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# MPOX outbreak in Africa: the urgent need for local manufacturing of the vaccine and decolonized health systems

Adanze Nge Cynthia[1,2*] and Gordon Takop Nchanji[3,4]

## Abstract

**Background** The resurgence of MPOX (formerly known as Monkeypox) across African countries has highlighted longstanding deficiencies in epidemic preparedness, vaccine access, and healthcare infrastructure on the continent. Despite bearing a significant disease burden, African nations continue to face delays in vaccine acquisition and distribution, reflecting more profound structural and historical inequities.

**Methods** This systematic review synthesizes literature published between 2016 and 2024, including peer-reviewed articles, policy documents, and institutional reports. The review aims to explore the dynamics of MPOX outbreaks in Africa, patterns of vaccine inequity, and the systemic limitations that hinder local response capacity. A narrative synthesis approach was employed to analyze data relating to vaccine access, production capacity, regulatory environments, and structural determinants of health.

**Results** The findings reveal Africa's continued dependency on external vaccine sources, shaped by colonial legacies and weak local pharmaceutical systems. During the 2022 global MPOX outbreak, high-income countries swiftly secured vaccine supplies, while African nations experienced significant delays despite high transmission rates. Although efforts to establish local manufacturing are emerging, they are constrained by limited infrastructure, fragmented regulatory systems, shortages of skilled workers, and restrictive intellectual property regimes. Furthermore, the review identifies a need for harmonized regulatory frameworks and sustainable investment in regional manufacturing capabilities.

**Conclusion** Addressing MPOX and future health threats in Africa demands a shift toward decolonized health systems that emphasize South-South collaboration, indigenous knowledge, and local ownership. Strategic interventions, such as regulatory harmonization, equitable technology transfer, and capacity-building, are essential to reduce external dependency. Coordinated short-term actions and long-term investments are crucial for fostering resilient, self-sustaining health systems that can respond effectively to emerging infectious diseases.

**Keywords** MPOX, Vaccine, Disease outbreaks, Decolonizing global health

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## Introduction

The recent outbreak of MPOX, a viral disease caused by the monkeypox virus of the genus Orthopoxvirus, has affected several African nations, including Nigeria, Rwanda, Uganda, Ivory Coast, Burundi, the Democratic Republic of Congo, and Kenya, raising significant concerns about the continent's preparedness for health emergencies [1]. MPOX has manifested in sporadic global outbreaks historically endemic to Central and West Africa. However, the episodes documented in 2022 and 2023 reveal the continent's persistent vulnerability to this disease, primarily exacerbated by reliance on international vaccine supplies and external health initiatives [2].

Africa's response to MPOX outbreaks has been significantly constrained by the stark imbalance in global vaccine distribution and limited local production capabilities [3]. Specifically, as of November 2024, the Access and Allocation Mechanism (AAM) for mpox has allocated only 899,000 vaccine doses for nine African countries hardest hit by the current outbreak, while by September 2024, of the 20.5 million vaccine doses required for Africa, only 5.6 million had been allocated, representing a 73% shortage [4, 5]. This disparity is further illustrated by Africa confirming 2,863 cases and 517 deaths in 2024, primarily in the Democratic Republic of the Congo (DRC), with suspected cases surging past 17,000 [6]. Additionally, vaccination has not yet started for children, one of the hardest-hit groups, because of regulatory and supply issues [7]."

While most African nations have been independent for decades, the structural dependencies created by colonial health systems, including reliance on external expertise, donor-driven priorities, and limited local research capacity, continue to influence current vaccine access patterns during the MPOX response [8]. However, these historical factors interact with contemporary challenges such as poor governance, resource constraints, and global power asymmetries in pharmaceutical markets [9].

These challenges are partly shaped by historical legacies that constrained Africa's industrial and regulatory base, but are more directly explained by proximal health system factors, including weak governance capacity, health workforce shortages, limited fiscal space, fragmented service integration, and supply-chain bottlenecks [10]. The consequences were evident in MPOX-specific outcomes: although the World Health Organization (WHO) first declared mpox a Public Health Emergency of International Concern (PHEIC) on 23 July 2022 [11], African countries experienced delays in vaccine access, particularly in the DRC. Despite having over 20,000 cases, the country received its first vaccine shipment only on September 5, 2024, while European and North American countries had stockpiled millions of doses from the 2022 outbreak [12]. WHO later declared a second PHEIC on 14 August 2024, in recognition of the escalating outbreak across Africa [13].

Current initiatives, such as the European Commission-coordinated 215,000-dose donation and the African Vaccine Manufacturing Accelerator's financing mechanisms, illustrate how present-day governance, financing, and procurement reforms, rather than history alone, are critical to strengthening Africa's outbreak response capacity [14].

This literature review examines the complexities of MPOX outbreaks in Africa, emphasizing the need to establish local vaccine manufacturing capabilities and advocate for decolonized health systems as sustainable approaches to addressing these public health challenges.

## Methodology

We conducted a scoping review of peer-reviewed literature, policy documents, and institutional reports on monkeypox (MPOX) in Africa published between 2016 and 2024. Our primary objective was to explore outbreak patterns, vaccine supply systems, inequities, and the implications of structural dependencies on Africa's health systems. To ensure methodological rigor, we followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) guidelines.

Study identification and selection were carried out using a predefined search strategy. We searched electronic databases including PubMed, Scopus, and Google Scholar, using Boolean search terms such as "Monkeypox," "MPOX," "vaccine equity," "Africa," "decolonized health systems," "epidemic preparedness," and "local vaccine manufacturing." Additional grey literature was sourced from the websites of the WHO, the Africa Center for Disease Control (CDC), and national public health authorities.

Studies were excluded based on the following predefined criteria: (1) review articles and meta-analyses to focus on primary research; (2) preprint publications not yet peer-reviewed to ensure quality assurance; (3) studies with unclear or insufficient data reporting that precluded meaningful analysis; (4) studies not primarily focused on the African context or MPOX; (5) conference abstracts and editorials lacking comprehensive methodology. Following these exclusions, 76 records underwent full-text screening for abstract quality, title relevance, and overall methodological rigor using standardized assessment criteria. Studies with inadequate sample sizes, poor methodological design, or insufficient reporting of outcomes were further excluded, resulting in 31 records for final inclusion in the systematic review.

We found 3,842 studies, including 1,247 on MPOX epidemiology, 968 on vaccine accessibility and manufacturing, 614 on regulatory frameworks, 452 on economic

impacts, and 561 on health system decolonization. Of these, 3,356 were duplicates or failed the initial screening criteria, leaving 486 records eligible for further review. 410 studies were excluded for specific reasons (methodology concerns, insufficient focus on Africa, and a lack of empirical data), leaving 76 studies for final evaluation and comprehensive review. This rigorous selection process ensured that our analysis was based on the most relevant and methodologically sound research on MPOX in Africa (Fig. 1).

## Dynamics of MPOX epidemics in Africa

### *Historical context and epidemiology of MPOX*

MPOX is a zoonotic disease caused by the Monkeypox virus (MPXV), a member of the Orthopoxvirus genus and a close relative of the smallpox-causing variola virus [15]. The disease's documented history in Africa began in 1970, when the first human case was recorded in the Democratic Republic of the Congo (DRC). Since this initial identification, MPOX has maintained a persistent presence across several African countries, with periodic outbreaks predominantly occurring throughout Central and West Africa [16]. The epidemiological landscape of MPOX in Africa has undergone a substantial transformation since 2022. The virus garnered unprecedented global attention when it rapidly spread across more than 100 countries, resulting in over 80,000 cases worldwide, prompting the World Health Organization (WHO) to declare MPOX a Public Health Emergency of International Concern (PHEIC) and officially rename the disease from monkeypox to MPOX to mitigate stigmatization; however, the WHO declared an end to the MPOX PHEIC on September 5, 2025 [17]. However, the 2024 resurgence has revealed more complex transmission dynamics specific to the African context. Recent comprehensive analyses [18] demonstrate that the evolving epidemiology of MPOX in Africa during 2024 shows distinct patterns compared to the 2022 global outbreak, with increased human-to-human transmission chains and altered demographic distributions. The epidemiological data from the Africa Centres for Disease Control and Prevention (Africa CDC) reveal troubling shifts in MPOX transmission patterns across the continent, with cases increasing by over 160% in 2024 compared to previous years

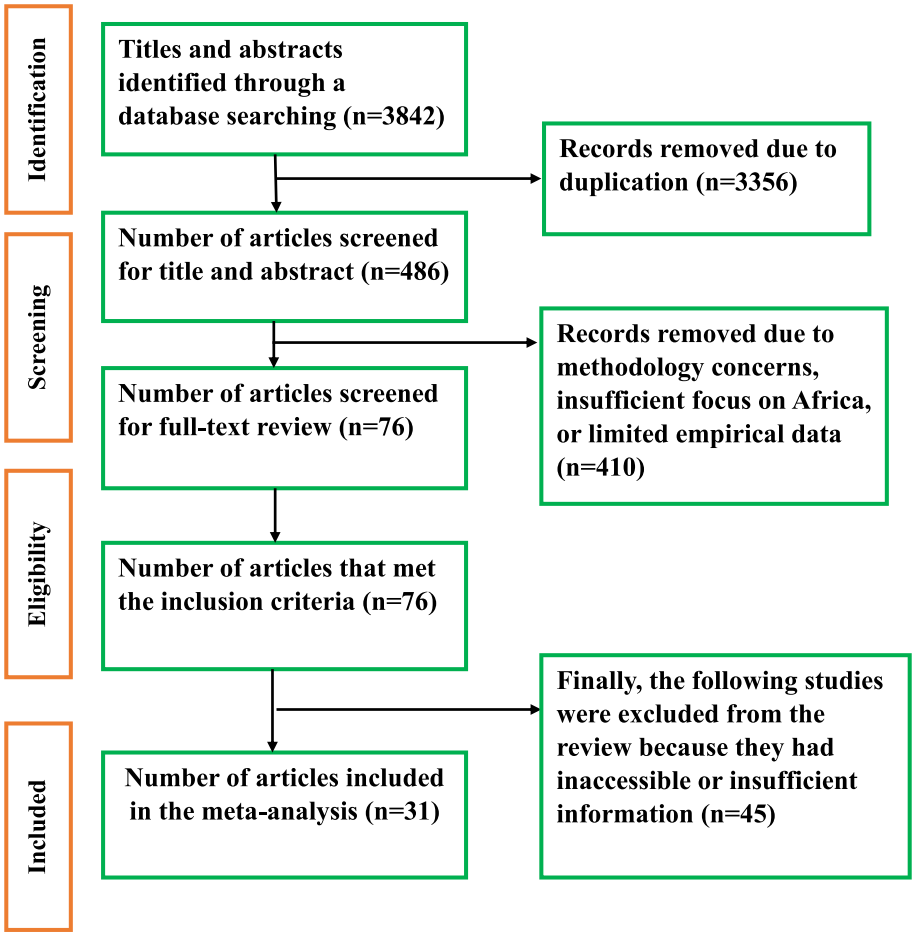


**Fig. 1** PRISMA flow diagram table for MPOX review

[19]. Contemporary research [20] identifies multiple interconnected drivers behind the MPOX resurgence in Africa, including environmental degradation leading to increased human-wildlife contact, weakened health systems following COVID-19, population displacement caused by conflict, and inadequate surveillance infrastructure in rural areas. These findings challenge previous assumptions about MPOX transmission being limited to specific high-risk populations. The complexity of MPOX epidemiology in Central Africa has been further elucidated by Halbrook et al. in 2024, who argue that the interconnected nature of transmission requires a "constellation approach" that considers zoonotic reservoirs, human behavioral factors, healthcare accessibility, and socioeconomic determinants simultaneously [21]. This multifaceted perspective is critical given that Central Africa continues to bear the highest burden of MPOX cases globally. Recent concurrent outbreaks across multiple African countries, as documented by Beiras et al. in 2025, demonstrate unprecedented geographic spread and temporal clustering, suggesting enhanced viral transmission capacity or improved detection systems [22]. The authors note that simultaneous outbreaks in previously unaffected regions indicate either viral adaptation or the unveiling of existing transmission networks through enhanced surveillance. A significant increase in cases has been observed, particularly among populations previously considered low-risk, including children under 15 years who now represent approximately 39% of cases in some regions [19]. This demographic shift raises concerns about potential viral evolution, changes in transmission modes, or whether improved diagnostic capabilities and enhanced surveillance systems are now detecting previously unrecognized cases.

The expanding geographical footprint of MPOX is evidenced by outbreaks in previously unaffected countries, including Gabon and Rwanda, which reported their first cases in 2022. Before this global outbreak, Nigeria had experienced a notable resurgence in 2017, reporting over 200 confirmed cases with an estimated 3% fatality rate, while the Central African Republic documented several outbreaks between 2018 and 2020, resulting in 49 confirmed cases [23]. MPOX's capacity to spread globally was first demonstrated in 2003 when the United States reported 47 confirmed cases linked to animals imported from Ghana. In 2018, the United Kingdom identified multiple cases associated with travellers from Nigeria. These cases, combined with the recent global outbreak, have generated sizable concern regarding the virus's evolution and its potential for broader geographical dissemination [24].

There are several reasons why MPOX is spreading more rapidly. One of them is that smallpox vaccination campaigns stopped more than 40 years ago, after smallpox was eradicated in 1980. This means that people born after the vaccination stopped do not have cross-protective immunity against MPOX [25]. Additional contributing factors include increased human-wildlife interactions resulting from deforestation and agricultural expansion, insufficient public health infrastructure (particularly in rural areas), delays in vaccine allocation to high-risk groups, and enhanced diagnostic capabilities that may uncover previously undetected cases [26]. The loss of population-level immunity from smallpox vaccination is particularly significant in Africa, where most younger individuals have no vaccination-derived protection, representing the majority of the current population and contributing substantially to increased susceptibility to MPOX infection [27].

Despite being the most severely impacted region, Africa faces significant obstacles in addressing MPOX outbreaks due to insufficient vaccine access and compromised public health infrastructure. In 2022, the WHO reported over 7,500 confirmed cases in Africa, with the DRC and Nigeria experiencing the most severe outbreaks [17]. These challenges are further compounded by healthcare systems already overburdened with endemic diseases such as tuberculosis, malaria, and HIV/AIDS, reinforcing the urgent need for a comprehensive and coordinated approach to effectively address the emerging MPOX situation across the continent [28].

## Vaccine accessibility and production

### *Global vaccine distribution: inequities and obstacles*

Currently, two primary vaccines are approved for MPOX prevention: JYNNEOS (also known as Imvamune or Imvanex), manufactured by Bavarian Nordic in Denmark, and ACAM2000, produced by Emergent BioSolutions in the United States [29]. JYNNEOS is a third-generation, live, non-replicating vaccinia virus vaccine that can be administered to immunocompromised individuals, while ACAM2000 is a second-generation, live, replicating smallpox vaccine with higher risks of adverse effects, particularly contraindicated in immunocompromised populations [30]. Additional vaccines in development include LC16m8 (Japan) and LCMV-based vaccines, though these remain in experimental phases [31].

Vaccines are a significant component of MPOX control efforts; however, the distribution of MPOX vaccines highlights a notable disparity between African nations and the Global North, reminiscent of the inequities faced during the COVID-19 pandemic. Despite being the most affected region during health crises, Africa consistently struggles to secure adequate vaccine supplies, largely due to its reliance on international organizations such as the WHO for procurement and distribution [32].

The 2022 global MPOX outbreak illustrated this issue vividly. Wealthy nations, including the U.S., Canada, and

several European countries, swiftly deployed vaccines and stockpiled large quantities. The U.S. allocated over 1 million vials of the Jynneos vaccine between 2022 and 2024, with a focus on high-risk groups [33]. The U.K. and Canada followed suit, amassing substantial reserves for their populations [34, 35]. Additionally, the U.S. had long prepared for future outbreaks by stockpiling ACAM2000, an alternative smallpox vaccine, despite its higher risk of adverse effects compared to Jynneos [36].

In stark contrast, early access to vaccines in several African countries was limited and delayed. Nigeria received 10,000 donated JYNNEOS doses in August 2024, with rollout commencing in November 2024; [37]. Rwanda began vaccination in September 2024 using 1,000 doses transferred from Nigeria and later received 5,420 additional doses via the EU's HERA [7], and the DRC's first shipments, approximately 200,000 doses, arrived in early September 2024 [38]. These patterns primarily reflected constrained global supply, early bilateral purchases and stockpiling by high-income countries, and the absence of a UN procurement pathway until WHO prequalification of MVA-BN in September 2024, rather than any policy to prioritise high-income countries by WHO or Gavi [39].

These inequities reflect multiple barriers: the purchasing power and political influence of wealthier nations, the absence of organized procurement mechanisms for low-income countries, limited financial capacity to independently secure vaccines, and weak surveillance/reporting systems that delay timely allocation [40]. Structural limitations thus compound supply challenges, leaving Africa heavily dependent on international organizations such as WHO and Gavi, which have historically prioritized developed nations in distribution [32]. Another overlooked factor is vaccine hesitancy and acceptance, which shape uptake even when vaccines are available. Recent studies highlight significant variation in willingness to receive MPOX vaccines globally. A 2024 systematic review reported wide disparities in acceptance, influenced by sociodemographic factors and trust in public health authorities [41]. Similarly, a multinational survey across African countries found that prior vaccination coverage, misinformation, and weak confidence in health systems strongly influenced hesitancy [42]. Taken together, inequities in supply, weak procurement and surveillance infrastructures, and challenges of hesitancy underscore the urgent need for a restructured global vaccine access framework that prioritizes timely and equitable allocation. Beyond procurement, strategies must also address demand-side barriers by investing in community engagement, transparent communication, and building trust to ensure vaccines are both available and acceptable. Addressing these inequities is both a moral imperative and a necessity for effective global disease control and prevention.

#### *Local vaccine manufacturing: progress and barriers*

Africa's continued reliance on external vaccine sources represents both a public health vulnerability and a missed economic opportunity. The Africa CDC's projection of 10 million needed MPOX vaccine doses starkly contrasts with the continent's minimal manufacturing capacity, highlighting the urgent need for self-sufficiency [43]. The WHO's MPOX emergency declaration in 2022 brought global attention but little practical change to Africa's vaccine access problem [44].

In recent years, a diverse vaccine manufacturing ecosystem has begun to emerge across the continent. Emerging initiatives at institutions like Senegal's Pasteur Institute and South Africa's Biovac represent promising first steps toward independence [45]. Alongside these established players, the African Vaccine Manufacturing Initiative (AVMI) has played a central role in coordinating stakeholders, advocating for policy reforms, and advancing the AU's 2040 target of producing 60% of vaccines locally [46]. Investments are also supported by continental strategies such as the Partnership for African Vaccine Manufacturing (PAVM), which seeks to align donor funding, technology transfer, and capacity building [47]. African leadership has embraced this vision, setting an ambitious target of 60% local production for medical products by 2040 [48]. Several reports emphasize that progress is visible but uneven. For example, Wellcome Trust in 2023 notes that while funding commitments have grown, financing gaps and overreliance on donor-driven models persist [49]. Structural barriers such as high capital costs, limited technology transfer, shortages in the skilled workforce, and fragmented regulatory systems continue to impede rapid progress [50]. Workforce development and training are particularly urgent, as highlighted by a study conducted by Kim et al. in 2025, who stress that vaccine inequities during COVID-19 exposed critical gaps in Africa's biomedical R&D capacity and clinical trial infrastructure [51].

Importantly, policy opportunities exist as Doua et al. argue that local manufacturing is not just a technical challenge but a political priority, requiring African governments to create enabling policy environments, invest in infrastructure, and negotiate more equitable global partnerships [50]. Similarly, Kim et al. in 2025 identify South-South collaborations and regional clinical trial platforms as promising mechanisms for reducing dependency on the Global North [51].

However, the path to manufacturing independence faces formidable obstacles that extend beyond building physical facilities. Some of the primary barriers include restrictive intellectual property regimes that block

technology transfer, infrastructure limitations, critical skills shortages in specialized production and quality assurance roles, and regulatory fragmentation across the continent. Equally, sustained government commitment that goes beyond political rhetoric at continental and regional levels remains a crucial challenge, as policy pronouncements often fail to translate into actionable long-term investments [52, 53]. These challenges reflect historical power dynamics in global health, where African nations have been positioned as consumers rather than producers of medical technologies.

The road to vaccine independence will require a dual strategy: leveraging strategic international partnerships for immediate capacity building while systematically developing sovereign capabilities. During this transition, Africa will continue to need external expertise and materials [54], but these relationships must be restructured as equitable partnerships centered on knowledge transfer rather than perpetual dependence.

Success will demand sustained investment in human capital development, regulatory harmonization across African regions, and negotiated intellectual property arrangements that prioritize public health over market exclusivity. Through this approach, Africa can gradually transform from a passive recipient of global health assistance to an active contributor to worldwide vaccine security.

#### The case for decolonizing African health systems

The colonial imprint on African vaccine manufacturing extends beyond physical infrastructure to governance models, funding relationships, and knowledge systems that perpetuate dependency in pharmaceutical production. Colonial legacies in vaccine manufacturing varied significantly across different colonial powers and regions. French colonial territories developed pharmaceutical systems oriented toward metropolitan needs, as seen in Senegal's Institut Pasteur, while British colonies were integrated into centralized London-based production networks [55]. The minimal pharmaceutical production capacity in the Democratic Republic of Congo (DRC) is a direct consequence of a colonial-era economic design, where Belgian policy intentionally suppressed local manufacturing by constructing infrastructure solely for resource extraction [56]. This historical underdevelopment path-dependency resulted in an industrial base incapable of producing essential goods. Consequently, the DRC, like most African nations, remains dependent on importing 90–95% of its medicines, a critical vulnerability identified in recent analyses [57]. These differentiated colonial experiences are now being reshaped through African regulatory leadership. While Francophone countries historically maintained regulatory dependencies on European systems and Anglophone nations operated through WHO prequalification frameworks [58], regional initiatives such as the African Vaccine Regulatory Forum (AVAREF) and the establishment of the African Medicines Agency (AMA) in 2021 have created unified, African-controlled regulatory pathways that transcend colonial divisions [59, 60]. Furthermore, the progress of several African countries in reaching WHO Maturity Level 3 (ML3) status, including Egypt and South Africa, signals the capacity of African regulatory systems to align with international standards while maintaining sovereign control [61–63].

African regulatory authorities face significant challenges in approving timely medical interventions due to limited expertise, limited capacity, and underutilized reliance mechanisms. Many countries do not invest enough in their regulatory infrastructure, resulting in delays during health emergencies like the MPOX outbreak [64–66]. However, several African countries have demonstrated remarkable regulatory leadership through initiatives such as AMA [67], AVAREF [68], and capacity-building efforts supported by the European & Developing Countries Clinical Trials Partnership (EDCTP) [69]. These examples illustrate Africa's potential for regulatory excellence when proper investment and support mechanisms are in place.

A decolonized vaccine manufacturing framework builds directly on these demonstrated regulatory achievements through four evidence-based strategies: First, countries with ML3 regulatory status can negotiate comprehensive technology transfer agreements rather than accepting limited fill-and-finish operations, as demonstrated by South Africa's advanced pharmaceutical sector. Second, AMA provides African-controlled regulatory pathways that reduce dependence on former colonial regulatory systems. Third, regional manufacturing hubs can leverage AVAREF's proven rapid approval capabilities to serve continental markets with locally prioritized vaccines, including measles-rubella, yellow fever, cholera, rotavirus, meningococcal, malaria, Ebola, pneumococcal, and Lassa fever [50]. Fourth, community engagement models proven during successful Ebola vaccine campaigns can ensure broad acceptance and equitable distribution.

These strategies demonstrate that decolonization represents practical pharmaceutical sovereignty already being implemented across Africa. African regulatory excellence through AVAREF, AMA, and ML3-certified national agencies provides the institutional foundation for manufacturing independence, transforming the continent from a passive recipient of global health assistance to an active leader in pharmaceutical innovation and production.

### African regulatory framework and prospects for accelerated vaccine production

In the face of recurrent health crises, Africa has begun to develop a more coordinated and robust pharmaceutical and vaccine regulatory infrastructure. These advances are exemplified by the efforts of AVAREF, which has played a pivotal role in streamlining clinical trial approvals and enhancing regulatory efficiency across the continent. During the 2013 to 2016 Ebola outbreak in West Africa, AVAREF demonstrated its effectiveness by reducing vaccine trial approval timelines from an average of two years to under 60 days. This accomplishment illustrated the potential of regionally tailored regulatory mechanisms to accelerate access to essential health products without compromising safety [70].

Building on this momentum, the establishment of the AMA in 2021 marked a significant milestone in the continent's push toward regulatory harmonization. As a continental authority, the AMA works in coordination with the African Union (AU) and eight recognized Regional Economic Communities (RECs) to create a unified framework for the approval, oversight, and distribution of pharmaceutical products [67]. Parallel efforts, including the African Medicines Regulatory Harmonization (AMRH) initiative and support from the West African Health Organization (WAHO), reflect a growing regional consensus around the need for collaborative regulatory solutions [71, 72].

At the national level, several African countries have made notable progress in strengthening their regulatory capacity, particularly through their National Regulatory Agencies (NRAs). According to the WHO's Global Benchmarking Tool, multiple African NRAs have now achieved Maturity Level 3 (ML3), signifying a stable and well-functioning regulatory system. As of 2024, the countries with NRAs operating at ML3 include Tanzania (2018), Ghana (2020), Egypt (2022), Nigeria (2022), South Africa (2022), and, more recently, Zimbabwe, Rwanda, and Senegal (2024). Notably, Egypt and South Africa have attained ML3 status specifically for vaccine production, while Tanzania, Nigeria, Rwanda, and Senegal have achieved ML3 for vaccines despite not currently producing them. This expanding regulatory competence represents a promising trend towards greater pharmaceutical sovereignty across the continent [61–63]. Egypt and Nigeria have also shown notable progress in their pharmaceutical regulation, indicating a wider trend of regulatory improvement across the continent [73].

However, despite these advancements, several challenges continue to hinder the establishment of a fully autonomous and efficient pharmaceutical ecosystem in Africa. Regulatory fragmentation, with differing standards and approval processes across countries, impedes cross-border collaboration and delays regional vaccine access. In addition, many NRAs continue to struggle with limited financial resources and a shortage of trained personnel, which restricts their ability to consistently oversee vaccine development, authorization, and distribution. Addressing these systemic gaps is crucial for establishing a resilient pharmaceutical system that can respond promptly to public health emergencies, such as the MPOX outbreak [74].

The MPOX outbreak's regulatory failures directly inform the proposed African Emergency Use Authorization (AEUA) framework (Fig. 2). The DRC's six-month delay in receiving vaccines, despite bearing the highest case burden, resulted from fragmented approval processes requiring separate negotiations with external authorities. The AEUA framework would enable continental emergency authorization through existing ML3-certified agencies, potentially reducing such delays from months to weeks. Similarly, regulatory barriers that prevented inter-country vaccine sharing during the 2024 outbreak demonstrate the need for streamlined reliance pathways outlined in the Local Manufacturing Independence Framework (Fig. 3). These frameworks transform Africa's demonstrated regulatory excellence into operational pandemic response mechanisms, warranting serious consideration as evidence-based solutions derived from MPOX-specific bottlenecks.

As Africa enhances its vaccine manufacturing capacity, it is crucial to ensure that locally produced vaccines meet established global safety and efficacy standards. Regulatory bodies, including AVAREF and AMA, are pivotal in this endeavor [75].

This regulatory evolution must also be accompanied by significant investments in workforce development, quality assurance systems, and post-market surveillance infrastructure. Additionally, incorporating indigenous knowledge systems and cultural practices into regulatory considerations can foster broader public trust and uptake. The recent launch of the African Vaccine Manufacturing Accelerator (AVMA), which has pledged up to $1 billion to support vaccine production and regulation, offers critical financial backing for these efforts [76]. Together, these initiatives lay the groundwork for a future in which African countries can produce, regulate, and distribute vaccines in ways that are locally governed, internationally credible, and equitably accessible.

### Economic impact of MPOX outbreaks and vaccine production in Africa

The economic implications of MPOX outbreaks in Africa are substantial and multifaceted. In the DRC alone, over 19,513 MPOX cases were reported before the 2024 emergency declaration with a case fatality rate of 3.1% [77], imposing considerable costs on national health systems through surge demands for patient care, isolation

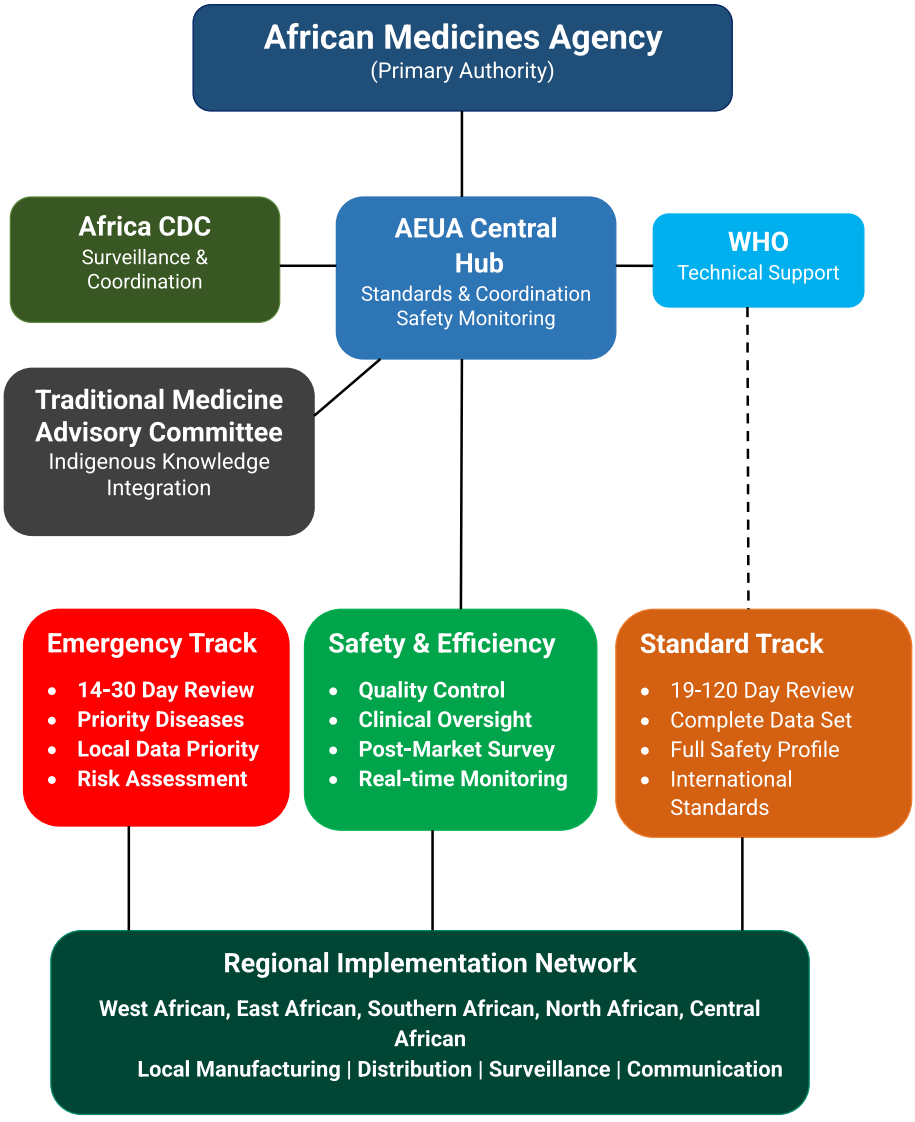


**Fig. 2** Tentative AUEA framework

facilities, medical supplies, and protective equipment. Quarantine measures for MPOX patients create additional economic burdens on the healthcare system. Indirect costs include workforce productivity losses, reduced tourism, and restricted cross-border trade. While investment in local vaccine manufacturing offers substantial benefits, it faces political and market pressures, as demonstrated by South Africa's decision to procure vaccines from India despite hosting an mRNA hub, saving approximately $133 million over three years, but highlighting tensions between cost pressures and support for local production capacity [78].

According to the African Union, shifting from vaccine importation to domestic production could save the continent between $4 billion and $7 billion annually [79]. These savings would result from reduced import costs, improved responsiveness to outbreaks, and decreased reliance on donor-funded procurement. Moreover, establishing local production capabilities generates broader economic spillovers. The infrastructure, skills, and technologies developed for vaccine manufacturing have the potential to catalyze growth in related sectors such as biotechnology, medical research, and pharmaceutical innovation [53].

The benefits, however, come with challenges. High initial capital costs, uncertain market demand, and the need to meet international quality standards present considerable barriers. African manufacturers must compete with established global firms and navigate complex intellectual property regimes. Despite these hurdles, strategic partnerships can offer pathways forward. The collaboration between Aspen Pharmacare in South Africa and Johnson & Johnson for COVID-19 vaccine production stands as a powerful example of how public-private alliances can

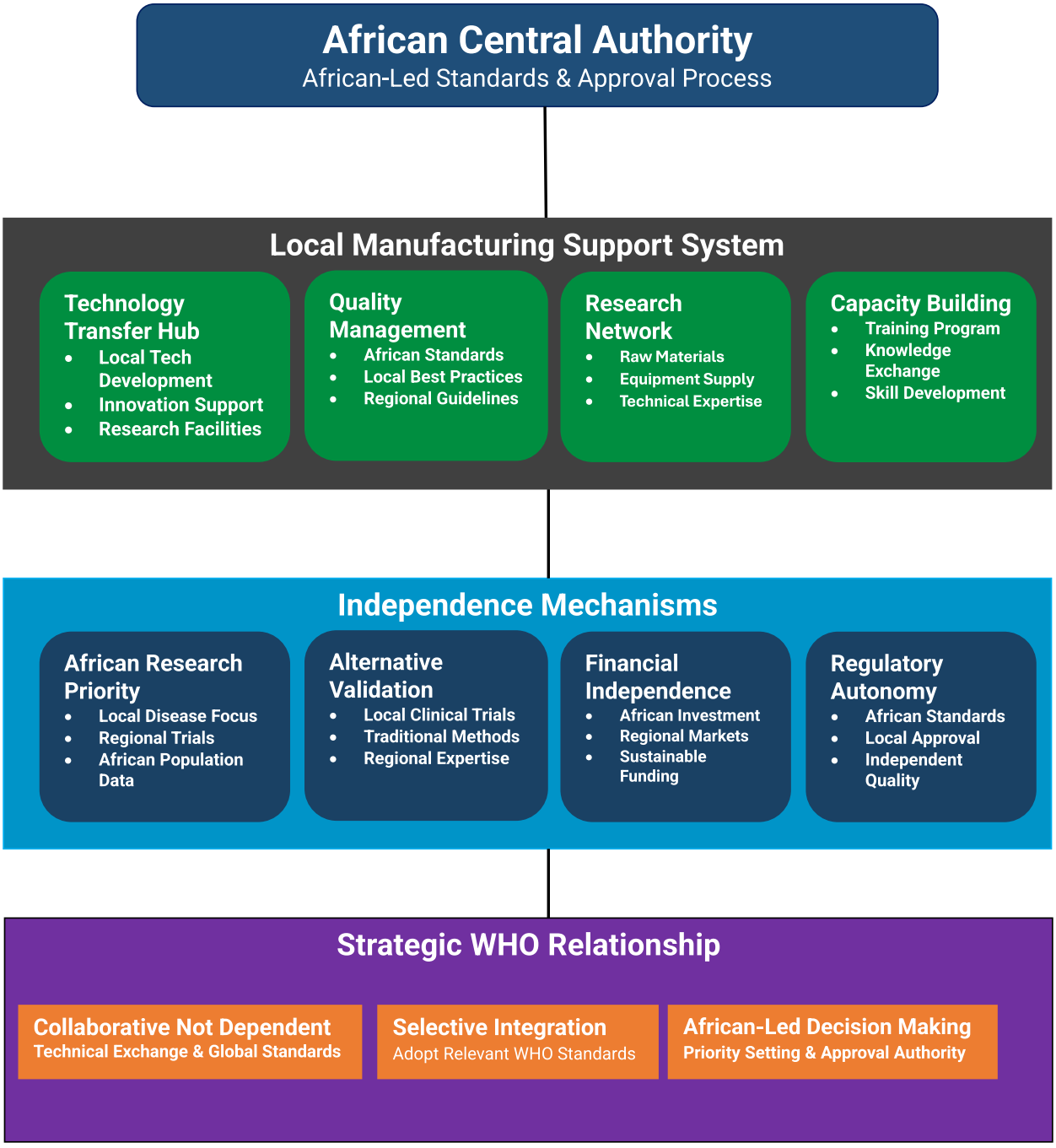


**Fig. 3** AEUA local manufacturing independence framework

accelerate local production while ensuring quality and compliance with global standards [80].

The COVID-19 pandemic exposed the risks of relying on global supply chains, highlighting the urgent need for regional self-sufficiency. Strengthening vaccine production in Africa is both a public health and economic imperative, offering greater control, faster access during outbreaks, and reduced vulnerability to external shocks. Though complex, local manufacturing is a strategic investment in health security and economic resilience, one with the potential to transform Africa's future.

### Study limitation

While this review offers a valuable synthesis of current literature and emerging policy discussions on MPOX, local vaccine manufacturing, and decolonized health systems in Africa, a few limitations should be noted. First, publicly available data on vaccine production initiatives

across the continent is still evolving, which may limit the granularity of insights into specific country-level capacities. Second, information on technology transfer agreements and collaborations with global pharmaceutical firms remains somewhat limited in scope and transparency, making it difficult to assess the full extent of progress in this area. Finally, although the discussion on decolonizing health systems is grounded in relevant scholarship, it may not fully reflect the breadth of stakeholder perspectives, particularly from community-level actors and traditional health systems.

## Conclusion

The resurgence of MPOX in Africa underscores structural weaknesses in the continent's health systems, compounded by global vaccine inequities and reliance on external actors. Despite bearing the highest burden, African countries again faced delays in vaccine access due to limited production capacity and fragmented regulation. Addressing these vulnerabilities requires building autonomous and resilient health systems, with local manufacturing, harmonized regulation, and stronger community leadership at the core. Realizing this vision demands sustained political commitment, equitable partnerships, and long-term investment. MPOX should serve not only as a warning but as a turning point toward health sovereignty and equity in global health governance.

### Recommendations for policy and practice

To translate this vision into action, African governments should prioritize concrete measures that can realistically strengthen health sovereignty and vaccine access. Investments in local vaccine production must be combined with targeted incentives for regional research, clinical trials, and development to ensure that manufacturing hubs are supported by strong innovation ecosystems. Regional procurement mechanisms, coordinated by the African Union and the Africa CDC, should be strengthened to pool demand, reduce costs, and secure timely vaccine access. Regulatory harmonization should move beyond broad alignment toward building reliance pathways between national authorities and continental bodies such as the AMA and AVAREF, allowing rapid approval of emergency-use vaccines. Equally, governments should negotiate technology transfer agreements that guarantee full production capacities rather than limited "fill-and-finish" roles, while incentivizing public–private partnerships to mobilize long-term investment. Finally, embedding community participation, traditional health practices, and transparent communication within vaccine rollouts is essential to overcome hesitancy and strengthen uptake. Taken together, these actionable strategies provide a roadmap for building a resilient and self-sufficient African health system that can respond effectively to MPOX and future epidemics.

#### Abbreviations

| | |
|---|---|
| WHO | World Health Organization |
| DRC | Democratic Republic of Congo |
| AMA | African Medicine Agency |
| AVAREF | African Vaccine Regulatory Forum |
| PHEIC | Public Health Emergency of International Concern |
| MPOX | Monkeypox |
| REC | Regional Economic Committee |
| AMRH | Africa Medicine Regulatory Harmonization |
| WAHO | West African Health Organization |
| WHO | World Health Organization |
| NRA | National Regulatory Agency |
| HIV/AIDS | Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome |
| CDC | Center for Disease Control |
| AU | African Union |
| AAM | Access and Allocation Mechanism |
| ML3 | Maturity Level 3 |

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#### Authors' contributions

ANC conceptualised and designed this work. ANC worked on data collection/documentation and initial analysis.NGT assisted in reviewing. All authors provided final approval of the version to be published and agreed to be accountable for all aspects of the work.

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#### Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

## Declarations

#### Ethics approval and consent to participate

Not Applicable.

#### Consent for publication

Not Applicable.

#### Competing interests

The authors declare no competing interests.

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## Publisher's Note