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Impact of regulatory policy changes on access to medicine in Nigeria, Africa

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Abstract

This paper explores the impact of regulatory policy changes on access to medicines in Nigeria, examining both the positive advancements and the challenges that have arisen. Recent reforms have accelerated access to innovative therapies through streamlined drug approval processes and improved pharmacovigilance measures, ensuring higher quality and safer medicines for the population. Furthermore, Nigeria's participation in regional initiatives like the African Medicines Agency (AMA) has fostered regulatory harmonization, improving cross-border medicine access across Africa. However, these regulatory changes have also placed financial burdens on local manufacturers, hindered by high compliance costs and registration fees. Additionally, intellectual property protections under TRIPS have delayed the availability of affordable generic medicines, increasing the country's reliance on imports. The paper highlights key recommendations for Nigeria to balance regulatory stringency with access to affordable medicines, including promoting local pharmaceutical manufacturing, refining intellectual property policies, and enhancing the capacity of regulatory agencies. Continuous reform and regional collaboration are essential to ensuring equitable access to medicines in Nigeria, supporting the nation's response to public health challenges, and fostering long-term improvements in healthcare outcomes.

Keywords: Regulatory Policy; Access to Medicines; Pharmacovigilance; NAFDAC; Intellectual Property (TRIPS); African Medicines Agency (AMA)

1. Introduction

Access to medicines is a cornerstone of public health, directly influencing disease control, treatment outcomes, and the overall well-being of populations. In Africa, and specifically Nigeria, the availability of essential medicines is particularly crucial, given the high prevalence of communicable and non-communicable diseases, such as malaria, tuberculosis, HIV/AIDS, and diabetes. The pharmaceutical sector in the country faces challenges related to infrastructure, regulatory capacity, and economic constraints, all of which affect the population's ability to obtain timely and affordable medications (Ahen and Salo-Ahen, 2018; Obembe et al., 2022). Regulatory capacity binds everything together and is vital in ensuring that medicines circulating in the market are safe, productive, and of high quality, while also being accessible to the entire population. However, regulatory policies in the country have not always functioned optimally in achieving these goals.

This paper seeks to examine how regulatory policy changes in Nigeria have influenced access to medicines. Specifically, it explores the intersection of policy reforms, regulatory capacity, local pharmaceutical production, and external pressures such as international trade agreements. The aim is to provide a comprehensive review of how these factors have shaped the availability and affordability of medicines in Nigeria and what this means for public health. The analysis presented here is based on a review of secondary sources, including policy analyses, research studies, government reports, and international guidelines. Key regulatory frameworks, such as those established by the National Agency for Food and Drug Administration and Control (NAFDAC) and the African Medicines Regulatory Harmonization (AMRH)

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initiative, will be examined (Klantschnig and Huang, 2018; Ndomondo-Sigonda et al., 2017). These sources provide insights into how regulatory bodies operate, the obstacles they face, and the implications for medicine access.

The central argument of this paper is that regulatory policy changes in Nigeria have both enabled and restricted access to medicines. On the one hand, efforts to strengthen regulatory oversight and harmonize standards across Africa have improved the quality and safety of medicines (Ncube, Dube and Ward, 2021). On the other hand, stringent regulations and bureaucratic hurdles have limited the ability of local manufacturers to compete and have delayed the introduction of affordable generic medicines (Ndomondo-Sigonda et al., 2017). Thus, while regulatory reforms are necessary for safeguarding public health, they must also be designed to enhance access and affordability.

2. Overview of the Nigerian Pharmaceutical Regulatory Environment

Pharmaceutical regulation in Nigeria has transformed over the decades. The Pharmaceutical Board of Nigeria, established in 1927, was the first regulatory body overseeing the sector, but its influence was limited. In response to increasing challenges posed by the prevalence of counterfeit medicines and the expanding drug market, NAFDAC was created in 1993 under Decree No. 15, empowering it to address drug adulteration and substandard products (Ahen and Salo-Ahen, 2018). Over the years, NAFDAC introduced stricter regulations and partnered with global organizations to enhance regulatory capacity. In 2001, a major reform under the leadership of Professor Dora Akunyili led to heightened enforcement and public awareness about counterfeit drugs, significantly reducing the circulation of substandard products (Narsai, Williams and Mantel-Teeuwisse, 2012). Nigeria's regulatory environment also took a step forward with the country's involvement in regional regulatory harmonization efforts, particularly under the African Medicines Regulatory Harmonization (AMRH) initiative. This effort seeks to streamline pharmaceutical regulatory processes across the continent (Ncube, Dube, and Ward, 2021).

Currently, two primary bodies are responsible for the regulation of pharmaceuticals in Nigeria: the National Agency for Food and Drug Administration and Control (NAFDAC) and the Pharmacists Council of Nigeria (PCN). NAFDAC oversees the registration, regulation, and control of pharmaceuticals, ensuring that only safe and effective medicines enter the Nigerian market. It also monitors the importation, exportation, and manufacturing of drugs. The Pharmacists Council of Nigeria, on the other hand, regulates the education and practice of pharmacists, ensuring they meet required professional standards. Together, these bodies play critical roles in safeguarding public health by enforcing regulatory standards across the pharmaceutical supply chain. Nigeria's drug approval process is handled by NAFDAC, which assesses pharmaceutical products for safety, efficacy, and quality before they can be marketed. The approval process includes preclinical testing, clinical trials, and an extensive review of the product's manufacturing processes. NAFDAC also mandates strict labeling and pharmacovigilance systems to track adverse drug reactions (ADRs) (Narsai, Williams and Mantel-Teeuwisse, 2012).

Pharmacovigilance in Nigeria is handled through a combination of systems, including NAFDAC's National Pharmacovigilance Centre and the Nigeria National Pharmacovigilance and Drug Safety System, which are aligned with global pharmacovigilance protocols. Reporting of ADRs is mandated for healthcare providers and pharmaceutical companies. Post-market surveillance, which monitors the quality of medicines already on the market, is another critical aspect of Nigeria's regulatory framework. NAFDAC's post-marketing surveillance includes a random sampling of drugs, inspections of manufacturing facilities, and monitoring of adverse events reported by healthcare professionals and consumers.

However, despite improvements in regulatory oversight, Nigeria's pharmaceutical regulatory environment faces several challenges. Corruption remains a problem, affecting both the importation of counterfeit drugs and the approval processes for genuine products (Ahen and Salo-Ahen, 2018). Bribery leads to the registration of substandard products and undermines public trust in the system. Infrastructure deficiencies also limit the effectiveness of regulatory efforts. NAFDAC's laboratories, while improved, still struggle with capacity issues that delay the timely analysis of drugs. This is particularly concerning for post-market surveillance activities, where delays in testing allow counterfeit or substandard products to circulate unchecked.

Additionally, the capacity of regulatory agencies is hindered by inadequate staffing, insufficient training, and a lack of resources. NAFDAC and PCN struggle to meet the demands of the rapidly growing pharmaceutical industry, which is compounded by the limited domestic manufacturing capabilities in Nigeria. Many of the medicines consumed in Nigeria are imported, adding another layer of complexity to regulatory efforts (Ncube, Dube and Ward, 2021). In the same vein, regional inconsistencies in regulatory practices across Africa complicate cross-border trade and drug registration (Ncube, Dube and Ward, 2021). Although harmonization efforts such as the African Medicines Agency (AMA) aim to address these issues, Nigeria's regulatory capacity remains uneven (Ncube, Dube and Ward, 2021). These challenges,

combined with the country's ongoing battle against counterfeit drugs, point to the need for continuous reform and capacity building in the pharmaceutical regulatory sector.

3. Regulatory Policy Changes in Nigeria

In recent years, Nigeria has implemented regulatory reforms to strengthen its pharmaceutical sector. One of the most impactful changes has been the streamlining of drug approval processes (Ahen and Salo-Ahen, 2018). Historically, drug registration in Nigeria was characterized by long delays, taking years to approve new drugs. Reforms initiated by NAFDAC reduced bureaucratic bottlenecks by digitizing application processes, which shortened approval timelines. This reform allows for faster access to essential medicines without compromising the integrity of safety evaluations (Ahen and Salo-Ahen, 2018).

Another notable development is the enhancement of pharmacovigilance systems. Recognizing the need for rigorous post-marketing surveillance, NAFDAC introduced stricter reporting requirements for adverse drug reactions (ADRs). These reforms aligned local practices with international pharmacovigilance standards and expanded NAFDAC's capacity to monitor drug safety across the country. Furthermore, recent collaborations with the World Health Organization (WHO) have provided Nigeria with improved surveillance tools, leading to better tracking of ADRs and the withdrawal of unsafe drugs from the market. To combat counterfeit medicines, NAFDAC introduced the Mobile Authentication Service (MAS). This policy mandates the use of scratch codes on drug packages, allowing consumers to verify the authenticity of a product using their mobile phones. This technological advancement has been particularly effective in reducing the prevalence of counterfeit drugs in the market (Klantschnig and Huang, 2018).

3.1. International Policy Collaborations

Furthermore, Nigeria has made strides in aligning with international regulatory frameworks (Ahen and Salo-Ahen, 2018). The country actively participates in the World Health Organization's prequalification program, which ensures that pharmaceuticals, vaccines, and diagnostics meet global safety and efficacy standards before they are marketed in the country (Ahen and Salo-Ahen, 2018). Adopting WHO prequalification criteria has helped Nigeria improve access to quality-assured medicines, particularly in the fight against diseases like HIV/AIDS and malaria (Ahen and Salo-Ahen, 2018; Ndomondo-Sigonda et al., 2017). In addition, Nigeria has aligned its intellectual property regulations with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement (Ncube, Dube and Ward, 2021). This alignment ensures that the country adheres to international patent protection laws, which have direct implications for access to generic medicines. While TRIPS compliance protects intellectual property, it also creates a balance by allowing Nigeria to utilize flexibilities, such as compulsory licensing, to import affordable generics during public health emergencies (Ncube, Dube and Ward, 2021).

Nigeria's involvement in the AMA harmonization efforts further demonstrates its commitment to international collaboration. The AMA aims to streamline regulatory processes across African nations, reducing duplication and ensuring faster drug approvals continent-wide. Nigeria's adoption of the African Medicines Regulatory Harmonization (AMRH) initiative supports this goal by harmonizing its regulatory standards with those of other African countries (Ncube, Dube and Ward, 2021).

3.2. Pharmaceutical Manufacturing Policies

Nigeria's local pharmaceutical industry has struggled due to high production costs and competition from imported medicines. To address this, the government introduced several policies aimed at bolstering local manufacturing, notably the enforcement of Good Manufacturing Practices (GMP). NAFDAC ensures that local manufacturers comply with internationally recognized GMP standards, which are critical in maintaining the quality and safety of medicines (Ndomondo-Sigonda et al., 2017). However, compliance with these standards has been challenging for many local manufacturers due to the high costs of infrastructure upgrades required to meet GMP criteria. To support local production, the Nigerian government has also implemented tax incentives. These include tax holidays for new pharmaceutical manufacturers, reduced import duties on raw materials, and VAT exemptions on locally produced medicines (Obembe et al., 2022). These policies are intended to create a more competitive environment for domestic manufacturers, enabling them to produce high-quality drugs at lower costs (Obembe et al., 2022). While these incentives have helped to some extent, challenges such as inconsistent power supply and poor infrastructure continue to hamper the full realization of local manufacturing potential.

3.3. Regulatory Incentives for Innovation

Nigeria has taken steps to incentivize the development and introduction of new therapies by creating a more favorable regulatory environment for pharmaceutical innovation (World Health Organization, 2022). NAFDAC has introduced fast-track approval pathways for medicines that address critical public health needs, such as vaccines and treatments for emerging diseases. This has been particularly relevant during the COVID-19 pandemic, where expedited approvals were granted for vaccines and treatments. Additionally, the government has fostered partnerships between local pharmaceutical companies and international research institutions to drive drug research and development. The establishment of public-private partnerships (PPPs) has allowed for the transfer of knowledge and technology, helping Nigeria's pharmaceutical sector innovate in areas such as drug formulation and clinical trials (Ncube, Dube and Ward, 2021). Furthermore, NAFDAC's recent policy of offering reduced registration fees for innovative products encourages pharmaceutical companies to invest in the development of new therapies that cater to the specific needs of the Nigerian population (World Health Organization, 2022).

These regulatory changes, while promoting innovation, also ensure that new therapies entering the Nigerian market undergo rigorous evaluation for safety and efficacy. The combination of fast-track approval processes and financial incentives positions Nigeria as a potential leader in pharmaceutical innovation in sub-Saharan Africa (World Health Organization, 2022). Through a combination of policy reforms, international alignment, support for local manufacturing, and incentives for innovation, Nigeria's regulatory environment is evolving. However, the effectiveness of these changes depends largely on addressing the systemic challenges that persist, such as infrastructure deficits and regulatory capacity limitations.

4. Impact of Regulatory Policy Changes on Access to Medicines

4.1. Positive Impacts

Regulatory policy changes in Nigeria, particularly the streamlining of approval processes, have accelerated access to new medicines and vaccines. Before recent reforms, delays in drug registration were a persistent issue, sometimes taking years to approve essential medicines. Reforms implemented by NAFDAC have reduced these bottlenecks by digitizing application processes and fast-tracking approvals, particularly during public health emergencies. For example, the rapid approval of COVID-19 vaccines under Emergency Use Authorizations (EUA) is a testament to these improvements. Between 2021 and 2022, Nigeria successfully imported and distributed multiple COVID-19 vaccines, including Pfizer, AstraZeneca, and Moderna, which passed stringent quality control tests under NAFDAC's supervision. These faster approval processes have allowed Nigeria to be better equipped to respond to public health crises. The introduction of fast-track pathways for medicines that address critical public health needs is also a critical improvement. NAFDAC's ability to expedite approvals without compromising safety has led to quicker access to innovative therapies for diseases like hepatitis, HIV, and other communicable diseases that disproportionately affect Nigeria.

The regulatory enhancements introduced by NAFDAC have improved the quality and safety of medicines available in the Nigerian market. One of the most effective measures has been the adoption of stringent pharmacovigilance requirements and post-market surveillance. These measures ensure that medicines are continuously monitored for adverse effects once they enter the market. For example, under NAFDAC's post-marketing surveillance, vaccines imported during the COVID-19 pandemic underwent rigorous quality control tests, including sterility, bacterial endotoxin, and protein content evaluations. These tests revealed that 95.5% of COVID-19 vaccines imported into Nigeria met all safety standards, with only minimal batches requiring withdrawal. Furthermore, the implementation of the MAS has empowered consumers to verify the authenticity of medicines using scratch codes on packaging, reducing the circulation of counterfeit drugs. This technological innovation has been a vital tool in ensuring that consumers have access to safe, quality-assured medicines (Klantschnig and Huang, 2018). These stringent safety and quality standards ensure that medicines available in Nigeria, whether locally manufactured or imported, meet international benchmarks, thus safeguarding public health.

Nigeria's participation in regional regulatory initiatives, particularly the AMA, represents a stride in harmonizing regulatory procedures across the continent. Through initiatives like the AMRH, Nigeria aligns its regulatory practices with those of other African countries, streamlining the approval and registration process for medicines across borders. This harmonization reduces duplication in regulatory reviews and cuts down approval timelines, making it easier for essential medicines to flow across African countries (Ndomondo-Sigonda et al., 2017; Ncube, Dube and Ward, 2021). Regional collaboration through the AMA allows Nigeria to leverage shared resources and regulatory expertise from other African nations, fostering a more cohesive regulatory environment. The goal is to create a single regulatory framework across Africa, which will not only accelerate access to medicines but also improve quality control and safety

across the continent (Ncube, Dube and Ward, 2021). Participating in this harmonization effort benefits Nigeria from a wider pool of resources and expertise, which has the potential to enhance the efficiency and effectiveness of its regulatory processes.

4.2. Negative Impacts

While regulatory reforms have accelerated the approval of new medicines, they have also placed a financial burden on local pharmaceutical manufacturers. Compliance with GMP and other stringent regulatory requirements has increased the costs associated with local production. High registration fees, costly infrastructure upgrades required to meet international GMP standards, and complex bureaucratic procedures have all contributed to these financial pressures. Many small and medium-sized manufacturers find it difficult to comply with these requirements, leading to delays in the approval of locally manufactured drugs. The high cost of compliance has hindered the growth of Nigeria's local pharmaceutical industry, forcing some companies to limit their production or exit the market altogether. This not only restricts the availability of affordable locally-produced medicines but also increases the country's dependence on imported drugs (Obembe et al., 2022). Despite government efforts to provide tax incentives and other financial support, the high cost of regulatory compliance remains a barrier to the growth of the local pharmaceutical sector (Obembe et al., 2022).

Nigeria's reliance on imported medicines has increased as a result of stringent regulatory policies and patent protections enforced under international agreements like TRIPS. While TRIPS protects intellectual property rights, it has delayed the introduction of generic medicines, prolonging Nigeria's reliance on more expensive patented drugs. Many locally produced medicines are generics, and delays in the approval of these drugs under TRIPS compliance have exacerbated the issue of access. The introduction of affordable generics, which is crucial for addressing public health concerns like HIV, tuberculosis, and malaria, is often stalled by patent protections (Ncube, Dube and Ward, 2021). The dependence on imports places the Nigerian healthcare system in a vulnerable position, as fluctuations in global supply chains and economic shocks disrupt the availability of essential medicines. This was evident during the COVID-19 pandemic when global supply chain disruptions affected the timely availability of vaccines and other critical medical supplies. Nigeria's heavy reliance on imported medicines has also increased healthcare costs for consumers, further limiting access to affordable healthcare for large segments of the population.

Enhanced pharmacovigilance efforts, while essential for ensuring drug safety, have sometimes led to the withdrawal of medicines from the market, thereby affecting their availability. NAFDAC's stringent post-marketing surveillance has resulted in the withdrawal of several substandard or counterfeit drugs. While these actions are necessary for safeguarding public health, they also create temporary gaps in medicine availability, especially when no immediate alternatives are available. For example, during the quality control assessments of COVID-19 vaccines imported into Nigeria, certain batches were found to fail sterility tests and were subsequently rejected by NAFDAC. Although these measures ensured that only safe vaccines were distributed, they also delayed the availability of critical vaccines during a public health emergency. Similar situations arise when locally produced or imported medicines fail to meet pharmacovigilance standards, leading to temporary shortages or delays in access. Additionally, the focus on stringent regulatory oversight inadvertently discourages manufacturers from entering the Nigerian market, further limiting the availability of innovative or essential drugs. Smaller pharmaceutical companies, in particular, struggle to comply with rigorous post-marketing surveillance requirements, leading to product recalls or market withdrawals.

5. Challenges and Opportunities in Regulatory Policy

5.1. Capacity Building in Regulatory Agencies

Nigeria's regulatory agencies, particularly NAFDAC, face considerable challenges related to funding, infrastructure, and expertise. Insufficient government funding has limited the agency's ability to expand its operations, maintain advanced testing facilities, and recruit skilled personnel. The agency's laboratories, although improved, still lack the full capacity to handle the increasing demand for drug approvals and post-market surveillance. Furthermore, the reliance on old systems and manual processes exacerbates inefficiencies. A shortage of trained experts, especially in areas like pharmacovigilance and biopharmaceutical regulation, hampers the agency's ability to monitor and enforce regulations effectively (Obembe et al., 2022).

To address these gaps, capacity-building initiatives are necessary. Continuous training programs for regulatory staff, funded by both government and international organizations, will help improve the technical capacity of agencies. This would ensure that regulators are equipped to evaluate complex medicines, including biologics and innovative therapies, which are becoming increasingly prevalent in Nigeria. Investment in infrastructure, such as modern testing laboratories

and digital platforms, is essential for ensuring that NAFDAC can effectively monitor the quality and safety of medicines circulating in the Nigerian market.

5.2. Opportunities for Digital Transformation

Digital health technologies and e-regulation platforms present a significant opportunity to enhance the efficiency and transparency of regulatory processes in Nigeria. NAFDAC has already taken steps toward digital transformation with the implementation of the MAS, which allows consumers to verify the authenticity of medicines through a mobile platform (Klantschnig and Huang, 2018). This system has been successful in curbing the circulation of counterfeit medicines in the Nigerian market. Further adoption of e-regulation platforms will streamline the drug registration process, making it faster and more transparent. Digital platforms will enable pharmaceutical companies to submit applications, track approval statuses, and communicate with regulators in real time. These systems would not only reduce bureaucratic delays but also ensure that regulatory decisions are made based on comprehensive and up-to-date information. In addition, adopting blockchain technologies has the potential to enhance the traceability of medicines throughout the supply chain, reducing the risk of counterfeiting and ensuring that only quality-assured medicines reach consumers.

5.3. The Role of Public-Private Partnerships (PPPs)

Public-Private Partnerships (PPPs) offer a strategic opportunity to address some of the challenges facing Nigeria's regulatory system. Collaboration between regulatory agencies, local pharmaceutical manufacturers, and international organizations could help overcome funding and infrastructure constraints. For example, partnerships with international organizations such as the WHO or Global Fund can provide technical assistance, funding for capacity building, and access to international best practices (Ncube, Dube and Ward, 2021).

Local manufacturers could also benefit from partnerships with multinational pharmaceutical companies, which could offer technology transfers, training, and resources to improve their production processes. PPPs could be particularly effective in facilitating the development of locally produced generic medicines, which are essential for improving access to affordable healthcare (Obembe et al., 2022;). Leveraging the expertise and resources of private sector partners will enhance NAFDAC's ability to conduct rigorous post-market surveillance and ensure the ongoing safety and quality of medicines in Nigeria.

5.4. Future Prospects for Harmonization

There is need to create a harmonized system where medicines can be approved and distributed more efficiently across African countries. For Nigeria, this represents a critical step in addressing regulatory delays and reducing the duplication of efforts in drug registration (Ncube, Dube and Ward, 2021).

Harmonization offers significant long-term benefits, particularly in terms of improving access to essential medicines. By adhering to common regulatory standards, Nigeria can reduce approval timelines, increase the availability of life-saving medicines, and enhance cross-border trade within Africa. Moreover, a unified regulatory framework will allow Nigeria to pool resources with other countries, improving both the quality and efficiency of drug evaluation processes (Ndomondo-Sigonda et al., 2017). As Nigeria continues to align itself with these regional initiatives, it positions itself as a leader in the pharmaceutical sector in Africa, with the potential to enhance its regulatory capacity and boost access to medicines for millions of its citizens.

Therefore, addressing the challenges of capacity building, leveraging digital technologies, promoting PPPs, and participating in regional harmonization will enhance the efficiency and effectiveness of Nigeria's regulatory system. These steps are crucial for ensuring that regulatory policies not only protect public health but also improve access to affordable and safe medicines across the country.

6. Conclusion

This paper has explored the dual impacts of regulatory policy changes on access to medicines in Nigeria. On the positive side, reforms have led to faster access to innovative medicines through streamlined drug approval processes, improved quality control measures, and regional harmonization efforts under initiatives like the AMA. These regulatory advancements have enhanced public health safety and facilitated quicker responses to public health emergencies, such as the COVID-19 pandemic. However, these reforms have also introduced challenges, particularly for local pharmaceutical manufacturers who face high compliance costs and registration fees. Additionally, the country's reliance on imports and stringent intellectual property protections under TRIPS have delayed access to affordable generics.

To balance stringent regulatory requirements with improved access to affordable medicines, Nigeria should focus on several key areas. First, promoting local pharmaceutical manufacturing through targeted incentives, such as further tax exemptions and subsidies, would help reduce dependence on imports. Second, refining intellectual property policies under TRIPS to allow for more flexible licensing of generic medicines in public health emergencies would enhance access to essential medicines(s12913-022-07579-1)(smr-05-031). Strengthening the capacity of regulatory agencies like NAFDAC, through funding and infrastructure investments, is essential for maintaining high regulatory standards while improving efficiency in approval processes.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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