Pharma Gate
GLOBAL PHARMA OPPORTUNITIES

PHARMA GATE INSIGHTS

Africa's Regulatory Readiness Gap

From WHO Maturity Levels to Market Access and Investment Opportunities

RECOGNITION / EXECUTION / COMMERCIAL ACCESS

A decision framework for pharmaceutical companies, regulators, manufacturers and investors.

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Executive intelligence summary

African pharmaceutical regulation is becoming more institutionally credible, but a maturity designation cannot determine an investment location or a product launch date. Pharma Gate's central finding is that the commercially relevant readiness gap lies between three separate conditions: a capable regulator, an executable product pathway, and a funded route to patients. Companies should evaluate all three before committing registration expenditure, inventory or manufacturing capital.

The verified WHO August 2026 baseline lists ten African countries at ML3 and none at ML4. Nine have a medicines scope. South Africa's designation is vaccine-specific. Egypt's vaccine and medicines milestones were announced separately in 2022 and 2024. These distinctions change which regulatory claims can support a manufacturing or market-entry proposition. [S01,S03,S09]

Operational evidence is much narrower than recognition coverage. The 2026 OpERA study provides comparable definitions for four authorities, but its approval cohorts are unequal and its elapsed times include applicant response periods. For new active substances approved in 2024, medians range from 70 to 1,242 calendar days. Two cohorts contain only three applications. The study cannot establish a continent-wide speed ranking or a causal effect of maturity. [S17]

Continental coordination has progressed beyond treaty announcements: AMA reports operations since October 2025, and inaugurated seven technical committees in October 2026. National product decisions remain necessary. A manufacturer should build a coordinated submission strategy with explicit national completion steps, rather than assume a single continental licence. [S39–S41]

Commercially credible near-term work includes reliance eligibility assessment, dossier adaptation, local representative diligence, quality-system remediation and procurement readiness. Manufacturing opportunities require a separate offtake and cost case. Nigeria's October 2026 import ceiling update makes product admissibility and local-manufacturing plans an immediate screening priority. APPM's live framework invitation provides a concrete procurement route, but explicitly guarantees no minimum purchase. [S23,S53]

Regulatory recognition	Observed performance	Commercial conversion
10 African ML3 countries	4 authorities in OpERA	AMA operational since Oct 2025
9 with medicines scope	48 NAS approvals in 2024	APPM RFB002 open at cut-off
0 African ML4 on baseline	Small cohorts: 3 at two NRAs	National decisions still needed

S01, S17, S39, S53 | Distinct dimensions; no composite readiness score.

Figure 1. Executive intelligence dashboard. Recognition, measured performance and commercial conversion are separate decision dimensions. Sources: S01, S17, S39, S53.

Decisions to take now

Decision owner	Immediate decision	Evidence required before commitment
Company regulatory lead	Select the pathway for each product and country	Reference approval, shareable assessment, sameness, current national eligibility
Commercial director	Approve an initial country shortlist conditional on product fit	Buyer demand, price, payment, import admissibility and channel capability
Investor or manufacturer	Fund staged diligence before plant expansion	Audited capacity, GMP gap cost, technology rights and credible offtake
Regulator or regional institution	Publish route-specific performance and transition rules	Definitions, cohort counts, regulator and applicant clocks, uptake after joint review
Pharma Gate	Offer evidence-led mandates with explicit decision outputs	Dated source pack, exclusions, authority confirmation and scenario assumptions

How to use this report

Use the recognition map to establish scope, the performance chapter to understand historical uncertainty, and the pathway and country chapters to define diligence. The opportunity framework identifies where further work has a defensible basis. It does not recommend buying securities, financing a named project or treating an announced programme as available funding. The accompanying workbook preserves observations, conflicts and figure data. Missing observations remain missing.

1 Research method and interpretation

Research cut-off is 22 November 2026. The WHO list dated 24 August 2026 is the verified designation baseline. Later primary material was screened through the cut-off; no later verified African ML4 recognition or additional African ML3 announcement was established in the sources reviewed. This is a documented public-source snapshot, not an assurance that every unpublished assessment or recent administrative change has been captured.

The analytical coverage comprises the ten listed African ML3 countries, Kenya and Morocco as explicit status-verification cases, and Zambia as an OpERA comparator. The maturity landscape spans geographic Africa. The AFRO strategy applies to the WHO African Region, a different institutional geography. Its baseline must not be compared directly with a geographic-African country count without reconciling membership and dates. [S01,S12]

Evidence hierarchy and audit trail

Designation evidence is anchored in WHO’s list and announcement pages. National rules and service standards come from regulators; legal treaty fields from the AU depositary snapshot; operational milestones from AMA, EMA, regional institutions and Africa CDC. Peer-reviewed research supplies approval observations. Company disclosures are identified as company-reported events. Search-index-only evidence is labelled in the source register and is not promoted to direct documentary verification.

Each source has a stable identifier. Each workbook observation records its source and locator, with product class, period and unit retained. Sources are cited at the point of material claims and in figure captions. An undated webpage is recorded as undated, even when its current content was accessed on the cut-off. Dates within an official list are not silently converted into exact announcement dates.

Evidence type	Treatment in this publication	Decision use
Verified documentary fact	Primary source inspected; scope and date preserved	Suitable for the stated historical or institutional claim
Published target or commitment	Explicitly labelled, with clock and starting condition	Planning reference subject to case confirmation
Reported observation	Published cohort or source statement, with denominator	Historical context, not an approval promise
Analytical interpretation	Pharma Gate inference separated from the source finding	Conditional strategy to test in diligence
Not Publicly Verified	No usable observation or amount established in this review	An open research requirement, never a zero or low score

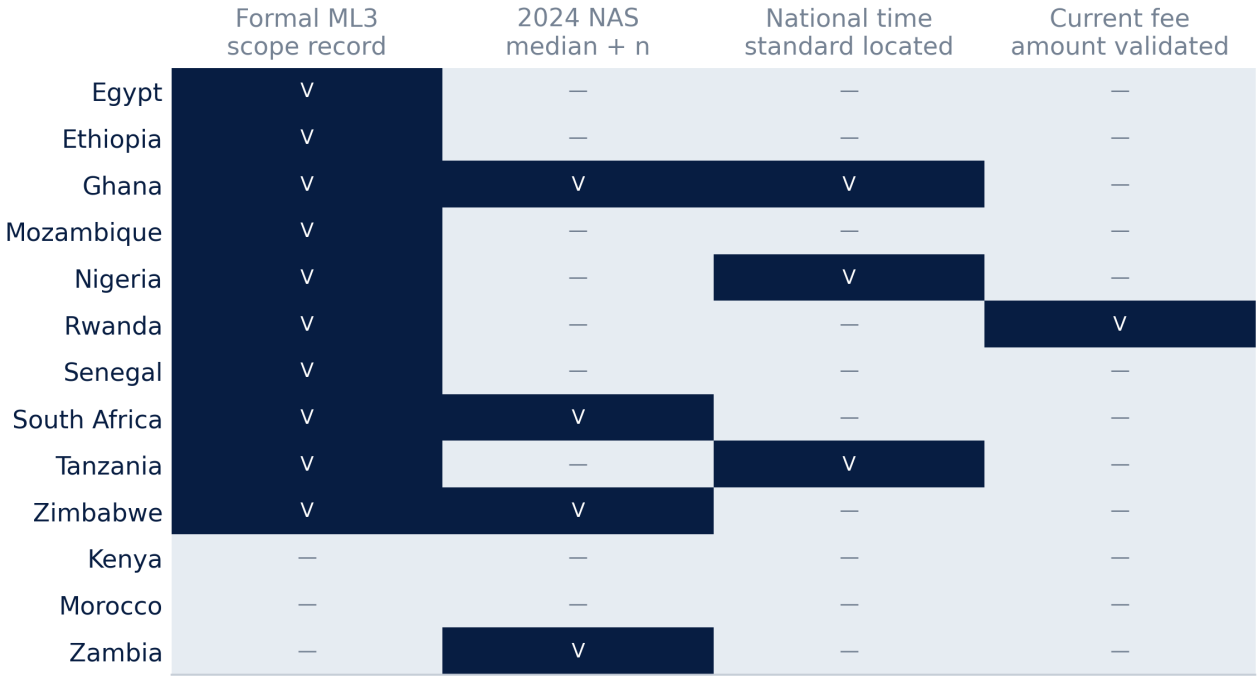
Comparison rules

Calendar days and working days are not converted into a common measure. An unspecified “days” standard stays unspecified. Total elapsed time, validation time, scientific assessment and final registration time are different metrics. A service target is not observed performance. Medians are not means, and medians for different stages or cohorts cannot be added to reconstruct an end-to-end median.

No composite readiness index, attractiveness score, weighted ranking or synthetic market forecast is used. Country comparisons are evidence matrices and decision gates. This avoids giving sparse public data a false precision. Sensitivity is addressed by stating the conditions that would change a decision: loss of pathway eligibility, an adverse import restriction, a delayed national decision, or failure to secure offtake.

Limits that matter commercially

Comparable national pharmaceutical sales, medicine import shares, factory utilization, registration fees and route-specific turnaround observations were not verified for every focus country. Consequently the report does not publish a market-size league table or calculate a continental addressable market. Unverified data are visible in the gap register. The evidence supports a regulatory and opportunity-screening framework, with product-specific transaction diligence still required.

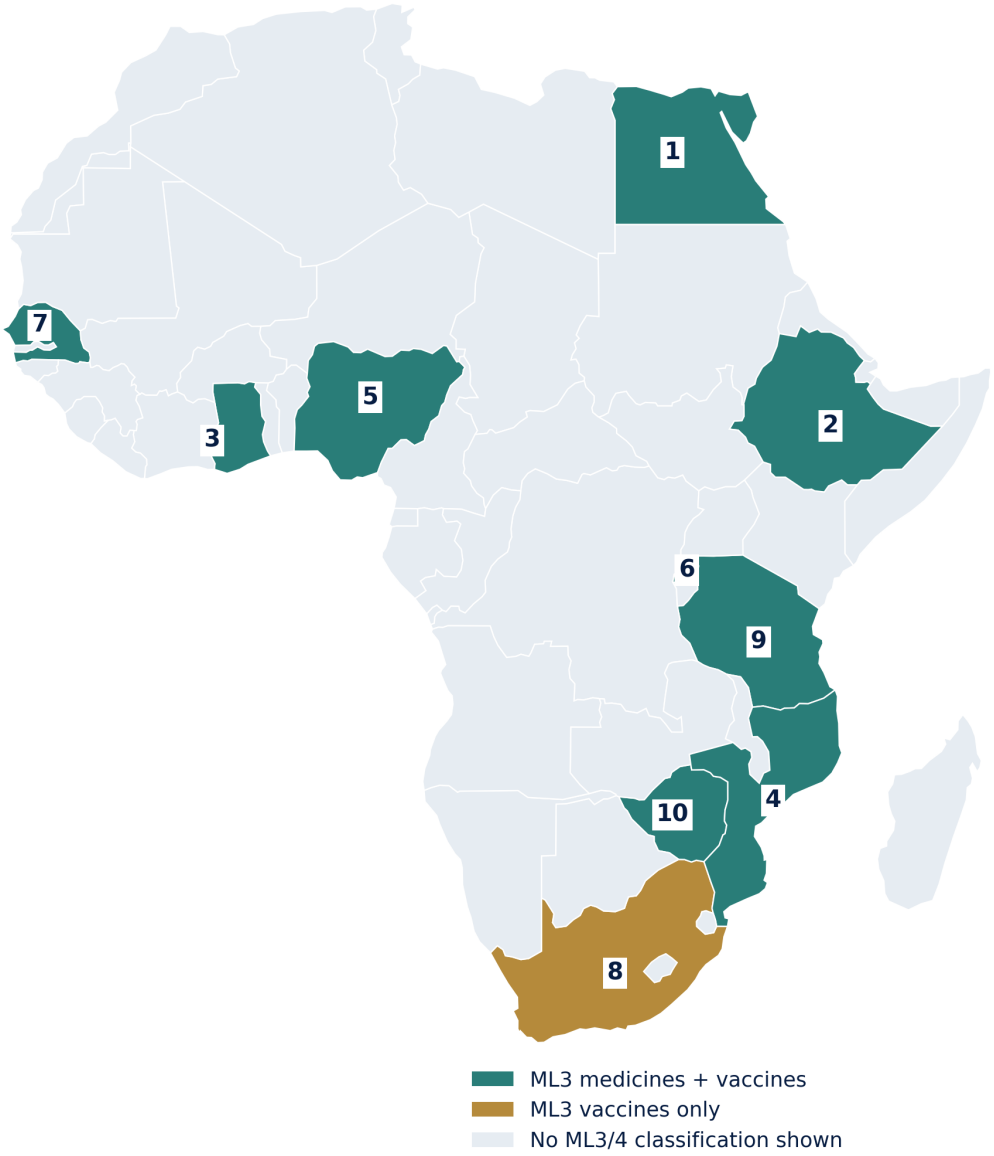


Pharma Gate evidence audit, 22 November 2026 | V = captured in this research. Blank evidence is not poor regulatory performance.

Figure 2. Evidence captured across the 13-country analytical set. This is research coverage, not a score of agency transparency or performance. Sources and field definitions: workbook Evidence gaps and Country master.

2 The African regulatory maturity landscape

GBT evaluates regulatory systems and helps authorities formulate institutional development plans. It covers medicines and vaccines and has supplemental criteria for other product types. ML3 denotes a stable and integrated system; ML4 denotes advanced performance with continuous improvement. Maturity is neither a market-size measure nor a guarantee of a short individual review. [S02]



01 Egypt

02 Ethiopia

03 Ghana

04 Mozambique

05 Nigeria

06 Rwanda

07 Senegal

08 South Africa

09 Tanzania

10 Zimbabwe

Scope matters
South Africa: vaccines
No African ML4 on list

S01 WHO, August 2026; S56 Natural Earth | Grey is not an ML1/2 designation. Boundaries schematic.

Figure 3. African ML3 landscape with product-scope distinctions. South Africa is shown separately for vaccines. Grey denotes no ML3/4 classification shown, not an inferred lower maturity. Sources: S01; S56 for schematic boundaries.

Verified country and product-scope register

Country and authority	Medicines	Vaccine scope in August list	List year cell
Egypt / Egyptian Drug Authority	ML3	Producing	Vaccines 2022; medicines 2024
Ethiopia / Ethiopian Food and Drug Authority	ML3	Non producing	2025
Ghana / Food and Drugs Authority	ML3	Non producing	2020;2025
Mozambique / Autoridade Nacional Reguladora de Medicamentos	ML3	Non producing	2026
Nigeria / National Agency for Food and Drug Administration and Control	ML3	Non producing	2022;2025
Rwanda / Rwanda Food and Drugs Authority	ML3	Non producing	2024
Senegal / Agence sénégalaise de Réglementation Pharmaceutique	ML3	Non producing	2024
South Africa / South African Health Products Regulatory Authority	Not listed	Producing	2022;2026
Tanzania / Tanzania Medicines and Medical Devices Authority	ML3	Non producing	2018;2025
Zimbabwe / Medicines Control Authority of Zimbabwe	ML3	Non producing	2024

Source: S01, pages 1–3. “Producing” and “non producing” reproduce WHO’s scope categories. They are not counts of factories or statements about all future products. Ghana, Nigeria and Tanzania have paired years in merged list cells; the publication does not assign a separate recognition date to each product scope from those cells.

Recognition dates must be kept separate from assessment dates

Country	Verified initial public announcement	Additional distinction
Egypt	30 Mar 2022 vaccines; 20 Dec 2024 medicines	Medicines benchmarking finalized Nov 2024 [S03,S04]
Ethiopia	30 Sep 2025	Benchmarking completed Sep 2025 [S05]
Ghana	13 May 2020 WHO feature	August 2026 list also records 2025 [S06,S01]
Mozambique	24 Aug 2026	Medicines and imported vaccines [S07]
Nigeria	30 Mar 2022	August 2026 list also records 2025 [S04,S01]
Rwanda and Senegal	5 Dec 2024	Assessment finalized Oct 2024 [S08]
South Africa	5 Oct 2022	Vaccine scope retained following 2026 assessment [S09,S07]
Tanzania	3 Dec 2018 WHO AFRO announcement	August 2026 list also records 2025 [S10,S01]
Zimbabwe	14 Jun 2024	Assessment finalized May 2024; ML3 [S11]

Three claims that require correction

Kenya. Government news reporting describes ML2 and a December 2026 ML3 objective. A January 2026 ministry article says ML3 had already been achieved, but the WHO August list omits Kenya and a ministry statement on 11 November still describes efforts towards ML3. This publication retains “reported ML2; formal ML3 not verified” and treats December as a target. It does not resolve the contradiction by accepting the most optimistic official sentence. [S13–S15,S01]

Morocco. WHO describes AMMPS reform and a roadmap towards ML3. That supports a strengthening trajectory, not an assigned ML2 or ML3 classification. Morocco is recorded as Not Publicly Verified for formal maturity status. The presence of manufacturing and laboratory capability must not be used to manufacture a WHO designation. [S16]

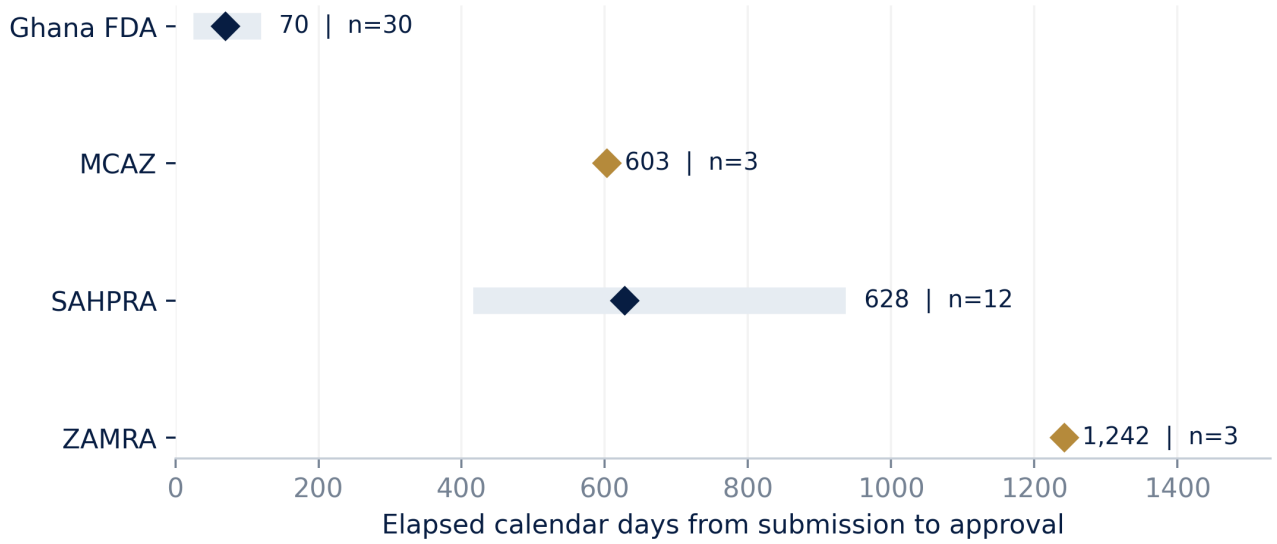
Zimbabwe. WHO’s announcement and current baseline both support ML3. Claims of ML4 are unsupported by the designation evidence reviewed. A statement about a specialized laboratory, certification or ambition cannot be substituted for recognition of the national regulatory system. [S11,S01]

What the regional distribution means

The ten-country recognition set spans North, East, West and Southern Africa. It is not evenly distributed, and no Central African country appears in that set. This identifies a geographic gap in published ML3 coverage, not the cause or quality of every non-listed system. For companies, regulatory preparation should follow the destination's actual rules and the proposed product, including reliance options where available. Excluding all non-ML3 markets would discard potentially workable access routes without examining them.

3 Maturity and approval performance answer different questions

OpERA's four-authority study covers Ghana FDA, MCAZ, SAHPRA and ZAMRA over 2020–2024. Its observational design does not isolate the effect of institutional maturity. The designation scope and recognition date also differ across authorities: South Africa's ML3 is vaccine-specific and Zimbabwe's public recognition occurred during 2024. Applying a 2026 status label retrospectively across all study years would be misleading. [S17,S01,S11]



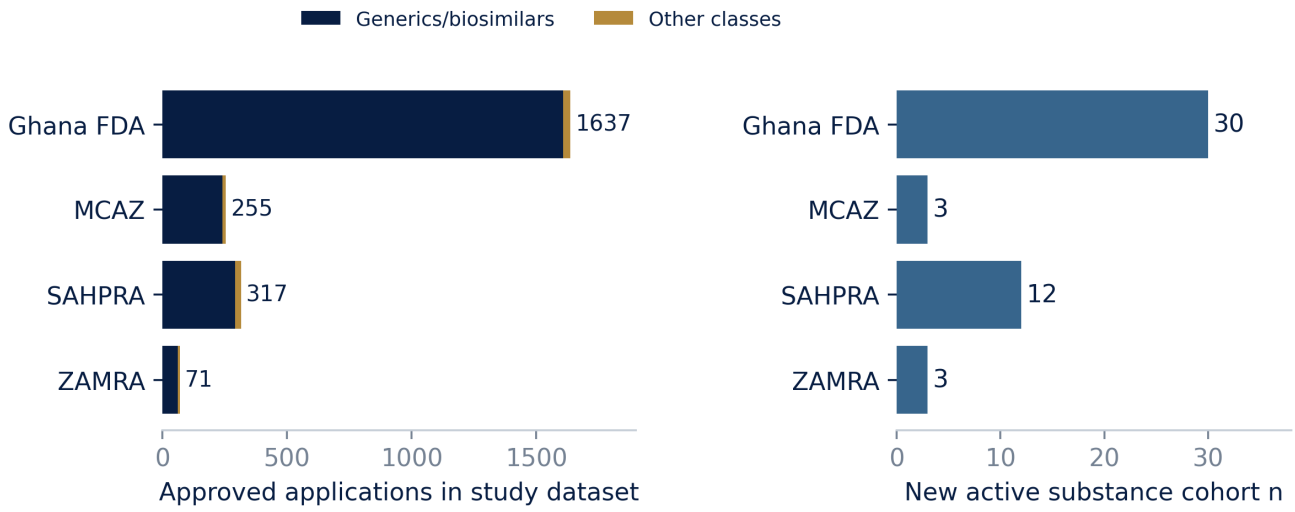
S17, abstract, Table 1, Figure 2 | Diamonds: medians. Bars: IQR where published. Small cohorts in gold.

Figure 4. New active substance approvals in 2024. Medians and published IQRs, with cohort n. All values are elapsed calendar days including applicant response. Source: S17 abstract, Table 1 and Figure 2.

Interpret the cohort before interpreting speed

The NAS comparison contains 48 approvals: 30 in Ghana, 3 in Zimbabwe, 12 in South Africa and 3 in Zambia. Ghana contributes 62.5% of those observations. A pooled headline would therefore be dominated by its cohort, while the other country medians have very different stability. No pooled median can be reconstructed from published authority medians. [S17; Pharma Gate calculations]

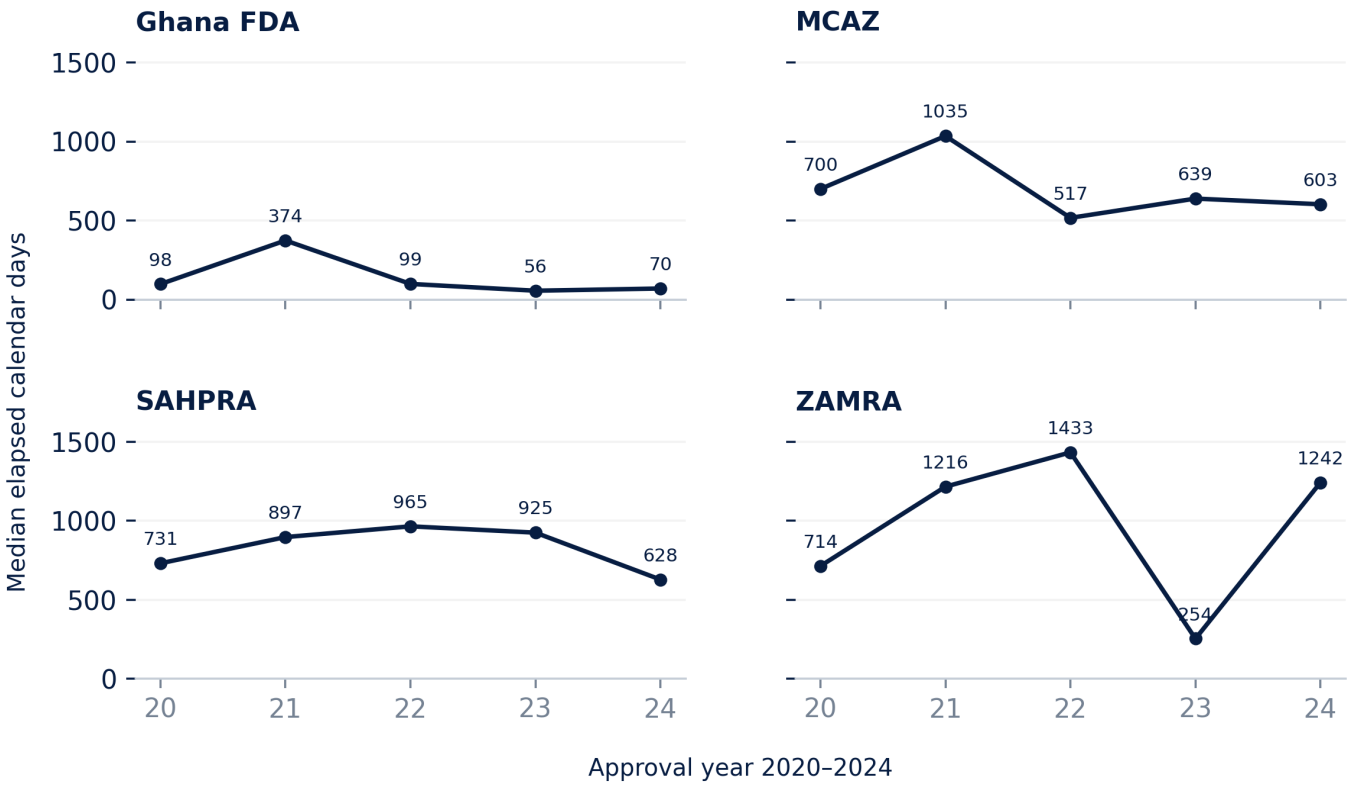
A median based on three approvals describes the middle of three historical observations. It does not establish a dependable launch calendar for a new sponsor. Even the larger cohorts mix products and pathways. Companies should use them to define diligence questions and contingency budgets, then seek comparable product and route evidence. They should not insert the country median directly into a revenue forecast as a promised approval date.



S17, Table 2 | Counts are dataset approvals, not throughput efficiency or demand.

Figure 5. Study approval volume and NAS cohort sizes. The large difference in denominators prevents interpreting counts as regulatory productivity. Source: S17 Table 2.

The dataset contains 2,280 approved applications across four authorities. Total approvals can reflect market demand, filing patterns, legacy cases, product mix and data capture. Without applications received, pending stock, reviewer time and comparable case complexity, approval counts do not identify capacity utilization or the probability that an individual submission succeeds. The required management metric is a defined cohort tracked through the process, including unresolved and withdrawn applications.



S17, Table 1 | Annual sample sizes incomplete; changes are descriptive, not adjusted trends.

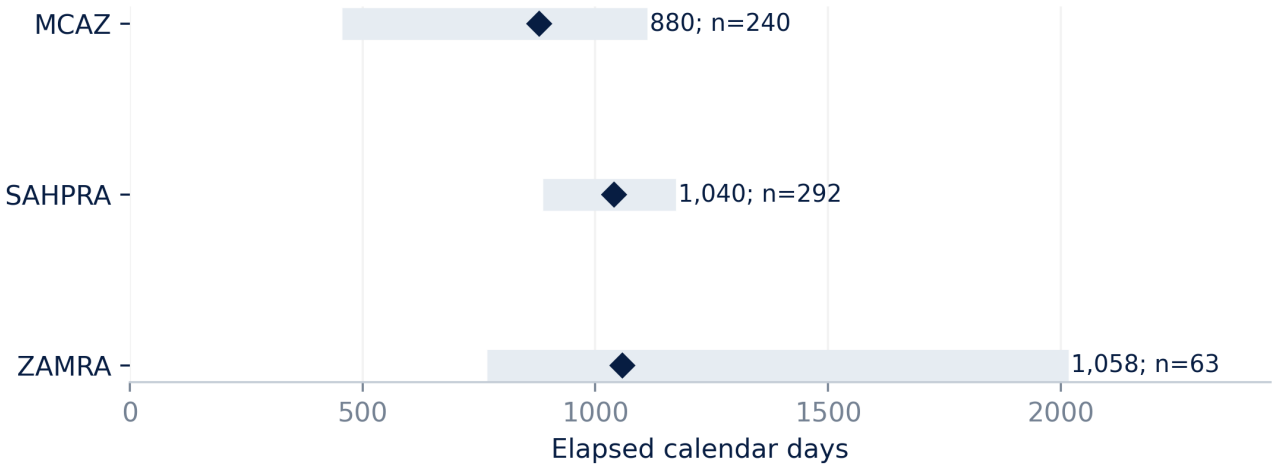
Figure 6. NAS annual medians from 2020 to 2024. Shared axes preserve scale. Annual sample sizes are incomplete; no inferential trend or causal performance claim is made. Source: S17 Table 1.

Approval-year analysis has a timing limitation

Approvals in a given year can include dossiers submitted years earlier. A high elapsed-time median can rise when old cases are cleared, even if current processing improves. Conversely a low median among approved cases can coexist with a long unresolved queue. The study does not supply a complete survival analysis of all incoming applications. Investors need the pending-age profile as well as the approved-case median before judging an agency’s current execution risk.

Generics and biosimilars cannot be separated from this dataset

The study combines generics and biosimilars in its reported category. It does not support an independent biosimilar timeline benchmark. This publication preserves the combined label and does not use the figures to price a biosimilar registration service or forecast a vaccine approval. Those products require separate evidence on comparability, manufacturing controls and applicable review pathways.



S17, Table 1 and Figure 3 | Median and IQR. Ghana omitted: unresolved 203 versus 69-day conflict.

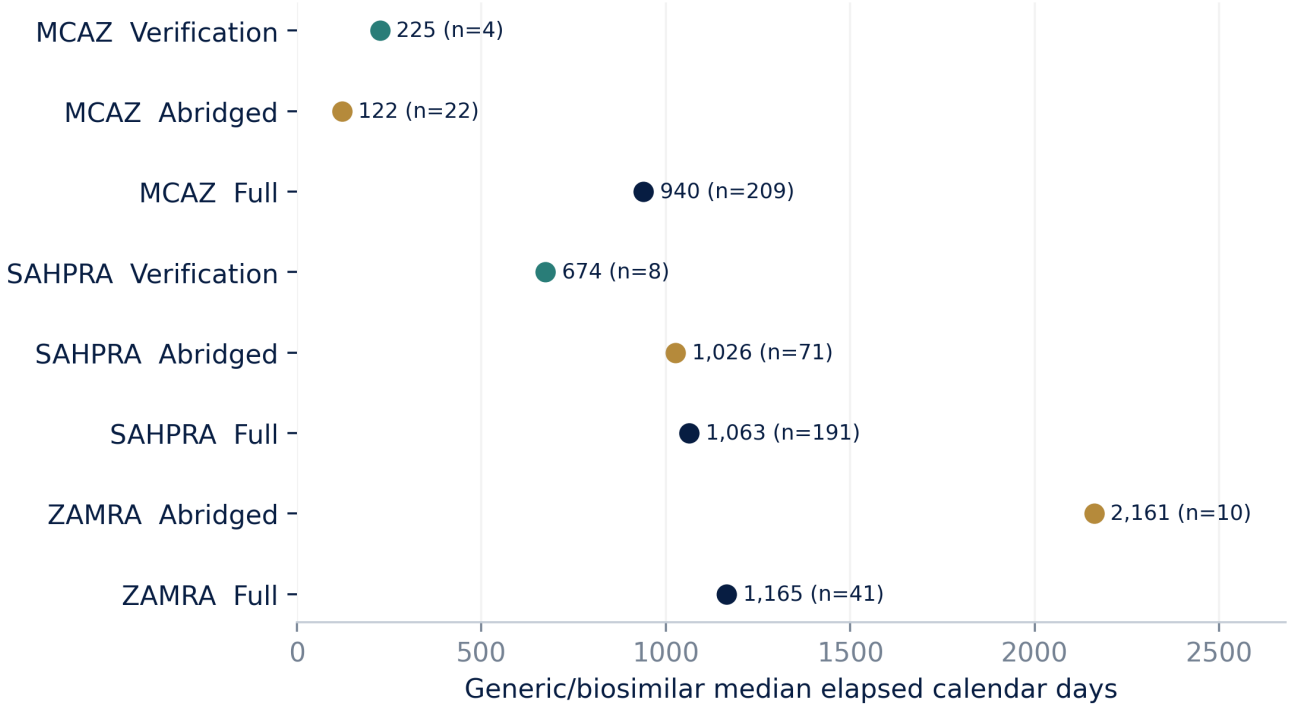
Figure 7. Published 2024 generic/biosimilar medians and IQRs for three authorities. Ghana is excluded because Table 1 and Figure 3 disagree. Source: S17.

Published evidence needs internal quality checks

Ghana’s generic/biosimilar median is 203 days in Table 1 but 69 in Figure 3 and narrative; the listed IQR is 23–136. The median in Table 1 lies outside that IQR. Figure 3 uses n=1,551, whereas the product-category count is 1,607. Cohort differences can explain different n, but do not resolve the conflicting median. Both values are retained in the conflict register, without selecting an assumed correction.

Further checks identify Ghana’s Table 2 review-model sum of 1,620 against a total of 1,637, and a Zimbabwe major-line-extension median despite zero extensions in Table 2. Figure 5 also shows Ghana verification cases while Table 2 records none. These findings limit particular comparisons; they do not invalidate all observations. The NAS abstract agrees with the corresponding published table, while disputed comparisons are withheld. [S17]

Reliance performance must be examined within each authority

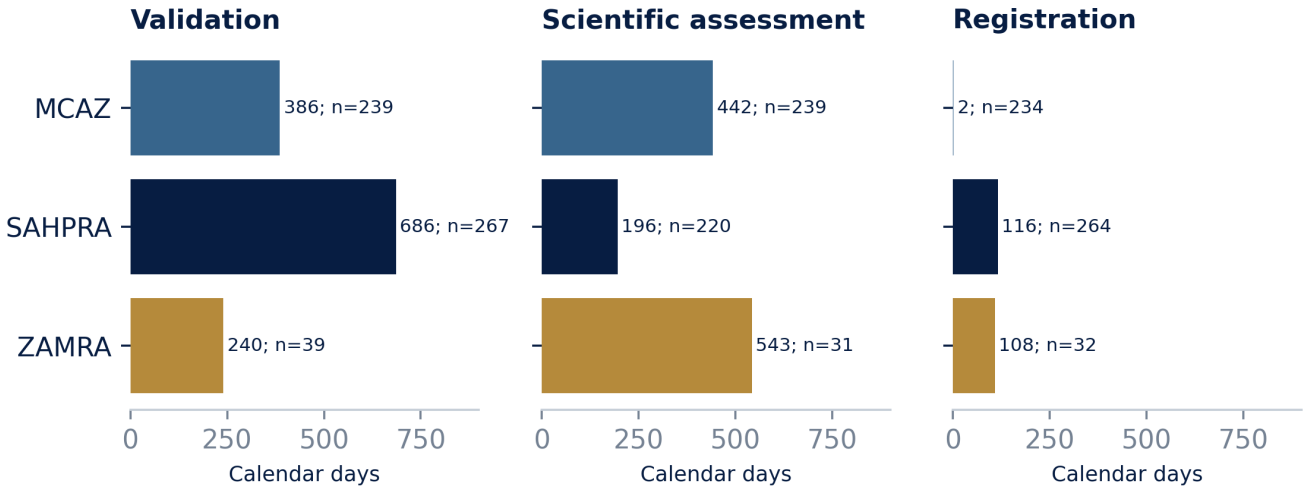


S17, Figure 5 (read directly) | Selected cohorts differ. Association does not establish a reliance effect.

Figure 8. Selected generic/biosimilar pathway medians and timeline cohort sizes. S17 Figure 5, read directly. Ghana is withheld because of pathway-count conflicts. No matching or causal adjustment is available.

Within the plotted historical cohorts, abridged review is shorter than full review at MCAZ, while Zambia’s abridged cohort is longer. This is a warning against assuming that the name of a facilitated pathway determines elapsed time. Product selection, queue age and completeness could differ; the data do not test those explanations. A sponsor should confirm operational acceptance, dossier sameness, access to reference reports and the national administrative steps for the proposed submission.

Find the bottleneck without adding incompatible medians



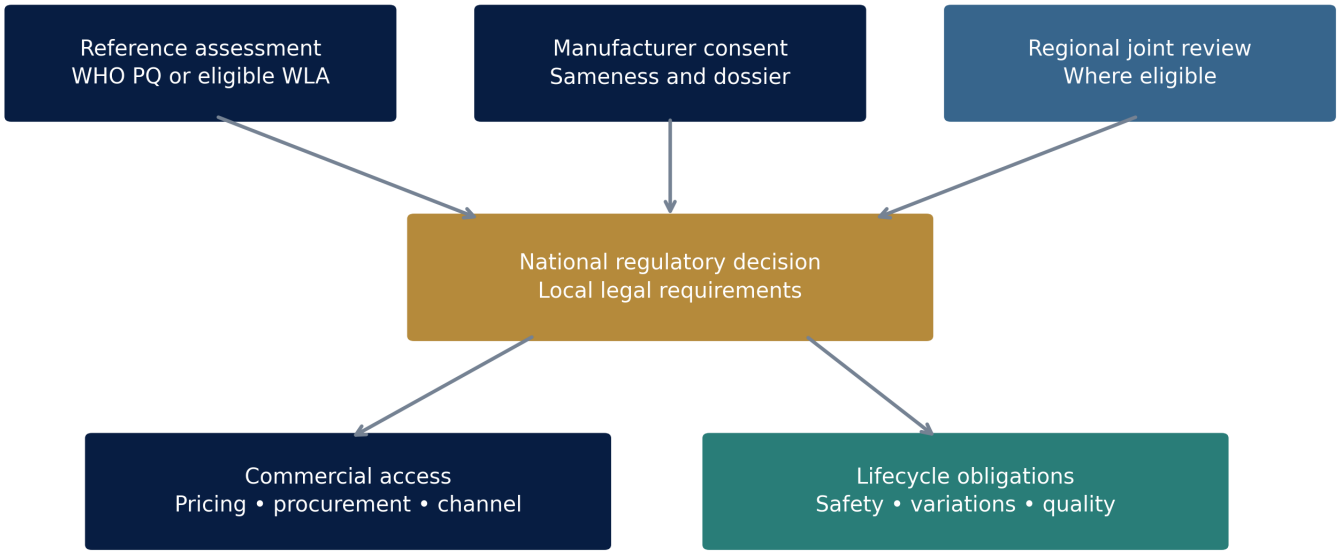
S17, Figure 4 (read directly) | Different milestone cohorts. Do not sum medians. Assessment includes applicant time.

Figure 9. Median validation, scientific assessment and registration times for generic/biosimilar cohorts at three authorities. Cohort n varies by milestone. Scientific assessment includes applicant response. Source: S17 Figure 4, read directly.

The stage data direct attention to validation and scientific assessment, but differing denominators prevent summing the medians into a total. A regulator should publish both elapsed and regulator-controlled clocks. A company should maintain a parallel query-response log and allocate accountable owners for technical replies. Without that separation, attributing all delay to the authority can conceal sponsor-side preparation problems.

4 Market access pathways and the economics of preparation

A credible filing strategy begins with product classification, prior approvals, dossier access and intended markets. Reliance can reduce repeated scientific work, but national authorization, fees and local requirements remain. The advantage is conditional on the product and evidence satisfying the applicable pathway. A reference-country certificate alone should never be treated as sufficient proof of eligibility.



S34–S36, S43–S44; Pharma Gate analysis | Regulatory cooperation does not replace the national decision or commercial access.

Figure 10. Regulatory reliance and market-access architecture. This is a procedural synthesis, not a universal legal flowchart. Sources: S34–S36, S43–S44; Pharma Gate analysis.

A practical sequence for choosing the route

Gate	Question to resolve	Action if unresolved
Product eligibility	Is this exact product permitted for import and eligible for the proposed route?	Stop fee commitments until current restrictions and classification are confirmed
Reference evidence	Is the approval or WHO PQ status current and are full reports shareable?	Secure consent and authority access; otherwise assess full-review route
Sameness	Do sites, formulation, strengths, specifications and indications match?	Prepare a transparent deviation matrix and obtain route confirmation
National completion	What local agent, legal documents, labels, samples and fees apply?	Obtain dated checklist and responsible local operator
Commercial launch	Who buys, pays, imports and maintains stock after authorization?	Separate regulatory approval milestone from launch readiness
Lifecycle	Who owns variations, safety reporting, quality complaints and recall execution?	Contract responsibility before the first supply

WHO collaborative pathways

The WLA CRP branch describes a 90-working-day decision commitment after all relevant information is available. It requires product sameness, reference reports and national participation. National fees and law still apply. The WHO PQ branch webpage says 90 days, while the overview says 90 working days. The workbook keeps the wording separate. Applicants should confirm the specific governing procedure and clock before using a commercial deadline. [S33–S35]

The practical opportunity is a reusable reference dossier with controlled national adaptations. This requires an auditable sameness assessment and rights to share non-public assessment and inspection information. A dossier with unresolved manufacturing-site changes may be unsuitable for the fastest route even when the brand has an eligible reference approval. Pharma Gate can identify this risk before a local agent is appointed or a fee is paid.

Published national targets are not a performance league table

Authority and route	Published standard	Clock and interpretation
Ghana standard / fast track / reliance	360 / 180 / 90 days	Working/calendar basis not specified on page; processing standards [S19]
TMDA domestic / imported / priority	60 / 180 / 90 days	Evaluation after complete application; query response evaluation separate [S20]
NAFDAC drug registration	240 working days	From acceptance, excluding applicant delays; dated May 2025 [S22]
NAFDAC FAQ	120 days	Conflicts with dated service standard; not adopted for forecast [S21]
Other focus countries	Not Publicly Verified	No comparable numeric route target validated in this review

Ghana’s service page and the OpERA medians refer to different constructs and cohorts. TMDA’s evaluation standard is not a complete elapsed-time forecast. Nigeria’s published 240-working-day process consists of 40 days verification, 50 inspection/sampling, 60 analysis, 68 final vetting and 22 approval/certificate. The sum reconciles to 240; it still excludes applicant delay and is a target rather than an observed median. [S19,S20,S22]

Fees must be current and product-specific

Rwanda’s version 4 tariff dated 31 December 2024 differentiates imported pharmaceutical and health products by origin: USD 300 from EAC, USD 750 from SRAs/WLAs and USD 2,000 from other sources for five-year registration. These are published categories, not an automatic discount for any product associated with an ML3 authority. The regulation’s explanatory annex includes GMP inspection in the imported registration fee. Confirm classification and any separate applicable services before paying. [S25]

Fee question	Treatment in the evidence workbook
Rwanda current published tariff	Three origin categories preserved; currency USD; version and locator recorded
Legacy Rwanda USD 1,250 imported fee	Not used as current; superseded-reference conflict recorded
Ghana current payable amount	Not Publicly Verified; official fee page identified, linked document not successfully parsed
Senegal current payable amount	Not Publicly Verified; fee decree identified, primary tariff not extracted
Remaining focus countries	Not Publicly Verified; no invented fee or currency conversion
All-in registration and launch cost	Not calculable from tariff alone; agents, translation, samples, logistics and lifecycle need quotations

Sources: S25,S26,S30,S32. A lower statutory tariff is not necessarily a lower total cost. The financially useful comparison is the product’s expected contribution after registration, dossier remediation, ongoing compliance, distribution and working capital. Where costs or timing are uncertain, a staged commitment is more defensible than an apparently precise national fee ranking.

Egypt illustrates the importance of reference evidence

Medicinal product pathway	Published eligibility basis	Implication for the dossier
Verification	At least two stringent authorities, or one reference authority plus WHO prequalification	Full product sameness, including CMC, must be demonstrated
Abridged	At least one stringent authority or WHO prequalification	Product sameness and eligible reference evidence remain necessary

Source: S27, version 4/2024, page 6. These medicinal-product criteria must not be transplanted into biological-product rules. A sponsor with one qualifying reference approval may have an abridged option without meeting verification eligibility. Obtain current confirmation of reference

acceptance, access to full reports and treatment of deviations before selecting the route. The separate biological guideline index identifies a June 2026 reliance procedure but does not establish identical eligibility. [S28]

Nigeria illustrates why admissibility comes first

NAFDAC's 28 October 2026 notice stops new applications for imported pharmaceuticals on its updated ceiling list. Renewals follow a 5+5 pathway requiring a local-manufacturing migration plan. The rule is list-specific. A sponsor must check the exact formulation and presentation rather than assume all imports are blocked or that all imports remain eligible. The applicable list and current interpretation should be retained with the product decision. [S23,S24]

For a foreign manufacturer, a commercially attractive Nigerian product may therefore require a local production partnership rather than an import-only registration strategy. For a local contract manufacturer, the same policy can create a diligence lead. Neither conclusion proves a viable contract: technical transfer, capacity, quality, pricing and buyer demand still need verification.

5 Harmonization is operational but national conversion remains decisive

AMA's operational start, treaty participation, scientific committees and product procedures are different milestones. Its own ratification page reports 33 Member States as of October 2026. The AU legal list dated 22 May 2026 separately records signature, ratification/accession and deposit dates. Older blank country cells are not used to assert current non-participation. A project should verify the latest legal position for each intended country. [S37–S40]

Layer	Verified evidence of operation	Remaining decision requirement
Continental AMA	Operations since Oct 2025; seven committees inaugurated Oct 2026 [S39,S40]	Confirm current product scope, call, fees and national implementation
AMRH continental pilot	EMA reports 21 assessed, 12 listed, 2 rejected, 7 withdrawn [S42]	A continental positive opinion is not a national marketing licence
EAC	Published CTD, joint review and abridged instruments [S44]	Check participation and national completion for the product
Southern Africa	WHO supports ZAZIBONA joint assessments [S43]	Confirm national submission and final decision obligations
West Africa	WAHO reports an actual Dec 2025 joint session [S45]	Confirm current submission window and participating authority actions
Procurement	APPM programme and framework tender; SPPS pilot preparation [S52–S54]	Eligibility, quality and purchase decisions remain distinct

A positive continental opinion is an intermediate asset

The continental pilot demonstrates a functioning assessment mechanism. Its 12 positive listings among 21 EMA-reported assessed products should not be interpreted as an approval probability for a new applicant. Withdrawals and rejections are different outcomes, while national registration is a further step. A company needs a conversion tracker: submitted to joint review, recommended, nationally filed, nationally authorized and commercially supplied. [S42]

The same product can be scientifically acceptable yet encounter national administrative delays, incomplete local labels or unresolved representation. Measuring only time to regional opinion hides this conversion risk. A multi-country mandate should allocate a named national completion owner and retain confirmation of authorization, rather than end its deliverable at a regional meeting decision.

Read the 2035 targets precisely

AFR/RC76/7 sets 2035 objectives of 15 ML3 NRAs, four at ML4 or WLA, and AMA designated as a WLA. It also targets 40 autonomous or semi-autonomous authorities, 20 eRIMS users, three RECs implementing joint assessments/inspections, and 30 NRAs prepared for public-health emergencies. These are targets within the WHO African Region, not achievements or a promise that every country reaches ML3. [S12, paragraph 16]

The annex and narrative differ on intermediate 2032 ML3 wording, while the annex REC baseline of zero sits alongside documented joint-assessment activity. This publication does not interpolate a smooth trajectory or infer that harmonization was absent. The appropriate institutional response is to clarify indicator definitions and publish a dated monitoring baseline. The long-term commercial implication is a plausible environment for convergence, with execution still dependent on current national practice.

6 Demand manufacturing and procurement must be assessed together

Published accounts agree that import dependence is substantial, but estimates vary in product coverage, geography, date and whether value or volume is measured. IFC describes imports exceeding 70% of medicines in Africa, while other publications use different estimates. This report does not turn these contextual statements into a harmonized 2026 market series or an investable import-substitution pool. [S48]

Import value alone would also be an incomplete opportunity measure. High-value originator products, pooled donor purchases and low-priced generics have different economics. A manufacturing thesis needs evidence at molecule, dosage-form, procurement-channel and price levels. A domestic-market gap is commercially meaningful only when demand is affordable, procurement is accessible and supply can meet the required quality at a sustainable landed cost.

What the verified industrial signals support

Signal	Verified fact or published target	What it supports
AIM2030	World Bank programme focuses on nine countries and an ambition to double capacity by 2030 [S46]	A policy and partner engagement map, not a bankable capital commitment
Quality upgrading	UNIDO reports over 100 GMP baseline assessments and country/regional roadmaps [S47]	Site remediation, training, validation and quality-service diligence
Morocco industrial base	WHO profile reports 39 production sites [S16]	Partner identification, followed by product and capacity verification
Senegal local production	UNIDO reports 95% import dependence and a 50% local-needs ambition [S47]	Targeted industrial diligence, not a validated market-size estimate
Vaccine incentives	Gavi AVMA envelope up to USD1.2bn over ten years from June 2024 [S49]	Eligibility-led financing work; no presumed entitlement
Existing transaction precedent	EUR500m Aspen loan package announced Sep 2024 [S50]	Evidence of financing structures for an established operator, not available funding for a new entrant
Technology-transfer precedent	EVA/Lilly report Egyptian insulin glargine approval Dec 2024 [S51]	A concrete regulatory/industrial collaboration example; expansion requires separate destination access

AIM2030 names Egypt, Ethiopia, Ghana, Kenya, Morocco, Nigeria, Rwanda, Senegal and South Africa. Two of these, Kenya and Morocco, do not have formal ML3 verified in the baseline. Conversely Mozambique, Tanzania and Zimbabwe are ML3-listed but not in that published focus set. Seven countries overlap. The implication is that industrial priorities and recognition are different filters. Neither set is a definitive investment shortlist. [S01,S46; Pharma Gate set comparison]

Procurement is a concrete opportunity with a distinct risk profile

Africa CDC reported eight APPM participation MoUs in October 2026. Its RFB002 invitation, issued 11 November, covers 172 products across medicines, diagnostics and PPE/consumables, with a 9 December 2026 deadline at 15:00 EAT. This invitation is for manufacturers outside AU Member States and their authorized suppliers; African manufacturers are covered separately. Framework agreements do not guarantee purchase allocation or a minimum commitment. [S52,S53]

A supplier screening exercise should therefore establish which invitation applies, the exact product specification, quality evidence, financial eligibility, manufacturing authorization and bid channel. A successful framework application is a permission to compete for or receive call-offs

under its terms, not a signed forecast of revenue. Working capital, payment protection and supply capacity must be evaluated against individual orders.

SADC's October 2026 account describes preparation towards the first SPPS pilot contracts. It is inappropriate to combine that preparatory stage with APPM participation or tender counts as though they were equivalent realized procurement volumes. Pharma Gate should track tender publication, qualification, framework award and paid deliveries separately. [S54]

7 Country intelligence and conditional market-entry priorities

The profiles below state what can be supported now, the strategic implication and the diligence that would change it. They are deliberately not ranked. A product without a reference approval, a WHO-prequalified generic, an imported biologic and a local manufacturing project can rationally generate different country sequences.

Egypt

EDA's medicines and vaccine recognition supports a credible institutional starting point for dossier and industrial partnership discussions. The medicinal-product reliance guideline distinguishes verification and abridged eligibility; biological reliance is addressed separately in the 2026 guideline index. [S03,S04,S27,S28]

Strategic interpretation. For an export-oriented Egyptian manufacturer, prioritize a destination-by-destination evidence pack rather than use EDA's ML3 as an automatic regional passport. The insulin collaboration reported by EVA/Lilly is a relevant technology-transfer precedent, with an access goal that remains a target. [S51]

Required diligence. Confirm the relevant product directorate, current version, reference approval, sameness and available assessment reports. Verify destination import rules, buyer qualification and distribution before promising export access.

Ethiopia

EFDA's ML3 announcement is dated September 2025. The registration guideline identifies eRIS-linked fee documentation and directs applicants to the applicable service-fee regulation. A current comparable fee and elapsed-time benchmark were not validated here. [S05,S30]

Strategic interpretation. AIM2030 identifies Ethiopia as a manufacturing focus. This supports early discussions on dossier systems, quality readiness and partner diligence, without proving factory competitiveness or immediate financing. [S46]

Required diligence. Request a current product-specific checklist and payable tariff, clarify the reference pathway, and verify import, procurement and payment arrangements. Test site economics and utilities separately from the regulator's maturity status.

Ghana

Ghana combines ML3 recognition with public standard, fast-track and reliance processing targets. The OpERA NAS cohort offers a historical signal, but the generic median and pathway data have unresolved internal inconsistencies. [S06,S19,S17]

Strategic interpretation. For an eligible reference-approved product, Ghana merits early pathway feasibility work. The basis is a visible procedure and relevant historical evidence, not a guarantee of an unusually fast registration. Generic launch forecasts should not use the disputed median.

Required diligence. Confirm scope, accepted reference evidence, complete-application clock and current fees. Build a credible local commercialization plan; a short regulatory pathway cannot compensate for absent demand or weak distributor execution.

Mozambique

WHO recognized ANARME at ML3 for medicines and imported vaccines in August 2026. The authority announced a SIRMED pilot in May for June–July operation; full rollout was not established by that announcement. [S07,S31]

Strategic interpretation. The institutional milestone supports a fresh market-entry review and demand for compliant dossier operations. Portuguese regulatory execution, local representation and post-market responsibilities are practical service areas to test with clients.

Required diligence. Confirm which submission system is operational, transition rules, product-specific route and current tariff. Verify the licensed import/distribution partner and actual buyers. No comparable observed approval median was validated here.

Nigeria

NAFDAC’s ML3 scope does not override product admissibility restrictions. The October 2026 ceiling update is a material trigger for imported-product screening. The public timeline sources conflict; the dated service page gives 240 working days excluding applicant delay. [S04,S21–S24]

Strategic interpretation. The most immediate mandate is a portfolio-level decision between eligible imports, local manufacturing partnerships and products to defer. A contract-manufacturing lead is conditional on the exact list coverage and a technically credible transfer plan.

Required diligence. Retain the current ceiling list, verify the precise formulation and presentation, confirm route and tariff, and obtain written clarity on any migration obligations. Model buyer payment, currency exposure and working capital independently.

Rwanda

Rwanda’s ML3 recognition covers medicines and non-producing vaccine regulation in the baseline. The current validated tariff provides origin-specific imported-product categories. The applicable interpretation must be confirmed for the product. [S08,S25]

Strategic interpretation. Rwanda is suitable for focused EAC pathway and partner diligence where a sponsor has a defined product and route. AMA's Kigali headquarters is not evidence that Rwanda automatically provides continental access or stronger product demand.

Required diligence. Confirm origin category, product scope, national documentation, EAC eligibility and local representative obligations. Do not budget the legacy USD1,250 fee as a current universal charge. Validate demand and logistics before using the market as a regional hub.

Senegal

Senegal's ML3 milestone was announced in December 2024. ARP's registration page describes the online portal and legal requirements, and identifies November 2026 committee and reliance-related decisions. A comparable current fee amount was not validated. [S08,S32]

Strategic interpretation. The Francophone market and documented industrial upgrading agenda support opportunities in dossier adaptation, GMP preparation and manufacturing partnerships. UNIDO's local-production ambition provides a policy signal, not an offtake contract. [S47]

Required diligence. Verify current implementation of the newly listed decisions, tariff decree, portal workflow and any regional pathway. Establish the buyer and distributor economics before assuming that regulatory recognition converts into manufacturing demand.

South Africa

The ML3 designation is for vaccines. It must not be presented as medicines-wide recognition. SAHPRA maintains an updated reliance guideline index; OpERA provides separate medicines-approval observations that do not expand the WHO designation scope. [S09,S07,S29,S17]

Strategic interpretation. An established manufacturing and financing precedent supports diligence on partnership, technology transfer and complex-product supply. The Aspen transaction demonstrates an announced financing structure, rather than finance available to an unrelated project. [S50]

Required diligence. Confirm the full current reliance guidance and product class, query and validation obligations, and the cohort appropriate for forecast planning. Audit manufacturing and commercial agreements before assuming regional production or sales capacity.

Tanzania

TMDA is ML3-listed for medicines and non-producing vaccines. Its public standards differentiate domestic, imported and priority applications. EAC publishes a suite of common dossier and abridged instruments. [S01,S10,S20,S44]

Strategic interpretation. Tanzania merits early EAC submission feasibility work for eligible products. The value is coordination and a documented national pathway, not automatic authorization throughout the community.

Required diligence. Confirm the route, dossier completeness criteria, product eligibility and national finalization. The public evaluation target excludes the need to understand query cycles and other launch activities. Obtain a current fee quotation and buyer-level demand evidence.

Zimbabwe

Zimbabwe’s supported status is ML3, not ML4. MCAZ is included in OpERA and in Southern African work-sharing context. Historical NAS observations are based on a very small 2024 cohort, and generic timelines vary by pathway. [S11,S17,S43]

Strategic interpretation. The opportunity is disciplined Southern African regulatory execution and transparent dossier tracking. An eligible facilitated pathway deserves assessment, while the historical cohort cannot determine a new product’s approval date.

Required diligence. Verify current route acceptance, national documents, fees and submission sequencing. Confirm the local importer’s capability and payment arrangements. Treat the major-line-extension inconsistency as unresolved rather than a usable benchmark.

Kenya

Kenya’s reported ML2 status and December 2026 ML3 objective remain separate from verified recognition. The January ministry statement claiming attainment conflicts with the WHO list and later ministry wording. [S13–S15,S01]

Strategic interpretation. Kenya remains relevant for manufacturing and EAC pathway diligence despite that unresolved designation claim. AIM2030 inclusion demonstrates industrial-policy attention; it is not evidence that the ML3 objective has been achieved. [S46,S44]

Required diligence. Verify the latest WHO announcement before changing the recognition field. Do not defer all regulatory preparation until the target date; assess current product requirements, partner quality, national route and actual commercial demand.

Morocco

Formal maturity classification was not established. WHO describes AMMPS reform, an institutional development plan and a manufacturing base of 39 production sites. These facts support a different conclusion from an invented ML2 or ML3 label. [S16]

Strategic interpretation. Industrial partnerships merit investigation on their own evidence. Morocco’s inclusion in AIM2030 supports engagement, while factory capabilities, product approvals and export economics must be verified individually. [S46]

Required diligence. Request current agency procedures and applicable fees, verify the legal manufacturing entity and audited GMP status, and determine destination access for the exact product. Laboratory recognition is not a substitute for a national system designation.

Zambia

ZAMRA is not on the verified August ML3/4 list. This report assigns no alternative WHO level. OpERA offers observed performance, with a three-application NAS cohort in 2024 and material variation across other pathways. [S01,S17]

Strategic interpretation. Zambia is useful for demonstrating why operational evidence and maturity designation must be kept distinct. A Southern African access project should examine actual work-sharing and national requirements rather than exclude or select the market by badge alone. [S43]

Required diligence. Confirm the live route and national completion process, investigate pending-case age and sponsor-response requirements, and obtain a current tariff. Apply a contingency to commercial timing based on product-specific diligence rather than a country-wide speed rank.

8 Commercial and investment opportunity framework

The strongest immediate opportunity is to reduce avoidable uncertainty before larger commitments. Regulatory services, quality preparation and commercial validation can be structured as bounded mandates with observable outputs. Manufacturing assets require more evidence and longer commitments. The following matrix is a screening framework proposed by Pharma Gate, not a list of confirmed investment projects.

Opportunity	Evidence trigger	Commercial offer to test	Condition that blocks commitment
Reliance and registration services	WHO CRP and national reliance instruments [S27–S36]	Eligibility review, sameness matrix, reference-report access and submission plan	Unshareable reports, product differences or route not accepted
Local manufacturing / contract transfer	Nigeria ceiling policy; technology-transfer precedent [S23,S51]	Partner shortlist, technical gap assessment and transfer diligence	No viable quality-compliant cost or buyer commitment
Quality infrastructure	UNIDO GMP roadmaps and institutional targets [S47,S12]	Validation, training, laboratory and quality-system implementation	Unfunded remediation or no accountable site management
Distribution and market entry	National authorization and APPM supplier requirements [S24,S53]	Licensed partner diligence, channel economics and supply plan	Unverified licence, weak payment or inadequate storage
Vaccine manufacturing diligence	AVMA and manufacturing programmes [S49,S46]	Eligibility mapping, technology and regulatory development plan	No product fit, PQ path, sustainable demand or financing

Opportunity	Evidence trigger	Commercial offer to test	Condition that blocks commitment
Regional procurement support	APPM tender and SPPS preparation [S52–S54]	Bid/no-bid review, compliance matrix and call-off risk assessment	Wrong manufacturer geography or no financial/quality eligibility
Business intelligence subscription	Documented conflicts and changing pathways	Versioned alerts tied to clients' products and markets	No material decision relevance or unreliable source coverage

An investment sequence with explicit stop conditions

First establish the product and buyer. Define dosage form, quality standard, annual demand evidence, tender or private channel, realistic price and payment period. Separate aspirational national demand from financially accessible demand. If the buyer and procurement route are unverified, commission demand diligence before selecting a manufacturing technology.

Second establish the legal and technical route. Verify import restrictions, national authorization, recognized reference evidence, GMP expectations, environmental obligations, technology rights and post-market responsibilities. Resolve whether the project supplies finished products, fill-and-finish, contract production or an input such as packaging. These are different businesses with different regulatory and scale requirements.

Third validate site economics. Audit installed and effective capacity, batch size, yields, quality release, utilities, maintenance, skilled labour, imported inputs, waste and cold-chain requirements. Use a product-level cost comparison with the relevant imported alternative. A regulatory designation cannot stand in for these operating assumptions.

Fourth structure capital against milestones. Commit successive tranches to validated demand, a credible remediation budget, technology transfer, dossier readiness, national authorization and initial supply. Negotiated offtake and quality acceptance should precede full utilization assumptions. A programme's announced envelope or a precedent transaction is not evidence that the project has secured finance.

Sensitivity without an invented score

Uncertain condition	Base diligence assumption	Adverse case to test	Decision affected
Reliance eligibility	Reference reports available and product same	Full review required or additional evidence needed	Sequence, dossier cost and launch contingency
National conversion	Joint opinion followed by complete local filing	Local document or policy delay	Inventory commitment and revenue timing
Buyer demand	Documented order or credible offtake	Framework without call-offs or lower order volume	Plant scale, utilization and working capital
Manufacturing cost	Validated yield and input quotation	Lower yields, higher utilities or currency cost	Make/buy choice and price competitiveness
Quality remediation	Audited and funded action plan	Additional validation or facility changes	Capex staging and delivery readiness

No financial ranges are fabricated for these cases. In a client mandate, replace the assumptions with quoted costs, evidenced volumes and dated regulatory milestones. The key test is whether the recommended action survives loss of the fastest route or a slower demand ramp. If it does not, defer irreversible capital until the uncertainty is reduced.

9 Recommendations by decision-maker

Regulatory authorities

Immediate. Publish a single authoritative service-standard register with product classes, pathway eligibility, clock start/stop definitions, fee version and contact route. Reconcile contradictory pages and make superseded documents identifiable. Publish approval cohorts with n and distinguish applicant time from regulator-controlled time. The conflicts found in this review show the commercial cost of ambiguous public information.

Medium term. Build end-to-end tracking from receipt through validation, queue, scientific review, queries and decision. Introduce route-specific service monitoring and a pending-case age profile. Use reliance where legally appropriate while strengthening local vigilance and market surveillance. Evaluate implementation through observed cohorts rather than the existence of a guideline alone. [S36,S12]

Longer term. Link workforce and financing plans to documented workload and institutional development gaps. Sustain quality management and retention of specialized assessors. Recognition should be maintained through performance and improvement, while public reporting makes the commercial effect of reform measurable.

Pharmaceutical companies

Immediate. Screen the exact product against import restrictions and route eligibility before committing fees. Build a single controlled master dossier and a country adaptation matrix. Assign responsibility for local documents, query response, national completion and lifecycle obligations. For Nigeria, record the ceiling-list check as a mandatory portfolio decision step. [S23,S24]

Medium term. Compare the same product class and pathway across proposed markets, including unresolved cases and sponsor response time. Develop reference-report sharing rights and a maintained sameness assessment. Use joint procedures where feasible, supported by national completion owners. Tie launch stock and promotional commitments to regulatory and buyer milestones.

Longer term. Select manufacturing and distribution partnerships on audited quality, sustainable cost and demand. Review portfolios when localization policies change. Maintain a market-entry playbook by product type, rather than a static country attractiveness list.

Manufacturers and investors

Immediate. Commission product-level demand, offtake and site diligence. Treat existing manufacturing, ML3 recognition and programme focus as separate evidence. Verify the financing status of a named project directly; announced packages in this report are historical precedents or programme envelopes.

Medium term. Prioritize quality remediation, technology-transfer readiness and supply contracts that can support sustainable production. Use staged capital commitments and independently validated technical milestones. Compare contract manufacturing with new capacity before assuming a greenfield plant is necessary.

Longer term. Build regional production and distribution options only where authorized access, logistics and buyer economics support scale. Maintain contingency for imported inputs, supplier concentration, payment delays and changes to procurement preferences. These are diligence variables, not quantified risk estimates in this report.

Regional institutions

Immediate. Publish current joint-procedure scope, submission windows, eligible products, fees and national completion rules in one versioned location. Clarify regional strategy indicator definitions and reconcile the different intermediate milestone statements. Report legal treaty milestones distinctly from operational participation. [S12,S38,S42–S45]

Medium term. Track conversion from joint recommendation to national authorization and first supply. Distinguish administrative non-completion from scientific rejection. Create interoperable data definitions and secure assessment-report exchange. Use procurement data to inform demand signals without presenting frameworks as binding offtake.

Longer term. Align regional regulatory capacity, quality infrastructure, manufacturing readiness and pooled procurement. Evaluate reforms by access outcomes and sustained quality, not only the number of memoranda, meetings or formal guideline adoptions.

Pharma Gate

Immediate. Establish a clear editorial standard for Insights: dated evidence, traceable sources, product-scope fields, explicit exclusions and a correction log. Use this report to demonstrate the service through a client decision, not through a generic research promise. Keep the public preview distinct from tailored client work and preserve confidentiality in submitted product information.

Medium term. Develop reusable evidence modules for product-country route selection, import admissibility, partner diligence, manufacturing readiness and procurement qualification. Sell or otherwise offer a defined output and turnaround only after validating delivery capacity and owner-approved commercial terms. Existing website services describe free advisory access; this research does not authorize a change to pricing. [S55]

Longer term. Build a maintained intelligence database with versioned rules and cohort definitions. Create alerts only for changes that affect a client's actual portfolio. The strongest differentiator is verified interpretation that prevents an unsuitable filing or premature investment, supported by documented national confirmation where needed.

10 A practical implementation roadmap

This is a proposed execution sequence for a product-country mandate. The time windows are management planning intervals, not regulatory deadlines or a commitment that Pharma Gate has already staffed the service.

Planning interval	Work and accountable lead	Reviewable output	Release condition
First 2 weeks	Regulatory lead: classify product, verify admissibility and reference evidence	Product-country route matrix and source pack	Material status and scope conflicts resolved or explicitly carried
Weeks 3–6	Regulatory and local partner leads: obtain current route and fee confirmation	Country checklists, quotations and deviation assessment	Eligible route and complete documentation plan
Weeks 6–12	Commercial and technical leads: validate buyer and supply economics	Partner diligence and make/buy or bid/no-bid recommendation	Evidence supports demand, quality and sustainable cost
Following quarter	Submission and quality owners: implement approved plan	Submission record, query tracker and GMP actions	National requirements satisfied and buyer milestones monitored

Planning interval	Work and accountable lead	Reviewable output	Release condition
Ongoing	Evidence owner: monitor material changes	Versioned alerts and outcome review	Defined client relevance; claims checked before issue

A decision-focused performance dashboard

Track the proportion of candidate products with confirmed pathway eligibility, dossiers with closed critical gaps, national submissions accepted, queries answered within the sponsor’s agreed time, and joint opinions converted to national authorizations. Track procurement qualification separately from framework awards, call-offs and payment. Define denominators and reporting dates before reporting rates. No baseline performance for these proposed services is claimed.

11 Implications for Pharma Gate Insights

The research supports five concrete offerings. A product-country entry dossier should answer whether to file, by which route, with which partner and with what unresolved evidence. A reliance assessment should identify shareable reference reports and sameness gaps. A manufacturing readiness mandate should establish technical and regulatory prerequisites for a specific investment. A procurement brief should deliver a verified bid/no-bid rationale. A regulatory change monitor should identify which portfolio decisions need revision.

Intelligence product	Core client decision	Required output and boundary
Product and country entry dossier	Where should this product enter first?	Conditional shortlist, pathway eligibility, fees, partner and buyer gaps; no unsupported ranking
Reliance feasibility assessment	Can existing evidence reduce duplicated work?	Reference-document access and sameness matrix; no approval guarantee
Manufacturing readiness review	What must be true before capital is committed?	Audited evidence requirements, quality gaps and milestone plan; engineering audit separately scoped
Procurement qualification brief	Should the company bid now?	Current notice, product and geographic eligibility, evidence checklist and call-off risks
Regulatory change monitor	Which decisions need revisiting?	Dated change log linked to products and countries; no generic alert volume target

The website specification delivered separately provides the publishing and inquiry architecture. Publication should use the final approved report and a concise executive preview, with the original

Pharma Gate identity. It should display the research cut-off and version beside each download. There has been no change to the live platform during this assignment.

Appendix A Evidence conflicts and exclusions

Issue	Evidence conflict or limit	Publication treatment
C01	Ghana generic median: Table 1 203; Figure 3 and prose 69; IQR23–136 excludes 203	Preserve both; omit Ghana from median chart; no correction assumed
C02	Ghana review counts: Table 2 0+50+1570+0=1620 versus total 1637	Do not calculate or chart Ghana review-model percentages; 17 unreconciled
C03	MCAZ major extensions: Table 1 2024 median 461; Table 2 count 0	Exclude extension comparison pending author clarification
C04	Kenya recognition: January ministry says attained ML3; WHO list omits Kenya; later ministry says pursuing	WHO designation not verified; retain reported ML2 separately and December target
C05	Nigeria service standards: FAQ 120 days versus dated service page 240 working days	Use dated 240-working-day published standard provisionally; request written case confirmation
C06	AFRO milestones: 2032 prose at least 3 additional ML3; annex one additional after 2029	Do not construct interpolated maturity trajectory; display 2035 endpoints only
C07	AFRO REC baseline: Annex 0 RECs versus documented joint work	Indicator baseline not used as proof no joint assessment operates
C08	Zimbabwe ML4 claim: No WHO evidence supporting ML4; current list ML3	Reject unsupported ML4 claim
C09	Legacy Rwanda tariff: Older regulation 1250 USD for imported human medicines; v 4 has origin tiers 300/750/2000	Use v 4 source tiers; do not quote 1250 as current
C10	CRP day units: Overview/WLA90 working days; PQ branch 90 days	Keep branch wording and obtain applicable procedure clock; no silent conversion
C11	Ghana pathway cohorts: Table 2 verification 0; Figure 5 generic verification n 17	Retain figure-specific counts; no merger with Table 2 review mix

Appendix B Definitions and reproduction notes

Term or field	Definition and use
ML3 or ML4	WHO GBT system maturity within the published product scope
WLA	WHO-listed authority designation; not assumed from ML3 or ML4 alone
NAS	New active substance; not interchangeable with all new registrations
Generic/biosimilar	Combined source category; standalone biosimilar inference not supported
Calendar days	Elapsed days including weekends and holidays; OpERA includes applicant time
Working days	Source-defined business-day clock; no generic conversion used
Median and IQR	50th percentile and 25th–75th range; not confidence intervals
n	Applications included in the stated cohort; milestone and category counts may differ
Target	Published administrative or policy objective; not realized performance
Not Publicly Verified	No applicable observation validated in this research; never zero
Recognition count	Distinct listed African countries; nine medicines scopes, ten vaccine scopes
Geography	Country grouping is descriptive; WHO AFRO, geographic Africa and AU membership differ
Figure reproduction	Charts are original redraws from cited observations; no raw distributions invented
Calculation	NAS n total 30+3+12+3=48; Ghana share30/48=62.5%; approval count total1637+255+317+71=2280
Reconciliation	Ghana review sum0+50+1570+0=1620, gap17; disputed fields excluded
Set comparison	AIM2030 nine-country set intersects August ML3 country set in seven countries
Cartography	Natural Earth boundaries are schematic and do not express a position on sovereignty

References and source notes

All online sources were accessed on 22 November 2026. Publication dates below distinguish document dates, reporting periods and undated webpages. Direct URLs are provided so the reader can inspect the underlying evidence. Source register details and evidence flags are retained in the workbook. Citations refer to documentary evidence, not endorsement by the cited institution.

S01 WHO. List of NRAs operating at ML3 and ML4. 2026-08-24. pp 1–3, August 2026. Downloaded and visually checked. Ghana, Nigeria and Tanzania year cells contain two years without scope-specific mapping.
https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/wla/list-of-nras-operating-at-ml3-and-ml4.pdf?sfvrsn=ee93064f_32

S02 WHO. Global Benchmarking Tools. Undated. Overview and product coverage.
https://www.who.int/tools/global-benchmarking-tools

S03 WHO. Egypt medicines regulation reaches ML3. 2024-12-20. Announcement.
https://www.who.int/news/item/20-12-2024-egypt-s-regulatory-system-reaches-who-maturity-level-3-in-medicines-regulation

S04 WHO. Egypt and Nigeria achieve high maturity level. 2022-03-30. Announcement.
https://www.who.int/news/item/30-03-2022-egypt-and-nigeria-medicines-regulators-achieve-high-maturity-level-in-who-classification-and-who-launches-list-of-regulatory-authorities-that-meet-international-standards

S05 WHO. Ethiopia reaches ML3. 2025-09-30. Announcement.
https://www.who.int/news/item/30-09-2025-ethiopia-achieves-major-milestone-in-medicines-regulation-reaching-who-maturity-level-3

S06 WHO. Ghana bolsters medicines regulatory system. 2020-05-13. Announcement.
https://www.who.int/news-room/feature-stories/detail/ghana-bolsters-medicines-regulatory-system-guarantees-product-quality

S07 WHO. Mozambique strengthens medicines and imported vaccines regulation. 2026-08-24. Announcement; South Africa retention.
https://www.who.int/news/item/24-08-2026-mozambique-strengthens-regulation-of-medicines-and-imported-vaccines--boosting-health-protection

S08 WHO. Senegal and Rwanda achieve ML3. 2024-12-05. Assessment completed October 2024.
https://www.who.int/vanuatu/news/detail-global/05-12-2024-senegal-and-rwanda-achieve-who-maturity-level-3-in-medicines-regulation

S09 WHO. South Africa vaccine regulator reaches ML3. 2022-10-05. Assessment completed September 2022.
https://www.who.int/news/item/05-10-2022-south-africa-s-vaccine-regulator-reaches-new-who-level-to-ensure-safety-quality-effectiveness

S10 WHO AFRO. Tanzania first to reach level 3. 2018-12-03. Benchmarking May 2018; separate WHO feature reports classification November 2018.
https://www.afro.who.int/countries/united-republic-tanzania/news/tanzania-food-and-drug-authority-becomes-first-reach-level

S11 WHO. Zimbabwe reaches ML3 for medicines. 2024-06-14. Assessment finalized May 2024.
https://www.who.int/news/item/14-06-2024-zimbabwe-becomes-the-sixth-country-in-africa-to-reach-who-maturity-level-3-in-regulation-of-medicines

S12 WHO AFRO. Regional strategy on regulation of medical products AFR/RC76/7. 2026-08. paragraph 16, annex table 1. Adopted 26 August 2026; file hosted October 2026. WHO African Region is not geographic Africa.
https://afro.who.int/sites/default/files/2026-10/AFR-RC76-7%20Regional%20strategy%20on%20regulation%20of%20medical%20products%20in%20the%20African%20Region.pdf

S13 Kenya News Agency. Kenya accelerates reforms to achieve ML3. 2026; exact publication date Not Publicly Verified. Reported ML2 and December 2026 target. Search-index text verified; full page timed out. Publication day not reliably resolved.
https://www.kenyanews.go.ke/kenya-accelerates-regulatory-reforms-to-achieve-who-ml3-status/

S14 Kenya Ministry of Health. BioVax strategic talks. 2026-01-13. body dated 12 January 2026. Contains unsupported claim Kenya already ML3; contradicted by WHO list and subsequent ministry statements.
https://www.health.go.ke/cs-duale-holds-strategic-talks-kenya-biovax-institute-local-vaccine-manufacturing

S15 Kenya Ministry of Health. Government calls for stronger private sector collaboration. 2026-11-11. ML3 still being pursued.
https://www.health.go.ke/index.php/government-calls-stronger-private-sector-collaboration-reduce-healthcare-costs

S16 WHO. Morocco results report country profile. 2025 reporting period. Regulatory reform and manufacturing. Undated online profile; no formal ML recognition established.
https://www.who.int/about/accountability/results/who-results-report-2024-2025-eob/country-profile/2025/morocco

S17 Chisha et al; BJCP; CIRS repository. OpERA African review models and timelines 2020–2024. 2026-10-26. Tables 1–2; methods 2.5; figures 2–5. DOI 10.1002/bcp.70849; CC BY. Internal inconsistencies recorded in the conflict register. Downloaded primary article.
https://cirsci.org/wp-content/uploads/dlm_uploads/2026/11/Chisha-2026-Analysis-of-regulatory-review-models-and-approval-timelines-across-African-regulators-using-OpERA.pdf

S18 CIRS. African medicines regulatory approval timelines. 2026-11. Study interpretation. Coauthor institution, corroborating explanation; not independent dataset.
https://cirsci.org/publications/african-medicines-regulatory-approval-timelines/

S19 Ghana FDA. Allopathic registration. Undated. Service timelines.
https://fdaghana.gov.gh/services-2/product-registration/allopathic-registration-3/

S20 TMDA. Procedures for marketing authorization. Undated. Service standards table. Indexed authority page verified; full fetch intermittent.
https://tmda.go.tz/pages/procedures-for-market-authorization

S21 NAFDAC. Drug registration and regulatory FAQs. Undated. 120 days claim. Conflicts with service page dated May 2025.
https://nafdac.gov.ng/about-nafdac/nafdac-organisation/directorates/drug-regulations-registration-drr-directorate/about-drr/

S22 NAFDAC. Product registration and regulation. 2025-05-27. 240 working days; process table. Applicant delays excluded; not observed performance.
https://nafdac.gov.ng/our-services/product-registrationevaluation/

S23 NAFDAC. Ceiling list update. 2026-10-28. Notice. List-specific ban on new imported product applications and 5+5 renewals.
https://nafdac.gov.ng/nafdac-ceiling-list/

S24 NAFDAC. Imported drug registration guidelines. 2025-01-08. pp 2 onward. Review date 2030 is not publication date.
https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/DR_And_R_Guidelines/Guidelines-for-Registration-of-Imported-Drug-Products-in-Nigeria-Human-and-Veterinary-Drugs.pdf

S25 Rwanda FDA. Regulations governing tariffs fees version 4. 2024-12-31. Annex I Part I; Annex III. Replaces legacy fee reference. Origin categories need product-specific interpretation.
https://www.rwandafda.gov.rw/fileadmin/user_upload/RwandaFDA/E-Library/Guidance/Fees_eRegulations_Governing_Fees_Rwanda_FDA_31DECEMBER2024.pdf

S26 Ghana FDA. Fees and charges. Undated. Linked fee document. Download target exceeded web parser limit; no current amount validated.
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