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Regulatory Lifecycle Management of Solid Oral Dosage Forms in Nigeria and Kenya

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Abstract

Solid oral dosage forms (SODFs), including tablets and capsules, are the most commonly used pharmaceutical products worldwide, requiring effective regulatory oversight throughout their lifecycle to ensure quality, safety, and efficacy. This review compares the regulatory lifecycle management frameworks for SODFs in Nigeria and Kenya, focusing on pre-market authorization, post-approval variation management, pharmacovigilance, and marketing authorization renewal. Drawing on regulatory guidelines, legislative frameworks, and relevant literature, the review finds that both Nigeria's NAFDAC and Kenya's PPB have adopted internationally aligned regulatory approaches, including CTD-based submissions, GMP inspections, and post-marketing surveillance systems. Despite progress in regulatory maturity and regional harmonization efforts, challenges such as limited resources, regulatory backlogs, and underreporting of adverse drug reactions remain. The experiences of both countries provide valuable insights for strengthening regulatory systems and supporting effective medicine lifecycle management across Africa.

Conclusion: Nigeria and Kenya have made significant progress in aligning SODF regulatory practices with international standards across the product life cycle. However, challenges in implementation particularly in Nigeria persist while on going regional harmonization efforts present promising opportunity to strengthen regulatory efficiency and consistency in sub–Saharan Africa.

Keywords: Solid oral dosage forms (SODFs); Regulatory lifecycle management; National Agency for Food and Drug Administration and Control (NAFDAC); Pharmacy and Poisons Board (PPB); Post-approval variations; Pharmacovigilance; Good Manufacturing Practice (GMP); African Medicines Regulatory Harmonization (AMRH); Regulatory convergence; Sub-Saharan Africa

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1. Introduction

SODFs are the dominant format for pharmaceuticals in the world, whether tablets or capsules. It has wide applications for managing infectious diseases and chronic non-communicable diseases, and as such, its use is consequently quite extensive. Regulatory oversight of these formulations is thus essential today. Due to the continuous development of the product and market development before marketing approval and after product release, quality cannot be seen as individual aspects that have been reached or limited. In low- and middle-income countries, the historical weakness of regulatory systems in the circulation of fake drugs and counterfeit or substandard medical products has led to a burgeoning global market that has embraced all varieties of medicine as main products. Strengthening national regulatory authorities (NRAs) is thus now the world's priority, wisdom in Africa for a global village. The World Health Organization (WHO)-sponsored Global Benchmarking Tool has been critical in evaluating and improving regulatory maturity across African countries. (1) This is a task hugely complicated by the diverse nature of health product manufacturing. Regulatory maturity levels correlate closely with a country's capacity to carry out effective lifecycle oversight.

Two of the most highly developed pharmaceutical regulatory systems in Sub-Saharan Africa lie in Nigeria and Kenya, respectively. Nigeria's NAFDAC (National Agency for Food and Drug Administration) regulates pharmaceutical products through structured dossier evaluation, inspections according to GMP guidelines, and, more recently, in line with the demands of quality control laws, pharmacovigilance. Kenya's PPB (Pharmacy and Poisons Board) also regulates product registration and post-approval changes and supervises the safety of medicines.

Life-cycle management (LCM) of this sort in both jurisdictions still faces a number of structural problems. These include resource shortages, backlogs with post-market application variation, and reliance mechanisms duly controlled and approved. (2) What's more, with the launch of the African Medicines Regulatory Harmonization (AMRH) plan, chances for overlap in country-by-country regulatory systems will be reduced. (3) How LCM functions in Nigeria and Kenya can shed light on how it will function in the larger regional regulatory system.

This review critically examines the regulatory lifecycle management systems for SODFs in Nigeria and Kenya. Particular emphasis is placed on pre-market appraisal, post-approval variations control, pharmacovigilance, and renewed reliability status within the context of harmonization.

2. Regulatory/Policy Analysis

Its findings are drawn from comparative regulatory analysis of a qualitative kind. We gained regulatory data such as product registration standards, post-approval adjustment provisions, requirements for product safety monitoring, and rules on renewing market authorizations, from official guidance documents and legislative frameworks issued by NAFDAC in Nigeria and the Pharmacy and Poisons Board (PPB) in Kenya. (4, 5)

To put practices occurring within individual nations into a global perspective of regulation, this section looks at peer-reviewed articles from the relevant literature on regulatory sciences. This was done by carrying out a systematic examination of such texts in different languages using academic databases. Its focus is on studies that demonstrate how regulatory capacity can be built up; that use a single direction of standardization toward multiple points of origin; and that examine regulatory convergence. (1,3)

This survey concentrated on solid oral dosage forms and did not involve any biologics or sterile injectables. Apart from pre-market authorization procedure processes, all phases of the life cycle also incorporate consideration of post-approval variations in both type and dosage; existing pharmacovigilance and risk management systems; Good Manufacturing Practice (GMP) supervision and compliance mechanisms; and product renewal programs. Data extracted was subsequently synthesized orally, comparing the structural resemblances and operational aspects. maturity indicators between Nigeria and divergences in Kenya.

3. Registration and Regulatory Requirement for Nigeria and Kenya

3.1 Legal and Institutional Frameworks

Kenya's PPB also requires CTD-form submissions using the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022, which derive five years of marketing authorization certificate renewal based on new data on safety, quality, and manufacturing. (6) The two authorities demand certification of Good Manufacturing Practice (GMP) and may inspect their facilities.

The regulatory lifecycle framework in Nigeria is centralized and run by NAFDAC, which has the power over product evaluation, laboratory analysis, inspection, and enforcement. The agency is obliged to receive dossiers in the Common Technical Document (CTD) format that conforms to the international standards that can be renewed after proving to be still compliant. (4)

3.2 Pre-Market Authorization of Solid Oral Dosage Forms

In Nigeria, the registration of SODFs requires administrative screening, assessment of dossiers (Modules 1-5), GMP inspection, laboratory analysis of samples, and final approval by regulatory committees. NAFDAC also has reliance schemes that enable fast-track evaluation for products already approved by strict regulatory authorities, if complete documentation is provided. (4)

In Kenya, the registration process also requires assessment of quality (Module 3), safety, and efficacy information, including bioequivalence studies for generic SODFs. (6) The PPB has increasingly incorporated risk assessment evaluation criteria aligned with WHO guidelines. The regulatory environment in Kenya has been improved by benchmarking exercises during WHO evaluations, reflecting organized assessment and inspection processes. (1)

3.3 Post-Approval Variation Management

Lifecycle management extends beyond marketing authorization to include changes post-approval. In Nigeria, variations are classified based on the potential differences they may entail in terms of quality, safety, or efficacy. (4) Major variations require changes that are evaluated and documented, such as stability studies or new specifications. Minor variations and notifications are submitted through abbreviated procedures.

Kenya uses a similar classification scheme that is in line with WHO variation guidelines. (6) Major variations involve changes to active pharmaceutical ingredient specifications or manufacturing facilities, while minor variations involve less important changes. The PPB demands adequate justification and payment, ensuring that lifecycle changes are traceable.

Limitations in human resources and, increasingly, in ever larger octant bases due to increasing file sizes have contributed to slow progress, a fact that is well recognized in African regulatory environments. (2) This directly affects lifecycle agility, especially in companies that handle large portfolios from outside.

3.4 Pharmacovigilance and Post-Marketing Surveillance

Pharmacovigilance is one of the important pillars of regulatory lifecycle management. Nigeria has a National Pharmacovigilance Centre established under NAFDAC. Marketing authorization holders who hold licenses for sales also have to send adverse drug reaction (ADR) reports and Periodic Safety Update Reports (PSURs). (5) A Risk Management Plan (RMP) may be requested for an injection in certain cases, e.g., new chemical entities. Kenya's pharmacovigilance system, which is administered

by the PPB, involves spontaneous reporting and signal detection, characterized by safety communications mechanisms. (6) County-level health systems provide support for decentralized ADR reporting. Both countries are members of the WHO's Programme for International Drug Monitoring, further affording opportunities to share global 'signals'. Despite established frameworks, literature suggests that underreporting of ADRs continues to be a systemic problem across the entirety of Sub-Saharan Africa, which suggests that training and digital tools are needed. (2)

The Pharmaceutical Product Life Cycle Showing Intersection of the Regulator at Different Points: IND/CTA, NDS/NDA, and Patents

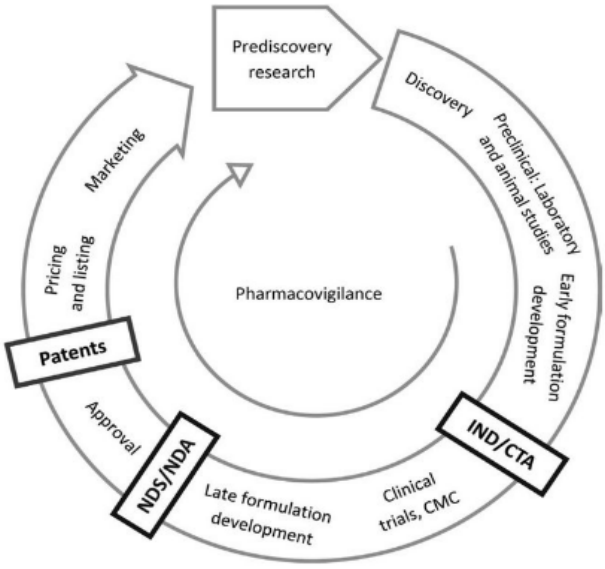

Figure 1. Pharmacovigilance Process Circle

(Source: https://www.researchgate.net/figure/The-Pharmaceutical-Product-Life-Cycle-Showing-Intersection-of-the-Regulator-at-Different_fig1_357607441)

3.5 Renewal and Lifecycle Continuity

Marketing authorization renewal marks a milestone for regulatory reassessment of product compliance. Following expiry in Nigeria, renewal applications are required - with updated documentation and evidence of GMP compliance necessary before renewal. (4)

In Kenya, for renewal, submissions must be made at least three months before the expiration date. This is because if not done, the authority will lapse. (6) Renewal of authorization also provides watchdogs with an opportunity to update safety data, changes in manufacturing, and labeling changes into records; this improves the integrity of the lifecycle.

Table 1. Comparative Regulatory Lifecycle Management of SODFs in Nigeria and Kenya

Lifecycle Stage	Nigeria (NAFDAC)	Kenya (PPB)
Legal Basis	NAFDAC Act Cap N1 LFN 2004	Pharmacy & Poisons Act Cap 244
Dossier Format	CTD	CTD
Registration Validity	5 years	5 years
Reliance Pathway	Limited structured reliance	Increasing alignment with WHO
GMP Inspection	Mandatory (local/foreign)	Mandatory (risk-based)
Variation Classification	Major, Minor, Notification	Major, Minor, Notification
Pharmacovigilance	National PV Centre	Central + County reporting
Renewal Timeline	Before expiry	3 months before expiry

4. Discussion

The regulatory life cycle management of solid oral dosage forms in Nigeria and Kenya shows a progressive trend towards compliance with global regulatory science. The use of CTD format, variation classification systems, GMP compliance, and pharmacovigilance reporting practices indicate maturity of institutions. WHO benchmarking evaluations show a positive shift in the regulatory capacity of African countries, including Kenya, where the advancement of maturity level indicates enhanced regulatory systems. (1,7)

The reliance mechanisms in Nigeria are a practical approach to resource limitations, enabling efficient use of review capacity for high-risk submissions. However, country-specific procedural requirements sometimes increase the evaluation period compared with reliance-optimized approaches seen in more harmonized environments. (3)

With authentication, renewal, and pharmacovigilance reporting, Kenya has a clear roadmap towards life cycle management. Both countries also face challenges in post-approval variation processing, which can slow down any changes the enterprise wants to implement in manufacturing or global harmonized labeling changes. (2)

Under the African Medicines Regulatory Harmonization (AMRH) program, Africa-based regulatory new drug applications can now be summarized instead of submitted for central regulatory scrutiny and approved by individual NRAs. (3**Error! Reference source not found.**) Therefore, such collaboration models should greatly improve the lifecycle efficiency of SODFs, in particular for essential generic drugs.

In the future, these efforts will require further investment in electronic submission portals or other means to digitize regulatory paper flow; moreover, digital transformation effects must also extend beyond manufacturing facilities. At the same time, there is a clear necessity for quick fixes of all kinds, and long-term formal capabilities are needed by youth until final realization. This will entail greater conformity with WHO criteria than the present practice covers, as well as increased reliance on mature regulation units to maintain both efficiency and security.

Although Nigeria and Kenya have undergone considerable changes in their regulatory environments, the best possible life-cycle management would depend on harmonization, digitization, and capacity building.

5. Conclusion

Regulatory lifecycle management of solid oral dosage forms in Nigeria and Kenya reflects significant alignment with global standards through structured frameworks for registration, variation control, and pharmacovigilance. While both systems demonstrate regulatory maturity, challenges in post-approval efficiency and resource capacity persist. Strengthening harmonization, reliance pathways, and digital regulatory systems will be essential to enhance lifecycle efficiency and ensure sustained access to quality medicines.

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Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

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Reference

1. Pharmacy and Poisons Board (PPB). Pharmacy and poisons (registration of health products and technologies) rules. Nairobi: PPB; 2022 [Internet]. [cited 2026 Mar 24]. Available from: https://web.pharmacyboardkenya.org/download/pharmacy-and-poisons-registration-of-health-products-and-technologies-rules-2022
2. Ndomondo-Sigonda M, Miot J, Naidoo S, Dodoo A, Kaale E. Medicines regulation in Africa: current state and opportunities. Pharm Med. [Internet]. 2017 [cited 2026 Mar 24];31:383–397. Available from: https://doi.org/10.1007/s40290-017-0210-x
3. Ncube BM, Dube A, Ward K. Establishment of the African Medicines Agency: progress, challenges and regulatory readiness. J Pharm Policy Pract. [Internet]. 2021 [cited 2026 Mar 24];14:25. Available from: https://doi.org/10.1186/s40545-020-00281-9
4. National Agency for Food and Drug Administration and Control (NAFDAC). Guidelines for registration of pharmaceutical products in Nigeria. Abuja: NAFDAC; 2024 [Internet]. [cited 2026 Mar 24]. https://nafdac.gov.ng/regulatory-resources/guidelines/
5. World Health Organization. WHO global benchmarking tool (GBT) for evaluation of national regulatory systems. Geneva: WHO; 2023 [Internet]. [cited 2026 Mar 24]. Available from: https://www.who.int/publications/i/item/9789240087637
6. National Agency for Food and Drug Administration and Control (NAFDAC). Pharmacovigilance and post-market surveillance regulations. Abuja: NAFDAC; 2023 [Internet]. [cited 2026 Mar 24]. Available from: https://nafdac.gov.ng/our-services/pharmacovigilance-post-market-surveillance/
7. World Health Organization. Good regulatory practices: guidelines for national regulatory authorities for medical products. Geneva: WHO; 2021 [Internet]. [cited 2026 Mar 24]. Available from: https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/norms-and-standards-for-pharmaceuticals/guidelines/regulatory-standard