



# Key Considerations for Investors vis-a-vis the Updates on the Legal Framework for Drug Approval and Market Entry in Nigeria



## INTRODUCTION

The Nigerian health and pharmaceutical sector is confronted with a rising demand for effective and adequate healthcare services and pharmaceutical products. However, the path to ensuring that effective, safe, and high-quality medications reach the Nigerian populace is complex and multifaceted. A robust legal and regulatory framework is essential to safeguard public health while fostering innovation and competition within the pharmaceutical sector.

The National Agency for Food and Drug Administration and Control (NAFDAC) is the primary regulatory authority overseeing drug approval and market entry in Nigeria.

Over the years, NAFDAC has implemented several reforms to align local pharmaceutical regulations with international standards and to address challenges such as counterfeit drugs and inadequate pharmacovigilance. Recently, the legal landscape for drug approval and market entry in Nigeria has witnessed significant updates reflecting a proactive approach to enhancing the efficacy, safety, and accessibility of pharmaceutical products in the country. This article explores these updates in detail, their impact on the pharmaceutical market, and critical considerations for stakeholders in the Nigerian pharmaceutical industry as well as those aiming to enter the Nigerian pharmaceutical industry.

# RECENT UPDATES ON THE LEGAL FRAMEWORK FOR DRUG APPROVAL AND MARKET ENTRY

In a bid to modernize and improve the drug approval process, the Pharmacy Council of Nigeria (PCN)<sup>1</sup> and NAFDAC have introduced several pivotal changes to the legal framework governing pharmaceutical products in Nigeria. These updates are designed to streamline procedures, enhance safety monitoring, and promote local pharmaceutical production. These updates include the following:

- 1. Market Entry:** In addition to adhering to the NAFDAC Good Manufacturing Practice for Pharmaceutical Products Guidelines 2021 (the "GMP Guidelines")<sup>2</sup>, stakeholders in the pharmaceutical industry must also ensure full compliance with the provisions of the Pharmacy Council of Nigeria (Establishment) Act 2022 (the "Act"). It is crucial to note that under the Act, the registration of premises for drug manufacturing goes beyond merely fulfilling the requirements set out in the GMP Guidelines. While the GMP Guidelines provide essential standards for the quality and safety of pharmaceutical products, it does not encompass the legal obligation to register manufacturing premises with the Pharmacy Council of Nigeria (PCN). Compliance with the GMP Guidelines alone is insufficient, thus obtaining PCN registration is a mandatory step for legally operating in the pharmaceutical manufacturing sector in Nigeria.<sup>3</sup>
- 2. Revised NAFDAC Guidelines:** The NAFDAC Good Distribution Guidelines for Pharmaceutical Products (the "Guidelines") was reviewed and published in 2023. The Guidelines impose a responsibility on parties involved in the distribution of pharmaceutical products to ensure that the quality of pharmaceutical products and the integrity of the distribution chain is maintained throughout the distribution process from the manufacturer to the end user.<sup>4</sup> The Guidelines also mandate distributors of pharmaceutical products to implement traceability measures to ensure a safe, transparent and secure distribution system.<sup>5</sup>
- 3. Pharmacovigilance and Post-Marketing Surveillance:** To ensure drug safety and efficacy, NAFDAC has bolstered its pharmacovigilance framework by mandating pharmaceutical companies to implement robust systems for monitoring and reporting adverse drug reactions.<sup>6</sup> This proactive approach helps to identify potential safety issues early, enabling prompt corrective actions. Additionally, as part of the approval process, companies must now submit comprehensive risk management plans.<sup>7</sup> These plans outline strategies for monitoring the safety of the drug post-market entry, identifying risks, and implementing mitigation measures.

1 The Pharmacy Council of Nigeria was established by the Pharmacy Council of Nigeria (Establishment) Act, 2022 as the government parastatal to regulate the standard of pharmacy practice and business in Nigeria.

2 NAFDAC Good Manufacturing Practice for Pharmaceutical Products Guidelines 2021.

3 Section 22 of the Pharmacy Council of Nigeria (Establishment) Act 2022.

4 Para. 1.1 of the NAFDAC Good Distribution Guidelines for Pharmaceutical Products

5 Para. 3.47 of the NAFDAC Good Distribution Guidelines for Pharmaceutical Products 2023.

6 Chapter 5 of the NAFDAC Good Pharmacovigilance Practice Guidelines 2021.

7 Chapter 3 of the NAFDAC Good Pharmacovigilance Practice Guidelines 2021.

This requirement ensures that pharmaceutical companies remain vigilant about the safety of their products throughout their lifecycle. Worthy of mention is the recent commissioning of the Narcotic Drug Serialization Project<sup>8</sup> (the “Project”) by NAFDAC. One of the objectives of the project is to track and trace pharmaceutical products with narcotic medicines from the manufacturing plant to the end user. The project is expected to span for one year through which NAFDAC will then deploy and fully implement the track and trace project for other drug classes.

#### **4. Strengthening International Regulatory Alignment and Regional Integration:**

Nigeria is increasingly aligning its regulatory framework with global standards by collaborating with international organizations such as the World Health Organization (WHO). A significant step in this direction is Nigeria's adoption of the WHO prequalification process for essential drugs. This initiative ensures that medicines entering the Nigerian market meet the highest international standards for safety, efficacy, and quality. By adhering to the WHO prequalification guidelines, Nigeria enhances the safety of its drug supply while facilitating the introduction of WHO-prequalified medicines into the local market. A recent example of this collaboration is noted in the attainment by NAFDAC of Maturity Level 3 in the WHO grading system for health regulatory agencies and the inclusion of a drug produced by Swiss Pharma (SWIPHA) Nigeria Limited,

a leading Nigerian pharmaceutical company on the WHO's list of prequalified medicines,<sup>9</sup> marking a milestone in the country's efforts to meet global health standards.<sup>10</sup> In addition to aligning with WHO standards, Nigeria is actively engaging in Mutual Recognition Agreements (MRAs) with neighbouring countries. These agreements aim to promote regional integration by harmonizing regulatory standards and simplifying the process for market entry across West Africa. This regional cooperation not only boosts the availability of essential medicines but also strengthens the overall healthcare infrastructure in the region.

#### **5. Regulatory Incentives and Compliance:**

To stimulate local pharmaceutical production in Nigeria, the Government has introduced various fiscal incentives, including tax breaks and subsidies. These measures are designed to attract investment into the domestic pharmaceutical manufacturing sector, reduce reliance on imported drugs, and enhance self-sufficiency. It is no gainsaying that promoting local production of drugs improves drug affordability and availability. Recently, an Executive Order was signed by the Federal Government of Nigeria, introducing zero tariffs, excise duties, and VAT on specified machinery, equipment, and raw materials within the Health and Pharmaceutical sector.<sup>11</sup> Through this, Local manufacturers can import pharmaceutical machinery, and raw materials needed to produce drugs without worrying about excise duties.

<sup>8</sup> The Narcotic Drug Serialization Project was commissioned on 18th January 2024.

<sup>9</sup> A prequalified medicine simply means a drug that has satisfied global standards and quality checks.

<sup>10</sup> <https://nafdac.gov.ng/press-briefing-by-the-director-general-nafdac-professor-mojisola-christianah-adeyeye-on-breakthrough-world-health-organization-who-prequalification-approval-of-finished-pharmaceutical-product-man/>

<sup>11</sup> <https://www.premiumtimesng.com/health/health-news/708106-tinubu-signs-new-executive-order-to-address-rising-cost-of-drugs-other-consumables.html>

# IMPACT OF THE RECENT UPDATES ON THE PHARMACEUTICAL MARKET

The recent updates to the legal landscape for drug approval and market entry in Nigeria have far-reaching implications for the pharmaceutical industry. These changes are positioned to transform the market landscape in several key ways:

- 1. Increased Market Efficiency:** The introduction of the online registration portal and accelerated approval processes significantly reduces the time required for new drugs to reach the market. This efficiency is particularly beneficial in addressing urgent public health needs and ensuring that essential medications are promptly available.
- 2. Enhanced Drug Safety:** Strengthened pharmacovigilance and post-marketing surveillance frameworks ensure that drugs remain safe and effective after they enter the market. This continuous monitoring helps identify and mitigate any potential safety issues, thereby enhancing public confidence in pharmaceutical products.

- 3. Greater Investment and Local Production:** The fiscal incentives for local pharmaceutical production will attract both domestic and international investment into the pharmaceutical sector. Encouraging local manufacturing reduces dependency on imported drugs, creates jobs, and stimulates economic growth.
- 4. Regional Market Integration:** Harmonization efforts and participation in MRAs facilitate easier market entry across multiple West African countries. This regional integration creates opportunities for pharmaceutical companies to expand their reach and tap into larger markets, ultimately benefiting consumers through increased access to essential medications.

## CONSIDERATIONS FOR EXISTING AND INTENDING INVESTORS IN THE PHARMACEUTICAL MARKET

In the light of the existing legal framework explained above, investors are enjoined to consider the following:

- 1. Compliance with Dual Regulatory Frameworks:** Stakeholders must ensure compliance with both NAFDAC and PCN regulations. While the NAFDAC Good Manufacturing Practice (GMP) Guidelines set essential standards for pharmaceutical product quality and safety, full legal compliance requires the registration of manufacturing premises with PCN.

The importance of obtaining expert legal assistance to navigate these complex regulatory requirements cannot be overstated.

- 2. Maximizing Regulatory Incentives:** Companies looking to invest in the health and pharmaceutical sector in Nigeria require comprehensive legal guidance to fully capitalize on the fiscal incentives available within the sector. Such guidance can reduce operational costs and enhance market competitiveness.

**3. Adherence to Revised Distribution Guidelines:** The updated NAFDAC Good Distribution Guidelines necessitate strict measures to maintain product quality throughout the supply chain. Stakeholders must implement robust traceability systems to secure the distribution chain and prevent counterfeit products from reaching consumers. This, will not only protect public health but will also preserve the reputation of legitimate distributors and manufacturers.

**4. Active Pharmacovigilance and Post-Marketing Surveillance:** With NAFDAC's enhanced pharmacovigilance framework, pharmaceutical companies must develop and maintain comprehensive internal and external risk management plans. These plans should include strategies for monitoring and addressing adverse drug reactions post-market entry. Companies need to be proactive in identifying and mitigating risks to ensure ongoing product safety and compliance.

## CONCLUSION

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The recent updates to the legal framework for drug approval and market entry in Nigeria signify a significant step towards enhancing the efficiency, safety, and accessibility of pharmaceutical products. These changes not only benefit the pharmaceutical market by fostering innovation and competition but also create new opportunities for local and international players. For those looking to enter the Nigerian pharmaceutical industry, staying abreast of these regulatory updates and strategically aligning with them is key to successful market entry and sustained growth.

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