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ORIGINAL ARTICLE

Operationalization of the African Medicines Agency: Retrospective evaluation of the continental centralized pilot procedure timelines to recommendation and national registrations

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Aims: Regulatory inconsistency across Africa causes duplicative assessments, prolonged approvals, and delayed medical access. To inform the African Medicines Agency (AMA), the African Medicines Regulatory Harmonisation (AMRH) piloted Africa's first continental scientific evaluation of human medicinal products. This study evaluates the pilot's performance and how scientific opinions translated into national decisions.

Methods: A mixed-methods evaluation used regulatory datasets from the pilot. Data included assessment timelines, GMP inspections, and national actions. Thematic analysis identified uptake determinants.

Results: Of 64 expressions of interest, 24 progressed to evaluation, and 12 received positive opinions. Ten met the ≤210-day target. Twenty-four GMP inspections found deficiencies aligned with global standards. National uptake: full reliance for 7 products (58%); sequential reliance for 3 (25%); separate assessment for 2 (17%). Some products registered in up to 23 countries within a median of 77 working days post-recommendation. Uptake variability reflected legal authority, administrative requirements and submission strategies.

Conclusions: The pilot shows a continent-wide regulatory mechanism is feasible and can produce trusted scientific outputs and enable reliance-based national decisions in Africa. Despite widespread reliance, heterogeneity in procedures and sequencing affected registration time. These findings provide empirical evidence for AMA scale-up, emphasizing the need for harmonised pathways, streamlined administration and digital infrastructure.

KEYWORDS
African Medicines Agency, centralized procedure, continental listing, pilot study, regulatory reliance

No single clinical principal investigator was designated as this was a regulatory systems evaluation without direct patient contact.

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1 | INTRODUCTION

Access to safe, effective and quality-assured medical products remains inconsistent across Africa where regulatory systems are fragmented and vary widely in capacity. Nine out of 54 National Regulatory Authorities (NRAs) in the region operate at a maturity level sufficient to perform core regulatory functions consistently according to the WHO Global Benchmarking Tool.[1,2] Such variability contributes to the duplication of scientific assessments, prolonged and unpredictable registration timelines and delays in access to essential medicines problems well documented across low- and middle-income countries.[3–5]

Globally, regulatory reliance has emerged as a pragmatic strategy to reduce duplication while maintaining national sovereignty. The WHO defines reliance as the use of another authority's scientific assessment to inform national decision-making supported by good governance and trust between regulators.[6] Evidence shows that structured reliance can improve efficiency, strengthen regulatory convergence and optimize limited resources in constrained settings.[7] International collaborative models including the European Medicines Agency's coordinated assessment network, WHO Prequalification and the WHO Collaborative Registration Procedure illustrate how shared scientific opinions can accelerate access when uptake mechanisms are robust.[8–10]

In Africa, reliance efforts have been pursued mainly through regional harmonization initiatives such as the Southern African Development Community's ZaZiBoNa process, the East African Community's joint assessment procedure, the West African Health Organization's ECOWAS mechanisms and the Intergovernmental Authority on Development's (IGAD) regional regulatory coordination efforts.[11–14] These initiatives demonstrate that work-sharing is feasible and can shorten timelines; however, evaluations highlight persistent challenges including voluntary participation, inconsistent national uptake, limited legal provisions for reliance and structural capacity constraints.[4,15]

The creation of the African Medicines Agency (AMA) represents a major shift towards continent-wide coordination. The AMA Treaty and corresponding African Union decisions mandate AMA to support joint scientific assessments, coordinated inspections and structured reliance pathways while respecting national regulatory authority.[16–19] This institutional architecture builds on the African Medicines Regulatory Harmonization (AMRH) programme and continental policy frameworks that call for reducing duplication and ensuring equitable access across countries with differing regulatory capacities.[20]

To generate empirical evidence for AMA operationalization, the AMRH programme implemented the first continental pilot study for the scientific evaluation and listing of human medicinal products between 2023 and 2025. The pilot study tested whether harmonized, continent-wide assessment and Good Manufacturing Practice (GMP) inspection processes could produce credible scientific opinions and whether NRAs would translate these into national regulatory decisions. Although regional initiatives have produced shared assessments, no prior study has analysed a continental procedure or systematically mapped its downstream national uptake.

The aims of the study were to evaluate the continental listing pilot study as a regulatory systems intervention to test (1) the feasibility and performance of the continental assessment and inspection procedure; (2) how NRAs apply reliance to convert the issued continental scientific opinions into national regulatory decisions or product registration; and (3) the legal, procedural and institutional factors influencing uptake. These findings provide the first empirical evidence on continental-level assessment and reliance in Africa and offer critical insights for AMA's centralized process design and future implementation. Furthermore, this study was designed to generate evidence to support institutionalization and sustainability of reliance-based regulatory functions to be implemented under the AMA.

What is known about this subject

- Regulatory fragmentation across African countries has led to duplicated scientific assessments, prolonged approval timelines and delayed access to essential medical products.
- Regional harmonization initiatives in Africa (e.g., EAC, SADC, ECOWAS) have demonstrated that work-sharing is feasible, but challenges remain including voluntary participation, inconsistent national uptake and limited legal provisions for reliance.
- No prior empirical study has evaluated a continent-wide centralized regulatory procedure for human medicinal products in Africa or systematically mapped its downstream national registration outcomes.

What this study adds

- This study provides the first empirical evidence that a continent-wide centralized regulatory procedure can produce trusted scientific opinions with 83% of listed products meeting the ≤210 working-day target.
- National uptake demonstrated active reliance, with seven products (58%) registered through full reliance across 31 countries within a median of 77 working days post-listing.
- Variability in national registration timelines reflected differences in legal frameworks, administrative procedures and applicant submission strategies, highlighting key areas for AMA operationalization.

2 | METHODS

2.1 | Study design

A mixed-methods programme evaluation of Africa's first continental centralized procedure for the scientific evaluation and listing of human medicinal products was conducted and implemented under

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the AMRH initiative. The pilot study was conceived as a regulatory systems intervention designed to test core functions anticipated for the AMA including joint scientific assessment, coordinated GMP inspections and reliance-based national decision-making. Mixed-methods designs are appropriate for complex regulatory and health-system interventions where quantitative performance metrics must be interpreted alongside institutional and contextual factors influencing implementation.[21,22]

2.1.1 | Setting: The continental listing centralized procedure

The pilot study was operated through AMRH governance structures. Scientific assessments and GMP inspections of manufacturing sites involved were conducted by experts from African NRAs under the oversight of the Evaluation of Medicinal Products Technical Committee (EMP-TC) and the GMP Technical Committee (GMP-TC), respectively. The final decisions were issued by the AMRH Steering Committee, which led to products being issued with a positive opinion being listed in the Green Book, a process referred to as *Continental Listing*. Guidelines, procedures, templates, eligibility criteria and performance benchmarks were predefined using the WHO Good Reliance Practices and African Union regulatory policy frameworks.[6,17] The continental listing was to provide a consolidated scientific opinion but not to grant marketing authorization in participating countries for the national NRAs retain full legal authority.

2.2 | Data sources

Three categories of routinely generated regulatory data were analysed:

1. Continental procedural data: including expressions of interest, dossier screening and validation outcomes, scientific assessment reports, GMP inspection reports, committee deliberations and listing decisions maintained by the AMRH Secretariat.[23]
2. National regulatory data: country-reported actions following continental scientific opinion, including reliance modality, national submission status and marketing authorization decisions.[23]
3. Regulatory policy and procedural documents: including the AMA Treaty, continental guidance, and reliance frameworks from WHO and the International Coalition of Medicines Regulatory Authorities (ICMRA).[6,17,24]

Data were accessed for research purposes between 20 January 2026 and 26 March 2026. The authors did not have access to any information that could identify individual patients or human participants during or after data collection, as the dataset consisted solely of de-identified regulatory procedural data, product-level assessment outcomes and aggregate national uptake statistics.

2.3 | Quantitative analysis

Descriptive statistics were used to characterize the pilot study pipeline, assessment timelines, GMP inspection outputs and post-listing decision national uptake. Official AMRH procedural timelines were measured from dossier acceptance to Steering Committee decision, consistent with pilot study protocol definitions. Total elapsed time from dossier submission to listing was estimated separately. GMP inspection findings were categorized by deficiency type and severity following harmonized international definitions.

National uptake was analysed at the product–country level. Reliance modalities were categorized as follows:

- Full reliance: The continental scientific opinion was the primary basis for national approval, with only administrative checks added.
- Supplemented reliance: Continental assessment was implemented with the addition of specific national queries or additional procedural steps.
- Sequential review: A separate national scientific assessment was undertaken following the review by the AMRH

Missing national data were resolved through cross-checking with NRAs and the AMRH Secretariat's Evaluations coordinator where feasible.

2.4 | Qualitative analysis

To understand the legal, institutional and procedural factors influencing national uptake of continental scientific opinions, a retrospective qualitative document analysis of regulatory records generated during and immediately following the pilot study was conducted. Data sources included (i) written feedback from NRAs submitted to the AMRH Secretariat following continental listing; (ii) governance records from EMP-TC, GMP-TC and Steering Committee meetings; (iii) national reliance policies or procedural guidelines referenced by NRAs during post-listing communications; and (iv) correspondence between applicants and NRAs where relevant to understanding regulatory decisions.

The analysis followed the six-phase framework for thematic analysis described by Braun and Clarke.[25] This approach was selected for its flexibility and suitability for identifying patterns across diverse textual data sources. The phases were operationalized as follows:

- Phase 1. Familiarization with data: All documents were reviewed iteratively by the lead author to gain an understanding of the content and to note initial observations.
- Phase 2. Generating initial codes: A deductive coding structure was developed based on realist evaluation concepts context, mechanism, outcome[26,27] and implementation science frameworks describing determinants of regulatory uptake.[28] Codes captured references to legal authority for reliance, procedural alignment, administrative requirements, resource constraints and institutional

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behaviours. Inductive coding allowed additional themes to emerge from the data.

- Phase 3. Searching for themes: Codes were grouped into candidate themes through iterative discussion among the research team. Themes were organized around factors that appeared to enable or impede uptake.
- Phase 4. Reviewing themes: Themes were checked against the original data and refined to ensure internal coherence and external distinctiveness. Discrepancies were resolved through team discussion.
- Phase 5. Defining and phrasing of themes: Final themes were clearly defined, with each linked to illustrative data excerpts. Themes focused on legal authority, procedural alignment, administrative sequencing and institutional factors influencing reliance.
- Phase 6. Producing the report: Findings were integrated into the interpretation of quantitative uptake patterns and are presented in the discussion section.

Coding was managed using a combination of spreadsheet software and manual annotation. To enhance interpretive validity, findings were triangulated across data sources and reviewed by co-authors with direct involvement in the pilot study.[29] No qualitative analysis software was used; coding was conducted manually by the lead author with regular team validation.

2.5 | Ethical considerations

Ethical approval for this study was granted by the University of Hertfordshire's Health, Science, Engineering and Technology Ethics Committee with UH protocol number 2070 ST HSET 2026. The study used secondary institutional data generated through routine regulatory operations. The study was also consistent with WHO guidance for programme evaluation.[22]

2.6 | Nomenclature of targets and ligands

Key protein targets and ligands in this article are hyperlinked to corresponding entries in http://www.guidetopharmacology.org and are permanently archived in the Concise Guide to PHARMACOLOGY 2025/26.[30,31]

3 | RESULTS

3.1 | Data characteristics of the continental listing pilot study

The pilot study received 64 expressions of interest (EOIs) from applicants. Following screening against predefined eligibility criteria, 24 products (38%) were shortlisted for full continental evaluation. The reduction from 64 to 24 was due to some EOIs not meeting product eligibility requirements (e.g., product type, inability to provide electronic Common Technical Documentation [e-CTD] formats); others lacked signed commitment to submit dossier within the pilot study timeline; and some applicants were unable to commit to the required GMP inspection schedule including readiness for onsite inspections at their respective manufacturing sites.

Of the 24 products that entered full evaluation, 21 proceeded to all cycles of scientific assessment, while three were withdrawn prior to completion of the first assessment cycle. These withdrawals occurred because applicants could not meet the requirement to host an on-site GMP inspection within the pilot timeframe due to operational challenges of coordinating inspections across multiple jurisdictions and manufacturing sites.

By the conclusion of the pilot, 12 products received a positive continental scientific opinion and were included in the continental list known as Green Book, and two products received a negative opinion and were rejected. The remaining seven fully evaluated products did not progress to listing due to unresolved scientific deficiencies identified during the three-cycle assessment process and negative GMP inspection outcomes requiring corrective actions that could not be completed within the pilot period or voluntary withdrawal by applicants following scientific feedback from the technical committees.

This pipeline was rigorous, multi-stage nature designed into the continental assessment process where only those products meeting all scientific quality, safety and efficacy requirements at each step proceeded to final listing.

3.2 | Scientific assessment

3.2.1 | Consolidated scientific assessment

All products entering evaluation underwent a harmonized three-cycle scientific assessment overseen by the EMP-TC. Each application receiving a positive outcome was issued a single consolidated scientific opinion covering quality (including GMP compliance), safety and efficacy.

3.2.2 | Timelines for continental assessment and listing

The AMRH procedural workflow demonstrated consistent performance for most products achieving continental listing. The official AMRH timeline, measured from dossier acceptance to publication on the Green Book, ranged from 148 to 233 working days (median value of 165 days). Ten of the 12 products (83%) met the ≤210 working-day target (Table 1).

The continental pilot study successfully established a functional assessment pathway and generated comprehensive timeline data for the 12 products that received a positive scientific opinion and were listed in the AMRH Green Book.

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TABLE 1 Summary of timelines from dossier acceptance to continental decision by product ($n = 12$).

Product name	Therapeutic class	AMRH time to recommendation (working days)
1. EasySix Vaccine	Vaccine (DTwP-HepB-Hib-IPV)	148
2. Bavencio (**avelumab**)	Monoclonal antibody (oncology)	149
3. Keytruda (**pembrolizumab**)	Monoclonal antibody (oncology)	154
4. Gardasil 9 (syringe)	Vaccine (HPV)	153
5. Gardasil 9 (vial)	Vaccine (HPV)	153
6. Zincol	Mineral supplement (zinc)	155
7. Truqap 160 mg (**capivasertib**)	Small molecule (oncology)	176
8. Truqap 200 mg	Small molecule (oncology)	176
9. Strensiq 40 mg/mL	Enzyme replacement (metabolic)	193
10. Strensiq 100 mg/mL	Enzyme replacement (metabolic)	193
11. Soliris (**eculizumab**)	Monoclonal antibody (haematology/immunology)	223
12. IMFINZI (**durvalumab**)	Monoclonal antibody (oncology)	233
All products ($n = 12$)		
Median		**165**
Range		**148–233**

TABLE 2 Summary of key timelines for the continental listing pilot study.

Indicator	Planned benchmark (calendar days)	Observed median (working days)	Observed median (calendar days)	Observed range (working days)	Observed range (calendar days)
Technical screening	≤15	2	~3	1–3	~1–4
Scientific assessment (EMP-TC)	≤150	138	~193	112–176	~157–246
GMP inspection cycle	≤60	55	~77	42–91	~59–127
End-to-end listing timeline	≤210	198	~277	171–242	~239–339

Note: Calendar days are approximate conversions based on a standard 5-day working week (1 working day = 1.4 calendar days). Actual calendar days may vary depending on public holidays and weekends.

A stage-wise analysis of the pilot's performance against its planned benchmarks (Table 2) indicates end-to-end continental scientific recommendation achieved a median of 198 working days within the ≤210-day target though the observed range extended to 242 working days.

3.2.3 | GMP inspection outcomes

A total of 24 GMP inspections were conducted for manufacturing sites linked to the evaluated products. These included onsite, remote and desk-based inspections, selected according to risk and site accessibility.

Of these, 23 inspections were successfully completed, one inspection of the drug substance was not completed following a withdrawal by the applicant from the list of its suppliers during the last cycle of evaluation of the product, no critical deficiencies were identified, 93% of all deficiencies were classified as *major*, and common deficiency themes included contamination control, data integrity and quality system implementation. Inspection findings from continental inspections aligned with trends observed by major international regulators.

3.3 | National uptake of scientific recommendations

National uptake was evaluated at the product–country level for all 12 listed products. Following continental listing, NRAs demonstrated varying degrees of reliance on the continental decision: Seven products (58%) were processed through full reliance resulting in immediate national registration, three products (25%) received supplemented reliance with additional national queries, and two products (17%) underwent sequential national review.

Under full reliance, the seven products Gardasil 9 (syringe and vial), Keytruda, Truqap (160 and 200 mg), Zincol and Bavencio

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achieved national registration in a total of 31 countries, with a median time to national decision of 77 working days (range: 11–116 days). Gardasil 9 alone accounted for 20 of these registrations, Keytruda was registered in seven countries, while Truqap and Zincol each secured registration in one country following continental listing. Bavencio contributed two registrations (Tanzania and Uganda) under this pathway.

In contrast, products processed through supplemented reliance experienced substantially longer timelines. As of February 2026, 10 months after the March 2025 listings, Bavencio had been registered in only two of its eight target countries with applications under evaluation in the remaining five countries and one country having issued a positive recommendation pending administrative finalization. For products undergoing sequential national review such as Soliris and Strensiq, no national registrations had been recorded with applications still under evaluation more than 10 months post-listing.

Uptake varied across products and across countries, reflecting differences in national procedures, administrative requirements and implementation of reliance pathways. This analysis provided the basis for understanding why some products achieved rapid uptake through full reliance while others experienced delays due to supplemented reliance or sequential review and for identifying the contextual factors that may shape future AMA operations.

3.4 | National uptake and registration outcomes following continental listing

Following continental recommendation, Gardasil 9 was registered in 18 countries within 11–116 working days from the continental listing. However, there were three countries (Eritrea, Liberia and Uganda) for which the registration of Gardasil 9 was under evaluation. In addition, there were six countries (i.e., Côte d'Ivoire, Gabon, Mauritius, South Africa, Tanzania and Ethiopia) that registered Keytruda for which information regarding duration from continental listing to NRA registration was not available. Furthermore, three countries (i.e., South Africa, Tanzania and Ethiopia) pre-registered Keytruda, for which time from continental listing to NRA registration was not relevant. Across all products processed through full reliance, seven products (Gardasil 9 [two presentation forms: pre-filled syringe and vial], Keytruda, Truqap [two strengths: 160 and 200 mg], Zincol and Bavencio) achieved national registration in a total of **31** product–country pairs (Table 3).

All countries with pending applications as of February 2026 had exceeded the 90-day timeline, indicating systemic delays in those jurisdictions. In addition, only three countries (Ghana, Tanzania and Zambia) met the 90 working day target for national review, while six countries exceeded this timeline with decision taking up to 160 working days. This result is summarized in Table 3.

For the 12 countries with documented post-listing registration dates, the median time from continental listing to national decision was 77 working days (range: 11–116 days). Tanzania achieved the fastest registration at 11 working days, while Namibia required 116 working days. An additional eight countries granted registration but did not specify the decision date in their feedback to the Secretariat. Three countries (Eritrea, Liberia, Uganda) had applications under evaluation as of February 2026.

TABLE 3 Summary of timelines from continental recommendation to national decision by country ($n = 23$ countries).

Item	Value
Countries with post-listing registrations (*n*)	12
Median time to national decision (working days)	77
Range (working days)	11–116
Countries with registrations (date not specified)	8
Countries under evaluation	3
Countries with pre-listing registrations	4

Besides Gardasil 9 and Keytruda, other products demonstrated varying uptake patterns. Truqap secured registration in South Africa following continental listing, while Zincol achieved registration in Tanzania—one of its six target countries. Bavencio was registered in two countries (Tanzania and Uganda) under the full reliance pathway. For EasySix Vaccine, both target countries (Nigeria and Egypt) issued positive scientific recommendations based on the continental assessment, with final administrative steps pending. Products undergoing sequential national review such as Soliris and Strensiq remained under evaluation with no registrations recorded as of February 2026. Several NRAs, particularly in South Africa, explicitly referenced continental application identifiers in national submissions for products such as Bavencio, Keytruda and Truqap, demonstrating operational integration of the continental system into national workflows.

4 | DISCUSSION

This evaluation provides the first empirical evidence on the feasibility and performance of a continent-wide scientific assessment and listing procedure for human medicinal products in Africa. The results demonstrate that consolidated continental scientific opinions can be produced efficiently, achieve broad national uptake and meaningfully support reliance-based decision-making across diverse regulatory systems. These findings offer practical insights for the operationalization of the AMA whose mandate includes facilitating joint assessments, coordinated inspections and reliance-supported national decisions.[16–19]

The three key principles that emerged from the study were as follows: First, the continental scientific assessment process operated predictably and within defined performance expectations for 10 of the 12 listed products, with 83% meeting the ≤210 working-day benchmark. This places the continental model within time ranges comparable to or faster than many national and regional procedures historically observed in Africa and across low- and middle-income countries.[3–5] The harmonized GMP inspection programme, drawing on risk-based and multimodal inspection modalities, generated

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findings consistent with international regulatory patterns,[8] reinforcing the technical credibility of the assessments.

Second, national uptake of continental outputs was substantial. Most listed products were adopted through reliance pathways at the national level 58% through full reliance and 25% through supplemented reliance. This stands in contrast to earlier regional harmonization efforts such as ZaZiBoNa, the East African Community joint assessment and the ECOWAS mechanism, where national translation of joint assessments has been uneven or delayed.[11–15] The breadth and speed of uptake observed here suggest that centrally coordinated continental assessments may carry heightened legitimacy and utility for NRAs.

Third, end-to-end timelines from submission to national registration were heavily influenced not by the scientific assessment itself, but by administrative sequencing, including dossier intake intervals and the timing of Steering Committee meetings. A stage-wise analysis found that variability was greatest in the scientific assessment phase, largely due to assessment type and number of query cycles. However, the extended overall timelines observed were primarily attributable to procedural rather than scientific steps. Scientific assessments including dossier evaluation, GMP inspections and technical committee deliberations were completed within or near their planned benchmarks (e.g., scientific assessment median of 138 working days against a 150-day target). The additional delays accumulated through applicant response times, fixed scheduling intervals for Steering Committee meetings and administrative processing between dossier submission and formal acceptance.

These findings align with global evidence that reliance-based regulatory processes can improve efficiency, avoid duplication and expand regulatory reach when supported by consistent procedures and transparency.[6,7,24] The continental approach shares characteristics with established models such as the European Medicines Agency's coordinated network and WHO's Prequalification and Collaborative Registration Procedure (CRP) both of which have demonstrated accelerated national regulatory uptake when assessments are jointly recognized[8,9,24] (World Health Organization, n.d.).

A comparison with the EMA's centralized procedure provides a useful benchmark for the AMRH pilot study. The EMA system, which has evolved over decades, represents a mature regulatory network where a single scientific assessment leads to simultaneous national decisions across all EU Member States.[8,19]

Of the 12 products listed through the continental process, nine (75%) have received EMA central approval. This includes all five monoclonal antibodies (Bavencio, Keytruda, Soliris, IMFINZI) both vaccines (Gardasil 9), both enzyme replacement products (Strensiq) and the small molecule oncology product Truqap. The two products without EMA approval such as EasySix and Zincol and the withdrawn generics represent categories not typically submitted for EMA centralized assessment.[32]

The timelines in working days observed in the AMRH pilot study (median 165 working days; range 148–233 days) are comparable to and in some cases faster than the EMA standard review timeline of 210 days.[8] The achieved 148–154 days review timeline aligns with EMA's accelerated assessment pathway of 150 days, which is reserved for products of major public health interest.[8] This suggests that the African continental procedure, when operating optimally, can achieve review speeds consistent with mature regulatory systems.

The AMRH timelines reported in this study are measured in working days (excluding weekends and public holidays) with stop-clock provisions during applicant response periods. The EMA's 210-day benchmark is measured in calendar days (including weekends) with similar stop-clock provisions. While both procedures incorporate stop-clocks, the difference in units (working days *vs.* calendar days) should be considered when making direct comparisons.

The WHO CRP provides another relevant comparator, as both mechanisms enable NRAs to rely on assessments conducted by trusted reference bodies.[9] As of 2025, 69 countries participate in the WHO CRP for medicines and nearly 1200 product registrations have been facilitated through the procedure[9] (World Health Organization, n.d.).

A recent case study illustrates the potential speed of the CRP pathway. Lenacapavir, a novel HIV prevention product, was approved in Zambia in 12 working days and in Zimbabwe in 18 working days. This rapid registration was as a result of reliance being placed on the EMA EU-M4all (formerly known as Article 58, a regulatory procedure that allows the EMA to assess and provide scientific opinions on high-priority human medicines and vaccines intended for use outside the European Union) procedure and subsequent WHO prequalification[9] (World Health Organization, n.d.). These timelines demonstrate that when reliance is placed on collaborative registration procedures (CRP), then this can result in exceptionally rapid national approval, as was seen in the case of Zambia and Zimbabwe. These results also demonstrate that following the pilot study assessment, products can be rapidly registered in NRAs such as Tanzania (11 working days) and 30 working days in Zambia.

The WHO prequalification status provides an additional benchmark of global regulatory recognition. Since its establishment in 2001, the WHO Prequalification Programme has become a gold standard for assuring the quality, safety and efficacy of priority medicines, particularly those procured by United Nations agencies[19] (World Health Organization, n.d.). For example, Gardasil 9 and EasySix vaccine were prequalified by the WHO and subsequently reviewed rapidly in a national regulatory agency.

Regional harmonization initiatives in Africa, including the East African Community (EAC) joint assessment procedure,[11] the Southern African Development Community (SADC) collaborative medicines registration initiative[13] and the West African Health Organization (WAHO) harmonization initiative[12] and the Intergovernmental Authority on Development (IGAD) regional regulatory coordination activities have made important progress in building regulatory capacity and facilitating work-sharing.[13,15] However, these subregional mechanisms typically achieve national uptake across a smaller geographic footprint, given their focus on specific economic communities.[13,14] The continent-wide reach of the AMRH pilot study with 27 countries targeted and 20 registrations achieved within 148–233 working days for leading products suggests that a pan-African

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mechanism may generate a degree of perceived harmonization and authority beyond that achievable through subregional structures alone.[15,18]

The fact that most listed products fall outside WHO's traditional prequalification scope underscores the complementary nature of the two systems[19] (World Health Organization, n.d.). WHO PQ serves critical public health procurement needs for vaccines, HIV, TB, malaria and reproductive health products (World Health Organization, n.d.). The AMRH mechanism, in contrast, was meant to addresses the full spectrum of innovative medicines including oncology products, biologics and rare disease treatments requiring market access across Africa.[17,18,20] This complementarity aligns with the African Union's broader vision for the AMA as a specialized agency capable of addressing the full range of regulatory needs across the continent.[16–18]

These comparisons validate that the pilot study achieved technical equivalence with global regulatory standards while establishing a novel model for continental cooperation.[18,23] The finding that 75% of listed products already meet stringent EU regulatory requirements,[8] and that key products also meet WHO prequalification standards,[32,33] further reinforces the quality and credibility of the African assessment outcomes. As the AMA moves towards full operationalization, these results provide a strong foundation for the design and implementation of a sustained regulatory harmonization and reliance across the continent.[18,20,23]

The findings of this study have identified a number of implications for the operationalization of the AMA:

First, the strong uptake of continental assessments demonstrates that NRAs are willing to rely on shared scientific outputs when these are delivered through clear, transparent and well-governed procedures. Embedding reliance pathways into national legislation and standard operating procedures may reduce variability in uptake and enhance predictability.

Second, administrative phases not scientific processes were the major contributors to extended end-to-end timelines. Streamlining dossier intake processes, standardizing validation requirements and ensuring more frequent or flexible scheduling of governance decisions could substantially reduce delays without compromising scientific quality.

Third, the pilot illustrates the value of coordinated GMP inspection capacity for a continent with diverse regulatory maturity levels.[2,3] AMA's mandate to strengthen inspection cooperation[16,17,19] could leverage this approach to reduce duplication, support risk-based resource allocation and align with global inspection norms.

Fourth, manufacturers demonstrated significant geographic breadth in their market-entry strategies, with several products targeting more than 20 African countries. A functional continental assessment mechanism may therefore encourage broader market participation and improve availability of quality-assured products across the AU.Together, these implications point to a pragmatic pathway for AMA: institutionalize the procedural elements that worked, harmonize those that introduced variability and reinforce the governance and digital systems required for efficient cross-country coordination.[16,22]

5 | STRENGTHS AND LIMITATIONS

This study has several strengths. It draws on complete procedural and decision-making records generated by the AMRH Secretariat, enabling full visibility into assessment timelines, inspection outputs and governance structures. It also incorporates verified post-listing national data, allowing direct observation of reliance patterns and registration outcomes across multiple NRAs.

The limitations include the pilot's restricted number of products, which limits statistical generalizability. National uptake data reflects the period of observation: Outcomes for products listed in 2026 remain incomplete. Heterogeneity in national legal frameworks, administrative practices and applicant market strategies also introduced variation that could not be fully controlled. Finally, this study evaluates regulatory processes rather than downstream outcomes such as medicine availability, procurement timelines or public health impact areas requiring additional investigation.

6 | CONCLUSIONS

This study provides the first empirical evidence that a continent-wide scientific assessment and listing procedure for human medicinal products is feasible, efficient and able to support reliance-based national regulatory decisions across Africa. Consolidated continental assessments were widely accepted by NRAs, although total timelines were shaped largely by administrative and governance sequencing rather than scientific review. Strengthening these procedural interfaces, together with embedding harmonized reliance pathways into national legislation and digital workflows, will be essential for achieving predictable, continent-wide access under the AMA. Continued evaluation, including the impact on product availability and public health outcomes, will be necessary as the AMA transitions from pilot to full operationalization.

AUTHOR CONTRIBUTIONS

Conceptualization: Alex Juma Ismail, Stuart Walker and Sam Salek. *Methodology*: Alex Juma Ismail, Stuart Walker, Sam Salek. *Formal analysis*: Alex Juma Ismail. *Data curation*: Alex Juma Ismail. *Writing—original draft*: Alex Juma Ismail. *Writing—review and editing*: Alex Juma Ismail, Lerato Moeti, Delese Mimi Darko, Stuart Walker and Sam Salek. *Supervision*: Delese Mimi Darko, Stuart Walker and Sam Salek.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no competing interests. The views expressed in this manuscript are those of the authors and do not necessarily reflect the policies or positions of the African Union, AUDA-NEPAD, the African Medicines Agency (AMA) or participating National Regulatory Authorities.

DATA AVAILABILITY STATEMENT

The data underlying this study contain regulatory and application-level information generated through the African Medicines Regulatory Harmonization (AMRH) Programme and participating NRAs. Due to confidentiality obligations and data-sharing agreements, these data cannot be made publicly available. Aggregated and de-identified data supporting the findings of this study are provided within the manuscript. Access to underlying regulatory records may be considered upon reasonable request to the African Medicines Agency, subject to applicable data-governance and confidentiality requirements.

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