Regulatory System Strengthening report insights: Proposed priorities for funders

Harris Access Consulting

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Background and current progress

There has been **great progress in regulatory strengthening in Africa** over the past decade through initiatives aiming to increase capacity, work-sharing, regional harmonisation and regulatory reliance.

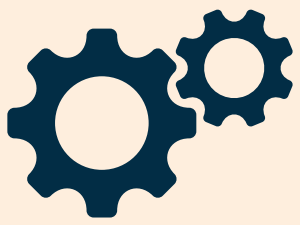
COVID-19 has brought to the fore the need for more reliable and timely supply of vaccines and medicines across the continent, prompting a resurgence of political support for local manufacturing. This in turn has raised awareness of the **need for appropriate regulatory oversight**.

Wellcome published a report in July 2022 on Strengthening Regulatory Systems in low- and middle-income countries (LMICs) with a specific focus on improving the regulatory ecosystem for vaccines in Africa. The report defines the remaining challenges and outlines the opportunities for investment by funding partners.

The establishment of the African Medicines Agency (AMA) will help to facilitate coordination of regulatory activities and further harmonisation across Member States. As of October 2022, **23 countries ratified the AMA treaty**.

A joint workplan has been developed that includes a roadmap for the AMA's first years, setting up AMA's core activities and developing AMA business processes.

Countries wishing to produce vaccines for export need to be operating at **WHO ML3** (Maturity Level-3). There are 5 countries with ML3 status in Africa (Egypt, Ghana, Tanzania and Nigeria for medicines; only **2 countries, Egypt and South Africa have this designation for vaccines**.



The African Union and African CDC have established the Partnership for African Vaccine Manufacturing (PAVM) with an ambitious goal of ensuring that **60% of vaccines in Africa are produced locally by 2040**.

The proposed priorities are mapped to three overall objectives

For effective regulatory system strengthening in Africa, investments should collectively address the needs at the national, regional and continental level, building on existing initiatives and aligning with the AMA/AMRH and the Partnerships for African Vaccines Manufacturing (PAVM) workplans.

1

The African Medicines Agency needs to add value to users and Member States, providing services that are additional to those already found or evolving on the continent and avoiding duplicating requirements.

2

All African countries to participate in reliance to improve the oversight of vaccines across the lifecycle, particularly in epidemic contexts

3

All vaccine-producing countries to reach WHO Maturity Level-3/4 status

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The African Medicines Agency needs to add value to users and Member States, providing additional services and avoiding duplication				
1	Optimise the legal basis for regulatory harmonisation and convergence	$$		5-10 years
2	Build capabilities within NRAs and AMA to enhance future workforce retention and sustainability	$$		5-10 years
3	Expand an end-to-end process to support product lifecycle management	$		1-2 years
All African countries to participate in reliance to improve the oversight of vaccines across the lifecycle, particularly in epidemic contexts				
4	Develop regulatory best practices for emergency use contexts and pathways for reliance, including improving ability to rely on ML4 agencies	$$		2-5 years
5	Develop a digital information management system that improves visibility on products, manufacturers and regulators across the continent	$$		5-10 years
6	Streamline pathways for clinical trials approvals incorporating ethics review and ensure data availability from trials	$$		5-10 years
7	Build capacity of regulators to respond to continental pharmacovigilance system	$$		2-5 years
8	Support WHO PQ programme in cold chain oversight and regulators' capacity for Good Distribution Practice	$$		2-5 years
All vaccine-producing countries to reach WHO ML3/4				
9	Prioritise regulators in manufacturing countries to address critical bottlenecks preventing them from to achieving WHO Maturity Level-3/4 status	$$$		5-10 years
10	Support the development of an African network of regional reference labs to conduct lot release (and batch testing for small molecules) via a hub and spoke model	$$$		5-10 years
All 3 pillars should be supported by strategic research agenda to fill knowledge gaps				

KEY

Scale of investment (indicative costs) defined by: **$** up to $1 million; **$$** $3-6 million, **$$$** over $6 million

Target/recipient defined by: Global Continental Regional National