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ORIGINAL ARTICLE

Analysis of regulatory review models and approval timelines across selected African medicines regulatory authorities using the OpERA framework (2020–2024)

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Background: The World Health Organization (WHO) developed the Global Benchmarking Tool (GBT) to assess national regulatory systems and support regulatory-system strengthening across regulatory functions. Several African National Medicines Regulatory Authorities (NMRAs) have achieved Maturity Level 3 (ML3). This study aimed to compare regulatory review models for medicines, approval timelines for applications for marketing authorisation of medicines and regulatory practices across four African NMRAs and explore how reported approval timelines and selected practices varied according to WHO maturity-level status.

Method: The Optimising Efficiency in Regulatory Agencies questionnaire was used in the study. The primary analysis focused on contextual trend analysis of overall approval median timelines for products from 2020 to 2024 for new active substances (NASs), biologicals, vaccines, biosimilars and generic products together with product characteristics. The timelines were summarized using medians, IQRs and sample sizes. Descriptive analyses were conducted across the NMRAs.

Results: Approval timelines varied substantially across agencies and product categories. The review of median approval timelines for NASs in 2024 demonstrated that Ghana FDA reported the shortest median approval timelines of 70 calendar days (IQR 25 to 120, $n = 30$); followed by MCAZ with 603 calendar days ($n = 3$) then SAHPRA with 628 calendar days (IQR 416 to 937, $n = 12$) and ZAMRA reported 1242 calendar days ($n = 3$).

Conclusion: From this study, it was observed that Ghana FDA has shorter median approval timelines throughout the period under review as compared with the other NMRAs. The findings suggest that evaluation of regulatory processes may assist NMRAs in identifying operational practices associated with improved efficiency.

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KEYWORDS
Good Review Practices, key milestones, quality decision-making process, regulatory approval, regulatory review models, review process, World Health Organization Global Benchmarking Tool

1 | INTRODUCTION

The National Medicines Regulatory Authorities (NMRAs) are established to regulate medicines and related health products to protect and promote public health.[1–3] Their functions cover the full lifecycle of medicinal products, including medicines, vaccines, blood and blood products as well as medical devices.[4] These functions include clinical trial oversight, product marketing authorization or registration, licensing of establishments, product importation, inspections, postmarketing surveillance and pharmacovigilance activities.[1] Well-functioning NMRAs ensure access to quality, safe, effective and affordable medicines meeting international standards.[2,5] Strengthened regulatory systems are essential for improving access to such products, while reduced regulatory capacity, limited technical resources and system inefficiencies contribute to delays in approval processes and limited patients' access to medicines.[6]

In order to evaluate the regulatory system performance of NMRAs, the WHO developed a regulatory benchmarking framework with over 250 indicators covering core regulatory functions.[7] The WHO GBT evaluates the NMRAs and classifies them into four maturity levels (ML1–ML4) based on their level of development and functionality.[7,8] A WHO Maturity Level 3 (ML3) classification reflects a stable and well-functioning regulatory system; while WHO Maturity Level 4, the highest classification level, represents an advanced regulatory system characterized by continuous improvement and innovation.[7,8] The WHO GBT framework evaluates NMRA performance across core regulatory functions, including registration and marketing authorization, pharmacovigilance, market surveillance and control, licensing establishments, regulatory inspection, laboratory testing, clinical trials oversight and national regulatory authority lot release.[8] The GBT provides a structured approach for identifying strengths and gaps across regulatory functions and for developing institutional development plans to strengthen national regulatory systems.[9] In Africa, there has been notable progress in regulatory system strengthening, with an increasing number of NMRAs attaining WHO ML3 status with 10 African NMRAs having achieved this status as of August 2026. These authorities include the Egyptian Drug Authority (EDA); the Ethiopian Food and Drug Administration (EFDA); the Food and Drugs Administration of Ghana (GFDA); the Mozambiques' Autoridade Nacional Reguladora de Medicamentos de Moçambique (ANARME); the National Agency for Food and Drug Administration and Control of Nigeria (NAFDAC); Senegal's Agency Sénégalaise de Réglementation Pharmaceutique (ARP); the South African Health Products Regulatory Authority (SAHPRA); the Tanzanian Medicines and Medical Devices Authority (TMDA); Rwanda Food and Drugs Administration (Rwanda FDA) and the Medicines Control Authority of Zimbabwe (MCAZ).[5,10] Despite this progress, substantial variability in reported marketing-authorisation timelines and regulatory review practices persists across agencies, reflecting differences in capacity, resources and implementation of regulatory review practices. This variability emphasizes the importance of analyses to better understand performance differentials among NMRAs operating at similar or different maturity levels.[11]

Marketing-authorisation timelines are one measure of the operational efficiency of regulatory review processes but do not, on their own, measure the quality of scientific assessment or overall regulatory performance.[12,13] However, Good Review Practices (GRevPs) were included in addition to Regulatory timelines. They directly measure the regulatory efficiency.[14] Prolonged timelines indicate inefficiencies in the review process as they hinder timely patient access to medicines.[14] Approval timelines for applications enable benchmarking across authorities and tracking of improvement initiatives, making them essential for regulatory system strengthening.[15] The Centre for Innovation in Regulatory Science (CIRS) has supported global efforts to strengthen regulatory systems in Asia, Latin America, Africa and the Middle East by collecting and analysing performance metrics across NMRAs. This analysis is undertaken using the Optimizing Efficiencies in Regulatory Agencies (OpERA) questionnaire, which facilitates the assessment of review timelines, key milestones and regulatory practices, providing a validated basis for cross-agency comparison and identification of best practices.[16]

While Zambia continues to strengthen its regulatory system toward achieving ML3 status, evaluation with ML3 authorities

What is already known about this subject?

- Attainment of World Health Organisation maturity level 3 (WHO ML3) improves efficiency in regulatory systems.
- Maturity level alone does not necessarily translate into shorter approval timelines, as regulatory authorities differ in capacity and resources.

What this study adds

- This study compares the performance of the Zambia Medicines Regulatory Authority (ZAMRA) with that of continental national medicines regulatory authorities that have attained WHO ML3, focusing on approval timelines and other regulatory functions.

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provides an opportunity to identify performance gaps and improvement priorities. Previous studies indicate that benchmarking against more mature systems supports capacity development; however, variability among ML3 authorities suggests that maturity level alone does not fully explain performance differences.[17] A comprehensive analysis is therefore required to assess cross-agency variation and explore the relationship between reported marketing-authorisation timelines and regulatory review practices and maturity status. The aim of this study was to descriptively benchmark regulatory review models, selected regulatory practices and marketing-authorisation timelines across Ghana FDA, MCAZ, SAHPRA and ZAMRA between 2020 and 2024.

2 | METHODS

2.1 | Study design and settings

A retrospective, descriptive cross-agency benchmarking study was conducted to characterize regulatory review models, selected regulatory practices and marketing-authorisation timelines across four African national medicines regulatory authorities between 2020 and 2024. The participating authorities were the Ghana Food and Drugs Authority (Ghana FDA), the Medicines Control Authority of Zimbabwe (MCAZ), the South African Health Products Regulatory Authority (SAHPRA) and the Zambia Medicines Regulatory Authority (ZAMRA). At the time of the study, Ghana FDA, MCAZ and SAHPRA had attained WHO Maturity Level 3, whereas ZAMRA had not yet attained this status.

The authorities were selected to allow descriptive benchmarking of ZAMRA against three African authorities that had attained WHO Maturity Level 3 and for which comparable OpERA data were available. The unit of analysis was the participating regulatory authority for organizational and regulatory-practice variables and the approved marketing-authorisation application for the timeline analyses.

2.2 | Data source and collection

Data were collected using the Optimizing Efficiencies in Regulatory Agencies (OpERA) questionnaire developed by the CIRS.[13,18,19] The questionnaire captures standardized information on organizational characteristics, regulatory review models, review milestones, approval timelines, GRevPs and quality decision-making practices.

The online questionnaire was distributed to the participating authorities by the principal investigator. It was completed by senior regulatory officers with knowledge of the marketing-authorisation review process in December 2025. The completed questionnaire and authority-specific data were reviewed and verified by the head of the marketing-authorisation department or another designated senior manager at each authority. Any incomplete, inconsistent or unclear responses were returned to the participating authority for clarification before analysis.

Questionnaire responses were mapped to predefined OpERA domains covering organizational characteristics, review pathways, regulatory milestones, GRevPs and quality decision-making practices. Closed-response items were summarized using frequencies and percentages. Narrative responses concerning barriers, enabling factors and improvement initiatives were grouped according to the corresponding OpERA domain and summarized descriptively.

2.3 | Variables of interest

Authority-level variables included organizational structure, funding sources, number of internal reviewers, use of external experts, regulatory review pathways, target timelines, review milestones, GRevPs, quality decision-making practices and reported barriers and enabling factors affecting the review process.

Product-level variables included product category, review pathway, priority-review status, year of approval and the dates of the principal regulatory milestones. Product categories comprised new active substances (NASs), major line extensions, biological products, vaccines, biosimilars, generic medicines and WHO-prequalified products, where applicable.

The overall approval timeline was defined as the elapsed time, in calendar days, from the time of submission of the application to the final regulatory decision. Validation time was defined as the time when the authority assesses the submission for its completeness and suitability for scientific assessment; scientific assessment time as the time it takes to assess the safety, quality and efficacy data; and registration time as the total time it takes to assess the submission excluding the applicant time. The overall approval timeline included both agency processing time and applicant-response time, including periods during which the regulatory clock was stopped.

2.4 | Classification of regulatory review models and practices

A verification review was defined as a limited assessment that relied substantially on the prior assessment and regulatory decision of a recognized reference authority. An abridged review was defined as an assessment of selected components of the application that relied partly on reports or decisions from recognized reference authorities. A full review was defined as an independent assessment of the complete quality, nonclinical and clinical evidence submitted in support of the application.

GRevPs and quality decision-making practices were classified using the response categories contained in the OpERA questionnaire. A practice was classified as formally implemented when it is defined and codified, informally implemented when it has never been clearly defined or codified but over time has become the process, and not implemented when the authority reported that the practice was absent. These classifications were based on information verified by senior representatives of the participating authorities.

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2.5 | Data processing and analysis

Approval timelines were summarized using the median, IQR and number of applications included in each analysis. The distributions were examined descriptively by authority, product category and year of approval.

Approval timelines were examined descriptively by authority, product category and approval year. For applications approved in 2024, distributions were presented using modified box plots in which diamonds represented the medians, boxes represented the IQRs and whiskers represented the 5th and 95th percentiles. Observed approval timelines were reported in calendar days and therefore included weekends, public holidays, agency processing time and applicant-response periods, including clock-stop periods. No adjustment for differences in national public-holiday calendars was applied because the outcome represented total elapsed time.

No inferential statistical comparison was undertaken because the study was designed as a descriptive benchmarking analysis and the authorities contributed markedly unequal numbers of applications, with particularly small numbers of NAS applications at some authorities. Consequently, observed differences between authorities were interpreted descriptively and were not treated as statistically significant differences.

Observed approval timelines were reported in calendar days and included weekends, public holidays, agency processing time and applicant-response time.

Categorical and narrative responses concerning regulatory practices, barriers and enabling factors were grouped according to the predefined OpERA domains and summarized descriptively. No causal relationships between organizational characteristics, regulatory practices and approval timelines were tested.

2.6 | Governance and data verification

A designated senior regulatory officer at each participating authority completed or coordinated completion of the questionnaire. The authority-level responses and application data were subsequently reviewed by the relevant head of the marketing-authorisation department or another designated senior manager to confirm their accuracy and completeness. Standard OpERA definitions and milestone criteria were used across participating authorities to support comparability.

The analysis used authority-level organizational information and regulatory data and did not include patient-level or personally identifiable information.

3 | RESULTS

The results of the study have been presented in six parts: Part 1: regulatory characteristics; Part 2: review models; Part 3: approval timelines; Part 4: 2024 timeline analysis; Part 5: GRevPs and Part 6: quality decision-making processes.

3.1 | Part 1: Regulatory characteristics

All selected NMRAs operate autonomously and independently from their respective Ministries of Health. The Authorities regulate medical products for human and veterinary use, medical devices and diagnostics. In addition, SAHPRA has regulatory oversight of radiation-related activities. The scope of the functions includes marketing authorization or product licences, postmarketing variation and surveillance, laboratory analysis of samples, clinical trial authorization, regulation of advertising and site inspections. Ghana FDA has a total of 45 reviewers, MCAZ 27, SAHPRA 113 and ZAMRA 23.

Funding sources varied across authorities and included service fees, government allocations and donor support. The government contribution to operational budgets per agency ranged from 0% (ZAMRA and MCAZ) to 70.0% (SAHPRA) while donor funding ranged from 2% (ZAMRA) to 14.8% (Ghana FDA). The MCAZ is fully self-funded through revenue generated by service fees, while ZAMRA is 98% self-funded.

3.2 | Part 2: Review models

All four NMRAs utilized three review pathways in the scientific assessment of medicines: Verification review (primarily WHO-prequalified products), abridged review (for products approved by reference authorities), and full review (for standard applications). Fast-track or priority pathways are applied to high-priority medicines.

3.3 | Part 3: Approval timelines

The timelines presented are agency-defined administrative or operational targets rather than statutory end-to-end approval deadlines. The applicable legislation establishes each authority's mandate and registration responsibilities, while the numerical review periods are specified through agency guidelines, service standards and operational procedures. The Authorities have set target timelines for the review and approval of the medicines. The review process for all NMRAs includes the following steps: receipt and validation of the application, scientific assessment, sending questions to the applicant, committee review and either approval or rejection of the application (Figure 1). The agencies generally permit a maximum of two rounds of applicant queries before the application proceeds to committee review for a final decision. All NMRAs utilized electronic application tracking systems, with the exception of Ghana FDA, which relied primarily on manual processes. Ghana FDA and MCAZ generally reported shorter review timelines compared with SAHPRA and ZAMRA.

3.3.1 | Target times for receipt and validation procedures

All the selected authorities screen applications before scientific assessment. Each milestone is noted and monitored either manually

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FIGURE 1 Regulatory review map for the NMRAs.

(A)	**Date application received**	***Milestone recorded***
	Receipt and validation procedures	*A CPP is not an absolute requirement before an application is accepted as valid*
(B)	**Accepted for review**	***Milestone recorded***
	Queuing for review	
(C)	**Scientific review starts**	***Milestone recorded***
	Quality **Safety** **Efficacy**	*Reviewed sequentially for Zambia, Zimbabwe and Ghana and in parallel South Africa*
	Scientific Assessment internal	*Primary scientific assessment by agency technical staff* *Internal and External Peer review*
(D)	**Questions to sponsor**	***Milestone recorded*** - *Clock stop*
	Questions processed by sponsor	***Company time***
(E)	**Reply from sponsor**	***Milestone recorded***
(F)	**Start of Committee procedure**	***Milestone recorded***
	Committee procedure	***Committee Time***
(G)	**Opinion is given to applicant**	***Milestone recorded***
(H)	**Scientific assessment ends**	
	Approval procedure	
(I)	**Approval granted**	***Milestone recorded***

or electronically. Once the application is received it is screened for completeness and acceptability and if it is found acceptable it is queued for scientific assessment.

In Ghana once the application is received it is screened within 1 week and is queued for scientific assessment. The target queue time ranges between 61 to 183 calendar days. The period for scientific assessment differs depending on the type of review model used. Full assessment takes about 6 months while abridged and fast track reviews are estimated at 3 months. Although milestones were not formally recorded electronically, dated correspondence was used to document procedural stages. The committee procedure is 1 working day while the target approval time is less than 2 months.

In Zambia, the key milestones are based on the type of product. The overall validation timeline ranges from 7 to 10 working days (9–13 calendar days) for a 2-day weekend. The scientific assessment ranges from 56 to 210 working days (78–294 calendar days) and the applicant is given 360 working days (504 calendar days) to respond to the queries sent. The overall target approval timeline ranged from 90 to 342 working days (126–479 calendar days) which excludes the sponsor's time to respond to queries given the clock stop principle applied. Priority and locally manufactured products are expected to be approved within 90 working days (126 calendar days).

In Zimbabwe the target screening time is 20 working days (28 calendar days) and once received they are queued for a maximum period of 90 working days (126 calendar days). The applicants are given 45 to 60 days (63–84 calendar days) to respond to queries. Based on the outcome of the review the product is taken to the expert committee for either approval or rejection. This usually takes about five working days (seven calendar days). The overall target approval time is 180 working days (252 calendar days).

In South Africa, the target validation time is 90 calendar days; once the application is received, it is queued for a maximum of 110 working days (154 calendar days). The target scientific review time is set at 120 working days. The approval procedure takes an estimated five working days (seven calendar days). The overall target approval time is 325 working days (455 calendar days).

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TABLE 1 The median approval time for products approved from 2020 to 2024 by the selected NMRAs (NA = none approved).

National medicines authority	Product characteristics	Median approval times in calendar days for products approved in a year				
		2020	2021	2022	2023	2024
Ghana FDA	New active substance	98	374	99	56	70 (IQR 25 to 120)
	Major line extension	NA	NA	NA	NA	NA
	Generic/biosimilar	175	135	90	58	203 (IQR 23 to 136)
	WHO PQ	NA	NA	NA	NA	NA
MCAZ	New active substance	700	1035	517	639	603[a]
	Major line extension	NA	NA	NA	NA	461
	Generic/biosimilar	710	791	807	791	880 (IQR 490 to 1077)
	WHO PQ	103	163	152	244	1045
SAHPRA	New active substance	731	897	965	925	628 (IQR 416 to 937; $n = 12$)
	Major line extension	NA	836	794	832	936
	Generic/biosimilar	827	851	1046	830	1040 (IQR 921 to 1138)
	WHO PQ	391	919	926	574	1042
ZAMRA	New active substance	714	1216	1433	254	1242[a]
	Major line extension	NA	NA	NA	NA	NA
	Generic/biosimilar	872	1097	1049	1091	1058 (IQR 801 to 1982)
	WHO PQ	60	60	75	95	135

Note: IQRs and annual application counts were not available for all authority-year and product-category combinations; Table 1 therefore presents medians only.

[a]For MCAZ and ZAMRA, IQRs were not calculated due to the small numbers of applications ($n < 5$).

TABLE 2 Characteristics of products approved in the year 2024.

Application characteristics		Authority			
		Ghana FDA	MCAZ	SAHPRA	ZAMRA
Product characteristics	New active substances	30	3	12	3
	Major line extensions	0	0	3	0
	Generics/biosimilars	1607	240	292	63
	Other/unknown	0	12	10	5
Review model	Verification	0	7	9	0
	Abridged	50	30	78	10
	Full	1570	216	208	45
	Unknown	0	2	22	16
Priority review	Yes	82	62	59	13
	No	1555	193	258	43
	Unknown	0	0	0	15
Total		1637	255	317	71

3.3.2 | Median approval timelines for approved products from 2020 to 2024

Median approval timelines varied across authorities, product categories and years between 2020 and 2024 (Table 1). Ghana FDA generally reported the shortest timelines for NAS and generic/biosimilar applications, although its annual medians fluctuated. MCAZ, SAHPRA and ZAMRA reported longer timelines across several product categories, with marked year-to-year variation for NAS and WHO-prequalified products. These patterns were examined descriptively and were not subjected to inferential trend testing.

3.4 | Part 4: Analysis of approval timelines for products approved in 2024

Analysis of products approved in 2024 showed that a total of 1637 products, 255, 317 and 71 products were approved by the Ghana FDA, MCAZ, SAHPRA and ZAMRA respectively (Table 2). The WHO

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ML3-listed authorities approved substantially more products than ZAMRA.

A total of 2280 applications were approved across the four NMRAs in 2024, with Ghana FDA accounting for the majority of approvals (1637), followed by SAHPRA (317), MCAZ (255) and ZAMRA (71). Across all authorities, approved applications were predominantly generics/biosimilars, accounting for more than 88% of approvals at each authority. Approvals for NASs and major line extensions were comparatively limited, with SAHPRA being the only authority to approve major line extensions during the study period. Full review remained the predominant review pathway across all authorities, accounting for approximately 64%–96% of approvals. Abridged review pathways were more frequently implemented by SAHPRA (25%) and ZAMRA (14%), while verification review was limited to MCAZ and SAHPRA. Priority review application varied across authorities, ranging from 5.0% at Ghana FDA to 24% at MCAZ. Application counts (*n*) presented in subsequent analyses varied depending on the availability and completeness of milestone dates required for timeline calculations.

3.4.1 | Overall median approval time for NASs in 2024

Median approval timelines for NASs varied substantially across the selected NMRAs in 2024 (Figure 2). Ghana FDA reported the shortest median approval timeline at 70 calendar days, compared with 603 calendar days for MCAZ, 628 calendar days for SAHPRA, and 1242 calendar days for ZAMRA. These findings demonstrate substantial differences which may relate to the way in which the review is carried out, review efficiency as well as Agency resources for NAS applications despite broadly similar regulatory frameworks.

3.4.2 | Overall median approval time for generics or biosimilars in 2024

Generics and biosimilars constituted the majority of approved applications across all authorities and demonstrated substantial variation in approval timelines (Figure 3): Ghana FDA, 98.2% (1607/1637); MCAZ, 94.1% (240/255); SAHPRA, 92.1% (292/317); and ZAMRA, 88.7% (63/71). Ghana FDA again reported the shortest median approval timeline at 69 calendar days, whereas substantially longer timelines were observed at MCAZ (880 days), SAHPRA (1040 days) and ZAMRA (1058 days).

3.4.3 | Validation, scientific review and registration time for generics/biosimilars by the NMRAs

Comparison of validation, scientific assessment and registration timelines for generics/biosimilars approved in 2024 revealed marked variation across authorities (Figure 4).

Ghana FDA reported the shortest median validation timeline (17 days), whereas SAHPRA reported the longest (686 days). Scientific assessment timelines were shortest at Ghana FDA (94 days) and longest at ZAMRA (543 days). Registration procedure timelines were comparatively shorter across all authorities, ranging from 2 days at MCAZ to 116 days at SAHPRA. These findings suggest that prolonged approval timelines are primarily associated with delays during validation and scientific assessment stages rather than during final registration procedures.

3.4.4 | Overall approval time

Overall approval time (submission date to approval date) for generics/biosimilars approved in 2024 is shown by review model for each

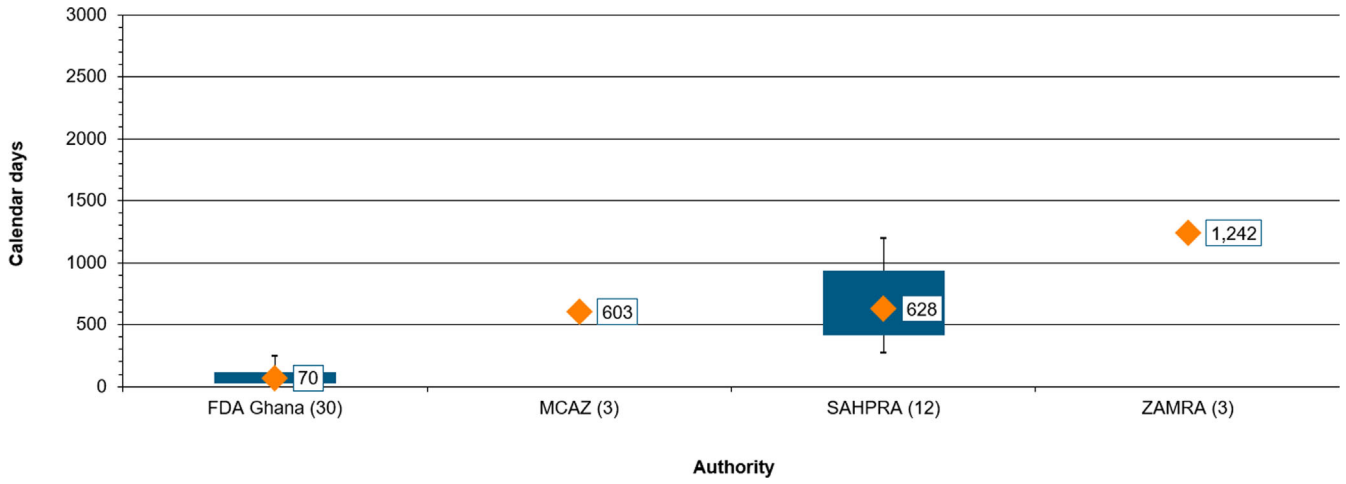


FIGURE 2 Comparison of overall median approval timelines for NAS among the selected NMRAs in 2024. The overall median timelines (50th percentiles) are represented by the diamond symbols, interquartile ranges (IQRs, i.e., 25th to 75th percentiles) are represented by the boxes, and the fifth and 95th percentiles are represented by the whiskers.

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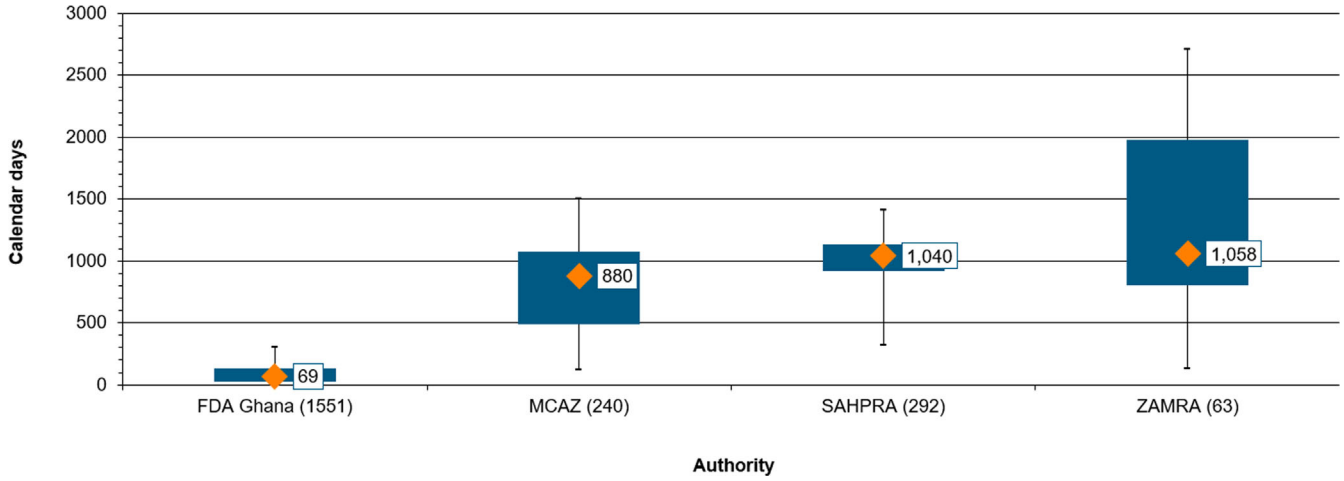


FIGURE 3 Overall median approval time for generics/biosimilars by authority in 2024.

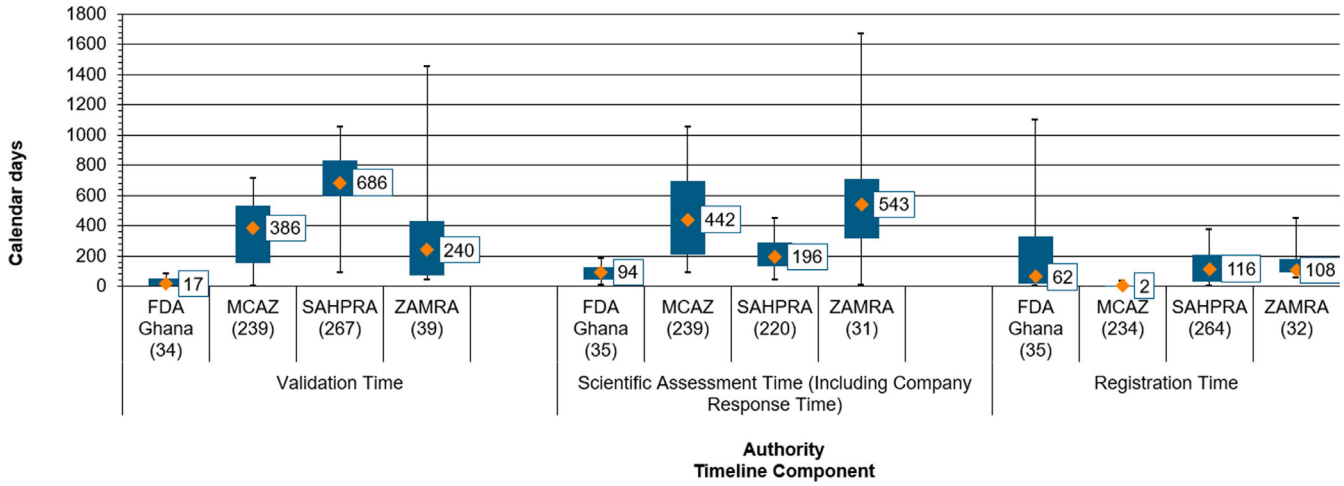


FIGURE 4 Comparison of the overall validation, scientific review and registration time for generics/biosimilars approved in 2024 across the NMRAs.

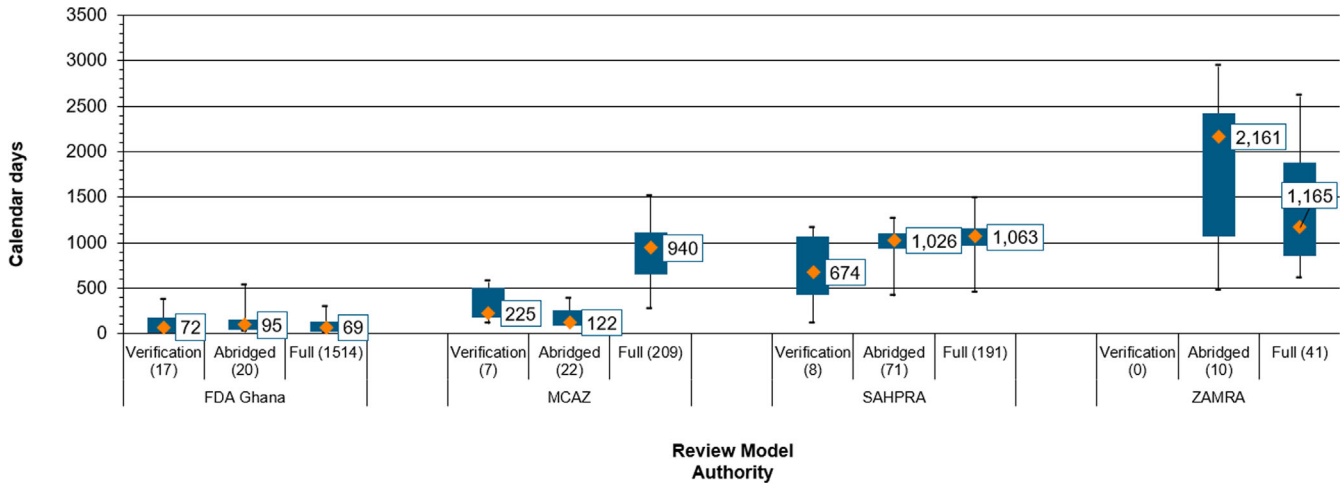


FIGURE 5 Overall approval time (submission date to approval date) for generics/biosimilars by review model and authority in 2024.

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authority (Figure 5). Approval timelines differed according to review model and authority.

At MCAZ and SAHPRA, abridged and verification pathways were generally associated with shorter timelines than full review pathways. Ghana FDA maintained comparatively short timelines across all review pathways, with median full approval timelines at 69 calendar days. In contrast, prolonged timelines persisted at ZAMRA irrespective of review model, with median approval timelines of 1165 calendar days for the full review pathways and surprisingly 2161 for the abridged review pathway. Applications with incomplete milestone data or unknown review pathways were excluded from analyses.

3.5 | Part 5: GRevPs

GRevPs were implemented across authorities to improve quality, consistency, transparency and efficiency in regulatory review. The selected authorities implemented several measures intended to strengthen quality assurance and consistency in the review process (Table 3).

3.5.1 | Quality measures

A comparison of the quality measures that authorities have put in place indicate that all of them are formally or informally implementing them. However, South Africa and Zimbabwe do not formally implement SOPs for the advisory committee during the review process.

3.5.2 | Transparency and communication

The authorities have formally and informally implemented measures in place to improve transparency and communication. However, Zimbabwe did not provide applicant access to technical staff during the review process.

3.5.3 | Continuous improvement initiatives

Zimbabwe demonstrated the most comprehensive implementation of continuous improvement initiatives among the selected authorities, formally implementing external and internal review in addition to review of assessor's feedback and stakeholder's feedback incorporating an internal tracking system. Ghana and South Africa do not conduct external peer review; Zambia and Ghana conduct internal review, but the exception is South Africa (Table 3).

3.5.4 | Training and education

All the selected authorities conduct induction training for new assessors and have training programmes for assessors as well as in international conferences as ways of building capacity. Ghana and South Africa sponsor assessors for postgraduate studies, while Zambia and Zimbabwe do not.

3.6 | Part 6: Quality decision-making processes

All selected authorities reported implementation of formal decision-making frameworks supported by policies, guidelines and legislation. The results show that authorities implement most of the 10 quality decision-making practices namely having a systematic, structured approach, assigning clear roles and responsibilities, assigning values and relative importance to decision criteria, evaluate both internal and external influences/biases, examine alternative solutions, consider uncertainty, re-evaluate as new information becomes available, performing impact analysis of the decision, ensuring transparency and provide a record trail and effectively communicate the basis of the decision. The authorities indicated that though they have the decision-making framework in place, they acknowledge the need for a more formal evaluation of decision-making processes.

4 | DISCUSSION

This study compared regulatory review performance across four African NMRAs, including three WHO ML3-listed authorities and one non-ML3 authority, and identified substantial variation in approval timelines despite broadly comparable regulatory frameworks. Substantial variability was also observed among the WHO ML3-listed authorities, with only Ghana FDA consistently reporting shorter median approval timelines. This may reflect differences in operational processes, workflow efficiency or implementation of regulatory strengthening initiatives.[20] The observed variation may also reflect differences in application case mix, backlog cohorts, pathway allocation, availability of reference assessment reports, applicant-response time, staffing, review workflow and completeness of milestone data. These factors were not analysed as determinants of timeline variation and should therefore be regarded as possible explanations rather than demonstrated causes. The findings suggest that ZAMRA may benefit from further optimisation of its review processes to improve operational efficiency.

It was noted that ZAMRA recorded extended median timelines as compared with the WHO ML3 listed NMRAs over the period 2020–2024. Possible contributing factors may include limited human resource capacity and delays in applicant responses, as previously reported by Chisha et al.[21] Although the authorities implemented risk-based approaches such as reliance including WHO collaborative procedures, extended timelines were still observed across these agencies.

Institutional autonomy is an important component of the WHO Global Benchmarking Tool (GBT) framework that requires that the NMRAs operate independently.[8] Most authorities were financially self-sustaining to varying degrees, although SAHPRA and Ghana FDA

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TABLE 3 Comparison of the Good Review Practices by the selected authorities.

Indicator	Ghana	South Africa	Zambia	Zimbabwe
	Status			
Quality measures				
Internal quality policy	✓	✓	✓	✓
good Review Practice system	✓	✓	✓	✓
Standard operating procedures (SOPs) for guidance of assessors	✓	✓	✓	✓
SOPs for the advisory committee consulted during the review process	✓	✓	✓	x
Assessment templates	✓	✓	✓	✓
Assessment report	✓	✓	✓	✓
SOP for completing the assessment report	✓	✓	✓	✓
SOPs for any other procedures in the regulatory review process (e.g., validation)	✓	✓	✓	✓
Dedicated quality department	✓	✓	✓	✓
Scientific committee	✓	✓	✓	✓
Shared and joint reviews	✓	✓	✓	✓
Transparency and communication parameters				
Feedback to industry on submitted dossiers	✓	✓	✓	✓
Details of technical staff to contact	✓	✓	✓	x
Pre-submission scientific advice to industry	✓	✓	✓	✓
Official guidelines to assist industry	✓	✓	✓	✓
Industry can track progress of applications	✓	✓	✓	✓
Summary of grounds on which approval was granted	✓	✓	✓	✓
Approval times	✓	✓	✓	✓
Advisory committee meeting dates	✓	✓	✓	✓
Approval of products	✓	✓	✓	✓
Continuous improvement initiatives				
External peer review	x	x	✓	✓
Internal peer review	✓	✓	✓	✓
Internal tracking systems	x	✓	✓	✓
Review of assessors' feedback	✓	✓	✓	✓
Reviews of stakeholders' feedback	✓	✓	✓	✓
Training and education				
Training programme for assessors	✓	✓	✓	✓
International workshops/conferences	✓	✓	✓	✓
External courses	✓	✓	✓	✓
In-house courses	✓	✓	✓	✓
On-the-job training	✓	✓	✓	✓
External speakers invited to the authority	✓	✓	✓	✓
Induction training	✓	✓	✓	✓
Sponsorship of postgraduate degrees	✓	✓	x	x
Placements and secondment in other regulatory authorities	✓	✓	✓	✓

Key:
✓ Formally implemented
✓ Informally implemented
x Not implemented

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are partially funded by government. The remaining authorities rely primarily on user fees and donor funding. Revenue generation through service fees contributes to operational autonomy and sustainability.[4,8]

All NMRAs employ full, abridged and verification review pathways, with reliance approaches applied to WHO-prequalified and reference-authority-approved products. Reliance pathways where regulatory assessments relied partially on evaluations conducted by reference authorities are associated with shorter review timelines in prior studies.[22] and may contribute to improved efficiency. While this is not the situation for SAHPRA in this study, it may relate to a backlog. However, a study conducted by Danks et al[23] who assessed the impact of reliance on the regulatory performance in the South African Agency found that the review times were reduced by at least half using the abridged model as compared with the full review model thereby expediting access to quality, safe and efficacious medicines and at the same time demonstrated a significant reduction in the economic evaluation using the abridged pathway.

Extended approval timelines were observed across multiple authorities included in this study. Notably, ML3 status did not consistently correspond with shorter approval timelines, as SAHPRA and MCAZ reported substantially longer timelines than Ghana FDA in several categories. Previous studies have documented prolonged regulatory timelines in multiple jurisdictions, with approval durations exceeding 700–1400 days,[18,22] consistent with the upper ranges observed in this study. The findings indicate that prolonged approval timelines remain a challenge at SAHPRA despite previous regulatory strengthening initiatives suggesting that additional process optimisation strategies may be required. Even though the selected NMRAs have set target timelines, most are failing to meet them with the exception of Ghana FDA. This has been associated with limited human resource capacity, delays in applicant responses and operational constraints.[12,22] The NMRAs demonstrated varying levels of staffing capacity, however staffing levels alone did not appear to explain the observed differences in approval timelines. Ghana FDA has a total of 45 reviewers, MCAZ 27, SAHPRA 113 and ZAMRA 23. Given its larger reviewer workforce, shorter approval timelines may have been anticipated at SAHPRA; however, this was not observed. Ghana FDA consistently reported shorter timelines; however, further analysis is required to determine whether this reflects process efficiency, differences in application complexity or reporting practices.[24] These findings suggest that further optimisation of regulatory workflows at ZAMRA may improve operational efficiency and reduce approval timelines.

Assessment of GRevPs indicated a broad implementation of quality assurance measures across the selected authorities. Implementation of the GRevPs plays a pivotal role in ensuring consistency, predictability, clarity and efficiency in the review process.[25] All NMRAs provided feedback to applicants regarding submitted dossiers and provided a summary of the grounds for the final decision, a practice that may enhance transparency and stakeholder engagement. Transparency could be further strengthened through publication of public assessment reports for approved medicines.[14,26] The implementation of GRevPs was broadly consistent across agencies, although differences in transparency and process formalization were observed. These factors may influence efficiency but were not directly related to approval timelines.

Although all authorities reported implementation of decision-making frameworks, several processes appeared to remain informal, potentially affecting consistency and transparency. Having a well-defined framework facilitates a consistent, transparent and predictable review process.[27] Further formalization of decision-making frameworks may strengthen consistency, transparency and predictability within the review process.

Ongoing performance evaluation and process monitoring may assist authorities in identifying operational bottlenecks and improving review efficiency.[19] Such measures may contribute to reduced approval timelines and improved patient access to medicines.

The efficiency of NAS review procedures was influenced by several operational barriers and enabling factors identified by participating authorities. The main barriers identified by the authorities included inadequate number of qualified reviewers which may contribute to delays in meeting target review timelines, thereby hindering access, limited implementation of formal reliance policies and frameworks, slow turnaround times for reference regulatory authorities (RRAs) to provide reports, inadequate support from industry and submission of incomplete or poor-quality dossiers, therefore contributing to a lengthening review process. Key enabling factors included use of WHO/SRA reliance pathways, availability of structured assessment guidelines, and collaboration through ZaZiBoNa and WHO initiatives. Continuous professional development, internal audits and publication of timelines were also identified as contributors to regulatory strengthening.

This study has several limitations. Application numbers differed markedly across authorities, and the small numbers of NAS applications at MCAZ and ZAMRA limited the precision of the corresponding estimates. Participating authorities assessed their own regulatory systems, introducing potential self-assessment bias. The analysis included only approved applications and may therefore be affected by approval-cohort and backlog bias. Differences in product complexity, pathway allocation, staffing structures, operational context across authorities, applicant-response time and the completeness of milestone data may also have affected comparability of approval timelines. Overall timelines combined agency and applicant time, and the study did not test associations between operational characteristics and approval timelines. No inferential statistical comparison was conducted, and the quality of scientific assessments was not evaluated. The study examined approval timelines and selected regulatory practices but did not assess the quality, scientific rigour or consistency of regulatory assessments. The study did not examine associations between staffing, workload and approval timelines, nor did it assess the scientific quality of reviews. Reviewer numbers should therefore not be interpreted as a measure of assessment capacity or quality. The findings should therefore be interpreted as descriptive benchmarking rather than a comprehensive or causal evaluation of regulatory performance.

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4.1 | Implications for future practice, policy and research

The findings of this study have implications for regulatory practice, policy and future research. For WHO ML3-listed authorities, there is a need to strengthen reliance pathways where appropriate to improve regulatory efficiency and reduce approval timelines. Regulatory authorities should also enhance transparency by publishing the public assessment reports and invest in regulatory capacity through digitalization of regulatory systems. Streamlining regulatory processes and conducting regular reviews of marketing-authorization timelines and regulatory review practices may further improve the quality of regulatory reviews.

For ZAMRA that is yet to attain WHO ML3 status, similar measures are recommended, with particular emphasis on strengthening reliance and abridged review pathways to reduce prolonged approval timelines. The authority should invest in human resource development and digitalization of systems, publish public assessment reports to improve transparency, and collaborate with WHO ML3-listed authorities to strengthen the capacity of assessors through knowledge sharing. Regular reviews of marketing-authorisation timelines and regulatory review practices should also be undertaken to identify opportunities for continuous improvement in the quality and efficiency of regulatory review processes.

5 | CONCLUSION

Descriptive benchmarking identified substantial variation in marketing-authorisation timelines across the four authorities, with Ghana FDA reporting the shortest median timelines, while WHO ML3 status was not consistently accompanied by shorter total elapsed approval times. Further research should distinguish agency processing time from applicant-response time and examine whether pathway allocation, workflow design, case mix, staffing and milestone monitoring contribute to timeline variation while maintaining the quality of regulatory assessment.

AUTHOR CONTRIBUTIONS

Constance Sakala Chisha devised the study, collected data, analysed the data and wrote the manuscript. Stephanie Leigh devised and supervised the study, analysed data and critically reviewed the manuscript. Makomani Siyanga supervised the study and critically reviewed the manuscript. Grace Matimba collected the data and critically reviewed the manuscript. Richard Rukwata supervised the study and critically reviewed the manuscript. Mercy Owusu-Asante collected and analysed the data and critically reviewed the manuscript. Kwabena Frimpong-Manso Opuni supervised the study and critically reviewed the manuscript. Pratibha Sobrun collected and analysed the data and critically reviewed the manuscript. Boitumelo Semete-Makokotlela supervised the study and critically reviewed the manuscript. Adem Kermad analysed data and critically reviewed the manuscript. Stuart Walker devised and supervised the study, analysed the data, and critically reviewed the manuscript. All the authors confirm that they have read and approved the final manuscript.

CONFLICT OF INTEREST STATEMENT

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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