CENTER FOR GLOBAL DEVELOPMENT

A Road Map for Strengthening and Diversifying Regulatory Pathways in Africa

JAVIER GUZMAN · AINHOA PETRI-HIDALGO

Abstract

Access to safe, effective, and quality-assured health technologies in low- and middle-income countries (LMICs) has historically depended on the World Health Organization's Prequalification Programme (WHO PQ), a centralized mechanism designed to support global procurement efforts. While WHO PQ has played a critical role in expanding access, it is increasingly misaligned with current priorities, including regional manufacturing, supply chain resilience, and the growing regulatory capacity of LMICs. The March 2025 draft revision of WHO PQ marks the most significant update in two decades, signaling a shift toward reliance, yet leaving key operational gaps unresolved. This paper examines the limitations of the existing regulatory framework—including its narrow scope, delayed timelines, and lack of automatic in-country approval—and assesses the extent to which newer global and regional efforts, such as the WHO Global Benchmarking Tool, WHO Listed Authorities (WLAs), and African regulatory harmonization initiatives, address these gaps. Drawing on recent developments in Africa and beyond, the paper proposes a three-part reform agenda: modernizing WHO PQ into a rapid, reliance-based validator; diversifying regional and national pathways through twinning, WLA designation, and mutual recognition; and aligning downstream enablers such as procurement rules, transparency standards, and legal frameworks. These reforms are essential for creating a more inclusive, efficient, and regionally grounded regulatory system that supports timely access to essential health products and aligns with the realities of LMICs today.

POLICY PAPER 377 • JANUARY 2026

A Road Map for Strengthening and Diversifying Regulatory Pathways in Africa

Javier Guzman
Center for Global Development

Ainhoa Petri-Hidalgo
Center for Global Development

Javier Guzman and Ainhoa Petri-Hidalgo. 2026. "A Road Map for Strengthening and Diversifying Regulatory Pathways in Africa." CGD Policy Paper 377. Washington, DC: Center for Global Development. https://www.cgdev.org/publication/road-map-strengthening-and-diversifying-regulatory-pathways-africa

CENTER FOR GLOBAL DEVELOPMENT
2055 L Street, NW Fifth Floor
Washington, DC 20036

1 Abbey Gardens
Great College Street
London
SW1P 3SE

www.cgdev.org

Contents

Figures

Acronyms

AMA	African Medicines Agency
CRP	Collaborative Registration Procedure
DGDA	Directorate General of Drug Administration
EMA	European Medicines Agency
EOIs	Expressions of Interest
FDA	Food and Drug Administration
GBT	Global Benchmarking Tool
GMP	Good Manufacturing Practice
HICs	High-income countries
ICMRA	International Coalition of Medicines Regulatory Authorities
LMICs	Low- and middle-income countries
MAH	Marketing authorization holder
ML3/4	Maturity-level 3 or 4
NRAs	National regulatory authorities
PQ	Prequalification Programme
PRV	Priority review voucher
RECs	Regional Economic Communities
SRA	Stringent regulatory authority
WHO	World Health Organization
WLAs	WHO Listed Authorities

Introduction

Robust regulatory systems are essential for ensuring timely and equitable access to safe, effective, and quality-assured health technologies—from vaccines and diagnostics to therapeutics and medical devices. Yet in many low- and middle-income countries (LMICs), limited regulatory capacity has long posed a barrier to accessing essential health products. Historically, the solution to help bridge this gap was the creation and expansion of the World Health Organization's Prequalification Programme (WHO PQ), established in 1987 to guide UNICEF's vaccine procurement. It later expanded to cover medicines in 2001 in response to the HIV/AIDS crisis, before broadening further to cover a wider range of health technologies.[1] The program was designed to support global health initiatives such as the Global Fund, PEPFAR, and Gavi, and enable the procurement of safe, effective, and quality-assured products for HIV/AIDS, tuberculosis, malaria, and childhood immunizations, among other key health technologies. This model was also leveraged during the COVID-19 pandemic to support the procurement of COVID-19 vaccines and antivirals by COVAX, UNICEF, and other donor funded initiatives.

Today, however, the context is shifting. Local manufacturing has become a policy priority for LMICs and donors as a means to strengthen supply chain resilience—a key lesson from the COVID-19 pandemic. At the same time, the global health architecture is adapting to major shocks, including reduced aid flows and the withdrawal of the U.S. from the development space. There are also growing calls for greater ownership and decision-making by LMIC governments, alongside a push for more coordinated and efficient systems. Many regulators are also steadily moving up the WHO Global Benchmarking Tool (GBT) maturity scale[2,3]—a framework used to assess the capacity of national regulatory authorities (NRAs) across core regulatory functions.

In response, WHO released a draft revision of its PQ procedure in March 2025 that, for the first time, offers abridged reviews for products already authorized by WHO-Listed Authorities (WLAs) and facilitated reliance pathways for those cleared by GBT maturity-level 3 or 4 (ML3/4).[4] These additions signal meaningful progress toward regulatory reliance, an approach in which WHO or an LMIC authority endorses a trusted regulator's decision instead of rerunning the full review. Yet important questions—such as how procurement mechanisms embrace this new regulatory landscape, what WHO PQ's future focus should be, and what the right balance between national, regional, and global efforts is—remain unresolved. There is still an urgent need to reassess how health technologies are evaluated and approved for use in LMICs—and whether the current regulatory architecture remains fit for purpose.

Against this backdrop, this paper examines the current state of global regulatory systems, highlighting both progress made and persistent limitations. It then outlines practical short- and long-term strategies to enhance regulatory capacity and ensure adequate regulation that underpins access to quality-assured health products moving forward. Over time, WHO PQ's role could evolve

from a direct evaluator to a global registrar of trusted regulatory decisions, maintaining oversight of mature authorities and documenting their ongoing approvals, variations, and safety alerts. This shift would allow WHO to focus on stewardship and regulatory quality assurance rather than duplicative review, better reflecting its comparative advantage in a diversified global regulatory ecosystem.

The current system

Drug regulation encompasses a comprehensive set of interlinked functions—ranging from product assessment and licensing to clinical-trial oversight, manufacturing inspections, market surveillance, and post-market vigilance—all aimed at ensuring that health technologies are safe, effective, and of assured quality throughout their life cycle. Because each jurisdiction conducts these functions independently, manufacturers often face multiple, duplicative reviews across markets. Increasingly, regulators are asked to address this challenge through "reliance," in which an authority bases its own decision on the scientific assessment or data from a trusted counterpart rather than repeating the full evaluation.

The current regulatory architecture has three interlocking tiers. At the global level, WHO-run mechanisms—Prequalification, Emergency Use Listing, GBT, and the roster of WLAs—collectively set standards, assess regulatory capacity, and screen products for global procurement. These serve distinct but complementary purposes. These mechanisms provide standards, capacity assessments, and high-quality evaluations that national and regional authorities can draw upon. Regional and subregional initiatives conduct joint reviews, inspections, and capacity-building efforts, promoting convergence across neighboring jurisdictions and reducing duplication. At the national level, regulatory authorities, now spanning GBT maturity levels 1 to 4, issue the final market authorizations, often drawing on global or regional assessments while retaining full legal responsibility for the products authorized within their borders.

The global architecture

The current global regulatory framework—largely anchored in WHO PQ—has played a vital role in ensuring that products supplied by global procurement agencies meet acceptable standards of safety, efficacy, and quality. By offering a centralized, trusted mechanism recognized by donors, recipient countries, and procurement agencies alike, WHO PQ has helped bridge regulatory gaps and accelerate access to life-saving health products for decades. By December 2024, there were roughly 1,143 prequalified products—medicines, vaccines, in vitro diagnostics, vector control, and immunization devices.[5–8] The framework also proved helpful during the COVID-19 pandemic, when WHO used its Emergency Use Listing process to evaluate a limited number of critical products. Countries lacking similar emergency procedures often relied on these decisions to fast-track access.

The global regulatory architecture has evolved significantly in recent years, expanding beyond the long-standing Prequalification Programme to incorporate newer WHO frameworks that continue to develop. It now rests on three WHO-led mechanisms with distinct but complementary functions. The Prequalification Programme conducts centralized scientific assessments of selected products to confirm their safety, efficacy, and quality for global procurement. The GBT evaluates the institutional performance of national regulatory authorities across a four-level maturity scale, with maturity levels 3 and 4 indicating stable, well-functioning systems capable of conducting core regulatory functions. Maturity under the GBT reflects how consistently a regulator performs key functions such as assessment, inspection, surveillance, and quality control: ML3 denotes a fully functional system, while ML4 reflects more advanced performance and continuous improvement. The WLA framework, in contrast, designates regulators that meet internationally recognized performance standards across multiple functions and whose assessments can serve as trusted scientific references within reliance pathways. Although both WLAs and ML3/4 regulators are considered mature, WLAs meet a higher performance threshold—an important distinction that shapes which reliance pathways a product can follow under the proposed PQ reforms. WLA assessments can generally support abridged reviews because they cover the full range of regulatory functions, including post-market surveillance. By contrast, ML3/4 regulators are fully functional but may have uneven strength across functions, meaning reliance on their decisions may require a narrower scope or supplemental verification.

This current architecture is the product of a gradual shift over the past decade, as WHO has spearheaded a series of reforms to expand regulatory capacity globally. Significant progress has been made in recent years, particularly in Africa. In 2018, it launched the Global Benchmarking Tool, a global standard for objectively assessing regulatory capacity for medicines and vaccines, as well as the overall maturity of national regulatory systems. As of October 2025, 19 national regulatory authorities worldwide have been externally assessed by WHO-led teams as operating at maturity level 3 or 4—signifying stable, well-functioning systems. Notably, nine of these authorities are in Africa: Egypt, Ethiopia, Ghana, Nigeria, Rwanda, Senegal, South Africa, Tanzania, and Zimbabwe.[2]

WHO has also released a version of the GBT to assess capacity to regulate devices and blood products. In 2021, WHO established an additional framework—the WHO Listed Authorities—to identify mature regulatory authorities operating at an advanced level of performance, replacing the former "stringent regulatory authority" (SRA) designation with a more inclusive and transparent process.[9] As of now, 39 NRAs from 37 high-income countries (HICs) have been designated as WLAs by WHO across a range of regulatory functions and product categories.[10]

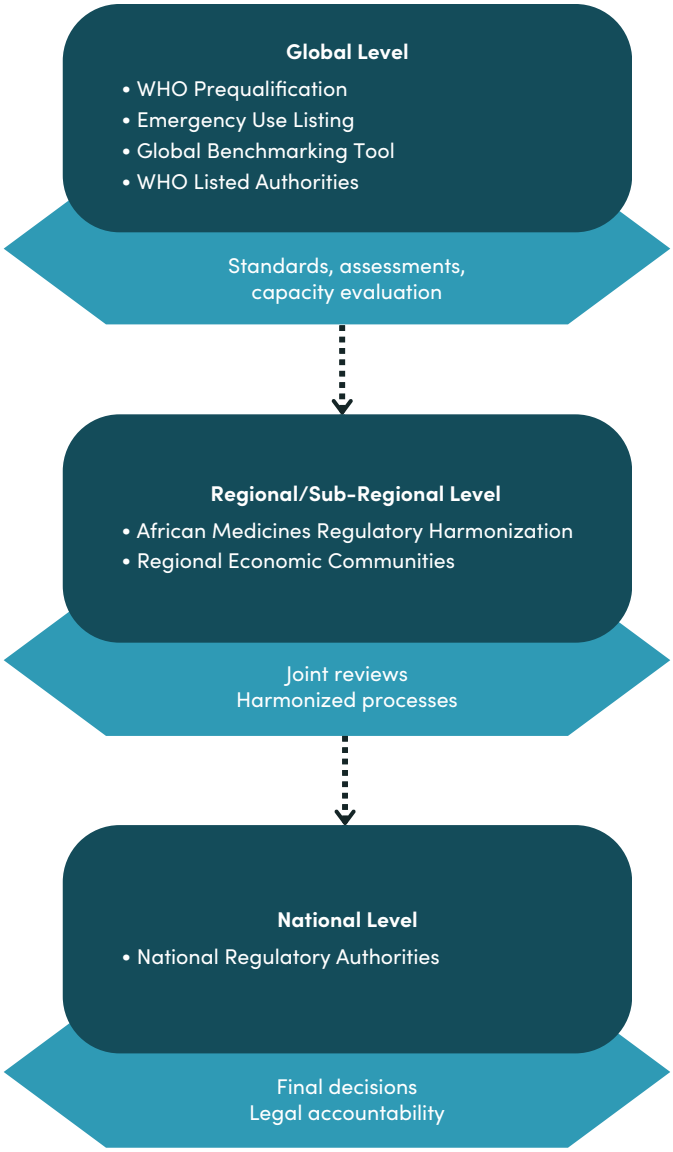
Building on this momentum, WHO's March 2025 draft PQ revision proposes two key regulatory innovations: an abridged review pathway for products already approved by WLAs and a facilitated reliance pathway for products authorized by ML3/4 regulators. These reforms signal a shift toward more streamlined, collaborative mechanisms. Their effectiveness, however, hinges on the gaps discussed below. Likewise, recent subregional initiatives in Africa demonstrate the potential for decentralized, cooperative regulation, but they also expose enduring financial, legal, and technical challenges that must be addressed to ensure that new pathways like those proposed in the March 2025 draft can succeed in practice.

Continental, regional, and sub-regional initiatives

An important continental milestone has been the African Medicines Agency (AMA), which is intended to provide an Africa-led pathway to strengthen regulatory convergence and support access to quality-assured products. The AU Assembly adopted the AMA treaty in February 2019, and after 15 African countries ratified it, the second specialized health agency of the African Union entered into force, with a mandate to harmonize regulation, support the growth of local pharmaceutical production, and work towards regional regulatory autonomy. AMA began full operations in October 2025, following an implementation period shaped by political disagreements, financial constraints, and varying regulatory perspectives across countries.38 As the agency scales up, sustained financing and institutional capacity will be central to its effectiveness, as it is estimated that $100 million will be needed to fund the AMA for its first five years of operations.

Alongside the establishment of the AMA, regional efforts to strengthen regulatory systems in Africa have also gained momentum (Figure 1). Launched in 2009, the African Medicines Regulatory Harmonization initiative has provided a common legal and technical framework to support the regulation of health technologies across the continent. It has facilitated joint reviews and standardized regulatory processes within five of the eight Regional Economic Communities (RECs), albeit with varying degrees of success.[11] Notable examples include the East African Community's Medicines Regulatory Harmonization program, which has significantly reduced medicine registration timelines through joint review, and the ZaZiBoNa initiative within the Southern African Development Community, which introduced shared dossier reviews to minimize duplication. In its first decade, ZaZiBoNa assessed 333 dossiers, achieving a median time to recommendation of 12 months—significantly shorter than the 650 days required under some national procedures.[12]

FIGURE 1. Current global regulatory architecture



As these regional mechanisms expand, maintaining clear lines of accountability remains essential. National regulators retain legal responsibility for the products they authorize, even when decisions are based on joint assessments or reliance on trusted authorities.

Key limitations to the current framework

Systemic limitations at the global level

Despite measurable gains, the current framework faces serious limitations:

Historical constraints

- **Overreliance on a single, centralized entity with capacity challenges:** The PQ is constrained by a small core team of permanent staff and relies heavily on external consultants.[13] These limitations were exacerbated during the COVID-19 pandemic, when the surge in demand for rapid product assessments led to delays and underscored the risks of overreliance on a single mechanism.[14,15] A more recent example of capacity challenges is the rollout of the first mpox vaccine, which was not prequalified by WHO until September 2024—well after outbreaks had already begun and nearly two years after the vaccine had been deployed in Europe and North America.[16] Although the March 2025 draft PQ procedure introduces abridged and reliance pathways, their success will hinge on true joint reviews and proactive dossier capture; without which, the same staffing bottleneck will persist.

- **Narrow scope:** Although WHO PQ has expanded significantly since its inception, it continues to focus on a relatively narrow range of diseases and products—largely reflecting its original mandate to support procurement by global health mechanisms. Some estimate that WHO-prequalified products account for only a small fraction—about 10 percent—of those listed in the WHO Essential Medicines List, reflecting the limited subset of products currently eligible for prequalification rather than an absence of regulatory oversight.[17] For instance, the program provides limited coverage for products targeting chronic non-communicable diseases, which now account for a growing share of the disease burden in Africa and other low- and middle-income countries.

- **Lack of an automatic pathway for in-country approval:** Obtaining WHO prequalification does not automatically lead to in-country authorization. Even after a product is prequalified, manufacturers must still navigate individual national registration processes—resulting in duplicative efforts that delay product rollout and extend approval timelines. Historically, it has taken four to seven years on average to register a new product in Sub-Saharan Africa, compared to just six to twelve months in HICs.[18,19] While this lag may be less relevant for products procured through vertical programs funded by global health initiatives—where waivers often replace national marketing authorizations—it remains a critical barrier for national and regional procurement efforts and for the success of local manufacturing initiatives.

  To address this issue, WHO introduced its Collaborative Registration Procedure (CRP) in 2019, offering a pathway for countries to access relevant information and rely on WHO assessments and decisions. However, participating in the CRP is more cumbersome than intended, and uptake remains limited. As of 2023, only 49 countries for vaccines and 59 for medicines had signed CRP agreements, and just a fraction had completed product registrations through this mechanism.[20] The March 2025 draft PQ revision pledges to "streamline" the CRP, yet it still relies on voluntary country opt-in and does not create an automatic, joint-review channel. Without proactive dossier-sharing and mutual timelines, the duplicative national step—and the multi-year lag—will persist.

- **Lack of support for local manufacturing projects, especially for vaccines:** Under current WHO PQ rules, vaccine manufacturers can only apply for PQ if the NRA in the country of manufacture is deemed 'functional.' As a result, most of the vaccine manufacturing initiatives announced in Africa face structural barriers to global market access: Only two of the 14 African countries—Egypt and South Africa—currently have NRAs operating at a functional level for vaccine production.[3] This is not merely a theoretical issue. For example, Bangladeshi manufacturer Incepta developed an oral cholera vaccine that was licensed by the country's Directorate General of Drug Administration (DGDA) in 2020. However, the vaccine remains ineligible for WHO PQ because DGDA has not yet achieved functional status. This restriction effectively prevents Bangladeshi manufacturers—and many others in LMICs—from contributing to global vaccine supply.[21]

Barriers that remain

- **Few WLA options, even less use:** Of the 39 regulatory authorities currently designated as WLAs,[22] only three—the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and Swissmedic—have specific regulatory pathways for products primarily intended for use in LMICs, and those pathways are mainly for innovator products. EMA's 'EU-Medicines for all,' formerly known as Article 58, has been operational since 2004 and enables the agency to issue scientific opinions on high-priority medicines and vaccines for non-EU markets. Although the procedure theoretically applies to a broad range of products, including vaccines and both novel and generic medicines, its practical use has been limited. In over two decades, only 12 innovator products have received positive scientific opinions through this route,[23] such as the malaria vaccine RTS,S (Mosquirix), the Hexaxim six-in-one pediatric vaccine, key medicines like ivermectin and albendazole for treating parasitic worm infections, and the dapivirine ring for HIV prevention.[24–27] Low uptake has been linked to limited incentives, high fees, and a historical lack of alignment with WHO PQ.[28] While some reforms have addressed some of these barriers, such as improved linkage with WHO PQ, allowance for parallel EU market authorization applications, and fee reductions or exemptions, challenges remain—particularly the absence of direct pathways to facilitate national registration in LMICs. The March 2025 draft PQ procedure introduces an "abridged review" for WLA-approved products, but unless WLAs expand these LMIC-specific routes and WHO publishes predictable timelines, uptake is unlikely to accelerate. In practice, this would mean broadening eligibility to include high-priority generics and vaccines for LMIC markets, reducing or waiving fees, and establishing data-sharing and joint-review mechanisms with WHO PQ and national regulators—steps further detailed under Theme 2 of the proposed solutions below.

  The U.S. FDA has two big pathways for products primarily intended for use in LMICs. The priority review voucher for innovator products and the tentative approval process for generics for the treatment of HIV. The priority review voucher program for tropical diseases,

established in 2007, was designed as an incentive for the development of vaccines and medicines for neglected conditions such as malaria, tuberculosis, and Chagas disease.[29] Companies that receive FDA approval for an eligible product are awarded a transferable voucher that grants a six-month priority review for another product of their choice.[30] So far, 13 innovator products have been registered through this mechanism.[31] The mechanism is not linked to registrations or use in LMICs, and some question if it has really driven innovation, given that some rewarded drugs had been developed independently of the incentive.[31] The FDA's tentative approval process has been crucial for PEPFAR's success in expanding access to HIV treatment in LMICs. As of August 2024, the FDA has granted 258 approvals or tentative approvals for antiretroviral drugs.[32] The process is fully linked with the WHO PQ, allowing opportune listing and procurement by the global health initiatives such as the Global Fund and PEPFAR. The pathway, however, does not translate into automatic in-country authorization, as mentioned before. While the lack of automatic in-country authorization is not a major obstacle for HIV medicines—since they are procured and distributed through vertical programs like PEPFAR and the Global Fund—the model has not been adapted for other disease areas. This represents a missed opportunity to apply the same benefits to a wider set of global health priorities, including both communicable and noncommunicable diseases. The absence of an equivalent pathway for innovator products cleared by an ML3/4 authority—another gap not addressed in the current WLA roster—further limits options for manufacturers based in emerging markets.

Finally, Swissmedic's Marketing Authorization for Global Health Products provides scientific advice and marketing authorization for global health products intended for LMICs. However, it has only been used once.[33]

- **Limited transparency among WLAs:** The lack of dedicated regulatory pathways for products primarily intended for LMICs is further compounded by limited transparency and restricted access to essential regulatory data. This creates significant barriers for NRAs seeking to rely on decisions made by WLAs for both originator and generic medicines. For originator products, not all WLAs publish the clinical data used to support marketing authorizations, or information on product refusals, suspensions, or withdrawals. While the European Medicines Agency provides this data, the U.S. FDA does not.[34,35] The situation is similarly problematic for generic medicines. A 2021 study by the Pan American Health Organization found that the FDA and Health Canada did not make key information publicly available—such as qualitative and quantitative composition, product characteristics, packaging details, and manufacturing site addresses.[36] These data are essential for NRAs to confirm that the product submitted locally is the same as the one authorized by a WLA. Without such transparency, reliance mechanisms are undermined, often forcing NRAs to duplicate regulatory reviews. A similar duplication problem persists on the inspection side: Although the March 2025 draft PQ text allows WHO to waive on-site inspections "subject

to desk review," it still stops short of automatically accepting recent audits conducted by inspectorates that belong to the PIC/S Participating Authorities, leaving manufacturers exposed to repeat site visits. The 2025 PQ draft does not yet condition its abridged pathway on the public availability of clinical and quality data—an omission that could perpetuate both transparency gaps and redundant oversight.

For reliance to work in practice—not just in theory—WLAs must commit to publishing core regulatory data and to sharing GMP inspection reports. While bilateral data-sharing agreements with all LMICs are impractical, regional bodies, such as the African Medicines Agency (AMA), could serve as intermediaries. Public access to essential information is critical to enabling efficient, trusted reliance and accelerating product access in LMICs.

- **Lack of incentives to strengthen LMIC regulatory capacity:** While the GBT and WLA frameworks offer a clear roadmap for strengthening regulatory capacity in LMICs, the current system provides limited incentives for countries to invest in this path. Manufacturers based in countries with mature regulatory systems who have secured marketing authorization from their own national authorities—but lack WHO prequalification—remain ineligible for global or regional procurement mechanisms, as well as national purchasing schemes in other African countries beyond their own. Existing quality assurance policies continue to reflect an outdated paradigm—one that assumed minimal regulatory capacity in LMICs—failing to acknowledge the significant progress made over the past decades and the evolving global regulatory landscape.

Limitations at the regional level

- **Uneven implementation of subregional initiatives**
  Despite these successes, progress under African Medicines Regulatory Harmonization initiative has been uneven, hampered by funding limitations, technical capacity constraints, inconsistent political commitment, and limited alignment with the WHO GBT. The March 2025 draft PQ procedure does not yet spell out how its new reliance pathways will plug into these subregional systems, leaving an important interface undefined. Moreover, continental and regional initiatives have not always been anchored in the national regulatory agencies with the greatest capacity. Even ZaZiBoNa, often cited as a model of subregional collaboration, faces ongoing challenges. Participation among the 16 Southern African Development Community member states is uneven, varying based on capacity to conduct dossier reviews and GMP inspections. The implementation of joint recommendations is inconsistent, and the absence of a centralized system for submission and tracking hinders efficiency and transparency.[12]

- **Delayed operationalization of the African Medicines Agency**
  The other big regional milestone in Africa has been the African Medicines Agency (AMA). The AU Assembly adopted the AMA treaty in February 2019, and after 15 African

countries ratified it, the second specialized health agency of the African Union entered into force, with great ambition to harmonize regulation in the continent and AMA, support the growth of local pharmaceutical production, and work towards regional regulatory autonomy.[37] However, six years after the adoption, only 37 out of the 55 members of the African Union have signed the AMA treaty and its implementation has been delayed due to political disagreements, financial constraints, and varying regulatory perspectives across countries.[38] It is estimated that $100 million will be needed to fund the AMA for its first five years of operations, raising concerns about financial sustainability.[38]

- **Limited recognition of subregional bodies in global benchmarking tools**
  Global efforts have historically focused on strengthening national systems rather than subregional initiatives. The GBT and WLA frameworks have primarily been applied to national regulatory systems in Africa. Subregional initiatives—many of which have emerged over the past decade—have not yet been assessed, partly because these tools were not originally designed for regional or subregional regulatory systems. However, this may be changing: the European Medicines Regulatory Network—which includes the European Commission, the EMA, and the medicines regulatory authorities of 30 countries—was recently assessed and designated as a WLA, setting a potential precedent for broader application.

  Ongoing efforts to modernize the WHO Prequalification Programme are beginning to take shape. The March 2025 draft represents the most comprehensive attempt to institutionalize reliance to date. Yet a closer look reveals key areas where the design falls short of fully leveraging the capacities of trusted regulators and minimizing duplication.

Recent reforms and remaining gaps

In March 2025, the WHO released a draft revision of its Procedure for Prequalification of Pharmaceutical Products (Working document QAS/25.974). The draft represents the program's most substantial update in two decades and, on paper, moves decisively toward a reliance-based model. Three elements are particularly salient:

- **Abridged review for products already authorized by a WLA:** If EMA, FDA, Swissmedic, or any future WLA has granted approval, WHO proposes a condensed, documentation-only assessment.
- **Facilitated reliance pathway for products cleared by ML3/4 national regulatory authorities:** This widens the eligibility net to regulators in countries such as Ghana, Nigeria, and Tanzania, whose capacity has been externally benchmarked by WHO.
- **A conditional waiver of on-site inspections:** WHO may forgo a factory visit when a recent, satisfactory inspection report is available.

These provisions mark real progress, yet the draft stops short of addressing several institutional and operational bottlenecks that have perpetuated long approval lags in LMICs. First, the document does not redesign the CRP to create a fully integrated, joint-review channel with WLAs or ML3/4 agencies; countries must still opt in case-by-case, and WHO is not obliged to import completed assessment reports. Second, the draft is reactive rather than proactive: It assumes manufacturers will initiate prequalification, whereas experience shows that systematic horizon-scanning of WLA and ML3/4 approvals—paired with targeted invitations—would capture dossiers much earlier. Third, it omits any explicit pathway for innovator products first approved by an ML3/4 regulator, a scenario that is increasingly plausible as African and Asian agencies advance. Fourth, while the inspection waiver is welcome, it does not automatically recognize recent audits performed by inspectorates that belong to the PIC/S, leaving manufacturers exposed to duplicate GMP visits. Finally, the draft does not include a dedicated section on post-approval life cycle oversight—for example, how the WHO will manage variations, Annual Product Quality Reviews, or pharmacovigilance signals already reviewed by trusted regulators—thus risking the reemergence of duplication after first approval.

The solutions

Strengthening Africa's regulatory landscape requires urgent action to improve efficiency, reduce delays, and ensure timely access to essential health products. The following six policy recommendations—grouped under three themes—outline priority actions to enhance the global regulatory system, with a particular focus on meeting Africa's needs and closing the operational gaps identified in WHO's March 2025-draft PQ procedure.

These reforms directly respond to three unresolved questions at the heart of this paper:

- What should WHO PQ's future role be within this evolving system?
- How can national, regional, and global efforts be balanced to ensure coherence, efficiency, and equitable access?
- How should procurement mechanisms adapt to a reliance-based regulatory landscape?

The six solutions offer a practical roadmap for addressing these questions—modernizing WHO PQ, diversifying regional and national pathways, and aligning downstream enablers to deliver faster, more equitable access to quality-assured products.

Theme 1: Modernize WHO prequalification

Implementer: WHO

To support a more distributed global regulatory model, WHO PQ should strengthen its coordination, standard-setting, and assurance functions, while reducing duplication in product-level assessments. Increasing PQ's capacity and enabling greater reliance on WLAs and ML3/4 regulators would allow WHO

to focus on oversight rather than primary assessment, improving efficiency without compromising quality. The first step is to overhaul WHO PQ. In its current form, PQ still conducts time-consuming, de-novo evaluations even when a product has already satisfied a trusted regulator. The March 2025 draft procedure takes an important step toward reliance, yet it leaves the core workflow essentially unchanged. Two concrete measures are required to turn PQ into a rapid, reliance-based verifier.

Solution 1. WHO should implement a 60-day abridged PQ process, triggered when a product is approved by an ML3/4 NRA, and adopt an administrative listing process for WLA-authorized products

Under this model, PQ would no longer repeat scientific assessment; instead, it would confirm the integrity of the originating dossier, check alignment with WHO norms, and publish a joint assessment report (revamped CRP model) that national regulators can adopt without further review, with WLA-authorized products moving through an administrative listing function. To keep the pipeline moving, PQ should run quarterly horizon-scans matching PQ EOIs to recent WLA approvals, send targeted EOIs to the relevant WLAs requesting outreach to the marketing authorization holder (MAH), and invite the MAH to submit for administrative listing, while requesting the WLA's assessment package (with MAH consent). PQ should mirror this process for ML3/4 approvals—contact the originating NRA, secure the redacted assessment/inspection package, and invite the MAH into the abridged PQ process. The pathway should cover lower-risk, lower-complexity products—such as locally produced, quality-assured small-molecule generics—including products that fall outside PQ's eligibility scope. For these ML3/4-authorized products, WHO PQ should issue the outcome within 60 calendar days of receiving a complete reliance package. WHO PQ should apply the same abridged reliance principles it currently uses for SRA-approved products to products authorized by ML3/4 NRAs and, where applicable, REC joint reviews. PQ should issue a global or regional listing, as appropriate, including an administrative listing for WLA-authorized products, without repeating scientific assessment.

WHO should revise the Collaborative Registration Procedure (CRP) to explicitly cover products already authorized by WLAs and ML3/4 NRAs and to operationalize a formal joint-review channel. PQ will request and import redacted assessment and inspection packages from the originating authority under standard MoUs and publish a reliance summary (revamped CRP model) that national regulators can adopt without further review.

Solution 2. Reforming WHO Prequalification to enable a decentralized global system by operationalizing reliance inside PQ and through inspection waivers and life cycle reliance

WHO should adopt a standing inspection-waiver policy that automatically accepts GMP reports issued within the past three years by any WLA, ML3/4 NRA, or PIC/S Participating Authority for the relevant manufacturing line, reserving WHO inspections for defined triggers, such as serious quality signals, scope gaps, and unresolved corrective and preventive actions.

As more WLAs are designated, WHO PQ's role should evolve toward a life cycle registrar rather than a perpetual reviewer. Instead of conducting full de novo reviews, its focus could shift toward:

- verifying that WLAs and ML3/4 authorities continue to meet WHO performance standards
- maintaining an administrative register that records trusted regulators' life cycle decisions, including post-approval variations, post-market safety alerts, and Annual Product Quality Reviews

Annual Product Quality Reviews are the yearly GMP-mandated reports that summarize batches produced, process performance, quality trends and any corrective actions—exactly the type of life cycle intelligence PQ should capture instead of repeating work already done by WLAs, ML3/4 agencies or PIC/S Participating Authorities. This evolution would increase global regulatory capacity, reduce duplication, and ensure WHO PQ remains a critical enabler of access to safe, effective, and quality-assured medical products globally.

To prevent duplication after listing, PQ should embed reliance in day-to-day operations. PQ will apply reliance for post-approval changes and quality surveillance when a WLA or ML3/4 NRA has already assessed the variation or signal and the report is available to WHO. Manufacturers will reference the originating authority's assessment; PQ's role will be to verify alignment with WHO norms and any PQ-specific conditions.

WHO should meet service targets—issuing administrative updates in 10 days, deciding minor quality or safety variations in 30 days, and deciding major variations within 60 days when relying on WLA or ML3/4 assessments. It should use de-novo timelines only when reliance is not possible.

Theme 2: Diversify regional and national pathways

Implementers: Donors/GHIs and African governments

With a 60-day reliance mechanism now embedded in WHO PQ, African regulators, donors, and procurement agencies can broaden their regulatory toolbox and embrace complementary routes outside PQ. Two reforms would make this diversification possible.

Solution 3. Global health initiatives, donors, and African governments should use alternative regulatory pathways beyond WHO PQ

These alternative approaches are necessary to accommodate products not covered under WHO PQ's current Expressions of Interest (EOIs)—particularly those intended for global pooled procurement by UN agencies and global health initiatives, complex or novel products deemed essential by regional health bodies such as Africa CDC, and products that address regional rather than global needs. These routes should be anchored in WLAs and subregional initiatives and, where relevant, supplemented by functional national authorities (GBT ML3/4). They are particularly important for region-specific priorities and noncommunicable diseases, and in regions where functional NRAs can support reliance.

African Regional Economic Communities should formalize joint reviews, so that once a REC issues a positive opinion, REC secretariats can upload the assessment to WHO's CRP portal, triggering PQ's 60-day abridged reliance process described in Theme 1 and allowing individual countries to grant national licenses without further dossier work.

Solution 4. Align procurement rules to recognize reliance-based routes

International procurement agencies—including the Global Fund, Gavi, UNICEF, UNFPA, UNDP, and major bilateral funders—which currently limit procurement to products approved through WHO PQ or by an WLA, should expand their eligibility criteria to include the alternative regulatory pathways outlined above. Procurement policies have lagged behind recent advances in regulatory capacity. While such restrictions were defensible when only a handful of LMIC regulators had attained full maturity, they now exclude products authorized through WLAs, ML3/4 authorities, and established regional reliance authorities. Expanding eligibility criteria in this way would support more timely access to essential products, promote local manufacturing, and enable regionally driven procurement in alignment with the WHO GBT and WLA frameworks.

To operationalize this shift, agencies should revise their quality assurance policies, tender templates, and framework-agreement annexes to explicitly list the proposed reliance routes: WHO's 60-day abridged desk review (Theme 1), REC joint-review positive opinions uploaded via the CRP (Theme 2), and national fast-track reliance on WLA or ML3/4 decisions, where applicable. They should also ensure these routes apply beyond current PQ EOIs to cover region-specific priorities and noncommunicable disease products, adjust bid-evaluation criteria so offers using these routes are not penalized, and revise grant guidance so implementers can purchase through them. Accepting goods authorized through Theme 1 (60-day PQ validation) or Theme 2 (REC joint-review) routes will shorten tender cycles and prevent stock-outs when PQ queues lengthen.

WHO and G-7 donors should invest in helping Africa's eight ML3/4 authorities—and the strongest subregional networks—to reach fully WLA status by 2030. This support should be tailored based on the specific strengths of each agency—whether in marketing authorization for medicines, vaccines, or in post-marketing surveillance and quality control. Efforts should also focus on helping transitional WLAs successfully meet the criteria to become full WLAs by the end of the transition period. Expanding the pool of WLAs and having representation from Africa would strengthen global reliance frameworks and support more regionally relevant and equitable regulatory oversight.

Theme 3: Downstream enablers

Implementers: WLAs and African governments

The two upstream themes cannot deliver faster access unless procurement rules, transparency norms, and legal frameworks are aligned.

Solution 5. Increase transparency among WLAs

WHO should embed a minimum disclosure package into the WLA framework, co-developed with regulators from both LMICs and HICs. At minimum, WLAs must publish redacted clinical and quality assessment reports, product characteristics, GMP inspection outcomes, and refusal, suspension, and withdrawal notices to enable effective reliance by other regulators. WHO will incorporate these transparency requirements into the WLA criteria and audit compliance; WLAs will implement; and African governments will update laws where needed to allow publication and cross-border data-sharing. Without this package, national regulators must re-review or reinspect, undermining reliance.

In the longer term, the International Coalition of Medicines Regulatory Authorities (ICMRA) should establish a centralized global repository of regulatory information as a global public good, where WLAs and mature NRAs can share these data. This repository—potentially hosted by ICMRA—would allow LMIC NRAs to access and rely on trusted regulatory decisions more efficiently, reducing duplication and strengthening the global regulatory system.

In some countries, increased transparency may require legislative changes. In the United States, for instance, Congress would need to mandate that the FDA disclose documents such as Clinical Study Reports (which summarize the methods, results, and conclusions of clinical trials), complete response letters (sent when an application is rejected), and "refuse-to-file" letters (issued when applications are deemed incomplete).[34] Without such reforms, WLAs cannot fully support reliance and transparency goals in the global regulatory ecosystem. Public posting of inspection outcomes will also reduce duplicate GMP visits, complementing the PIC/S waiver in Theme 1.

Solution 6. WLAs and African governments should expand trusted routes and enable legal mutual recognition

WLAs should create or expand LMIC-specific regulatory routes and share redacted assessment reports, ideally waiving duplicative fees, and fund twinning arrangements with mature NRAs in LMICs and with subregional regulatory initiatives. Twinning—originally developed by the European Union to support the EU accession process[39]—has already been used in early regulatory collaborations between European and African agencies.[40] Expanding its use could enhance regulatory convergence, capacity building, and mutual recognition, strengthening regional systems and improving access to essential health technologies.

Under this pathway, manufacturers from countries without functional national regulatory authorities would submit their products to WLAs, regardless of geography or income level. For example, a vaccine manufacturer based in Bangladesh could submit a dossier to South Korea's Ministry of Food and Drug Safety, while an Asian or African manufacturer producing a new antimalarial could submit their dossier to Singapore's Health Sciences Authority or to the U.S. FDA through an expanded tentative approval process.

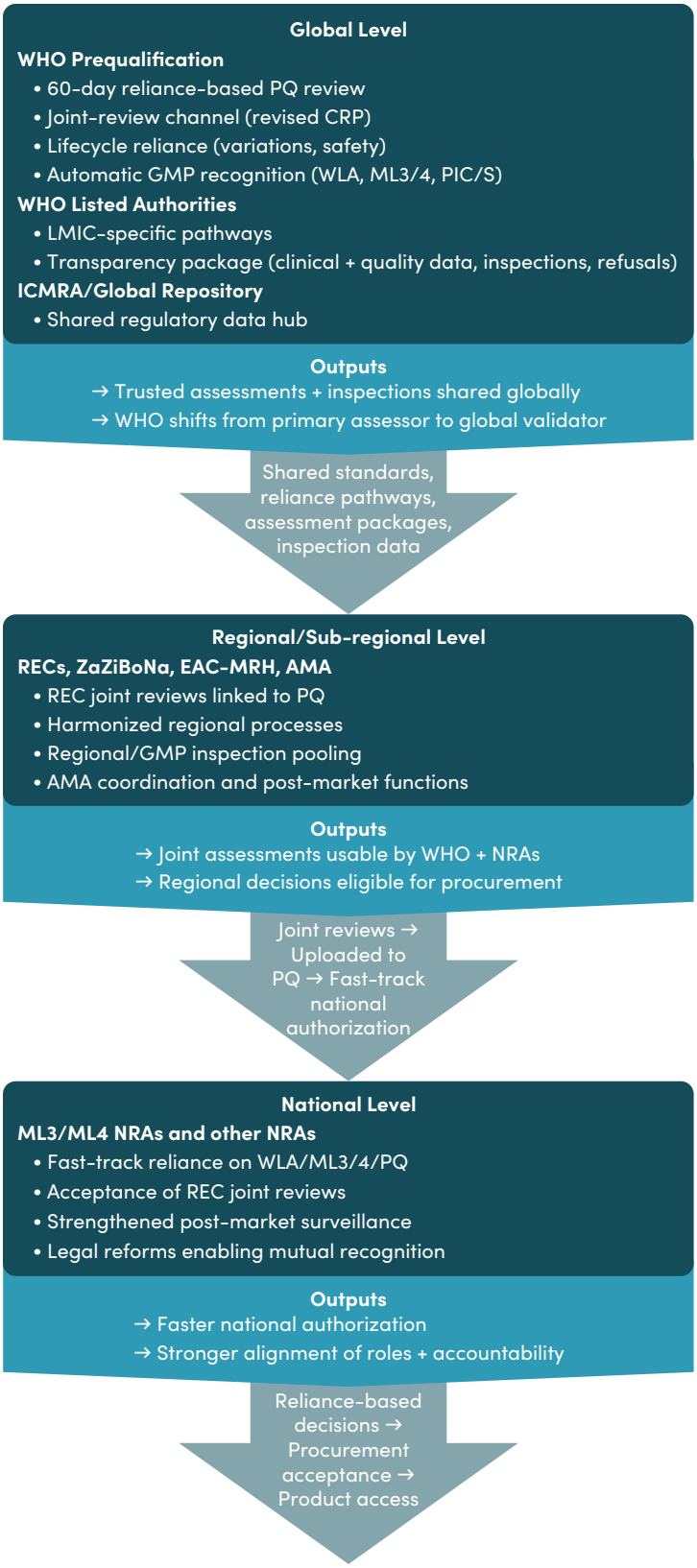
This approach would build on subregional regulatory initiatives developed within African RECs—such as the East African Community and the Southern African Development Community—and be reinforced by the eight African NRAs that have achieved functional status for medicines and/or vaccines regulation, as assessed by the WHO GBT. Anchoring this pathway in existing regional structures would align with Africa's broader regionalization efforts, bring regulatory decision-making closer to the point of use, enhance post-marketing surveillance, and should be designed to plug into the African Medicines Agency's now operational continental pathway, with AMA providing oversight, recognition, and coordination across REC mechanisms as they mature. To operationalize this pathway, RECs and African governments should commission GBT-based assessments—coordinated by AMA/AU—with WHO providing technical support to apply the tool.

Moreover, the pathway could be further strengthened through the integration of third-party certification, particularly to address the widespread shortage of capacity for conducting GMP inspections. Africa could adapt a model similar to the Medical Device Single Audit Program, which allows a single third-party audit to satisfy the requirements of multiple regulatory authorities. By accrediting independent, trusted third-party auditors, regional or national regulators could access high-quality GMP assessments more efficiently—reducing duplication, accelerating product registration timelines, and ensuring that regionally prioritized products meet robust quality standards.

African countries must modernize their legal frameworks to support subregional and regional regulatory harmonization. This is essential for the African Medicines Agency to be successful but also for the alternative regulatory pathways to work. Even the best joint review is of little use if every country must still issue its own license. The African Union should establish a continent-wide mutual recognition approval framework. Under this system, once a product—such as a vaccine, medicine, or health technology—is approved by an AMA-recognized regulatory body, participating member states would progressively accept that decision without requiring additional national-level approvals. This would draw from the European Medicines Agency's centralized procedure, where a centralized decision enables automatic or near-automatic recognition across participating jurisdictions. The legislation should reference WHO's updated CRP to ensure documentation flows seamlessly from AMA to national registers. This system would not only strengthen the quality of medicines but would also support local manufacturing, regional procurement and access to quality assured products. As reliance deepens, establishing a shared accountability framework anchored in WHO's Good Reliance Practices will be essential to clarify the respective responsibilities of WHO, WLAs, regional bodies, and national regulators. Such alignment would ensure that reliance strengthens oversight rather than diffusing it. (Figure 2 shows the proposed global regulatory architecture.)

Taken together, these downstream reforms ensure that the reliance engines built into Themes 1 and 2 translate into real world uptake: faster tenders, fewer duplicative reviews, and legally binding access across the continent.

FIGURE 2. Proposed global regulatory architecture with solutions



While these six reforms collectively offer a practical roadmap toward a reliance-based regulatory model, their success will depend on implementation within the constraints outlined earlier. Many systemic barriers—limited transparency, uneven regional capacity, and fragmented legal frameworks—will persist without sustained political commitment and investment in institutional strengthening. Moving toward a distributed reliance model also introduces more complex lines of accountability, requiring clear delineation of roles among WHO, WLAs, regional bodies, and national authorities to ensure shared responsibility does not dilute oversight.

Because these reforms vary in their complexity and political feasibility, they are unlikely to be implemented simultaneously. Some measures require substantial legal or institutional change, while others build on existing mechanisms and could advance more quickly. Nonetheless, articulating the full set of reforms is essential to define the direction of travel: All six are ultimately necessary for a functional, equitable, and efficient global regulatory ecosystem, even if progress occurs in phases.

Conclusion

The current global regulatory architecture has delivered important gains in access to essential health products, particularly for low- and middle-income countries. But it is increasingly out of step with today's priorities: expanding local manufacturing, improving regional supply resilience, and accelerating access to a broader range of products that meet region-specific needs. While the WHO Prequalification Programme remains a key part of the global system, its limitations—narrow scope, slow timelines, and misalignment with evolving regulatory capacity in LMICs—have become more pronounced.

At the same time, meaningful progress is already underway. Several African countries now have national regulatory authorities operating at functional levels, and regional initiatives such as ZaZiBoNa and the East African Community Medicines Regulatory Harmonization program have demonstrated that decentralized, cooperative models are both feasible and effective. The March 2025 draft revision of WHO PQ signals a shift toward reliance, but its success will depend on bold implementation and complementary reforms across the system.

To meet this moment, the system must evolve. Regulatory pathways should be updated to better reflect current capacity, reduce duplication, and support timely access through reliance on trusted authorities and regionally grounded mechanisms. This paper outlines a coherent, three-part strategy for regulatory modernization: updating WHO PQ to function as a fast, reliance-based validator; diversifying regional and national pathways through twinning, WLA designation, and mutual recognition; and enabling downstream uptake through procurement reform, transparency, and legal alignment. Taken together the six policy recommendations outlined in this paper offer a practical roadmap for operationalizing reliance, reducing duplication, and improving timely access to quality-assured products in Africa and beyond.

Implementing these changes will require political commitment from global health actors, national governments, and regional institutions. But without them, ongoing efforts to strengthen local manufacturing, streamline regional procurement, and ensure access to quality-assured health technologies will continue to be hampered by outdated systems and institutional inertia. A more adaptive and inclusive regulatory model is not just a technical adjustment—it is a necessary condition for building more responsive, resilient health systems. The upcoming WHO Executive Board meeting in February 2026, and the World Health Assembly in May, offer immediate forums to advance these recommendations.

References

1. T Hoen EFM, Hogerzeil HV, Quick JD, Sillo HB. A Quiet Revolution in Global Public Health: The World Health Organization's Prequalification of Medicines Programme. *J Public Health Policy*. 2014;35(2):137–161. doi:10.1057/jphp.2013.53

2. Senegal and Rwanda achieve WHO Maturity Level 3 in medicines regulation. World Health Organization. December 5, 2024. Accessed April 18, 2025. https://www.who.int/news/item/05-12-2024-senegal-and-rwanda-achieve-who-maturity-level-3-in-medicines-regulation

3. Egypt and Nigeria medicines regulators achieve high maturity level in WHO classification and WHO launches list of regulatory authorities that meet international standards. World Health Organization. March 30, 2022. Accessed April 18, 2025. https://www.who.int/news/item/30-03-2022-egypt-and-nigeria-medicines-regulators-achieve-high-maturity-level-in-who-classification-and-who-launches-list-of-regulatory-authorities-that-meet-international-standards

4. Procedure for prequalification of pharmaceutical products (Working documment QAS/25.974, draft for comments). Published online March 2025. Accessed August 8, 2025. https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/current-projects/2025-04-02_pq-procedure-_revised_01.pdf?sfvrsn=bf98c403_3

5. World Health Organization. List of Prequalified Vaccines. Accessed April 18, 2025. https://extranet.who.int/prequal/vaccines/prequalified-vaccines

6. World Health Organization. List of Prequalified Medicines (Finished Pharmaceutical Products/ Biotherapeutic products). Accessed April 18, 2025. https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products

7. World Health Organization. List of Prequalified In Vitro Diagnostic Products. Accessed April 18, 2025. https://extranet.who.int/prequal/vitro-diagnostics/prequalified/in-vitro-diagnostics

8. World Health Organization. Prequalified Vector Control Product List. Accessed April 18, 2025. https://extranet.who.int/prequal/vector-control-products/prequalified-product-list

9. WHO Listed Authorities. World Health Organization. March 1, 2024. Accessed April 18, 2025. https://www.who.int/news-room/questions-and-answers/item/who-listed-authorities

10. Zuzanna Stawiska. WHO Expands List of Trusted Regulatory Agencies to 36, including US FDA and European Medicines Agency. Health Policy Watch. May 21, 2024. Accessed April 18, 2025. https://healthpolicy-watch.news/who-expands-list-of-trusted-regulatory-agencies-to-36-including-us-fda-and-european-medicines-agency/#:~:text=thirty%20national%20regulatory%20agencies

11. AMRH Regional Economic Communities. African Union Development Agency. Accessed April 18, 2025. https://amrh.nepad.org/amrh-recs

12. Sithole T, Mahlangu G, Walker S, Salek S. Regulatory Authority Evaluation of the Effectiveness and Efficiency of the ZaZiBoNa Collaborative Medicines Registration Initiative: The Way Forward. *Front Med*. 2022;9:898743. doi:10.3389/fmed.2022.898743

13. Raisa Santos, Elaine Ruth Fletcher. Despite Reforms, WHO 'Prequalification' Program for Vital Medicines and Diagnostics Is Inconsistent and Full of Delays. Published online November 8, 2022. Accessed August 22, 2025. https://healthpolicy-watch.news/who-prequalification-program/

14. Jenny Lei Ravelo. Why Paxlovid is still not available in many LMICs. *Devex*. https://www.devex.com/news/why-paxlovid-is-still-not-available-in-many-lmics-103904. September 1, 2022. Accessed April 18, 2025.

15. Elina Urli Hodges, Kate Crissman, Victoria Hsiung, et al. *Navigating Complexity to Improve Global Access: Supporting a More Efficient and Effective World Health Organization Prequalification Program*. Duke Global Health Innovation Center and the Global Health Technoligies Coalition; 2022:39. Accessed April 18, 2025. https://dukeghic.org/wp-content/uploads/sites/20/2022/08/Navigating-complexity-to-improve-global-access-supporting-a-more-efficient-and-effective-WHO-prequalification-program.pdf

16. WHO prequalifies the first vaccine against mpox. World Health Organization. September 13, 2024. Accessed April 18, 2025. https://www.who.int/news/item/13-09-2024-who-prequalifies-the-first-vaccine-against-mpox#:~:text=The%20World%20Health%20Organization%20,added%20to%20its%20prequalification%20list

17. Aisling Leow, James Hu, Tom Hird. *An Overview of WHO Prequalification*. Rethink Priorities; 2023:41. Accessed April 18, 2025. https://rethinkpriorities.org/wp-content/uploads/2023/07/WHO-PQ.pdf

18. Ahonkhai V, Martins SF, Portet A, Lumpkin M, Hartman D. Speeding Access to Vaccines and Medicines in Low- and Middle-Income Countries: A Case for Change and a Framework for Optimized Product Market Authorization. Renzaho A, ed. *PLoS ONE*. 2016;11(11):e0166515. doi:10.1371/journal.pone.0166515

19. Mridu Bhutani. Getting Quality Medicines to Patients Faster in Africa: How to Solve Access Issues. IQVIA. January 16, 2023. Accessed April 18, 2025. https://www.iqvia.com/locations/middle-east-and-africa/blogs/2023/01/getting-quality-medicines-to-patients-faster-in-africa-how-to-solve-for-access-issues

20. *WHO RPQ Impact Assessment: Regulation and Prequalification Activities*. World Health Organization; 2023:118. Accessed April 18, 2025. https://cdn.who.int/media/docs/default-source/medicines/regulatory-updates/rpq/who-rpq-impact-assessment-report_2023.pdf?sfvrsn=3b3a9b8_1

21. Sophia Greenhoe, Javier Guzman. The Role of Regulation in Advancing African Vaccine Manufacturing: Policy Options for Gavi. Center for Global Development. November 29, 2023. https://www.cgdev.org/blog/role-regulation-advancing-african-vaccine-manufacturing-policy-options-gavi

22. WHO designates new WHO-Listed Authorities, strengthening global access to quality-assured medical products. Published online August 7, 2025. Accessed August 22, 2025. https://www.who.int/news/item/07-08-2025-who-designates-new-who-listed-authorities--strengthening-global-access-to-quality-assured-medical-products

23. Medicines for use outside the European Union. European Medicines Agency. Accessed April 18, 2025. https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/medicines-use-outside-european-union#applying-in-parallel-with-an-eu-marketing-authorisation-application-10771

24. Mosquirix: Opinion on medicine for use outside EU. European Medicines Agency. July 23, 2015. https://www.ema.europa.eu/en/opinion-medicine-use-outside-EU/human/mosquirix

25. Hexaxim: Opinion on medicine for use outside EU. European Medicines Agency. June 21, 2012. Accessed April 18, 2025. https://www.ema.europa.eu/en/opinion-medicine-use-outside-EU/human/hexaxim

26. Ivermectin/Albendazole: Opinion on medicine for use outside EU. European Medicines Agency. January 30, 2025. Accessed April 18, 2025. https://www.ema.europa.eu/en/opinion-medicine-use-outside-EU/human/ivermectin-albendazole

27. Dapivirine Vaginal Ring 25 mg: Opinion on medicine for use outside EU. European Medicines Agency. July 23, 2020. Accessed April 18, 2025. https://www.ema.europa.eu/en/opinion-medicine-use-outside-EU/human/dapivirine-vaginal-ring-25-mg

28. *Article 58 Strategic Review*. European Medicines Agency. 2016:8. Accessed April 18, 2025. https://www.ema.europa.eu/en/documents/other/article-58-strategic-review-summary_en.pdf

29. Mukherjee S. The United States Food and Drug Administration (FDA) regulatory response to combat Neglected Tropical Diseases (NTDs): A review. *PLoS Negl Trop Dis*. 2023;17(1):e0011010. doi:10.1371/journal.pntd.0011010

30. Tropical Disease Priority Review Voucher Program. FDA. Accessed April 18, 2025. https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program

31. Greer Gosnell, James Hu, Erin Braid, Tom Hird. *Priority Review Vouchers for Tropical Diseases: Impact, Distribution, Effectiveness, and Potential Improvements*. Rethink Priorities; 2023:30. https://rethinkpriorities.org/publications/priority-review-vouchers

32. *PEPFAR ARV Formulation Prioritization*. U.S. Department of State. 2024:21. https://www.state.gov/wp-content/uploads/2024/12/NOV-2024-PEPFAR-ARV-Formulation-Prioritization.pdf

33. Swissmedic authorises a medicinal product under the Marketing Authorisation for Global Health Products (MAGHP) procedure for the first time. Swissmedic. May 13, 2020. Accessed April 18, 2025. https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/authorisations/information/first-maghp-approval-inswitzerland.html

34. Stuart Buck. *Improving FDA Transparency for Public Health*. Institute for Progress. 2024:6. Accessed April 18, 2025. https://acrobat.adobe.com/id/urn:aaid:sc:VA6C2:ffbd2b71-1f4a-4a90-8c8e-a8fc34e60d89

35. FDA Continues to Support Transparency and Collaboration in Drug Approval Process as the Clinical Data Summary Pilot Concludes. FDA. March 26, 2020. Accessed April 18, 2025. https://www.fda.gov/news-events/press-announcements/fda-continues-support-transparency-and-collaboration-drug-approval-process-clinical-data-summary

36. Pan American Health Organization, World Health Organization, eds. *Regulatory System Strengthening in the Americas: Lessons Learned from the National Regulatory Authorities of Regional Reference*. Pan American Health Organization. 2022.

37. Morgan Pincombe, Javier Guzman. A Defining Moment for Medicines Regulation in Africa: The Establishment of the African Medicines Agency. Center for Global Development. February 3, 2022. Accessed April 18, 2025. https://www.cgdev.org/blog/defining-moment-medicines-regulation-africa-establishment-african-medicines-agency

38. Abdulwahab AA, Okafor UG, Adesuyi DS, Miranda AV, Yusuf RO, Eliseo Lucero-Prisno D. The African Medicines Agency and Medicines Regulation: Progress, challenges, and recommendations. *Health Care Sci*. 2024;3(5):350–359. doi:10.1002/hcs2.117

39. Twinning. European Commission. Accessed April 18, 2025. https://enlargement.ec.europa.eu/funding-technical-assistance/twinning_en

40. Lessons and successes from a Rwanda Food and Drug Authority and Team Europe twinning project. European Commission. Accessed April 18, 2025. https://international-partnerships.ec.europa.eu/news-and-events/stories/lessons-and-successes-rwanda-food-and-drug-authority-and-team-europe-twinning-project_en#:~:text=The%20twinning%20project%20pairs%20Rwanda,a%20groundbreaking%20and%20successful%20partnership