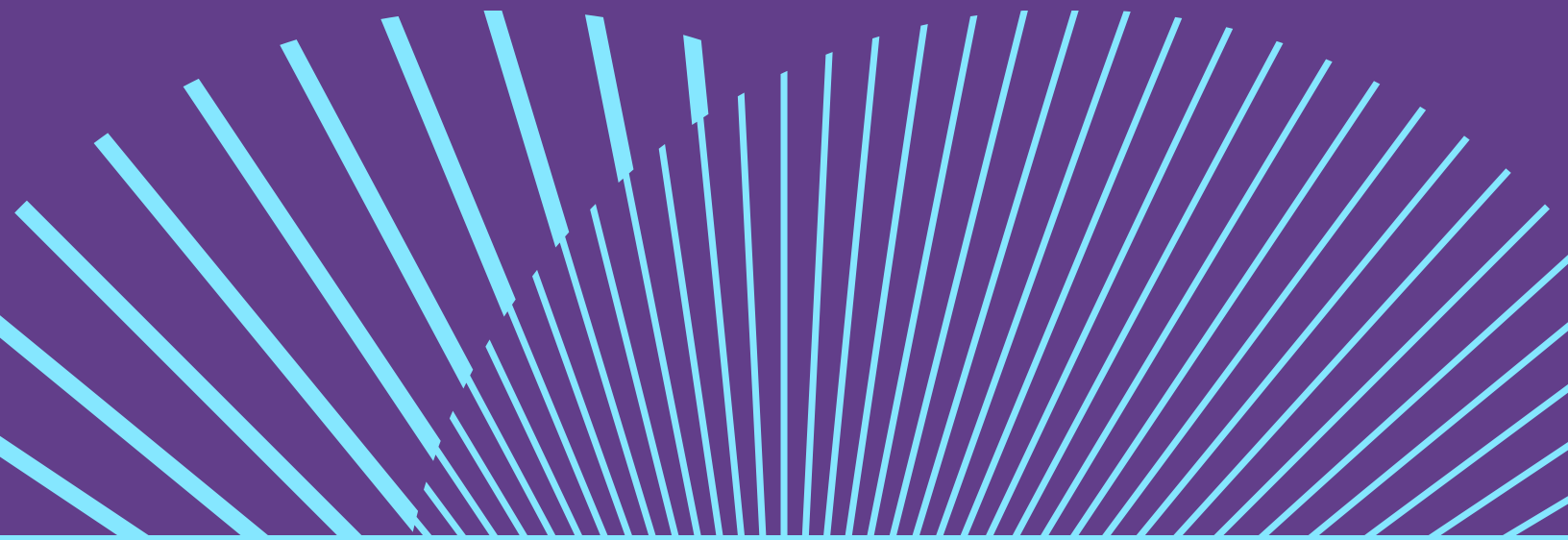
# Africa's Healthcare Revolution:

## The Role of Regulatory Convergence



U.S. Chamber of Commerce

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This paper was prepared by Tim Wilsdon, Rajini Jayasuriya, Charlotte Poon, Hugh Nicholl, and Temi Olufotebi of Charles River Associates. The authors would like to thank the U.S.-Africa Business Center of the U.S. Chamber of Commerce for its leadership and stewardship of this work. We are grateful for the inputs from representatives in the biopharmaceutical, medical device, healthcare, and diagnostics sectors who contributed to the research including Africa Centres for Disease Control and Prevention, African Continental Free Trade Area, African Union Development Agency-NEPAD, the Bill and Melinda Gates Foundation, the Kenya Association of Pharmaceutical Industry, FIND, South African Health Products Regulatory Authority, and United States Trade and Development Agency.

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# Foreword

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It is my distinct honor to introduce this paper on “Africa’s Healthcare Revolution: The Role of Regulatory Convergence,” developed by the U.S. Chamber of Commerce’s Africa Business Center in partnership with Charles River Associates. This document arrives at a critical juncture in Africa’s healthcare evolution and underscores the transformative power of regulatory convergence in unlocking the potential of our continent’s healthcare sector.

As we stand at the cusp of a transformative era in African healthcare, the importance of regulatory convergence cannot be overstated. My years of experience in public health across Africa have shown me firsthand the critical need for harmonized regulatory systems to improve access to quality, safe, and efficacious medical products for all Africans.

The report’s comprehensive analysis and strategic recommendations provide a roadmap for national, regional, and continental stakeholders to enhance regulatory systems. It emphasizes the importance of harmonized regulatory frameworks that can facilitate the swift movement of medical products across borders, reduce the burden of disease, and catalyze economic development through healthcare innovation.

This white paper comes at a crucial juncture, as we work towards operationalizing the African Medicines Agency (AMA). The AMA represents a monumental step forward in our continent’s journey towards regulatory excellence and healthcare equity. It embodies our collective vision of a unified African approach to medical product regulation, one that will accelerate access to life-saving medicines and foster innovation across Africa. We recognize that a robust regulatory environment is a cornerstone of a resilient healthcare system and a thriving economy.

As we move forward, it is my hope that this white paper will serve as a valuable resource and catalyst for action. The path to regulatory convergence is complex, but the potential benefits for public health, economic growth, and scientific advancement in Africa are immeasurable. Together, we will strive to create an enabling ecosystem that fosters innovation, protects public health, and promotes the well-being of all Africans.

This paper is a call to action for all of us to collaborate more closely, share expertise, and commit resources to achieve the vision of a unified regulatory framework for healthcare products in Africa. I am confident that, with the collective efforts of our member states and partners, we will realize the promise of regulatory convergence and usher in a new era of healthcare prosperity for our continent.

Let us embrace the insights and guidance provided in this paper to forge a future where regulatory convergence is not just an aspiration but a reality that propels Africa towards greater health equity and economic vitality.

# Executive Summary

The U.S- Africa Business Center commissioned Charles River Associates (CRA) to analyze how advancing regulatory convergence (defined below) can address regulatory challenges affecting access to health technologies on the African continent. This paper reviews the role that regulatory convergence has to play in improving access to health technologies as well as strengthening health systems and achieving investment and economic objectives, describes the progress made toward convergence over the last decades, and highlights opportunities to ensure that the full benefits of convergence are realized.

This paper was developed with input from regulatory leaders on the African continent, local and U.S-based industry, and global health stakeholders. We present recommendations to advance regulatory convergence that are targeted at stakeholders at the national, regional, and continental levels, followed by a discussion of the role of the global community and other international partners.

## Progress toward regulatory convergence is vital for improving access to health technologies across the continent, strengthening health systems, and attracting more investment

Across the African continent, the regulatory environment for health technologies is composed of a patchwork of separate and varied requirements determined by different national and regional authorities. This heterogeneity of regulatory systems acts as a major barrier to access to health technologies, including therapeutics, vaccines, diagnostics, and medical devices. Regulatory convergence can

**Box 1: Definitions of key terms related to regulatory convergence**

### Centralization

A regulatory framework where a single regulatory agency is responsible for establishing and enforcing consistent standards to ensure that medicines meet uniform safety, efficacy, and quality criteria across all countries within the region.[1]

### Harmonization

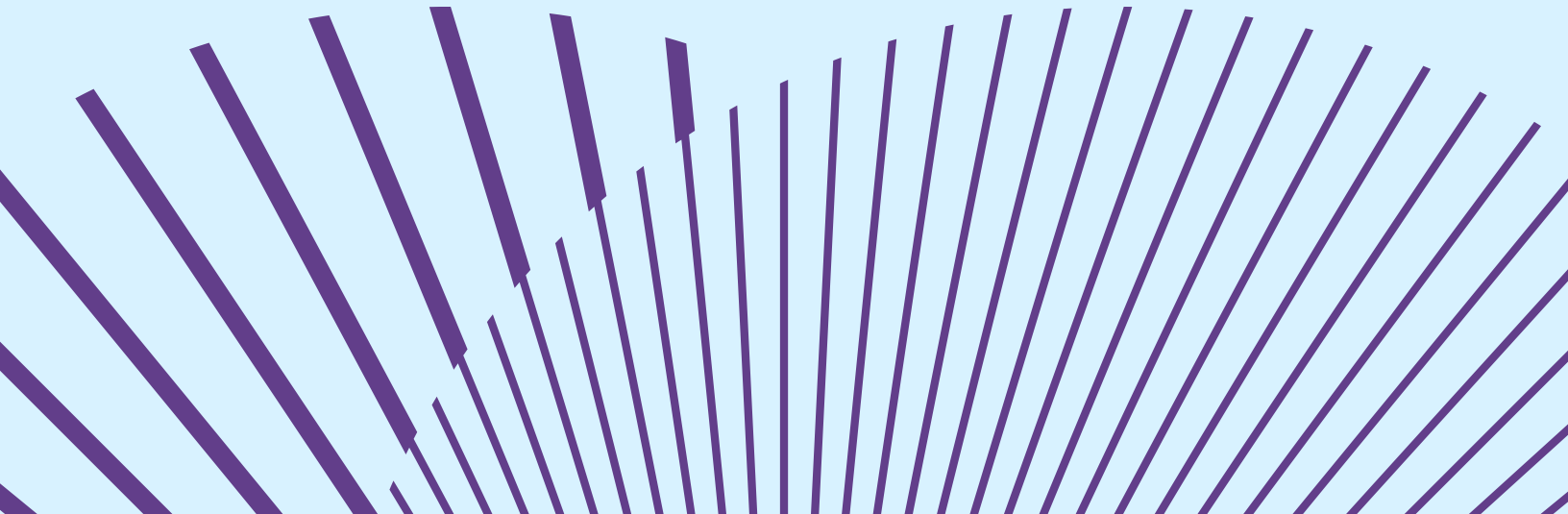
The process by which regulatory authorities align on technical requirements for the development and marketing of health products. This alignment facilitates favorable marketing conditions, supports early access to medical products, promotes competition and efficiency, and reduces unnecessary duplication.[2]

### Reliance

The act whereby the national regulatory authority in one jurisdiction may take into account and give significant weight to assessments performed by another national regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent and responsible and accountable for the decisions made, even when it relies on the decisions and information of others.[3]

reduce the workload of each national regulatory authority (NRA), supporting the development of their capacity and capabilities and reducing costs by streamlining duplicative processes. Ultimately, regulatory convergence can improve access to high-quality, safe, and effective health technologies for people on the continent.

Although substantial progress has been made in strengthening regulatory systems in Africa, several key challenges to efficient national-, regional-, and continental-level convergence remain.[4] Many NRAs across the continent do not conduct all core regulatory functions because they are not included in the legislation that sets out their role.[5] Funding is a challenge because many NRAs do not have large enough budgets to finance regulatory functions, and in particular to pay competitive salaries to their workforce.[6] This can lead to a shortage of the staff and experience needed to make quick and well-informed regulatory decisions, such as whether to approve new health technologies and clinical trial applications, especially as new complex medicines and manufacturing processes emerge.[7] Critically, the regulatory environment in Africa is often characterized by NRAs acting independently from one other, which leads to duplication and divergent requirements across countries that manufacturers must comply with, increasing the time and cost to bring new products to the population.[8] For example, to make a new product available to patients, a separate and lengthy regulatory process that is highly specific to NRA requests is often required for each country.[9] Finally, many NRAs do not operate in the context of infrastructure that is sufficiently well developed to support their regulatory activities, such as electronic systems for managing applications and enabling pharmacovigilance reports for substandard and falsified medicines.[10] These challenges continue to be significant impediments to access to health technologies in many African countries, and they are exacerbated by the continued impact of regulatory fragmentation.

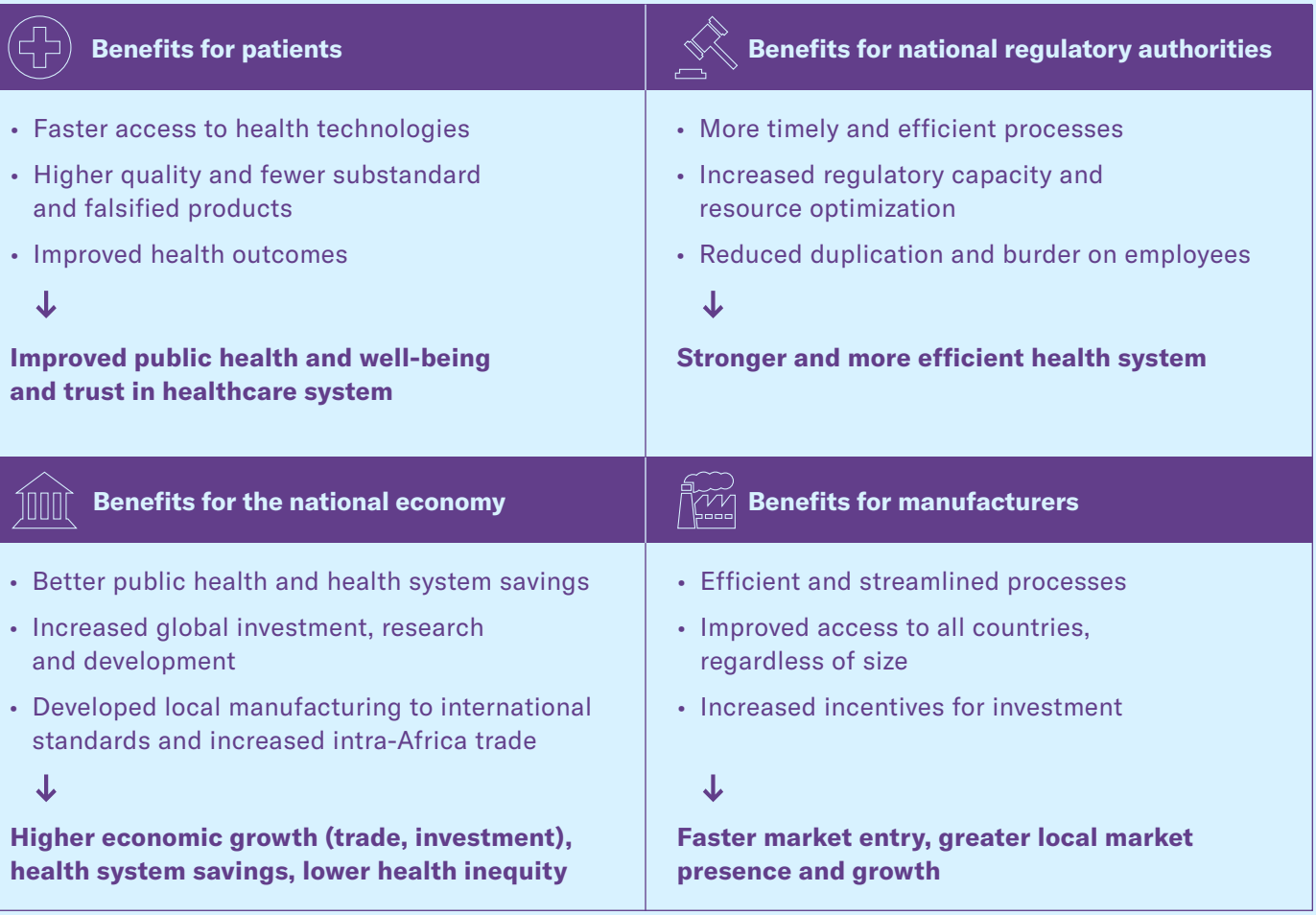


## The benefits of convergence start at regulatory efficiency and extend to public health and economic growth

While the predominant direct benefit of convergence is improved patient access to health technologies, it also leads to significant wider benefits (see Figure 1). Regulatory convergence also enhances the international competitiveness of a life sciences industry, boosts global trade and intercontinental collaboration, and, ultimately, encourages economic growth.[11,12] R&D and manufacturing of health technologies take place around the world, and Africa accounts for only a small share of this activity: despite being the home of 17% of the world's population, only 3% of global production of medicines and less than 3% of clinical research takes place there.[13,14] It is anticipated that Africa's share of clinical trials and manufacturing will rise in the future, but the fragmented regulatory landscape currently inhibits this growth. Convergence also contributes to political and economic integration, boosting intra-African trade and thereby supporting the vision of the African Continental Free Trade Area (AfCFTA). Ultimately, regulatory convergence presents an opportunity for Africa to capitalize on global health technology innovation and bring its local life sciences industry to the global stage. A key component of this is ensuring that the Africa Medicines Agency (AMA) is recognized as a contributor to the global regulatory environment in the same way that today's international leading regulators, such as the US Food and Drug Administration and the European Medicines Agency, are.

**Figure 1: Benefits of regulatory convergence, by stakeholder.**

Source: Adapted from World Bank (2016)[15]



The benefits for Africa of regulatory convergence are increasingly widely acknowledged, and progress toward regulatory convergence on the continent over the past few decades has been notable. Milestones include a growing number of NRAs reaching (World Health Organization (WHO) Global Benchmarking Tool) Maturity Level 3, evidence of regional-level efficiencies through African Medicines Regulatory Harmonization (AMRH) initiatives (such as the East African Community and Southern African Development Community initiatives), and the establishment of the AMA at the continental level. However, opportunities to further progress and fully realize the benefits of regulatory convergence in Africa still exist.

## National-level recommendations

A baseline of functionality needs to be achieved at the national level to fully realize the benefits of regulatory convergence. Stakeholders agreed that establishing legislative frameworks should be priorities, especially as they relate to innovative medicines and medical devices access. Next, policy provisions should ensure the sustainable financing of NRAs as they become more established. Finally, although countries have already acknowledged the need to improve NRA workforce capacity, expand pharmacovigilance, and implement digital transformation, stakeholders agreed on the need for more urgent prioritization and improvement in these areas. In combination, these actions by national governments would support NRAs to achieve Maturity Level 3 status and higher.

1. **In countries where NRAs do not have legal authority as autonomous bodies, including the ability to leverage reliance and harmonization mechanisms, national governments should establish such legal frameworks. This should at a minimum support NRAs to achieve ML3 status as quickly as possible.**

2. **National governments should establish sustainable funding structures for NRAs and incentivize timely adoption of reliance and harmonization of regulatory requirements through performance-related fees.**

3. **National governments should increase their investments into the institutional and technical capacity of NRAs, including their workforce, quality management systems, and digital infrastructure, such as information management systems, to support convergence.**

4. **National governments should empower NRAs to maximize streamlining of approvals for WHO prequalified products, such as through the WHO Collaborative Registration Procedure.**

## Regional-level recommendations

Regional harmonization initiatives over the past decade established by the AMRH have been instrumental in reducing duplication and driving regulatory convergence across Africa. Stakeholders agree that while these initiatives have been set up across Regional Economic Communities (RECs), the priority should now be ensuring their efficient functioning and sustainability. Going forward, leveraging digital tools and sustainable funding mechanisms will support efficient growth of the initiatives to serve as the foundation for the AMA. Further development of the RECs will be crucial for streamlining national approvals and ensuring an abridged process that accelerates the time to patient access.

1. **Establish standardized operating procedures within RECs to strengthen institutional capabilities around implementing AMRH initiatives.**

2. **Develop digital tools for centralized tracking, public reporting of achievements against key performance indicators, and facilitating access to information to enhance transparency of REC decisions and seamless follow-up by NRAs.**

3. **RECs should establish a legal framework for a centralized joint assessment pathway for products that would not be reviewed by the AMA.**

4. **Establish a dedicated funding mechanism for joint procedures within RECs.**

5. **To address the relatively slow uptake of reliance mechanisms, mature RECs should more effectively promote, collaborate with, and communicate the benefits of regional reliance efforts to NRAs and other RECs.**

## Continental-level recommendations

While the immediate priority for continental-level convergence is for the countries that have not ratified the AMA treaty to do so, further policy change is needed to ensure its successful operationalization. The AMA's pilot for the continent listing of medicinal products is at an early stage, but taking action to cement the long-term operation of the AMA so that it delivers improved access to health technologies is important. Continental regulatory stakeholders should establish a clear pathway from pilot to full AMA operationalization and a strategy to ensure that the AMA matures into a WHO Listed Authority (WLA) that represents Africa on the global regulatory stage.

1. **Clarify the delineation of responsibilities and scope among the AMA, RECs, and NRAs.**

2. **Establish continental-level data collection systems that can support monitoring, impact evaluation, and public reporting of regulatory activities and how convergence is working.**

3. **Establish a process, with guidance, for NRAs to conduct an abridged, confirmatory approval process following AMA evaluation and establish a strategy to support ongoing maturity of AMA to reach WLA status.**

4. **Publish a strategic plan and timelines for next steps for AMA operationalization to support accountability.**

## Global regulatory development and partner coordination

Collaboration and coordination are needed, including among global health organizations, international regulatory bodies, and industry. All international partners that have supported convergence to date will continue to have an important role to play. Examples are the Bill and Melinda Gates Foundation's support for AMA operationalization and the WHO's technical assistance for convergence initiative pilots. In particular, two key recommendations were noted by interviewed stakeholders:

1. **Ensure continued engagement with industry (such as by establishing an AMA industry standing group), especially to leverage institutional knowledge and participation in regulatory procedures to facilitate timely health technology access across the continent.**

2. **The WHO should continue efforts to refresh the prequalification (PQ) program to address challenges in access to essential medicines and diagnostics and expand the program to include medical devices.**

Convergence is critical for improving access to health technologies, and it supports economic, trade, and investment activities on the continent. Together, these recommendations outline the changes that are needed to realize the full benefits of convergence. In particular, the AfCFTA can help to scale the recommended efforts by acting as a liaison between local manufacturers and the AMA. The AfCFTA can also support countries that face disproportionate challenges to regulatory-strengthening initiatives so that they are able to align standards and regulatory practices, which will ensure that the benefits of convergence accrue equitably to Africa.[16]

# Introduction

The U.S-Africa Business Center commissioned Charles River Associates (CRA) to analyze how advancing regulatory convergence can help address regulatory challenges affecting access to health technologies on the African continent. Considering the crucial importance of regulatory convergence for improving access to health technologies, as well as for strengthening health systems and delivering improved innovative and investment activities, the objective of the study is to review the progress made toward regulatory convergence over the last decade, highlight opportunities to address the challenges affecting patient access, and understand the roles of various stakeholders.

## Background

### The growth of Africa's life sciences industry and access to health technologies

The introduction of the flagship African Continental Free Trade Area (AfCFTA) agreement in 2019 has been seen as a significant step toward a single market and advanced trading system across the African continent. The AfCFTA has provided a foundation for a single market for health products—though more is needed to make this a reality—and greater health security on the continent.[17] The addition of the African Union as a permanent member of the G20 in fall 2023 further demonstrates the growing influence of the continent and Africa's voice on the global stage for health reforms and life sciences investment.

### The benefits of convergence start with regulatory efficiency and extend to public health and economic growth

Regulatory convergence is a key driver of a reduced NRA workload; fewer time-consuming and costly, duplicative regulatory efforts; and ultimately improvement in the timely regulatory approval of, and access to, health technologies.[18,19]

Regulatory convergence (our definition of "convergence" encompasses regulatory centralization, harmonization, or reliance (see Box 1)) is vital for ensuring the quality, safety, and efficacy of healthcare technologies and thereby safeguarding public health. Regulatory convergence has also been shown to support the innovative and competitive edge of regions' life sciences industry and economic growth. A summary of how regulatory convergence can support government priorities in public health, industry growth, and economic development follows.

#### 1. Public health

- **Access to health technologies for high-quality healthcare**

  Convergence can streamline regulatory approval processes across countries and reduce the time and cost associated with bringing new health technology to people.[23] Harmonized regulations can facilitate the faster and more efficient distribution of medicines and medical technologies across countries, helping the population in all of Africa gain timely access to the latest health technologies.[24,25]

**Box 1: Definitions of key terms related to regulatory convergence**

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### Harmonization

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### Reliance

The act whereby the national regulatory authority in one jurisdiction may take into account and give significant weight to assessments performed by another national regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent and responsible and accountable for the decisions made, even when it relies on the decisions and information of others.[22]

- **Safety and quality of locally manufactured health technologies**

  Regulatory convergence can expand regulatory capacity and capabilities for Good Manufacturing Practice (GMP) inspections, post-marketing surveillance, and pharmacovigilance, thereby ensuring that patients have access to safe and high-quality products. This can help to address the challenge of substandard and falsified (SF) medicines on the continent: 42% of such medicines reported to the WHO between 2013 and 2017 came from Africa.[26]

- **Universal health coverage**

  The WHO considers strong regulatory systems—for which convergence is a key driver—essential to reaching universal health coverage.[27] This is also in line with the aspirations and goals 1 and 3 of the African Union Agenda 2063 and Sustainable Development Goals on access to quality, safe, and efficacious health products.[28]

## 2. Innovation and competitiveness

- **Development and competitive advantage of Africa's life sciences industry**

  Aligning with international manufacturing and safety standards improves the quality of locally manufactured products. Moreover, achieving at least maturity level 3 (ML3) status on the WHO Global Benchmarking Tool facilitates entry into global markets because locally produced products that are NRA-reviewed products can be exported, boosting the local life sciences industry and trade.[29] For example, following the strengthening of Mexican's regulatory authority, COFEPRIS,

it was recognized by the Pan American Health Organization as a reference authority, which led to a 13% growth in the local pharmaceutical market in 2011–2014.[30]

- **More local clinical trials**

  Regulatory convergence, including through reliance and regional work sharing, can ensure an efficient clinical trial approval process that includes an ethics review and can address potential uncertainties and delays in review timelines. This could allow timely recruitment of African patients in global trials. This is a significant opportunity for the continent, where, despite being home to 17% of the global population and carrying 25% of the global disease burden, Africa accounts for less than 3% of clinical trials.[31]

## 3. Economic growth and development

- **International investment**

  Harmonized standards and a consistent regulatory process that meets international standards can incentivize international investment in local health technology research, development, and manufacturing, boosting local jobs and economic growth for African countries.[32,33]

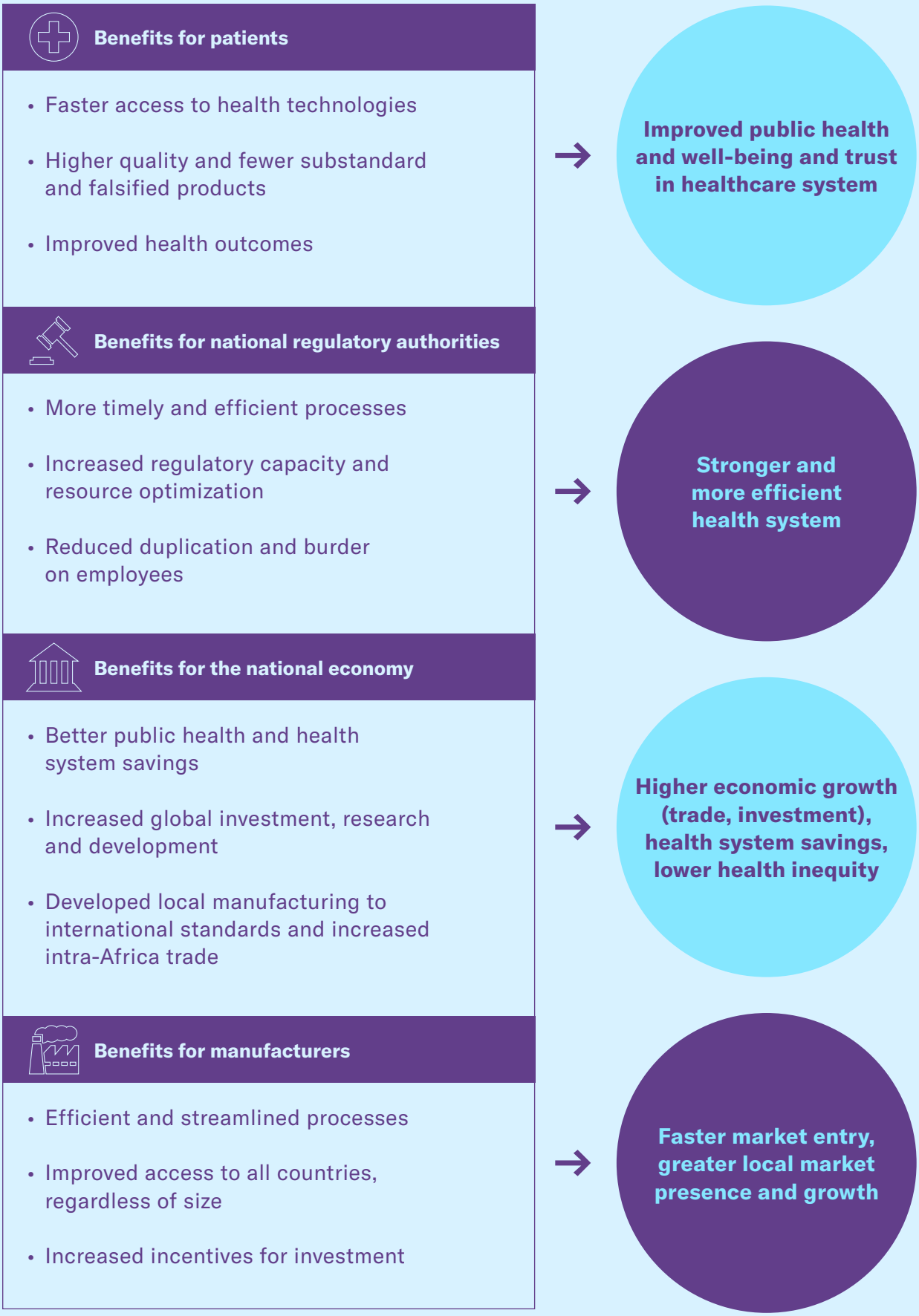
- **Opportunity to support intra-Africa trade and the vision of the AfCFTA**

  By promoting political and economic integration, regulatory convergence will support the elimination of trade barriers and boost intra-African trade. While today only 3% of the demand for packaged medicines is met by intra-African trade (the rest is either imported or not traded), this could be transformed with the successful implementation of convergence.[34] Regulatory convergence has a critical role to play in catalyzing trade by aligning standards for the quality and safety of health technologies across the continent.

The benefits of regulatory convergence have been demonstrated to accrue to all stakeholders (Figure 2).

**Figure 2: Benefits of regulatory convergence, by stakeholder.**

Source: Adapted from World Bank (2016)[35]

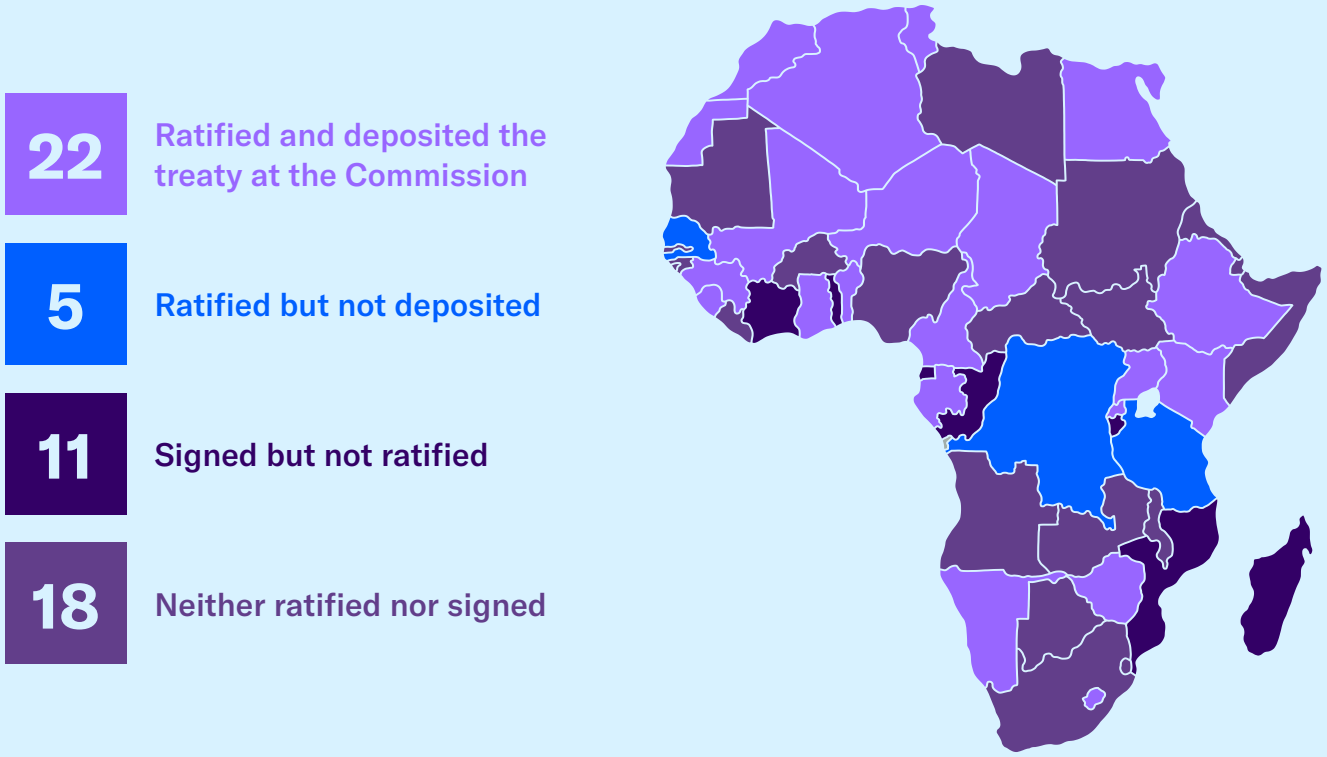


## Progress towards regulatory convergence is vital for improving access to health technologies across the continent

Progress towards regulatory convergence in Africa over the last decade has been considerable. A significant milestone was achieved in November 2021 with the establishment of the Treaty for the Establishment of the African Medicines Agency (AMA). As of March 2024, 38 of the 55 countries have shown support, with 27 countries ratifying the treaty (see Figure 3).[36] Once operationalized, and in accordance with the AMA Treaty, the AMA will be governed by Member States and aligned to the global standards established by the WHO and the International Conference on Harmonisation. The AMA has since entered the pilot phase of continental listings, as continental dossier reviews and inspections began in March 2024 to pressure test the framework.[37]

Although progress has been made, there is still some distance to travel before full regulatory convergence is reached. For example, a full regulatory review is needed in most countries, and NRAs often have very specific time- and resource-intensive requirements that can delay patient access. With a growing population and an expected increase in healthcare demands, the need for regulatory convergence has never been more pressing.[39] The objective of this report is to identify the remaining challenges in achieving regulatory convergence and the next steps in fashioning a regulatory system in Africa that supports efficient access to high-quality, efficacious, and safe health technologies.

**Figure 3: Countries that have ratified the AMA (as of March 2024).**
Source: Health Policy Watch[38]



The foundation of health security is access to quality, safe, and effective medical products.[A] A resilient and well-managed regulatory system protects the population from substandard and falsified products and therefore potential harm. Well-functioning NRAs are equipped to support multiple facets of the value chain—manufacturing, storage, distribution, and dispensation—which ultimately supports timely access to medicines and other medical modalities. A mature NRA can carry out regulatory functions efficiently without delaying access to crucial and lifesaving medicines. This is always important, but particularly so in times of health emergencies.[40] However, in reality, many countries still lack the foundation necessary to carry out regulatory functions effectively. In 2021, a survey found that 70% of the world has weak national regulatory systems for health products.[41] This is a particular concern in Africa. As of June 2024, only six countries in Africa—Egypt (vaccines), Ghana (medicines and vaccines), Nigeria (medicines and vaccines), South Africa (vaccines), Tanzania (medicines and vaccines), and Zimbabwe (medicines and vaccines)—have achieved maturity level 3, meaning the NRA has been assessed as having a stable, well-functioning, and integrated regulatory system.[42] Further progress in this area is therefore critical. Nearly two-fifths (38.5%) of the African population do not have access to essential medicines, and much higher levels of the population (72.7%) have only limited access to nonessential medicines.[43] The paucity of ML3 NRAs on the continent is a barrier to achieving the continent's local manufacturing production, trade, and economic goals set out in the Pharmaceutical Manufacturing Plan for Africa.[44]

A "Access," as defined by the WHO, is ensuring health technologies are "available within the context of functional health systems at all times in adequate amounts, appropriate dosage with assured quality and adequate information and at a price the individual and community can afford."

# Methodology

We adopted a three-step approach. Firstly, we conducted a targeted literature review of the progress to date of regulatory convergence initiatives and their impact and identified the remaining regulatory system challenges to accessing health technologies in Africa. The literature review covered regulatory challenges associated with access to all health technologies (medicines, vaccines, medical devices, and diagnostics) and included a review of initiatives to address challenges that have been implemented at the national, regional, and continental level and those driven by global health stakeholders. The literature review also aimed to capture current debates about how regulatory convergence can be further enhanced.

Second, we interviewed 12 key stakeholders: four representatives of the global life sciences industry (developers of innovative pharmaceuticals, medical devices, and generics and biosimilars) and eight key regulatory stakeholders on the continent (e.g., African Union Development Agency (AUDA-NEPAD), Africa Centres for Disease Control and Prevention, South African Health Products Regulatory Authority) and in the global health community (e.g., the WHO and the Bill & Melinda Gates Foundation (Gates Foundation)). The objective of the interviews was to capture relevant stakeholders' experiences of regulatory systems in Africa and their perspectives on how regulatory convergence can be advanced.

Finally, we sought to identify lessons from instances of regulatory convergence. Our case studies included examples of regional convergence in Africa and other emerging markets and a review of the European Medicines Agency. The aim was to identify how challenges to regulatory strengthening and achieving convergence have been addressed and identify any lessons for stakeholders on the African continent.

Further details on the methodology used to develop this report can be found in the Appendix.

# Structure of the report

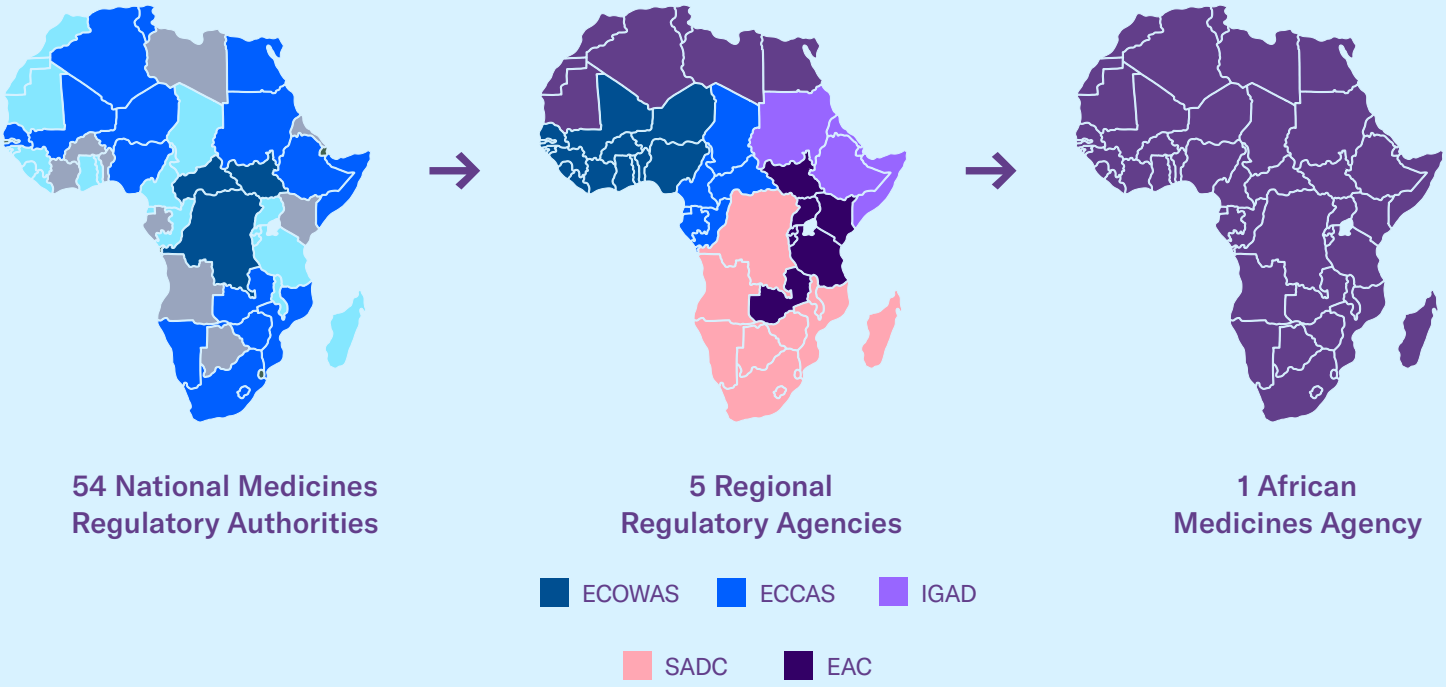
The remainder of this report is structured as follows:

- Chapter 2 outlines the progress toward regulatory convergence in Africa in recent years, covering developments at the national, regional, and continental levels, and support from the international community.
- Chapter 3 examines the remaining regulatory challenges to convergence and optimizing access to health technologies in Africa.
- Chapter 4 summarizes the recommendations for strengthening regulatory systems and achieving regulatory convergence, directed in turn at stakeholders at the national, regional, continental, and global levels.

# Progress toward regulatory convergence in Africa

Significant movement toward the goal of regulatory convergence in Africa has occurred over the last decade, with progress being made at the national, regional, and continental levels. Nationally, this is illustrated by the developing maturity levels of NRAs. Regional convergence initiatives via Regional Economic Communities (RECs) cover most of the continent, while the establishment of the AMA reflects progress continentally (see Figure 4). Regional initiatives and the AMA play distinct, additive roles and are intended to complement national processes and initiatives. Therefore, aligned and consistent progress toward regulatory convergence at each level is essential to ongoing and future regulatory strengthening. In this section, we provide an overview of progress toward regulatory convergence in Africa.

**Figure 4: Evolution of regulatory convergence in Africa.**
Source: Adapted from Chattu et al. 2021[45]



# National regulatory agency maturity: The starting point for regulatory convergence

The aim of regulatory convergence is to ensure that best practices are used to efficiently accelerate patient access to health technologies. Therefore, mature regulatory systems are the starting point for regulatory convergence.

Four maturity levels are used to assess regulatory agencies. Level 3 is the second highest and represents the minimum target established by World Health Assembly (WHA) Resolution 67.20 for Regulatory System Strengthening.[46] As of April 2024, two NRAs on the continent have been designated maturity level 3 (ML3) for vaccine production (Egypt and South Africa); three, for vaccine imports (Ghana, Nigeria, and Tanzania).[47] Four NRAs are at ML3 for medicines (Egypt, Ghana, Nigeria, and Tanzania). Interviews with industry representatives highlighted the importance of an NRA achieving ML3: it reflects the ability to support quality assurance, ensure safe production of health technologies, and support cross-border distribution.[48] Industry representatives also highlighted that countries with more mature regulatory frameworks are viewed favorably as product launch destinations and that a reliable and stable regulatory system safeguards quality standards (ensuring a level competitive playing field) and patient safety.[49]

The achievement of ML3 status also allows inclusion of the NRA on the WHO Transitional List of Regulatory Authorities, a list of NRAs operating at an advanced level. It can be a used as a point of reference for other countries' regulatory approval assessments of new drugs and vaccines, and it ultimately determines eligibility for consideration as a WHO-listed authority (WLA) facilitating regulatory convergence.[50] Currently, most African countries producing or aspiring to produce health technologies still lack the testing and lot-release capacities needed to reach ML3.[51]

# The growing role of regional convergence initiatives

The AMRH program was created in 2009 with the goal of bolstering regulatory standards and processes for medicines throughout Africa. It plays a pivotal role in driving regulatory system strengthening activities. The initiative has supported convergence through the establishment of effective regulatory networks within the RECs in Africa.[52,B] AMRH initiatives have been implemented in five RECs: East African Community (EAC), Southern African Development Community (SADC), Economic Community of West African States (ECOWAS), Economic Community of Central African States (ECCAS), and Intergovernmental Authority for Development (IGAD).[53]

B Africa has eight RECs: Arab Maghreb Union (UMA), Common Market for Eastern and Southern Africa (COMESA), Community of Sahel-Saharan States (CEN-SAD), East African Community (EAC), Economic Community of Central African States (ECCAS), Economic Community of West African States (ECOWAS), Intergovernmental Authority on Development (IGAD), and the Southern African Development Community (SADC).

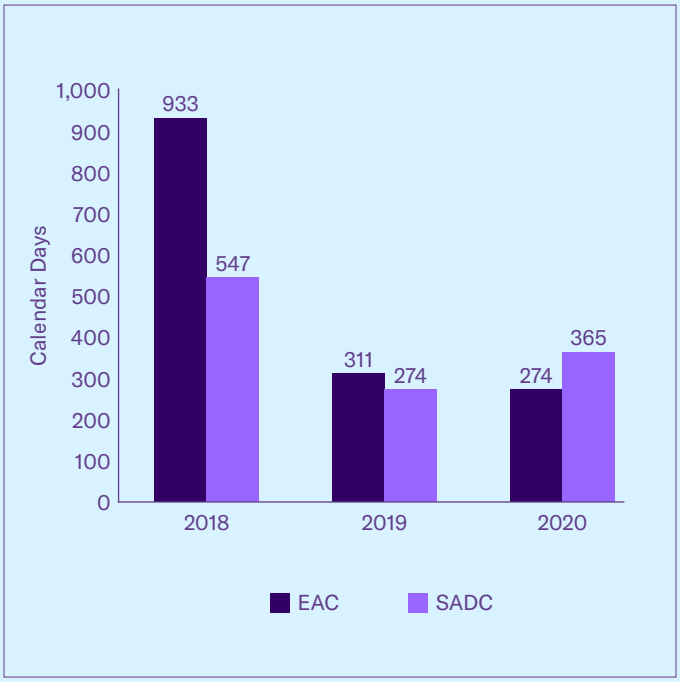
REC initiatives have fostered knowledge exchange and strengthened inter-state relationships, allowing the less mature NRAs to learn from the experiences and successes of more mature NRAs. This has helped to bridge capacity gaps and build technical proficiency among regulatory staff, enabling these countries to more effectively carry out regulatory functions. Second, twinning programs promoted collaboration and networking within the regulatory community. By fostering relationships between NRAs across countries, twinning encouraged information sharing, peer support, and mutual learning. This collaboration facilitated harmonization efforts and promoted greater consistency in regulatory decision-making across borders, which strengthened the regulatory systems. *See Appendix 2: Evidence of progress toward regulatory convergence in Africa, for evidence of how joint activities and twinning programs that pair newer NRAs with more mature counterparts have supported NRAs to achieve greater autonomy in regulatory functions.*[54]

Furthermore, reliance practices to streamline procedures and reduce duplicative efforts have been shown to accelerate access to healthcare technologies in EAC and SADC. Both the EAC and SADC initiatives have integrated reliance practices, including the use of abridged applications for medicinal products already registered by WHO-listed regulatory bodies, expediting their entry into the market. Notably, the implementation of these practices has led to reductions in median timelines for regulatory decisions at the regional level over time (see Figure 5). In the case of the EAC MRH initiative, this has resulted in a significant shortening of the timeline for these products, from 933 days in 2018 to 274 days in 2020.[55] The work-sharing initiative in SADC (ZaZiBoNa) resulted in a median time to a market approval recommendation of 12 months (2021), whereas individual countries had a market approval recommendation time of over 21 months (2020).[56]

These efforts have been supported by expert working groups, technical working groups, and steering committees at the regional level,

**Figure 5: Median Approval Timelines Observed via Regional Initiatives**

Sources: Mashingia et al. (2023),[57] Sithole et al. (2020),[58] Sithole et al. (2022)[59]




as well as direct support via the AMRH Technical Committees (TC) organized at a continental level (*see Appendix 2 for more detail*).

# Looking to the future: The development of the AMA and continental regulatory convergence

The establishment of the AMA builds on the foundation laid by the AMRH initiative.[60] The AMA aims to do the following:

- Streamline and strengthen regional harmonization efforts via the domestication and implementation of the African Union (AU) Model Law (a non-prescriptive legislative framework aimed at harmonizing regulatory systems and enhancing collaboration across countries that is intended to be domesticated by AU member states and RECs)[61]

- Evaluate medical products for the treatment of priority diseases as determined by the AU[62]
- Coordinate joint reviews of clinical trial applications for vaccines and "highly complex" product dossiers and coordinate joint inspections of Active Pharmaceutical Ingredients (API) manufacturing sites.[63]
- Provide harmonized standards and processes for the approval and oversight of medical products, thereby strengthening the capacity of AU countries to regulate health technologies[64]
- Complement the initiatives of RECs through the pooling of expertise, resources, and networks[65]
- Provide guidance and support to NRAs through dedicated technical committees tasked with specific assessments and scientific reviews, including quality evaluations and clinical trial application[66]

Ultimately the AMA aims to enhance access to safe, quality-assured healthcare products across the continent.[67] In support of the operationalization of the AMA, in November 2023, AMRH launched the pilot phase of the continental procedure for the evaluation of specific medicinal products, which is expected to last about a year.[68] Specifically, the Evaluation of Medicinal Products Technical Committee is undertaking an evaluation of the quality, safety, and efficacy of priority medicinal products, with the assessment outputs being shared with the NRAs.[69] The first reviews are understood to have begun in March 2024, following receipt of more than 30 applications for inclusion in the pilot phase from manufacturers.[70]

Despite the notable progress that the establishment the AMA signals, operationalizing the AMA has been slow. For example, only 15 countries adopted the AU Model Law in its first five years (2016–2021), and only 27 of the 55 countries have ratified the AMA treaty.[71,72]

Notably missing from the AMA ratification to date are two of the continents' largest markets, Nigeria and South Africa. Stakeholder interviews noted several factors that may be contributing to slow ratification.[73] First, levels of political will vary among member states of the AU, with some countries deprioritizing regulatory convergence. Additionally, legal complexities and the need for amendments to national legislation to domesticate the AU Model Law and align with the AMA's mandates pose hurdles to ratification. Last, concerns over sovereignty and the delegation of regulatory authority have led to hesitancy by certain member states.[74] Addressing misconceptions about the role of the AMA may overcome the challenges to countries' AMA Treaty ratification. This should include ensuring that the processes of ratification and providing formal consent (depositing written instruments), including the differences between signing the treaty and full treaty ratification, are well understood by each country's government.[75] Stakeholders should emphasize that the AMA will strengthen NRA capacity by streamlining the work of NRAs. Demonstrating these benefits may encourage NRAs to lead the process of ratification, as was seen in Kenya and South Africa, where NRAs followed up on documentation with the ministries of health, led dialogues, and hosted stakeholder meetings.[76]

## The role of the international community in supporting regulatory convergence

While African national governments and regional communities have been the driving forces of regulatory convergence, their actions have been supported by various global stakeholders. Through the AMRH Partnership Platform (AMRH PP), multilateral organizations (e.g., the WHO), nonprofit organizations such as the Gates Foundation, industry stakeholders such as the International

Federation of Pharmaceutical Manufacturers & Associations (IFPMA), and WLAs such as the US Food and Drug Administration (FDA) and the European Medicines Agency have supported regulatory strengthening on the continent. These stakeholders have collaborated with national, regional, and continental stakeholders to enhance coordination and optimize resources in Africa's regulatory environment. *See Appendix 2: Evidence of progress toward regulatory convergence in Africa for examples of how the international community and global stakeholders have supported convergence on the continent.*

- The AMRH PP is the steering group that facilitates partner coordination. It is committed to providing support for capacity assessments and promotes mutual accountability through regular progress reviews.[77]

- A key focus of the WHO has been to reduce NRA capacity constraints on the continent. In 2013, the WHO launched its collaborative procedure for accelerated registration of prequalified finished pharmaceutical products (the Prequalification (PQ) Program). The program seeks to accelerate registration through information sharing between WHO prequalification and NRAs.[78] The program has successfully registered over 110 products that address key healthcare priorities on the continent, including HIV/AIDS, tuberculosis, malaria, and reproductive health products.[79]

- Despite successes, the PQ process has its limitations and has suffered from lengthy review and approval times, which was especially evident during the COVID-19 pandemic.[80] Furthermore, WHO PQ covers only a small subset (around 10% of those on the Essential Medicines List).[81]

- The Gates Foundation's financial and technical capacity contributions to AMRH initiatives have facilitated the implementation of diverse programs and projects aimed at bolstering regulatory systems, enhancing access to quality medicines, and aligning regulatory standards across African nations.

- Support from WLAs have enhanced regulatory efforts across the continent. For example, in May 2021 the European Medicines Agency launched the "Team Europe" initiative, which committed experts and provided training to strengthen the governance and scientific processes of AMA, alongside offering regulatory expertise.[82] This effort is part of a broader European Union (EU) strategy aimed at enhancing access to healthcare technologies in Africa, with significant financial backing and collaboration with EU member states, African Union agencies, and global health organizations.[83] Similarly the FDA has committed to supporting the operationalization of the AMA through the Office of Global Policy and Strategy.[84]

- Industry stakeholders such as the IFPMA actively promote the ratification and implementation of the AMA Treaty. The IFPMA is a founding member of the African Medicines Agency Treaty Alliance (AMATA), a stakeholder alliance backing the AMA. The AMATA also engages in technical and political discussions and aims to shape the governance of the AMA, with the goal of ensuring equitable access to quality health technologies and supporting pandemic preparedness in Africa.[85]

# Overall considerations

Our review has captured the progress toward convergence in Africa achieved in the last decade. While there are NRAs that have strengthened to meet global standards, significant diversity in levels of maturity exist, and progress is needed until all African NRAs are able to perform all regulatory functions at international standards. Similarly, some REC MRH initiatives have proven to be more successful than others (partially due to time since establishment). To ensure that the benefits of convergence are realized equitably across the continent, it will be crucial to expand good practices and lessons learned across the RECs. Finally, the regulatory landscape is evolving, and given the development of continent-wide convergence initiatives with the AMA, policy coherence at the national, regional, and continent levels is increasingly needed to ensure an optimized and efficient regulatory system. In the next section, we identify the remaining challenges to advancing regulatory convergence.

# Regulatory challenges affecting access to health technologies in Africa

Despite the progress that has been made toward regulatory convergence, regulatory challenges continue to be a significant impediment to access in many African countries. They fall into five broad categories (Figure 6).

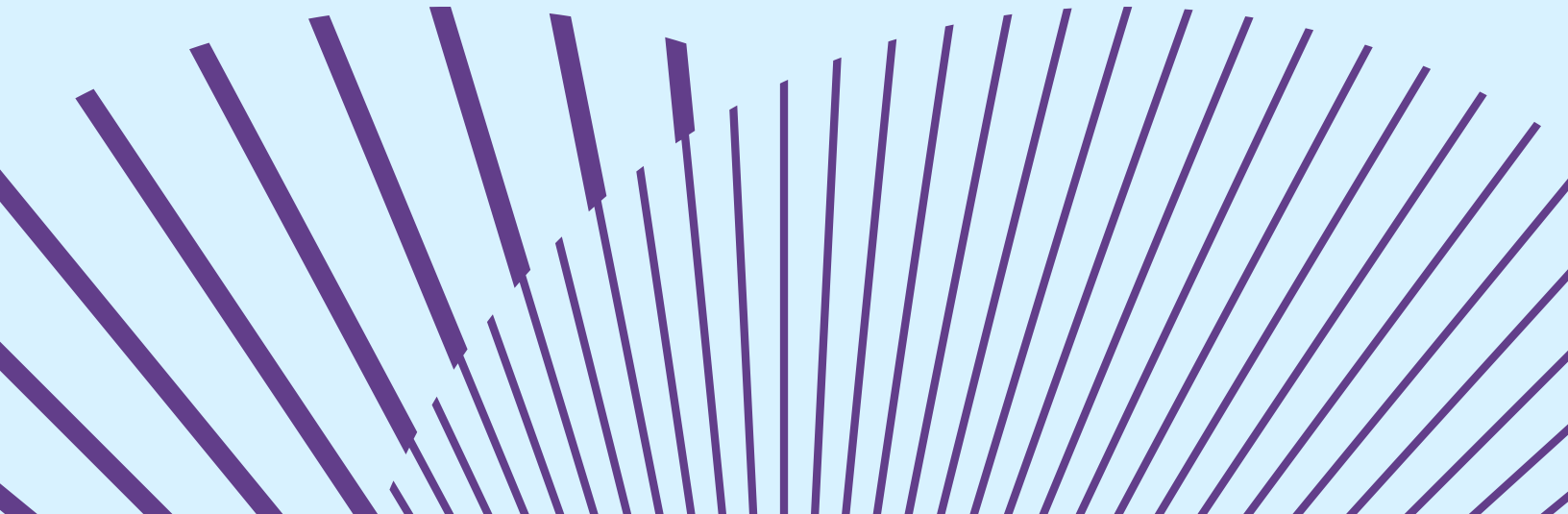
The impact of these challenges is material. One study found that the lag in regulatory approvals of new health products in sub-Saharan Africa is typically four to seven years after first regulatory submission in high-income countries, meaning that patients are unable to access the most innovative products for a significant period of time.[86] A study from PATH found that if regulatory reforms could accelerate access to just two health products by two years, more than 23,000 lives in eastern and southern Africa could be saved.[87] As noted, these challenges also affect innovation, competitiveness, economic growth, trade, and development of the continent. For example, regulatory barriers limit manufacturer incentives to conduct R&D and investment on the African continent, depriving patients of the opportunity to benefit from cutting-edge research through clinical trials.

**Figure 6: Overview of key regulatory challenges**

| | |
|---|---|
| **Limited mandate through legislation and governance** | Some NRAs are not legally mandated to perform all core regulatory functions, lack operational independence from the Ministry of Health or other government bodies. In some countries, the legislation needed to allow NRAs to engage with reliance is not in place. |
| **Lack of sustainable funding** | Many NRAs lack reliable funding to finance regulatory functions and personnel. Budgets may be relatively small and with limited fundings for salaries and infrastructure development, and fee structures may be outdated. |
| **Insufficient workforce capacity and capabilities** | Too few personnel, shortage of experience, and lack of diversity in expertise leads to backlogs in regulatory decisions. This is exacerbated by low staff retention and insufficient career progression structures. |
| **Duplicative or divergent requirements between countries** | Each country operating independently leads to duplication and complexities due to divergences in requirements which are highly specific, increasing the administrative burden on NRAs and manufacturers. |
| **Lack of supporting infrastructure** | Shortcomings in wider infrastructure to conduct regulatory activities e.g., information management systems; quality-control laboratories for post-marketing surveillance activities; lack of electronic pharmacovigilance reporting systems. |

# Limited mandate through legislation and governance

According to the WHO's Global Benchmarking Tool, NRAs should cover seven common functions that apply to the regulation of all medical products identified for the evaluation of national regulatory systems.[88] These include the registration and marketing authorization of health technologies, vigilance and market surveillance, laboratory testing, and clinical trials oversight. Some African national regulatory systems are characterized by a limited legislative mandate and challenges related to their governance, which act as barriers to conducting core regulatory functions.[89] Historically only a small number of NRAs have undertaken all regulatory functions. For example, in 2010 only 15% of WHO-AFRO region NRAs were legally mandated to perform all critical regulatory functions.[90] The same study noted that African regulatory systems are characterized by a dispersion of regulatory authority among more than one institution (such as multiple departments within the Ministry of Health), which limits the autonomy and effective functioning of NRAs.[91] Although substantial effort has been exerted to introduce supporting regulatory legislation and governance in Africa over the last decade (such as through the development of the AU Model Law on Medical Products Regulation), it is still the case that many NRAs do not have legislation enabling the conduct of all regulatory functions.[92] For example, this means that several countries have no legal framework for pharmacovigilance, which can lead to gaps in safety monitoring systems and therefore risk exposing patients to substandard and falsified products.[93]



The legislative challenges impeding regulatory convergence in Africa are threefold:

1. Legislation supports the governance of NRAs and therefore their authority. For example, some NRAs are not given autonomy from the Ministry of Health through the existing mandate and therefore lack operational independence.[94] One impact of this is that countries lack autonomy to collect fees; fees are redirected to the central government treasury, bypassing opportunities for NRAs to strengthen their systems because a sustainable source of income cannot be secured.[95]

2. Many countries in Africa require specific legislation to permit the NRAs to engage with reliance, and this is not yet widespread.[96] The AU Model Law aims to address this challenge; it includes a section on international cooperation and regulatory harmonization initiatives. For example, there are provisions stating that the NRA should cooperate with other NRAs to harmonize medical product registrations and inspections, provide for mutual recognition of marketing authorization decisions, and establish quality management systems and information management systems based on common regional and continental requirements.[97] The WHO guidance on good reliance practices also states that reliance should be supported by clear mandates and regulations, either through explicit provision for the application of reliance or through interpretation of existing regulations.[98]

3. Legislation supports the regulatory scope of NRAs and is a particular challenge for achieving marketing approval of medical devices and diagnostics. Much of African nations' regulatory legislation for their NRAs were designed with medicines as the primary focus, with no specific provisions for other types of health technology.[99] In fact, many African countries continue to have no regulatory scheme for medical devices and diagnostics—a cause of the variability in maturity between health technology types.[100] About 40% of countries in the WHO Africa region do not regulate medical devices.[101] This may lead to lower-quality medical devices (because they may be subjected to less scrutiny regarding efficacy and safety) or slower access due to insufficient pathways for bringing them to market. Legislative changes may also become more important within the context of regulatory convergence in Africa—most countries require specific legislation permitting NRAs to engage with reliance, which is not always in place.[102]

Several stakeholders driving regulatory system strengthening on the continent, and those in the global community supporting it, emphasized in interviews that a robust legislative and governance framework supporting African NRAs is a crucial prerequisite to improving access.[103] Ensuring NRA autonomy can also help to address the issue of sustainable funding (see below), because it can result in designated budgets to support regulatory functions and regulatory fees not being diverted to other areas of public funding rather than being reinvested into building regulatory capacity.[104]

## Lack of sustainable funding

Many NRAs in Africa lack the permanent funding they need to finance regulatory functions and pay regulatory personnel. Most regulatory systems are predominantly or wholly self-funded, but the NRAs still have relatively small annual budgets, much of them earmarked for operational costs, leaving limited funding

for salaries and infrastructure development.[105] Limited funding in turn undermines the development of infrastructure needed to support core regulatory functions and development of a skilled workforce through competitive salaries. While NRAs are using application fees as their main source of funding, some NRAs continue to depend on donor funding, which is perceived as ad hoc and unsustainable, especially as countries graduate from the Global Alliance for Vaccines and Immunization (GAVI) and the U.S. President's Emergency Plan for AIDS Relief funding as they move to middle-income status.[106] A review of the state of medicines regulation in 2017 (while slightly outdated) shows that 15% of the 26 countries included in the study received donor funding.[107]

The optimal approach to the funding of NRAs likely requires a combination of application fees, government funding and donor funding, and the composition is important. For example, dependence on fees from industry can in some cases disincentivize manufacturers from applying for clinical trials or marketing authorizations, given the great uncertainty of achieving market access in the country.[108] Research has revealed that manufacturers consider registration costs and GMP inspection fees as a key reason to not supply medicines to some countries.[109] Interviews with health technology manufacturers suggest that manufacturers often face long and unpredictable delays in the review of applications for clinical trials and marketing authorizations, despite increases in the fees associated with these applications.[110] On the other hand, NRAs may have fee structures that are significantly outdated and therefore unlikely to provide sufficient financing for the regulatory body. Kenya provides one example: there, fees have not been updated since 1981.[111] Importantly, industry stakeholders noted in interviews that the level of application fees is itself not the barrier to product registration; the barrier is the failure to receive the corresponding benefits (a timely and predictable approvals process).

## Insufficient workforce capacity and capabilities

In many African countries, NRA personnel are insufficient in number or expertise for the timely completion of all regulatory activities.[112,113] Key challenges faced by many NRAs include shortages of expert regulatory professionals and a lack of diversity in scientific opinion, which can result in backlogs of regulatory decisions.[114] Academic commentators on access to medicines in Africa have also raised concerns about the hiring practices used by some NRAs.[115] For example, sometimes pharmacists are hired in roles requiring different competencies than they were trained for, which is particularly detrimental to the technical assessments needed for medical devices.[116] Lack of personnel at NRAs have been linked to the challenge of low staff retention levels and insufficient career progression structures—NRAs find it difficult to attract, develop, and retain their workforce because they do not provide competitive salaries or desirable career paths.[117]

Workforce shortages result in delays in all NRA activities and decisions. Most evidently, this is seen in the review timelines for approval of new medicines and medical devices: having few assessors or assessors with inappropriate expertise means that timely review of applications is very challenging. Lack of capacity also contributes to a low rate of post-marketing withdrawal of medicinal products that are harmful due to adverse drug reactions, contributing to the number of substandard or falsified medicines on the market.[118]

# Duplicative or divergent processes across countries

Across the African continent, duplicative and divergent processes continue to be a barrier to access to medicines, medical devices, and other health technologies:[119,120]

- **Duplicative processes**

  As noted above, although convergence progress in the region has reduced the degree of fragmentation, it is nevertheless still the case that reliance mechanisms are underutilized, and separate and lengthy regulatory processes are frequently required country by country. For example, while ZaZiBoNa (the collaboration between NRAs Zambia, Zimbabwe, Botswana, Namibia, and South Africa) provides a timely assessment recommendation for a product within the set time frame, in practice, access by patients is slowed by the delayed uptake of the regional recommendation at the national level, where agreed timelines are not met.[121]

- **Fragmentation**

  Despite the harmonization efforts by RECs, many countries have regulatory requirements that are highly specific. They can include country-specific requirements across all regulatory domains, such as how post-approval changes are handled or the languages on packaging, which can mean that manufacturers are required to provide a separate pack for some NRAs.[122] While each country emphasizes the importance of maintaining its sovereignty in regulatory affairs, this results in fewer opportunities to benefit from reliance and harmonization, and the potential for faster reviews is not realized.[123] In the context of already-low resources, this increases the administrative burden on regulatory bodies and manufacturers alike.

- **Delays**

  The impact of multiple submissions means that patients access new health technologies far later than those in countries with regulatory systems that have been mature longer, such as the United States: a gap of four to seven years between first global regulatory approval and approval in sub-Saharan African countries has been reported.[124] Within the RECs, the length of regulatory processes varies greatly. For example, in SADC in 2019, mean approval times for generics were between 218 and 890 calendar days.[125]

To some degree, the divergent requirements of countries across the continent are the result of variation in the regulatory scope of the REC MRH initiatives. For example, the EAC evaluates product dossiers, conducts joint inspections of manufacturing sites and clinical sites (in accordance with EAC Guidelines and GMP, respectively), and post-marketing quality surveillance. ZaZiBona, on the other hand, conducts joint GMP inspections and collaborative assessments of new products.[126] Notably, beyond the EAC, no REC MRH initiative has a regulatory scope that covers the whole regulatory life cycle of a product. Industry also noted that timely and efficient post-marketing activities such as post-approval changes are a key challenge in Africa.[127] As a consequence of the varying scopes of RECs, NRAs have implemented country-specific requirements for establishing the safety of a product. For example, although the ZaZiBona initiative requires dossier submissions through the Common Technical Document (CTD), countries within the SADC region may separately require information on labeling and a local Quality Information Summary (QIS) and Quality Overall Summary (QOS).[128] Interviews with industry revealed that these separate requirements cause delayed access to products and ultimately limit the realization of the benefits of reliance to the region.[129]

# Lack of supporting infrastructure

Core regulatory functions of an NRA need to be supported by well-developed, broader infrastructure.[130,131] The following are some of the important components of this infrastructure:

- Digital tools and information management systems at the national and regional levels to avoid delays and backlogs and make regulatory processes and information sharing more efficient. For example, RECs leverage digital tools to track regulatory processes (e.g., the uptake of REC decisions at the national level) and conduct regulatory functions, such as the monitoring of substandard and falsified medicines.
    - Interviews with regulatory stakeholders highlighted how NRAs receive a large number of applications but are not able to prioritize those that have already been assessed by the RECs without the digital tools to identify them.[132]
- Quality-control laboratories for post-marketing surveillance activities.
- Electronic adverse event and pharmacovigilance reporting systems to optimize ongoing surveillance of medicines, building on African Union Smart Safety Surveillance launched in 2020.

Shortcomings in infrastructure can be particularly negatively impactful when they result in harm to patients through the wider use of substandard and falsified medicines and medical devices. One review has estimated that almost 19% of medicines in sub-Saharan Africa are poor quality, demonstrating the importance of effective pharmacovigilance systems with adequate surveillance and monitoring tools.[133]

# Regulatory convergence: policy opportunities

Significant progress in strengthening regulatory convergence has taken place over the last decade. Notable milestones include a growing number of NRAs reaching ML3, evidence of regional-level efficiencies through AMRH initiatives (e.g., EAC, SADC), and the establishment of the AMA at the continental level.

However, progress in realizing the full benefits of convergence remains slow. The next section presents policy proposals that could help address the remaining challenges and the role of stakeholders at the national, regional, and continental level, followed by the role of the global community and other international partners. Where possible, we draw on learnings from successes of regional convergence, both within and outside Africa.

## National-level recommendations

A baseline of functionality needs to be achieved at the national level to recognize the benefits of regulatory convergence. Stakeholders agreed that establishing legislative frameworks should be made a priority to realize the full benefits of convergence, especially as they relate to access to innovative medicines and medical devices. Next, policy provisions should ensure the sustainable financing of NRAs as they become more established. Finally, although countries have already acknowledged the need to improve NRA workforce capacity, expand pharmacovigilance, and implement digital transformation, stakeholders agreed on the need for more urgent prioritization and improvement in these areas. In combination, these actions by national governments would support NRAs to achieve ML3 status and higher.

**1. National governments should establish legal frameworks—where they don't yet exist—that increase the authority of NRA as autonomous bodies, including the ability to leverage reliance and harmonization mechanisms. This should at a minimum support NRAs to achieve ML3 status as quickly as possible.**

Countries that have not yet fully domesticated the AU Model Law should do so, given the Law's objective to ensure that all African NRAs conduct core regulatory functions for medicines, vaccines, diagnostics, and medical devices.[134] Alternatively, bilateral agreements for memoranda of understanding between RECs and the NRAs could be used to support reliance. There are no examples of this on the continent yet; however, the South Africa Health Products Regulatory Agency (SAHPRA) has recently signed a Memorandum of Understanding (MOU) with the Egyptian Drug Authority in July 2023 for collaboration and reliance on pharmaceuticals, biological products, and medical devices, including knowledge sharing on market authorization, pharmacovigilance, Good Manufacturing Practices (GMP), and clinical trials.[135]

The main components of enhancing the autonomy of NRAs are the implementation of the AU Model Law and ensuring their financial independence (as outlined in the subsequent recommendation). National governments should identify additional actions that are needed to empower their NRAs. In particular, some NRAs do not have operational independence from the government because they are part of the Ministry of Health.[137] Separating NRAs formally from the government is an important mechanism for empowering these agencies.

## Case study success: Reform of regulatory frameworks in South Africa

Practically, countries should establish an abridged pathway for timely national approval after a regional assessment. These can be defined by national regulators. For example, South Africa's NRA, SAHPRA, serves as an exemplary case study demonstrating how regulatory frameworks can be updated to accommodate reliance mechanisms. In 2017, SAHPRA replaced the Medicines Control Council to address operational challenges and resource limitations that had been leading to prolonged regulatory reviews and hindering timely access to medical products. In so doing, SAHPRA included several WLAs, the FDA, the European Medicines Agency, Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and Health Canada as reference agencies to rely on for product evaluation decisions. The results of SAHPRA's reliance efforts were significant: a 63% reduction in the median approval timeline for New Chemical Entities (NCEs) by 2020 compared to the highest recorded median timeline in 2018.[136]

## Case study success: Regulatory fees and authorizing legislation in the United States

In the United States, the collection of regulatory fees is negotiated with the industry in exchange for commitments from the FDA to meet certain goals, such as making decisions on regulatory authorizations within a predictable timeline.[138] This may require changes to the underlying legislation. The FDA's fees are reauthorized on a five-year cycle through legislation such as the Prescription Drug User Fee Act and Generic Drug User Fee Amendments.[139]

## Case study success: Investment in pharmacovigilance systems in Brazil

An example of effective transformation in pharmacovigilance (PV) systems is demonstrated by Brazil's investment in digital systems. In 2018, Brazil transitioned from its previous PV system (Notivisa) to VigiFlow, an advanced electronic reporting system. This was driven by operational inefficiencies and the imperative to meet international standards. Since adopting VigiFlow, adverse drug reaction (ADR) reporting from the general public has increased, more than doubling compared to the year prior to its implementation. This improvement highlights the efficacy of VigiFlow in facilitating the collection, processing, and sharing of ADR data. Notably, VigiFlow has ensured the successful transmission of 100% of ADR reports to VigiBase, a WHO global database managed by the Uppsala Monitoring Centre, which was not feasible under the previous PV system.[140]

**2. National governments should establish sustainable funding structures for NRAs and incentivize timely adoption of reliance and harmonization of regulatory requirements through performance-related fees.**

A self-sustaining source of funds can come from application fee systems, but this should be tied to specific performance goals to ensure tangible benefits, as described in section 3. Although in some countries fees have recently been raised with the promise of more efficient reviews and tied to informal goals, this has not always translated into more timely or predictable regulatory decisions, so there is a need for fees to be more clearly tied to the expected procedural outcomes associated with them.

Although the example of the United States is currently aspirational for the continent—which first requires further capacity building and efficiencies—it does demonstrate the necessary direction of travel for ensuring financial sustainability of African NRAs and ensuring that all countries have a clear strategy for sustainable funding, including the resources needed for convergence.

Performance-related fees will also incentivize NRAs to make greater and more timely use of reliance as a means of reducing the time needed to reach regulatory decisions and achieving performance targets. Granting NRAs autonomy through legislation (as set out in the recommendation above) will provide NRAs financial freedom and the flexibility and agility to respond quickly to changing needs.

**3. National governments should increase investment into institutional and technical capacity of NRAs, including their workforce, quality management systems (QMS), and digital infrastructure such as information management systems to support convergence. National governments should continue to invest in several key areas.**

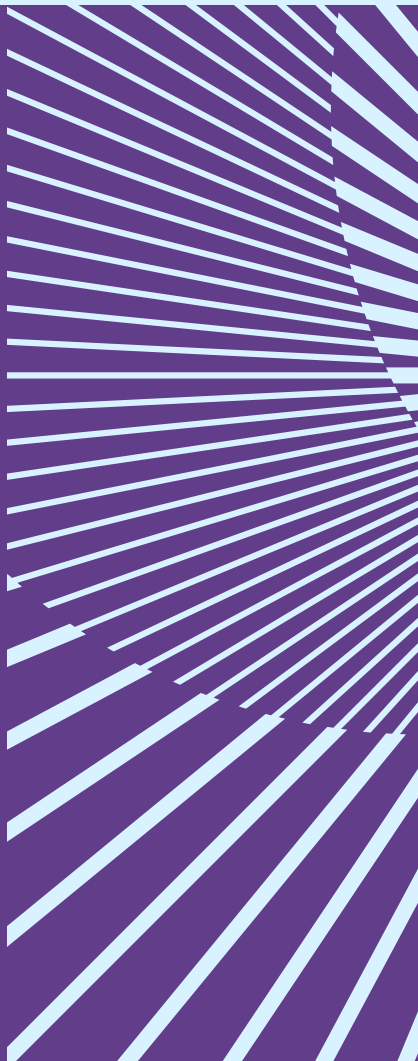
(a) NRAs should develop workforce capabilities and a strategy to attract and retain talent, leveraging existing initiatives where possible (such as the WHO Global Competency Framework), and also develop new materials, such as training manuals. This must include providing employees of NRAs with competitive salaries and incentives for developing a career within each national body. Workforce capacity building can also be enabled through participation in twinning programs with other NRAs, both on the continent and globally.

(b) Investment in pharmacovigilance and QMS is needed. This can be achieved through collaborative efforts aimed at implementing robust monitoring tools, improving reporting mechanisms, and conducting regular inspections to identify and mitigate risks associated with poor-quality products. Well-developed QMS are required to ensure access to quality health technologies. NRAs should support their strengthening by establishing key performance indicators relating to the timeliness of QMS and integration with pharmacovigilance systems.

(c) Supporting digital infrastructure in Africa has been recognized by many stakeholders as a solution that will support effective uptake of reliance mechanisms and achieving regulatory convergence.[141] National governments could support implementation of digital regulatory information management systems to improve efficiencies in regulatory processes and support convergence. Additional examples of the digitization of processes are increasing the use of electronic platforms, e-communications, e-documents, and virtual work sharing. Improving digital capacity and infrastructure of NRAs has the potential to support convergence and improve efficiencies for all key regulatory functions, such as oversight of complex clinical trials, rapid information sharing of marketing authorization dossiers and reports, and pharmacovigilance processing.

## Case study success: Investment in digital infrastructure across Gulf Cooperation Council members

An example of investment in digital tools to support to regulatory processes can be seen across the Gulf Cooperation Council (GCC) member states, including Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, the United Arab Emirates, and Yemen, which enhanced their regulatory processes via digitalization beginning in 2015. Although further regulatory convergence is needed in the GCC region, the introduction of a shared file storage system has improved review processes, resulting in substantial reductions in approval times. Notably, the average approval time for generics and new active substances decreased significantly, from 838 calendar days in 2015 to 411 calendar days by 2020. The adoption of electronic communication methods has further expedited reviews, contributing to overall efficiency gains. Moreover, regulatory procedures were realigned with reliance principles outlined by the WHO, with standardized document formats and increased use of electronic platforms, e.g., electronic Clinical Trial Document. These concerted efforts have yielded tangible improvements in the efficiency and effectiveness of medicine approvals across the GCC member states.[142]



**4. National governments should empower NRAs to maximize streamlining of approvals for WHO prequalified products, particularly through the WHO Collaborative Registration Procedure.**

The PQ program is a major opportunity to streamline national approvals of certain products through reliance on the WHO's decision regarding their efficacy and safety. However, in many countries, duplicative assessments at the national level of prequalified products lead to a delay of around two years.[143] A key mechanism for accelerating country registration of WHO PQ-ed products is via the Collaborative Registration Procedure (CRP) for prequalified products, which a reasonable number of African NRAs already participate in.[144] The CRP enables WHO-PQ assessment reports and manufacturer submissions to be shared directly with participating countries' NRAs, which can form the basis for national approvals. To maximize the potential for WHO PQ to streamline national approvals, all African countries should participate in the CRP. Doing so has the potential to significantly accelerate national approvals, as the target timeline is 90 days for a decision (with an additional 30 days for communication to WHO-PQ and the manufacturer).[145]

# Regional-level recommendations

Regional harmonization initiatives over the past decade, established by the AMRH, have been instrumental in driving regulatory convergence across Africa. Stakeholders agreed that while these initiatives have been set up across RECs, the priority should now be on ensuring implementation and sustainability. Going forward, leveraging digital tools and sustainable funding mechanisms will support efficient growth of the initiatives to serve as the foundation for the AMA.

**1. Establish standardized operating procedures (SOPs) within RECs to strengthen institutional capabilities in implementing MRH initiatives.**

To facilitate harmonization initiatives at the regional level, the RECs should establish SOPs that comprehensively outline processes throughout the regulatory life cycle, including post-authorization activities such as post-approval changes, renewals, pharmacovigilance, and market surveillance.

## Case study success: Benefits of SOPs in the EAC MRH initiative

A compelling case illustrating the benefits of such SOPs is observed within the EAC MRH initiative. Through this initiative, the timeline for national assessments significantly decreased from 2012 to 2017, with assessment durations reduced from roughly 24 months at baseline to 8 to 14 months in Kenya and 10 to 12 months in Tanzania. This achievement was facilitated by the adoption of a modified version of the CTD developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Manufacturers could use this standardized CTD to apply for medicine registration in any EAC partner state. The initiative's Medicines Evaluation & Registration Working Group was spearheaded by Tanzania's NRA, which played a pivotal role in creating this standardized CTD as part of the broader mandate to harmonize technical requirements, standards, and SOPs for medicines assessment and registration across the region.[146]

Additionally, developing clear procedures for RECs to monitor subsequent national registrations, ensuring adherence to agreed timelines, is essential. Stakeholders involved in regulatory convergence efforts should collaborate to draft, review, and implement these SOPs, ensuring consistency and efficiency in regulatory processes across member states and maximizing their effectiveness for reducing duplication between countries.

One area where additional harmonization is needed is the standardization of language and packaging regulations. These requirements can lead to manufacturers needing to prepare distinct packaging for approval of different NRAs, which limits the extent of convergence. Greater standardization of or mutual recognition of language and packaging should take place within the scope of the AMRH initiative, with English the most feasible language to align to given its use by other regulatory authorities globally.

**2. Develop digital tools for centralized tracking, public reporting of achievements against key performance indicators, and facilitating access to information to enhance transparency of REC decisions and seamless follow-up by NRAs.**

To enhance REC decision-making processes and increase transparency, it is important to develop digital tools for centralized tracking and reporting of key performance indicators. These tools should enable efficient monitoring of product rejections and the identification of substandard and falsified products, thereby promoting accountability in regulatory activities. By streamlining communication and information sharing among stakeholders, these digital tracking systems will ensure that NRAs have access to timely and accurate data on REC-recommended products. A centralized platform also facilitates follow-up with NRAs on what occurs after an REC decision and ensures transparency related to key performance indicators, e.g., adherence to agreed timelines.

## Case study success: Digital tools to support pharmacovigilance in the Caribbean region: VigiCarib

The formation of VigiCarib is an example of enhancing REC decision-making processes through the development of digital tools for centralized tracking. VigiCarib, launched by CARPHA and CRS in December 2017 with the support of the Pan American Health Organization, enables stakeholders to submit reports on adverse reactions and substandard medicines for regulatory analysis and action. This platform fosters transparency and accountability by allowing government focal points, health professionals, industries, and the public to contribute to the regulatory process. By sharing information and pooling data among CARICOM members, VigiCarib facilitates the identification of safety signals and the recommendation of regulatory actions to relevant authorities. The platform has received 528 case reports since its launch, covering ADRs, substandard or falsified medical products, and adverse events following immunization. This demonstrates the effectiveness of digital tracking systems in ensuring timely and accurate data on REC-recommended products, thereby promoting public health and safety across the region.[147]

### 3. RECs should establish a legal framework for a centralized joint assessment pathway for products that would not be reviewed by the AMA.

A centralized pathway can accelerate the marketing authorization process. Regulatory and procedural inspiration could be drawn from SADC, which launched a pilot for a centralized joint assessment pathway for medicines in January 2024.[148] ZaZiBoNa is transitioning to a centralized process, moving away from dossiers being submitted to each member state. The outcome is a recommendation of products for participating member states. The ZaZiBoNa portal aims to serve as a centralized platform for submissions and outcomes; a positive recommendation can expedite the review and registration process when submitting applications for marketing authorization. A centralized platform would simplify the process if paired with legislation that authorizes the REC centralized recommendation to be valid in member states, thus requiring participating countries to conduct an abridged, confirmatory review.

### 4. Establish a dedicated funding mechanism for joint procedures within RECs.

A permanent funding mechanism for joint procedures within RECs is needed. A sustainable financing framework that can accommodate additional fees, such as top-up charges or coordination fees, must be established to support collaborative regulatory activities. By securing adequate financial resources, RECs can effectively conduct joint assessments and streamline regulatory processes, thereby advancing harmonization objectives and facilitating efficient market access for healthcare products across member states. While the level of fees used in Europe is unlikely to be transferable to the African continent, the funding systems for the European Medicines Agency nevertheless demonstrate how joint processes can be handled through a structured fee system.

## Case study success: User fee system in the European Union

The European Medicines Agency uses user fees for joint processes through a structured fee system that supports collaborative regulatory activities. Applicants are required to pay fees for various regulatory activities, including marketing authorization applications, scientific advice, and inspections. For joint procedures involving multiple member states, such as mutual recognition procedures, the Agency calculates fees based on the number of concerned member states involved in the procedure. This approach ensures that the costs associated with joint procedures are distributed equitably among the involved parties, fostering financial sustainability and fairness in collaborative regulatory efforts in the European Union.[149]

**5. To address the relatively slow uptake of reliance mechanisms, mature RECs should more effectively promote and communicate the benefits of regional reliance efforts to NRAs and other RECs.**

Mature RECs should further engage in active dialogue and collaboration with industry, NRAs, and other RECs. This could involve organizing stakeholder forums, workshops, and information sessions to highlight the successes and advantages of regional reliance mechanisms. Furthermore, stakeholders should actively seek feedback and input from industry stakeholders to ensure that their perspectives are adequately represented and integrated into regional initiatives. By fostering greater industry engagement and promoting transparency in regional reliance efforts, stakeholders can build trust, enhance credibility, and ultimately strengthen regulatory convergence across regions, addressing the identified need for increased industry involvement by stakeholders.[150] Enhancing reliance mechanisms within RECs also presents a strategic opportunity to improve the coherence and effectiveness of regulatory convergence efforts between regions.

# Continental-level recommendations

While the immediate priority for continental-level convergence is for the remaining countries to ratify the AMA treaty, other actions are needed to ensure its successful operationalization. Although the AMA pilot of continental listing is at an early stage, we suggest some novel, forward-looking actions that will cement the long-term operation of AMA and ensure that it effectively reduces duplicative processes across countries and delivers improved access to health technologies. Continental regulatory stakeholders should establish a clear pathway from pilot to full AMA operationalization and a strategy to ensure that the AMA matures into a WLA that represents Africa on the global regulatory stage.

**1. Clarify the delineation of responsibilities and scope among AMA, RECs, and NRAs.**

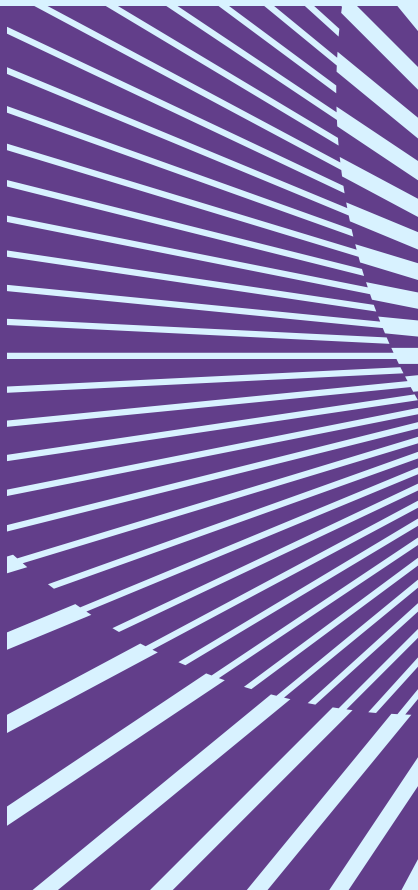
For seamless regulatory activities, especially as the AMA develops into a WLA, greater clarity is needed on which types of health technologies the AMA will focus on and which will continue to be assessed at the regional and national level. Although AUDA-NEPAD have stated that the AMA will coordinate joint reviews of trial applications for vaccines and assessment of "highly complex" product dossiers, the only example of this given is biosimilars.[151] As a starting point, then, the AMA should clarify which other product types are considered "highly complex" and whether it expects to have any other focus areas.

**2. Establish continental-level data collection systems that can support monitoring, impact evaluation, and public reporting of regulatory activities and how convergence is working.**

Continental-level data collection systems could serve as centralized platforms for gathering, managing, and analyzing data pertinent to regulatory harmonization initiatives across the continent. By systematically collecting data on regulatory policies, capacity-building endeavors, and their impact on access to healthcare technologies, stakeholders can effectively monitor progress, identify challenges, and evaluate the efficacy of regulatory convergence

## Case study success: A centralized procedure at the continental level, in Europe

Through its centralized procedure, the European Medicines Agency conducts assessments at the continental level for specific categories of medicinal products. These include human medicines containing new active substances for critical therapeutic areas such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune disorders, and viral diseases, as well as medicines derived from biotechnology processes, advanced-therapy medicines, orphan medicines, and certain veterinary medicines. While the centralized procedure is compulsory for these products, it is optional for others, such as medicines with new active substances for indications not listed above, significant therapeutic innovations, and those deemed to be in the interest of public or animal health at the EU level. Subsequently, national regulatory authorities within the EU recognize these assessments, fostering a clear connection between continental evaluations and national decision-making processes. This model facilitates efficient regulatory convergence by streamlining procedures and ensuring consistency in regulatory decisions across member states.[152]



efforts. Moreover, these data collection systems can play a pivotal role in enhancing pharmacovigilance on the continent by facilitating the monitoring of ADRs, ensuring the safety and efficacy of pharmaceutical products across borders, and enabling rapid response to emerging safety concerns.

**3. Establish a process and guidance for NRAs to conduct an abridged, confirmatory approval process following AMA evaluation, and establish a strategy to support ongoing maturity of AMA to reach WLA status.**

Linkage between AMA regulatory recommendations and NRAs will maximize the benefits of reliance and support full regulatory convergence. AMA should establish guidance and SOPs around how continental-level regulatory recommendations should be recognized by NRAs in their assessments of health technologies and ensuring that they can contribute to an abridged and streamlined national process. This will ensure that the benefits of AMA recommendations are carried forward through the regulatory pathway to support sustainable health technology supply and patient access. African policymakers and global stakeholders should develop and support a strategy that sets out how the AMA can mature to reach WLA status. This will ensure that the AMA is recognized as a regulatory agency not only for Africa, but for the rest of the world too.

**4. Publish a strategic plan and timelines for the next steps for AMA operationalization to support accountability.**

Implementation of the AMA has been slowed by the slow ratification process, but it is critical that work on operationalizing the Agency continues apace. To facilitate this, AUDA-NEPAD should publish a clear work plan outlining the next steps and timelines for the agency, including the steps to be taken following the conclusion of the pilot for continental listings. This will ensure that all stakeholders involved are held accountable for supporting the timely implementation of the AMA and preventing additional delays in this crucial milestone for convergence.

## Case study success: A data processing network and management system in the EU: EudraVigilance

By efficiently aggregating and analyzing reports of ADRs within the European Union, EudraVigilance supports robust pharmacovigilance efforts, enabling rapid identification of safety concerns, facilitating risk assessment, and informing regulatory decision-making.[153]

# Global regulatory development and partner coordination

Collaboration and coordination among all global stakeholders beyond the continent that have supported regulatory system strengthening to date is still needed to steadily enhance regulatory convergence. Such stakeholders include global health organizations, other international regulatory bodies, and the industry. Two key recommendations were noted by stakeholders.

**1. Ensure continued engagement with industry (such as by establishing an AMA industry standing group), especially to leverage institutional knowledge and participation in regulatory procedures to facilitate timely health technology access across the continent.**

Whether at the national, regional, continental, or global level, the industry must be engaged to enable the successful development and implementation of regulatory convergence initiatives. The industry has institutional knowledge on global regulatory processes and can provide feedback on best practices. Industry elements are also willing partners in pilot programs, including the latest AMA pilot.

Once the AMA continental listing process is underway, manufacturers need to commit resources to fully use AMA regulatory processes, such as by providing timely responses to the questions of regulatory reviewers and providing feedback on the implementation of its initiatives. While this will be particularly important as the AMA is operationalized, manufacturers must also continue to support regulatory convergence at the national level, including leveraging regulatory processes, sharing knowledge, and participating in joint forums. Also important is that engagement with industry not be limited to the formation of AMA, but rather be embedded in its operations more systematically. For example, a formalized working group analogous to the European Medicines Agency Industry Standing Group would ensure continued dialogue with industry. Also required is continued partnership among other global health stakeholders, e.g. the WHO and the Gates Foundation, which have been supporting progress toward convergence by supporting knowledge transfer and establishing forums for dialogue.

The AfCFTA can help to scale the recommended efforts by acting as a liaison between local manufacturers and the AMA. AfCFTA can also support countries that face disproportionate challenges to regulatory-strengthening initiatives so that they are also able to align standards and regulatory practices to achieve the benefits of convergence.[155]

## Case study success: Establishing an industry standing group in Europe

In 2022, the European Medicines Agency established an Industry Standing Group to enable regular dialogue with industry stakeholders on issues relating to medicines and medical devices. The group meets four times per year to enable an exchange of views between the Agency and stakeholders in these industries. It is intended to complement other forums for dialogue, such as industry stakeholder platform meetings and bilateral meetings with industry associations representing specific sectors.[154]

**2. The WHO should continue efforts to refresh the PQ program to address access challenges to essential medicines and diagnostics and expand the program to include medical devices.**

Challenges associated with the PQ program, including lack of transparency in how dossiers are assessed, personnel capacity restrictions, too few opportunities for stakeholder engagement, duplicative procedures, and delayed assessments, have been recognized in the literature and were noted by stakeholders.[156,157] The WHO is developing a work plan to implement reforms based on a self-assessment (due in 2024, to be implemented 2025–2028). The objective of these recommendations should be to address the challenges to timely essential medicine, vaccine, and diagnostic PQ approval.[158] However, the WHO could further enhance its role in driving regulatory convergence in Africa. Specifically, the WHO PQ could be expanded to include medical devices. This would allow NRAs to rely on PQ dossier submissions for medical devices and accelerate national approval decisions.

In addition to these two key recommendations, it is important to recognize that all international partners will continue to have an important role in supporting further regulatory convergence on the continent. Some of the key initiatives needed, such as the WHO PQ program, have already been noted. Other relevant partners include the Gates Foundation, whose donor support will be crucial for enabling the operationalization of AMA. The WHO has also been a key technical partner for AMRH initiatives, and its technical assistance will be important for further convergence initiative pilots as they become more ambitious in the future.

# Conclusion

Regulatory systems are the gateway to providing safe and high-quality healthcare products to patients. Regulatory convergence is vital for safeguarding public health by ensuring the quality and safety of medicines, devices, and vaccines, and it affects global investment, local production, and trade. However, it is important to remember that a robust regulatory system is just one of multiple key components of a healthcare ecosystem that will ensure broad, equitable access to health technologies on the continent. Stakeholders agreed that in addition to continued policy action to intensify regulatory convergence, a focus on the strengthening of intellectual property rights, procurement systems, and healthcare infrastructure and delivery mechanisms is needed.[159]

# Appendix 1: Methodology

To examine the key regulatory barriers to access to health technologies in Africa and the potential role for greater regulatory convergence, we adopted a three-step approach.

## 1. Structured review of literature

Our literature review covered the regulatory barriers to access in Africa, progress to date with regard to regulatory convergence initiatives and their impact, and current debates about how regulatory convergence can be further enhanced. Table 1 summarizes our approach to the review of literature.

**Table 1: Structured literature review of access to health technologies and localization**

| Topic | Description |
|---|---|
| **Example search terms** | "Africa," "health technologies," "medicines," "therapeutics," "vaccines," "diagnostics," "medical devices," "regulatory systems," "regulatory unification," "regulatory harmonization," "regulatory reliance," "regulatory convergence," "regulatory centralization" |
| **Search engines** | Google Scholar, Google, and PubMed, complemented with hand search of websites of key institutions: WHO, World Trade Organization, etc. |
| **Date range** | Earliest date of publication was set at 2010 |
| **Search language** | English |
| **Reviewing process** | Peer-reviewed papers and white papers with relevant titles and abstracts were first selected for thorough reading and consideration for analysis of access barriers and impact of localization policies. |
| **Selection process** | The search included academic journals and articles, governmental official sources, and white papers from notable global health organizations. |

## 2. Interview program

Alongside the literature review, we conducted an external interview program including the following:

| Stakeholder type | Organization |
|---|---|
| **Global and bilateral funders** | Bill and Melinda Gates Foundation (Gates Foundation) |
| | United States Trade and Development Agency (USTDA) |
| **Regional leaders** | Africa Centres for Disease Control and Prevention (CDC) |
| | Africa Union: African Continental Free Trade Area (ACFTA) |
| | South African Health Products Regulatory Authority (SAHPRA) |
| | African Union Development Agency (AUDA-NEPAD) |
| **Pharma & Medtech** | Kenya Association of Pharmaceutical Industry (KAPI) |
| | Pfizer |
| | MSD |
| | Viatris |
| | GE Healthcare |
| **Nonprofit/advocacy** | FIND |

## 3. Case studies

To ensure the delivery of sound policy recommendations, we employed a comprehensive approach in selecting case studies, which help facilitate the development of policy recommendations and regulatory best practices for Africa. Our case studies targeted emerging markets both at the regional level in Africa and in regions outside Africa, allowing us to identify policies addressing regulatory barriers and global best practices for enhancing access to healthcare technologies. Furthermore, we conducted an examination of the European Medicines Agency due to its role as a potential model for the formation of the AMA and its provision of technical and financial support to the development of the AMA to identify lessons learned that can be leveraged on the continent.

# Appendix 2: Evidence of progress toward regulatory convergence in Africa

## A. The EAC Medicines Regulatory Harmonization

The EAC Medicines Regulatory Harmonization (EAC-MRH) was the first REC to implement the MRH initiative, which it did in 2012. The EAC comprises seven NRAs and has implemented policies and procedures to support regulatory reliance, harmonization, and work sharing through the development of a common technical document, requirements, standards, and guidelines for regulatory assessments.[160] Evidence of the benefits of regional reliance can be seen in the EAC. For example, in 2012, only Kenya, Tanzania, and Uganda had established semi-autonomous NRAs, indicating that these regulatory bodies operated with a certain degree of independence from their respective ministries of health, while Burundi, Rwanda, and Zanzibar (the NRA is autonomous with relation to mainland Tanzania's NRA) operated regulatory departments or boards within their ministries of health. However, by 2023, Rwanda, Zanzibar, and Burundi had established semi-autonomous or autonomous NRAs.[161] The shift toward greater autonomy in regulatory functions has, in part, been attributed to joint activities and the EAC's twinning program, which paired newer NRAs with more mature counterparts.[162]

## B. AMRH Technical Committees

AMRH technical committees (TCs) consist of experts in various fields related to medicine regulation, including pharmaceutical science, regulatory affairs, pharmacovigilance, quality assurance, and legal aspects of regulation. Collectively, ten TCs cover the steps of the regulatory life cycle from clinical trials oversight to good manufacturing practices and pharmacovigilance and market surveillance, and each has specific objectives and programs in place. In addition, specific TCs for different modalities, medical devices, and blood products have been established.[163]

## C. Examples of WHO convergence-building activities

WHO prequalification aims to leverage assessment and inspection outputs that have already been produced to eliminate duplicative regulatory work, accelerate in-country registration of quality-assured products, and contribute to their wider availability.[164] Since its inception, the program has helped to successfully register over 110 products that address key healthcare priorities on the continent, including HIV/AIDS, tuberculosis, malaria, and reproductive health products.[165] For example, in 2021, the Zimbabwe NRA used the WHO PQ assessments of two essential HIV prevention products to provide an expedited approval within 160 days (a significant improvement from previous drug registration timelines of 516–1,673 days).[166]

The WHO, supporting harmonized approaches in medicine registration, capacity building, training, and joint activities, has also been a key technical partner for AMRH initiatives. The direct impact of WHO initiatives is exemplified by evidence of accelerated access to health technologies on the continent:

- Through pilot programs supported by WHO, EAC countries enhanced their regulatory capabilities by conducting joint assessments of pharmaceutical products, resulting in successful recommendations for licensing of generic products. The WHO's technical assistance enabled the expansion of joint assessments beyond generic products to innovative biotherapeutic products, such as Avastin and Herceptin, resulting in recommendations that they be licensed in EAC markets.[167]

- WHO technical assistance has facilitated collaboration among NRAs within the SADC region to streamline medicine registration processes. This collaborative procedure, guided by SADC and WHO standards, led to the assessment of at least 125 generic products since the inception of the initiative in 2015.

## D. Examples of convergence-building activities by the Gates Foundation

In acknowledgment of its role in advancing regional convergence, the Gates Foundation, alongside other WLAs (e.g., the European Medicines Agency) and EU member states (Belgium, France, and Germany), had pledged more than €100 million as of February 2022 to be allocated in supporting establishment of the AMA and other African medicines regulatory initiatives at regional and national levels.[168] Additionally, the Gates Foundation launched Grand Challenges Africa in 2015, partnering with the AUDA-NEPAD to address key health and development issues. Through these initiatives, the Gates Foundation aims to fill gaps in the scientific ecosystem, fostering skilled scientists and researchers to tackle Africa's challenges and generate evidence for policymaking and development agendas.[169]

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