REVIEW ARTICLE

# Regulatory Barriers and Harmonization Prospects for Generic Drug Approval in South Africa, Nigeria, Tanzania, and Zimbabwe

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## Abstract

The African pharmaceutical market is undergoing rapid transformation, fueled by a rising disease burden, demographic growth, and heightened healthcare needs. Generic medicines – affordable, high-quality alternatives to branded drugs – are central to expanding access to essential treatments. Yet, regulatory requirements for generic drug registration remain highly fragmented across African nations, posing significant hurdles for pharmaceutical companies seeking multi-country entry. This comparative study critically examines the generic drug registration frameworks in South Africa, Nigeria, Tanzania, and Zimbabwe, analyzing dossier formats, approval timelines, fee structures, stability data expectations, and bioequivalence requirements. Key disparities are highlighted, revealing operational inefficiencies that can delay patient access and inflate costs. The findings underscore the urgent need for regulatory harmonization across Africa, offering strategic insights for industry stakeholders and policymakers. In light of ongoing initiatives such as the African Medicines Regulatory Harmonization and the emerging African Medicines Agency, this paper proposes pathways toward streamlined approval processes to accelerate access to affordable generics. A unified regulatory ecosystem could serve as a catalyst for improved public health outcomes and pharmaceutical innovation across the continent.

**Key words:** African medicines agency harmonization, African regulatory agencies, drug registration challenges in Africa, generic drug approval in Africa, pharmaceutical regulation in Africa, regulatory barriers to generic drugs

## INTRODUCTION

Healthcare systems rely heavily on the availability of medicines that are safe, effective, and reasonably priced. Medical products such as pharmaceuticals, vaccines, diagnostic tools, and devices are essential for preventing, detecting, and treating diseases. Ensuring their quality, efficacy, and safety demands robust regulatory oversight, supported by sound scientific principles and enforced through strong legal frameworks. Across Africa, regulatory systems for medicines exhibit profound diversity.[1-3] According to the World Health Organization (WHO), 54 National Medicines Regulatory Authorities (NMRAs) operate across the continent, each varying widely in organizational structure, mandate, and maturity. Some function as semi-autonomous bodies; others are directly administered by Ministries of Health. While certain NMRAs oversee only medicinal products, others extend their reach to foods, cosmetics, and medical devices. Despite these variations, ultimate accountability typically rests with National Ministries of Health.[4] Africa, home to approximately 1.5 billion people across 55 countries, is geographically segmented into five sub-regions: North, West, Middle, East, and Southern Africa. These sub-regions differ not only in population size and

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economic development but also in regulatory sophistication, creating a fragmented environment for pharmaceutical registration and market entry.[5,6]

Generic medicines play an increasingly critical role in African healthcare systems. Offering equivalent quality, safety, and therapeutic efficacy as innovator drugs, generics are vital for controlling public healthcare costs and improving access to essential treatments.[7] Given that generic drug prices are typically 10–80% lower than those of branded products, ensuring their rapid market entry is both an economic imperative and a public health priority. Every regulatory delay represents a missed opportunity to lower healthcare expenditures and enhance patient outcomes. However, significant challenges persist. Regulatory requirements for generic drug registration differ considerably among African nations in dossier format, evaluation timelines, stability data expectations, and bioequivalence (BE) study demands. This regulatory heterogeneity forces pharmaceutical companies to duplicate efforts, leading to higher costs, extended approval times, and slower access to critical medicines.[8,9]

This study aims to critically compare the registration requirements for generic medicines in four key African countries, South Africa, Nigeria, Tanzania, and Zimbabwe, focusing on dossier formats, approval timelines, fee structures, and BE considerations. By illuminating the regulator, disparities, and operational hurdles, the paper highlights the pressing need for harmonization initiatives that can streamline registration pathways, promote market access, and ultimately enhance public health across Africa.[10] In every nation, medical supplies such as medications, vaccinations, blood products, diagnostic tools, and medical gadgets are vital to the provision of healthcare. In each given country, ensuring the safety, effectiveness, quality, and affordability of medical products is essential to advancing patient care and public health. Strong regulatory frameworks are needed to ensure the effectiveness, safety, and quality of medical products as well as to promote trade and socioeconomic development.[1,11,12]

Many Africans continue to struggle with limited access to drugs, which has a detrimental impact on many countries' overall health statistics. The availability and affordability of medications, along with other essential medical supplies and equipment, are critical to maintaining and ensuring high standards of patient care in healthcare facilities. One of the biggest obstacles to society acquiring better healthcare services is the lack of access to pharmaceuticals.[13,14]

### Key challenges in African countries

- High burden of infectious and non-infectious diseases: Overwhelms weak healthcare systems and increases medicine demand
- Limited local pharmaceutical manufacturing capacity: Africa produces only 3% of global medicines despite high disease burden
- Heavy reliance on imported medicines and raw materials: 70–90% of medicines are imported, increasing vulnerability to shortages
- Poor and inefficient supply chain systems: Leads to frequent stock-outs, high costs, and circulation of counterfeit drugs
- Government underinvestment in healthcare and pharmaceuticals: Low healthcare budgets, poor policy implementation, and lack of incentives for local manufacturing
- High out-of-pocket healthcare spending: Most people pay for medicines themselves due to limited insurance coverage
- Unfavorable manufacturing conditions: High costs, unreliable electricity, and lack of infrastructure hinder local drug production
- Widespread circulation of fake and counterfeit medicines: Africa accounts for 42% of global cases, endangering public health
- Shortage and migration of healthcare workforce: Limits medicine distribution and effective treatment access
- Lack of effective medicine pricing and regulation: Medicines are often unaffordable and overpriced compared to global standards.[15-17]

## COUNTRY-SPECIFIC REQUIREMENTS

### South Africa

Regulatory law: Medicines and Related Substances Control Act No. 101 of 1965

Dossier format: Common technical document (eCTD)/CTD

Language: English

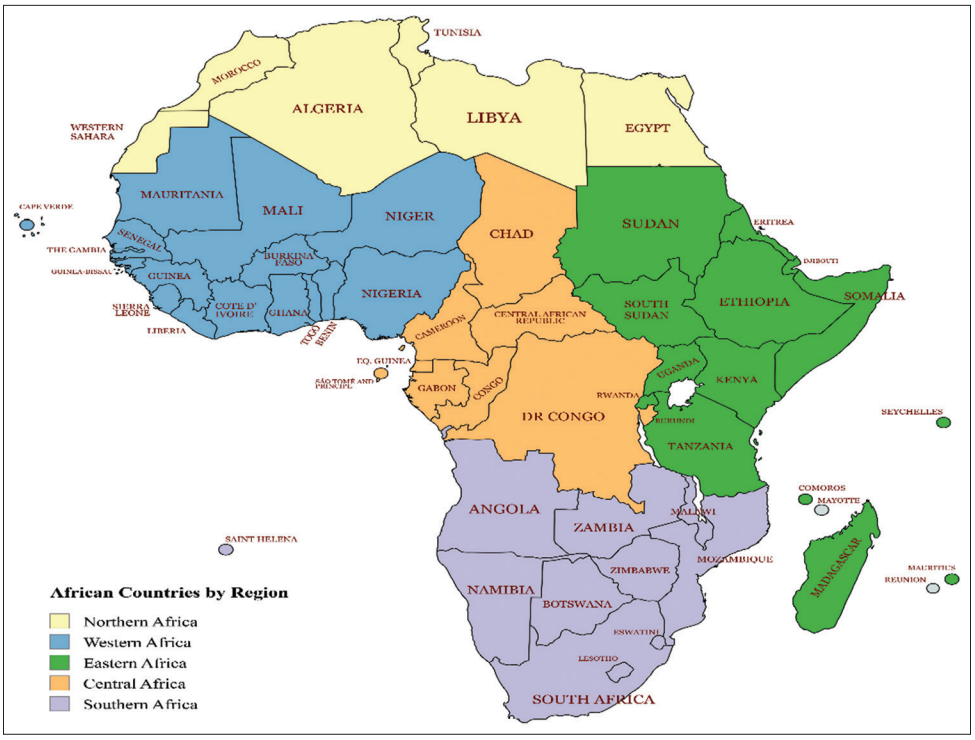
Approval Timeline: 8–24 months

Registration fee: USD 3,370

Stability zone: Zone II (subtropical/Mediterranean).

Stability data required:
- Long-term: 25 ± 2°C/60 ± 5% RH (12 months)
- Accelerated: 40 ± 2°C/75 ± 5% RH (6 months)

The South African Health Products Regulatory Authority (SAHPRA) oversees the safety, effectiveness, and quality of pharmaceuticals and health products for humans and animals. It licenses pharmaceutical establishments, oversees clinical trials, and monitors adverse events and radiation-emitting devices. SAHPRA operates under laws including




AQ4 **Figure 1:** African countries by region

the Medicines Act (1965), National Health Act (2003), and Hazardous Substances Act (1973). The Quality and BE Guideline describes how the SAHPRA assesses the safety, effectiveness, and quality of pharmaceutical products. For generic medicines, applicants are required to provide a BE Trial Information Form to support and simplify the review process.[18-20,51]

### *Regulatory approval procedure*

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## Nigeria

Regulatory law: NAFDAC Act CAP N1 (LFN) 2004

Dossier format: CTD

Language: English

Approval timeline: 6–12 months

Registration fee: USD 1,100

Stability zone: Zone IVB (Hot/Higher Humidity Zone).

Stability data required:

- Long-term: 30 ± 2°C/65 ± 5% or 75 ± 5% RH (6 months)
- Accelerated: 40 ± 2°C/75 ± 5% RH (6 months).

The National Agency for Food and Drug Administration and Control (NAFDAC) functions as the central body responsible for regulating pharmaceuticals and biological products in Nigeria. NAFDAC was created by Decree No. 15 of 1993, with further revisions introduced through Decree No. 19 of 1999, and now functions under the NAFDAC Act, Cap N1, Laws of the Federation of Nigeria (2004). The production, importation, exportation, distribution, advertising, sale, and usage of regulated goods, including food, medications, cosmetics, medical equipment, chemicals, and detergents, are all governed by NAFDAC. The "Quality guidelines for the registration of pharmaceutical products" streamline international regulatory procedures by providing rules for regulatory submissions using the CTD format, which complies with International Council for Harmonization standards.[23,24]

### *Regulatory approval procedure*

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## Tanzania

Regulatory law: Tanzania food, drugs and cosmetics act (CAP. 219)

Dossier format: CTD

Language: English

Approval timeline: 6–18 months

Registration fee: USD 2,000

Stability zone: Zone II (Subtropical/Mediterranean zone).

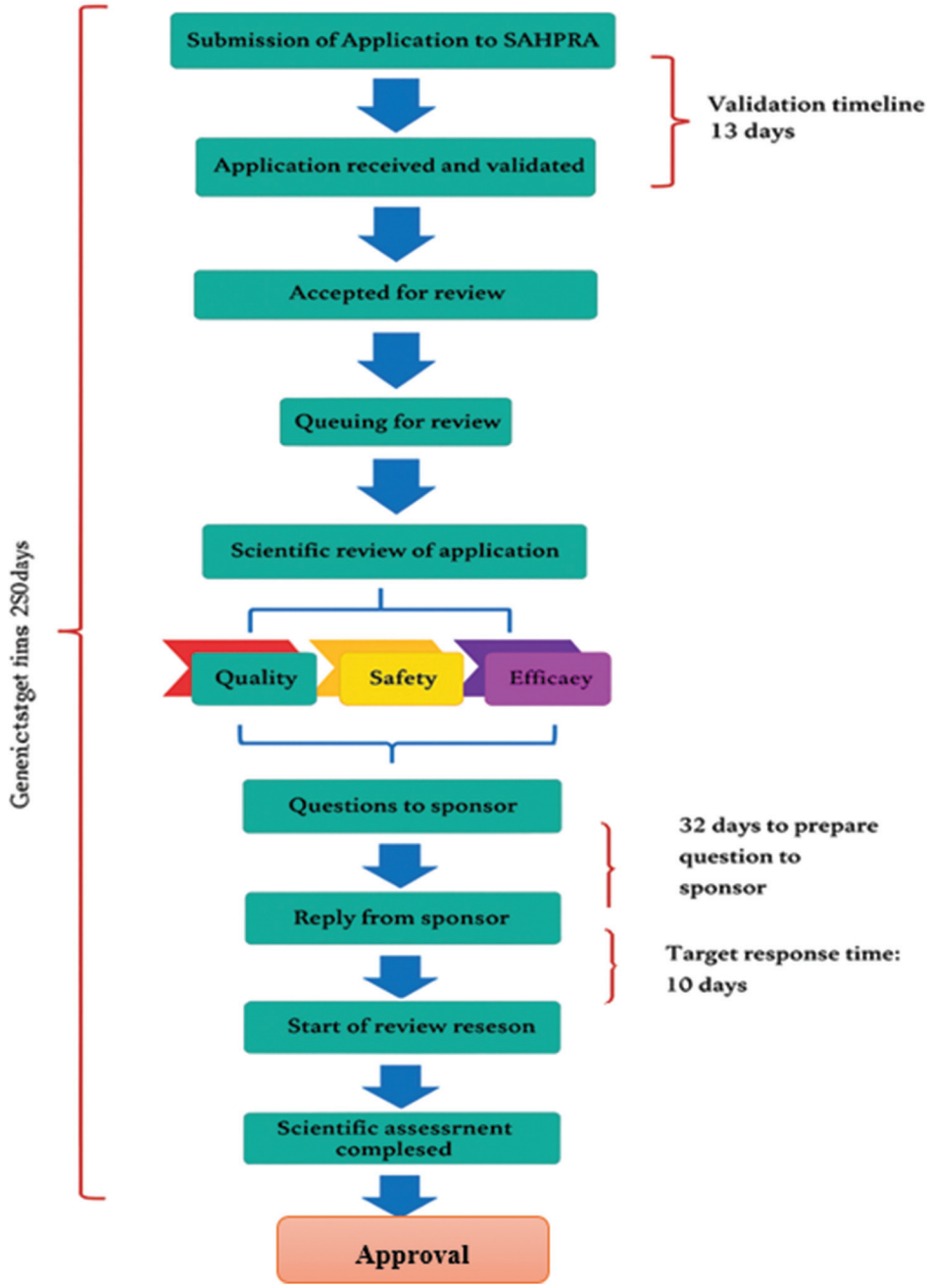


**Figure 2:** Regulatory approval procedure in South Africa[21,22]

Stability data required:

- Long-term: 30 ± 2°C/65 ± 5% or 75 ± 5% RH (12 months)
- Accelerated: 40 ± 2°C/75 ± 5% RH (6 months).

The Tanzania Medicines and Medical Devices Authority (TMDA), established in 2003, oversees the quality, safety, and effectiveness of medicines, medical devices, and associated goods in Tanzania. The Food, Drugs, and Cosmetics Act of 2003 requires pharmaceutical importers to have their products certified by TMDA. The Tanzania Bureau of Standards took over the regulation of food and cosmetics in 2019. For importers and exporters, the "Guidelines for Importation and Exportation of Pharmaceutical Products and Raw Materials, 2011" offer detailed information. Drugs that are generic must be bioequivalent to their reference counterparts. The CTD format is used for regulatory submissions, with five modules covering administrative requirements, quality, pre-clinical, and clinical data, providing a structured approach for product registration.[26,27]

### *Regulatory approval procedure*

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### *Zimbabwe*

Regulatory law: Medicines and Allied Substances Control Act [15:03] of 1969

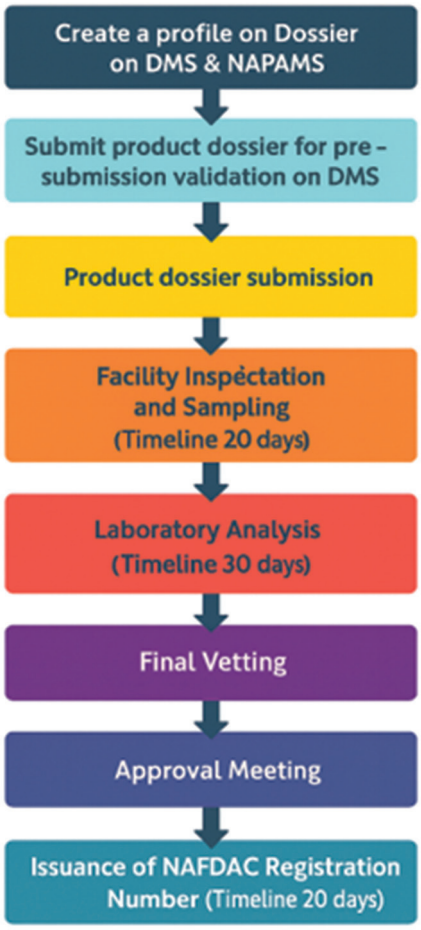


**Figure 3:** Regulatory approval procedure in Nigeria[25]

Dossier format: CTD

Language: English

Approval timeline: 12–24 months

Registration fee: USD 2,500

Stability zone: Zone II and IVB (subtropical/Mediterranean zone and hot/higher humidity zone).

Stability data required:

- Long-term: 30 ± 2°C/65 ± 5% or 75 ± 5% RH (12 months)
- Accelerated: 40 ± 2°C/75 ± 5% RH (6 months).

The Medicines and Allied Substances Control Act (Chapter 15:03) of 1969 established the Medicines Control Authority of Zimbabwe (MCAZ), which is responsible for ensuring the efficacy, safety, and quality of medications and medical equipment. It manages clinical trial approvals, laboratory testing, marketing authorizations, post-marketing surveillance, and manufacturer and distributor licensing. MCAZ evaluates pharmaceutical applications through its Evaluation and Registration Division. Recognized by the WHO and ZAZIBONA, it plays a key role in Zimbabwe's 2021–2025 National Development Strategy. Applicants must submit Form EVF03 in hard copy and MS Word format on CD in accordance with the MCAZ Guideline on Submission of Documentation for Registration of a Multi-Source (Generic) finished pharmaceutical products (FPPs), which is based on the WHO Technical Report Series No. 937, 2006, Annex 7, to register multi-source (generic) FPPs.[30-32]

### *Regulatory approval procedure*

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## COMPARATIVE ANALYSIS

A detailed comparative analysis was conducted to evaluate the regulatory requirements for generic drug registration across South Africa, Nigeria, Tanzania, and Zimbabwe. The comparison focused on key operational parameters, including regulatory authorities, legal frameworks, dossier formats, approval timelines, fee structures, stability data expectations, and BE requirements [Table 1].

### Regulatory frameworks and dossier formats

All four countries mandate the use of the CTD format for regulatory submissions, with South Africa also accepting the electronic CTD (eCTD). English is the standard submission language across all jurisdictions, facilitating regional accessibility.[34]

### *Approval timelines*

Approval timelines varied significantly. Nigeria and Tanzania exhibited relatively shorter review periods (6–12 months and 6–18 months, respectively), while South Africa and Zimbabwe demonstrated longer timelines (8–24 months and 12–24 months, respectively), posing potential delays for market access.

### *Registration fees*

Registration fees ranged widely. Nigeria offered the most economical pathway (USD 1,100), whereas South Africa imposed the highest fee (USD 3,370). Tanzania and Zimbabwe fell in the moderate range, with fees of USD 2,000 and USD 2,500, respectively.

### *Stability requirements*

Stability zone classifications and requirements differed between regions. South Africa and Tanzania primarily operate under Zone II conditions (subtropical/Mediterranean), while Nigeria and Zimbabwe apply Zone IVB conditions

**Table 1:** Comparative analysis of generic drug registration requirement

| Parameter | South Africa | Nigeria | Tanzania | Zimbabwe |
|---|---|---|---|---|
| Regulatory agency | SAHPRA | NAFDAC | TMDA | MCAZ |
| Website | https://www.sahpra.org.za/ | https://nafdac.gov.ng/ | https://www.tmda.go.tz/ | https://www.mcaz.co.zw/ |
| Drug law | Act 101 of 1965 | NAFDAC act CAP N1 (LFN) 2004 | €TFDC Act (CAP. 219) | ¥MASCA (15:03) of 1969 |
| Dossier format | eCTD/CTD | CTD | CTD | CTD |
| Dossier language | English | English | English | English |
| Registration validity | 5 years | 5 years | 5 years | 5 years |
| Approval timeline | 8–24 months | 6–12 months | 6–18 months | 12–24 months |
| Manufacturing license | Required | Required | Required | Required |
| COPP/free sale certificate | Required | Required | Required | Required |
| Registration fee | $3,370 | $1,100 | $2,000 | $2,500 |
| GMP inspection validity | 3 years | 3 years | 3 years | 3 years |
| Stability zone | Zone II | Zone IVB | Zone II | Zone II and IVB |
| Stability data | *LT: 12m/°ACC: 6 m | *LT: 6m/°ACC: 6m | *LT: 12m/°ACC: 6 m | *LT: 12m/°ACC: 6 m |
| LT conditions | 25°C±2/60%±5 RH | 30°C±2/65–75% RH | 30°C±2/65–75% RH | 30°C±2/65–75% RH |
| ACC conditions | 40°C±2/75%±5 RH | 40°C±2/75% RH | 40°C±2/75% RH | 40°C±2/75% RH |
| BE study requirement | US/EU or SA innovator | US/EU innovator | US/EU innovator | US/EU innovator |
| BE acceptance criteria | 90% αCI of ®AUC and $Cmax: 80–125% | 90% αCI of ®AUC and $Cmax: 80–125% | 90% αCI of ®AUC and $Cmax: 80–125% | 90% αCI of ®AUC and $Cmax: 80–125% |

*LT: Long term, °ACC: Accelerated, αCI: Confidence interval, ®AUC: Area under curve, $$C_{max}$$: Maximum concentration, €TFDC: Tanzania food, drugs, and cosmetics, ¥MASCA: Medicines and allied substances control act

(hot/higher humidity zones). Notably, Zimbabwe requires compliance with both Zone II and IVB conditions.[35,47]

### *BE requirements*

All four regulatory bodies mandate demonstration of BE to reference products sourced from recognized markets (US, European Union [EU], or locally registered innovators). Acceptance criteria uniformly followed the 90% confidence interval for area under curve and maximum concentration within 80–125%, consistent with international standards.[36,45]

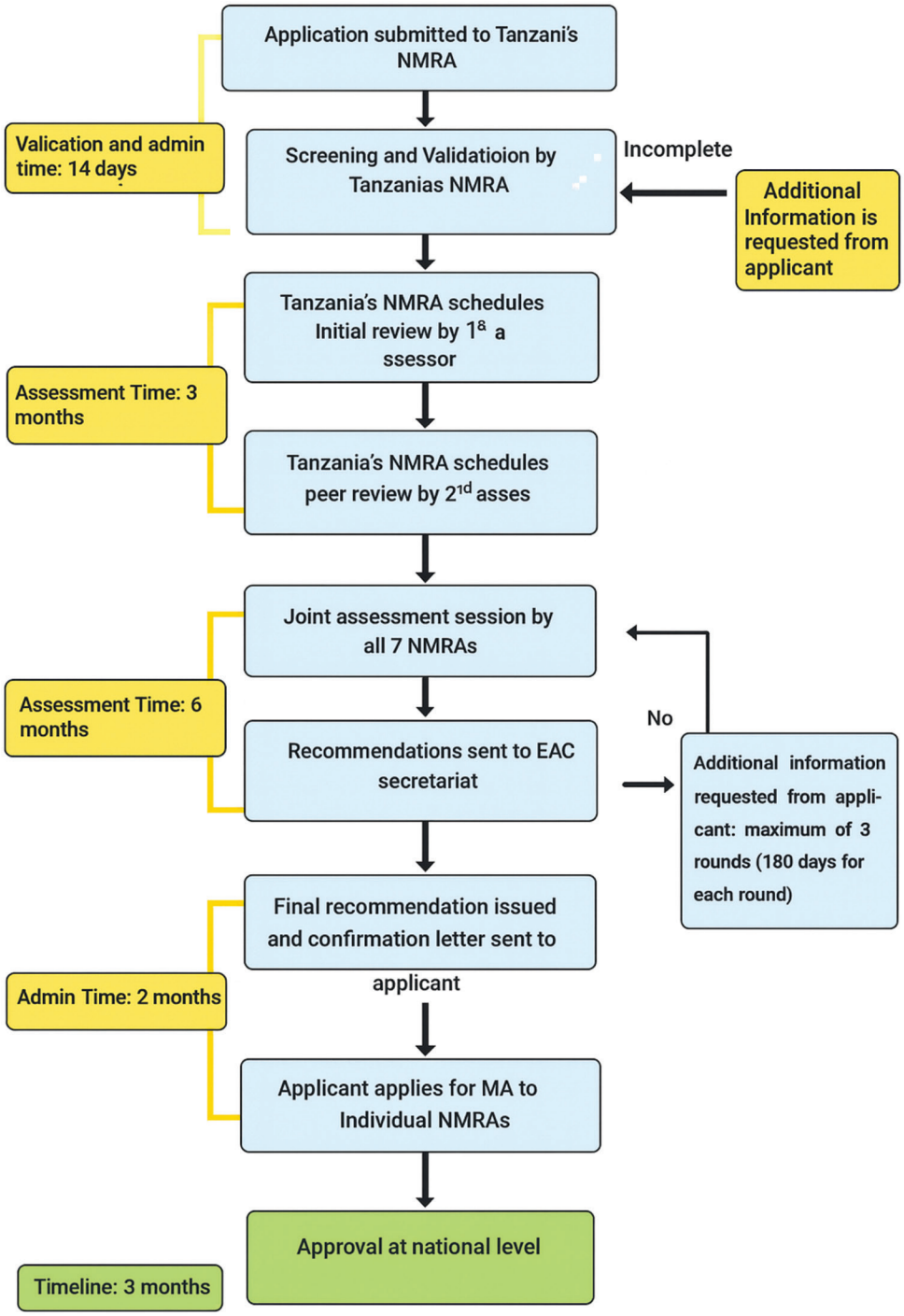
Overall, while a degree of alignment exists in dossier structures and BE criteria, significant disparities in approval timelines, registration fees, and stability data requirements present operational challenges for pharmaceutical companies seeking multi-country access across Africa.

## DISCUSSION

South Africa, Nigeria, Tanzania, and Zimbabwe each have distinct pharmaceutical regulatory frameworks, yet they face challenges in aligning with global standards. In contrast, the EU has established stringent regulatory frameworks that set a high benchmark for drug development, processing, and approval. The European Medicines Agency (EMA), a decentralized body of the EU, is responsible for assessing applications for European marketing authorization through the centralized procedure, where companies submit a single marketing authorization application. The EMA continuously monitors the safety of medicines through a robust pharmacovigilance program to ensure compliance and public safety. The EU pharmaceutical legislation prioritizes public health while facilitating the free movement of medicinal products across member states. Compared to regulatory frameworks in South Africa, Nigeria, Tanzania, and Zimbabwe, the EU system is more centralized, with harmonized approval processes that streamline market access.[37]

### Pharmaceutical market growth in Africa

Africa's pharmaceutical market is undergoing rapid expansion, driven by population growth, urbanization, economic development, and the rising burden of non-communicable and infectious diseases. Although the continent's healthcare infrastructure remains underdeveloped




AQ4 **Figure 4:** Regulatory approval procedure in Tanzania[28,29,48]

compared to other global regions, growing investment, political commitment, and increased public health awareness are creating substantial opportunities for the pharmaceutical sector growth.

The COVID-19 pandemic served as a critical inflection point, exposing vulnerabilities in Africa's health systems and underscoring the urgent need for self-sufficiency in healthcare products. The pandemic accelerated initiatives that had previously been slow to gain momentum, notably the push for regulatory harmonization and local pharmaceutical manufacturing. With oncology drugs and chronic disease treatments leading market expansion, the African pharmaceutical industry is poised for sustained growth, provided regulatory systems can adapt to support innovation and ensure equitable access.[38,39]

## Regulatory harmonization in Africa

Africa's nations are represented by the 55 member states that make up the African Union (AU), a continental

organization. The Organization of African Unity, which existed from 1963 until 1999, was superseded by the AU in 2002. Key components of the AU's structure include the Regional Economic Communities and the African Peer Review Mechanism. The AU established the African Medicines Agency (AMA) to increase access to high-quality, safe, and effective medications, medical supplies, and health technologies throughout the continent by strengthening the regulatory capacities of African countries.[40]

The African Medicines Regulatory Harmonization (AMRH) Initiative was established in 2009 with the intention of standardizing laws across the continent and enhancing national regulatory systems. The goal of this initiative is to improve access to quality-assured medications by standardizing regional regulatory procedures. The East African Community (EAC) Medicines Regulatory Harmonization (MRH), the Southern African Development Community (SADC)/ZaZiBoNa MRH, and the Economic Community of West African States (ECOWAS) MRH are the three primary regional initiatives under the AMRH, as indicated in Table 2. These initiatives aim to establish a common framework and standardize regulatory procedures within their individual regions. Together, they supported the creation of the AMA, which aims to enhance access to high-quality medications throughout the continent by strengthening and streamlining Africa's pharmaceutical regulations.[41-43]

## Regulatory fragmentation and its implications

This study highlights considerable regulatory fragmentation across South Africa, Nigeria, Tanzania, and Zimbabwe. Although dossier structures (CTD format) and BE acceptance criteria have largely converged with international standards, critical divergences remain in approval timelines, registration costs, and stability data requirements.

Approval timelines varied by as much as 18 months between countries, significantly impacting the speed at which generic medicines become available to patients. Delays in regulatory approval not only hinder public health improvements but also increase costs for manufacturers, discouraging investment and reducing the affordability of medicines. Similarly, large disparities in registration fees create financial barriers for small and medium-sized pharmaceutical companies seeking multi-country market entry.

The lack of standardized stability zone requirements and differing interpretations of long-term and accelerated data further complicate the process, requiring companies to conduct redundant studies or maintain multiple stability profiles, thus escalating development costs.

Without greater regulatory convergence, the operational and financial inefficiencies associated with fragmented approval processes are likely to persist, limiting the benefits of expanded pharmaceutical production capacity and market growth.

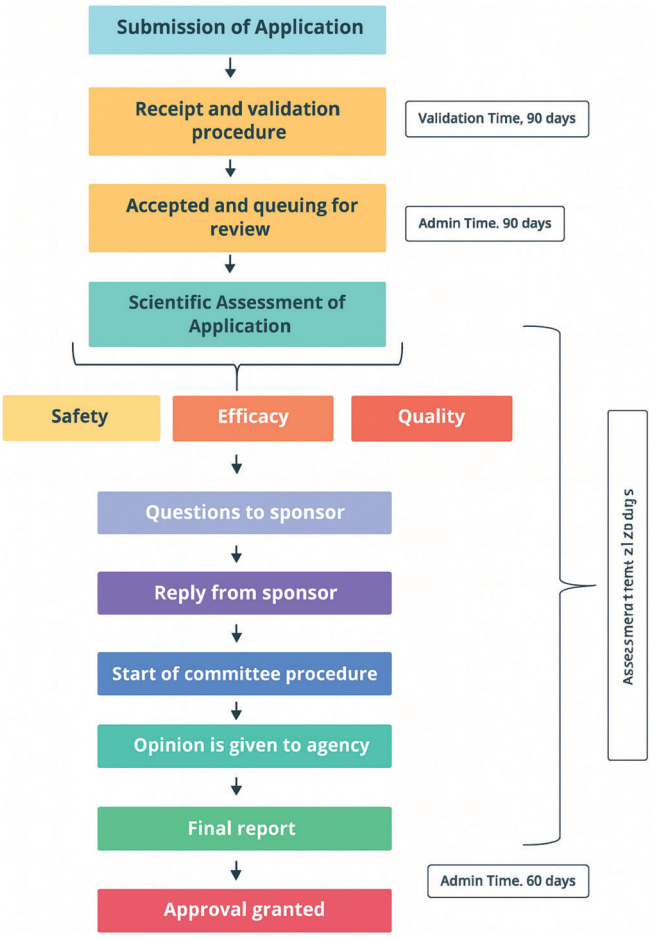



**Figure 5:** Regulatory approval procedure in Zimbabwe[33]

**Table 2:** EAC, SADC, and ECOWAS country categories

| Regional economic communities | Countries |
|---|---|
| East African community | Kenya, Uganda, Tanzania, Rwanda, Burundi, South Sudan |
| Southern African Development Community (SADC) | South Africa, Botswana, Namibia, Angola, Zimbabwe, Mozambique, Zambia, Lesotho, Eswatini (Swaziland), Malawi, Seychelles, Mauritius, Democratic Republic of Congo, Tanzania |
| Economic community of West African states (ECOWAS) | Nigeria, Ghana, Senegal, Côte d'Ivoire, Benin, Burkina Faso, Cape Verde, Gambia, Guinea, Guinea-Bissau, Liberia, Mali, Niger, Sierra Leone, Togo |

### Emerging initiatives toward regulatory harmonization

Recognizing the challenges posed by regulatory fragmentation, African nations have launched several regional initiatives aimed at harmonizing medicines regulation. The AMRH initiative, established in 2009, seeks to strengthen national regulatory capacities and streamline approval processes through regional collaboration.

The Economic Community of West AMRH (ECOWAS-MRH), the SADC-ZAZIBONA, and the East AMRH (EAC-MRH) are three major regional harmonization projects that have made significant progress in coordinating technical requirements, creating joint assessment procedures, and constructing mutual recognition frameworks.

The establishment of the AMA under the AU further represents a significant step toward continent-wide regulatory harmonization. AMA's mandate to coordinate regulatory activities, set common standards, and support national authorities could profoundly transform Africa's pharmaceutical landscape by reducing duplication, speeding access to generics, and attracting greater investment.[40,49,50]

### Pathways to accelerate access to generics

Building on current initiatives, several strategic actions could further accelerate access to generic medicines in Africa:

#### *Standardizing registration fees and approval timelines*

Establishing regionally harmonized fee structures and target review timelines would reduce market entry barriers, particularly for smaller manufacturers.

#### *Mutual recognition agreements*

Wider adoption of mutual recognition of regulatory decisions across African countries would minimize redundant assessments and facilitate faster product approvals.

#### *Unified stability zone guidelines*

Adopting harmonized stability testing requirements (aligned with WHO climatic zones) would streamline dossier preparation and reduce unnecessary testing burdens.

#### *Digitalization and centralized platforms*

Expansion of electronic submission systems (eCTD) and centralized application platforms could enhance regulatory efficiency and transparency across multiple countries.

Progress in these areas would not only facilitate faster access to affordable medicines but also strengthen Africa's resilience to future health emergencies by supporting a more self-reliant pharmaceutical ecosystem.[46]

This comparative study highlights the significant regulatory differences in generic drug registration requirements among South Africa, Nigeria, Tanzania, and Zimbabwe. The analysis reveals notable differences in dossier formats, approval timelines, stability data requirements, BE study expectations, and registration fees, all of which present operational and strategic challenges for pharmaceutical companies aiming for multi-country market access.

Approval timelines emerged as a major point of variation, with Nigeria and Tanzania offering relatively faster review times (6–18 months), while South Africa and Zimbabwe demonstrated longer approval windows (8–24 months). These delays in market access can increase costs and limit the timely availability of affordable generic medicines, undermining public health objectives. Registration fees also showed considerable differences. South Africa and Zimbabwe charged the highest fees, Tanzania maintained moderate fees, and Nigeria remained the most economical registration destination.

To address these regulatory discrepancies and inefficiencies, regional harmonization initiatives such as the AMRH and the AMA have been introduced. In addition, the implementation of globally recognized dossier formats like the CTD has facilitated better alignment with international regulatory expectations and reduced the redundancy in dossier compilation.

However, full harmonization across Africa remains a work in progress. While progress has been made through regional initiatives such as EAC-MRH, SADC-ZAZIBONA, and ECOWAS-MRH, further integration and mutual recognition of regulatory decisions are essential. Standardizing technical requirements, streamlining approval timelines, and establishing regionally harmonized fee structures could dramatically improve access to affordable, quality-assured generic medicines across Africa.

This study underscores the importance of harmonization in reducing regulatory burdens, accelerating market access, and ultimately enhancing public health outcomes. As African markets continue to expand, collaborative regulatory frameworks will be pivotal in ensuring faster, more equitable access to essential medicines across the continent.

## CONCLUSION

Achieving equitable access to high-quality, affordable generic medicines is essential for strengthening healthcare systems across Africa. However, this study highlights that significant regulatory fragmentation persists among major African markets, creating operational barriers, prolonging approval timelines, and increasing the cost of bringing generics to patients. While initiatives such as the AMRH and the AMA offer promising pathways toward greater convergence, sustained commitment

is required to fully realize their potential. Standardizing dossier requirements, harmonizing stability testing expectations, aligning fee structures, and advancing mutual recognition frameworks could substantially reduce duplication and streamline market access for generic medicines across the continent. Generic medicines, by providing cost-effective alternatives to branded drugs, have the power to transform public health outcomes and reduce healthcare expenditure. As Africa's pharmaceutical market continues to grow, regulatory harmonization must be prioritized as a critical enabler of innovation, investment, and improved patient care. Strategic collaboration between regulators, industry stakeholders, and policymakers will be essential to unlock the full potential of generics in Africa – ensuring faster, more equitable access to essential medicines for all.

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