

## **A REVIEW OF GENERIC DRUG REGISTRATION STANDARDS IN NIGERIA**

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### **ABSTRACT**

This article offers a thorough analysis of the requirements to be taken into account while registering generic drugs in the Nigerian region, with a focus on Kenya, Ghana, and Botswana. Therefore, this article will eventually result in a greater understanding of the variations in dossier registration within different locations and will aid in the systematic adoption of necessary medications for more significant objectives in the near future. To prevent major surprises after applying, it is imperative that the regulatory approach for product development be set before developmental activity begins. The regulatory bodies have a vital responsibility to guarantee the efficacy, safety, and quality of any medications that are dispensed within their nation. Due to the lack of harmonization between the various regions, product registration in the rest of the world may also present difficulties. It comprises not just the procedure for manufacturing, distributing, and promoting pharmaceuticals in addition to controlling and overseeing their use.

**Keywords:** Generic, Global, Regulatory, Quality, Registration, Row Countries.

### **1. INTRODUCTION**

#### **MARKET FOR GENERIC DRUGS**

A generic drug is a prescription medication that is manufactured and sold after a patent or other exclusive rights expire. It is usually defined as the same as an inventive product. Generic drugs are marketed under an approved name, sometimes known as a non-proprietary name, rather than a proprietary or brand name. Compared to name-brand drugs, their costs are lower. The global market for generic drugs was estimated to be worth US\$ 386 billion in 2020. Global sales of generic medications are projected to rise from \$411.6 billion in 2020 to \$650.3 billion by 2025, with a 9.6% compound annual growth rate (CAGR). (1) The active ingredients in the original formulation and the generic drug should be identical. The forerunner or trademark drug and its the amount of the active ingredient that is infused into the bloodstream should be the same or the dosage should be bioequivalent to that of the generic medication. It is estimated that over \$150 billion worth of pharmaceuticals would go off-patent between 2010 and 2017 based on global market trends, giving pharmaceutical companies a platform to manufacture generic versions of their products. (2)

#### **DEFINITION**

The dosage should be bioequivalent to the quantity found in the generic drug, or the amount of the active ingredient pumped into the bloodstream should be the same. Global market trends indicate that between 2010 and 2017, about \$150 billion worth of medications are expected to go off-patent, providing a platform for pharmaceutical companies to produce generic copies of their goods. (3)

#### **Key factors driving the growth of generic drugs**

The market is affected by a number of factors, such as rising rates of diabetes and cardiovascular disease, chronic illness prevalence, the aging of the population, rising demand for generic medications, rising healthcare costs, and a significant number of branded medication patents that have expired. Nonetheless, it is anticipated that the market's growth will be constrained by strict government laws and the negative effects of medications. The market for generic medications is significantly driven by factors such as the growing need for more recent iterations of the medication, various clinical trials, and the numerous licensing and partnership tactics used by major vendors to introduce new goods.

#### **INTRODUCTION**

The quality, effectiveness, and safety characteristics of generic medications are identical to those of original (branded) medications, but they are more reasonably priced. The National Agency for Food and Drug Administration (NAFDAC) is Nigeria's primary regulatory authority for pharmaceuticals, including biologicals. It is in charge of approving the marketing of all pharmaceuticals, both branded and generic, in the nation. (4)The definition of "generic product" varies slightly depending on the jurisdiction. As a result, the phrase "multisource pharmaceutical product" has been used in place of this one whenever possible (see the definition below). Products with several sources can be sold under a brand name (proprietary) or the authorized non-proprietary name. They might be sold with doses and/or strengths that differ from the pioneering products'. Where a pharmaceutical product is referred to as a "generic," it usually refers to one that

is meant to be used interchangeably with the innovator product. It is typically produced without the innovator company's permission and sold after the patent or other exclusive rights expire. The term and generic names for APIs are not the same. (5)

Generic medications Together with pervasive hunger and poverty, HIV/AIDS, TB, and malaria constitute a double burden of disease on the populace. Heart-related illnesses are also becoming more common. This explains why a significant portion of the market is occupied by over-the-counter (OTC) medications such multivitamins, antimalarials, and analgesics. Antiretroviral (ARV), artemisinin combination therapy (ACT), anti-TB, and antibacterial anti-diarrheal medications are among the other often used medications. The Federal Ministry of Health (FMoH) of Nigeria reports that approximately 30% of hospital admissions and 60% of outpatient visits are related to malaria. Due to its accessibility and affordability in both urban and rural areas, the class of analgesics, antirheumatics, and antipyretics has the highest percentage of local manufacture & communities, as well as widespread use and misuse of these products for a wide range of symptoms. (6)

#### **ROW COUNTRIES:**

This region is primarily made up of nations in the Asia-Pacific, Latin America, Africa, Eastern Europe, and Gulf countries. whereas Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia, and Zimbabwe are nations in the Asia-Pacific and Gulf region. Harmonizing pharmaceutical trade and regulation was the main goal. Every nation abides by its own regulations, despite the fact that some acts are still going on. (1)

#### **Nigeria's regulations compared with other countries**

Every nation has laws governing the production, importation, and distribution of prescription medications. But when it comes to imports, several nations employ various trade and non-trade obstacles to either advance certain economic goals, safeguard domestic sectors, or boost the economy. There are a lot of parallels in the laws and regulations controlling conventional and alternative medicine in seven nations, including Nigeria. One important aspect of each of these nations is the presence of laws, rules, and policies designed to guarantee thorough oversight of the pharmaceutical industries and goods' development, manufacturing, importation, distribution, and marketing. Despite the existence of these regulations, there are a few little variations in terms of:

- Inspections of factories and manufacturing sites;
- Examinations of distribution channels;
- Control of prescriptions;
- Priority/fast track applications for pharmaceutical product registration;
- Product samples needed for testing prior to registration;
- and Products for registration, such as water, chemicals, cosmetics, and veterinary drugs

## **2. DRUG FILING REQUIREMENTS IN NIGERIA**

Currently, the region's pharmaceutical manufacturing sector can supply 25% of the demand. Manufacturers in Nigeria create ointments, lotions, creams, pills, capsules, liquid preparations, and ophthalmic preparations. For certain drug classes, the domestic demand can be satisfied by the regional pharmaceutical companies. Imports from Asian businesses are progressively controlling the remaining 75% of the market. According to analysis by Business Monitor International (B.M.I.), Nigeria's pharmaceutical sector will bring in \$9.61 billion by 2025. The growing accessibility of affordable generic medications is anticipated to propel growth in the pharmaceutical sector.

#### **Drug Registration Procedure**

The product may be introduced to the market by the proposed Certificate of Registration (Phcr) holder. The pharmacist who is permitted to speak with the council should sign the application that has been submitted. This pharmacist ought to work for the organization full-time. The dossier is generally formatted in CTD. The approval procedure is the same for both generic and replacement medications. For generic medications, the applicant must offer proof that the product has a therapeutic effect that is similar to that of the original product.(7)

#### **PROCEDURE:**

To obtain a license number, each imported product needs to go through a series of stages.

STEP 1: The Nigerian Ministry of Commerce must receive the name registration from the applicant. The only requirement is that the applicant's chosen brand name not violate any existing trademarks in the marketplace. Subsequently, the candidate needs to submit a formal application to the Registration Division of NAFDAC, including the manufacturer's name, generic name (brand name), strength, and indications. They also need to obtain the application form, which needs to be filled out completely with all the necessary information. Once N500.00 for each product has been paid, this form, designated "FORM D- R.E.G./001," will be sent. For each drug product, which refers to a different

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medication formulation, a new form must be submitted. Nevertheless, the registration application for one dosage form that comes in various strengths could also be produced on an equivalent basis.

**STEP 2:** Before proceeding with any further steps, the NAFDAC-described required documentation for each product's registration must be deemed enough. If the paperwork satisfies NAFDAC regulations, the petitioner is granted permission to import product samples. In order to be used for screening and laboratory analysis, the applicant must import the designated samples (National Chemical Laboratory).

**STEP 3:** At this point, product samples that have been presented are vetted, which involves looking at the labels, pamphlets, and medication information. Product labels must have the following basic information: the name of the medication, the manufacturer's name and address, the date of production and expiration, the batch number, and so on.

Documents to be submitted during the vetting are:

1. copies of the payment receipt and the import authorization.
2. A drug dossier that complies with the NAFDAC format.
3. Samples of each item available.
4. A letter inviting an examination.
5. Study certificate with compression.

**STEP 4:** Following the screening process, the candidate must bring some samples for analysis in a lab. Send in the appropriate number of sample products, together with copies of the application letter and processing fee receipt. After that, the product or products are sent to a lab for analysis to ensure that they meet standard criteria.

**STEP 5 :** Whether the product is eligible for a NAFDAC registration number or not is decided at this point. An identification number is provided if the product satisfies every desire. After the product is assigned a registration number, the applicant must obtain the notification number, make the license certificate payment, and show the receipt in order to request the notification. The product certificate is valid for importation by the applicant for a period of five years. (8)

#### **Requirements for Drug Registration in Nigeria:**

- A product's registration does not immediately grant an advertising permit. If the product is to be advertised, additional Agency permission is needed.
- In the case that the product is advertised without the Agency's express approval, NAFDAC has the right to revoke the Certificate of Registration.
- NAFDAC retains the authority to cancel, postpone, or alter the certificate while it is still in effect.
- Registration status is not conferred by filling out an application or paying for one.
- The application will immediately be suspended from further processing if you do not promptly respond to queries posed by NAFDAC regarding the application. (9)

#### **National Agency for Food and Drug Administration and Control (NAFDAC)**

Under the Federal Ministry of Health, the National Agency for Food and Drug Administration and Control (NAFDAC) is Nigeria's drug regulatory body. It oversees the production, import, export, marketing, distribution, sale, and use of food, medications, cosmetics, medical equipment, chemicals, and prepackaged water.

#### **Please Note:**

- The application's processing will automatically be suspended if NAFDAC's questions or inquiries are not answered in a timely manner within 30 workdays.
- One hundred (100) workdays is the registration deadline following the submission of the vetting samples.

### **3. CONCLUSION**

A nation's regulatory agency may be in charge of regulating medicines. The people of this nation hold this agency responsible for guaranteeing the availability, effectiveness, caliber, and security of pharmaceuticals. Generic pharmaceuticals are starting to pose a serious threat to branded drugs in many regional pharmaceutical markets. The need to lower healthcare expenditures and the rising demand for pharmaceutical items are the main drivers of this increase. In parallel, health plan providers are working to control the amount of money spent on pricey prescription pharmaceuticals, which is helping the pharmaceutical sector.

### **4. REFERENCES**

- [1] Shailaja Pashikanti, Nirupama Koribilli. Generic Drug Registration Requirements in ROW Countries. *Journal of Pharmaceutical Sciences and Research (JPSR)*. 2021; 13(10).
- [2] Handoo, Shweta & Arora, Vandana & Khera, Deepak & Nandi, Prafulla & Sahu, Susanta. (2012). A comprehensive study on regulatory requirements for development and filing of generic drugs globally. *International journal of pharmaceutical investigation*. 2. 99-105. 10.4103/2230-973X.104392.

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- [3] Rafi, Nazyia & Ds, Sandeep & Narayanan V, Anoop. (2018). Regulatory Requirements and Registration Procedure for Generic Drugs in USA. Indian Journal of Pharmaceutical Education and Research. 52. 544-549. 10.5530/ijper.52.4.63.
- [4] Nandini Warier, Priti Mehta. Comparative Study of Generic Drug Registration Requirements for Dossier Submission in African Region-Kenya, Ghana, Nigeria, and Botswana Volume 3 , Issue 2 , 2016. DOI : 10.2174/2213476X03666160605111335
- [5] [https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/R\\_and\\_R\\_Guidelines/GENERAL/Quality-Guidelines-for-Registration-of-Pharmaceutical-Products26381.pdf](https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/R_and_R_Guidelines/GENERAL/Quality-Guidelines-for-Registration-of-Pharmaceutical-Products26381.pdf)(Doc. Ref. No: R&R-GDL-O18-OO)
- [6] [https://pharmexcil.com/docs/DRProcedures/NIGERIA/Aregprocedure\\_nigeria.pdf](https://pharmexcil.com/docs/DRProcedures/NIGERIA/Aregprocedure_nigeria.pdf)
- [7] B. Jayalakshmi, R. Seetharaman, R. Kamaraj. Registration and Regulatory Requirements of Generic Drugs Marketing Authorization in "BRICS" Countries. Research J. Pharm. and Tech. 2019; 12(3): 1403-1408. DOI: 10.5958/0974-360X.2019.00234.8
- [8] Senthil V, L. Srianitha R. Baviyapriyadharshini. Regulatory Requirements For Drug Products Registration In South Africa February 2018 International Journal of Drug Regulatory Affairs 3(4):1-8 DOI:10.22270/ijdra.v3i4.171
- [9] Nandini Warier, Priti Mehta. Comparative Study of Generic Drug Registration Requirements for Dossier Submission in African Region-Kenya, Ghana, Nigeria, and Botswana Volume 3 , Issue 2 , 2016. DOI : 10.2174/2213476X03666160605111335