLUSION

Tanzania presents a highly regulated business environment and more specifically, strict regulations within the pharmaceutical market pose many challenges. The pharmaceutical products like drugs for human use (New and generics) have well defined guidelines among all pharmaceutical products and the application for registration must be compiled in a specified format as mentioned in guideline, "Guidelines on Submission of Documentation for Registration of Human Medicinal Products". Well organized and compiled documents will facilitate the evaluation process and decrease the screening time. The study points towards a positive trend stating that despite prevailing challenges, the market for pharmaceutical products is likely to remain strong in the wake of lifestyle changes region wide. The prospects for the sector are likely to improve over time as local and national legislation

continues to be in closer agreement with international standards. Growing population and incomes underpin the growth-dynamic for the foreseeable future.

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