PATH

Streamlining regulatory processes to save lives and achieve health for all

As African countries advance plans for achieving universal health coverage, there is widespread recognition that the goal will not be met without innovation of all kinds. Particularly, the need for research and development to advance new tools to deliver quality, affordable health care has been elevated as a priority. Unfortunately, complex and disparate regulatory processes delay products from having the impact they could.

Regulatory approvals are essential in ensuring safety and efficacy of health products. However, across Africa regulatory processes differ from country to country resulting in delays in introduction and scale-up. In addition, many regulatory agencies are under-resourced and over-burdened, creating bottlenecks and backlogs.

To address these challenges, efforts are underway to harmonise regulatory activities. In order to fully realise the potential impact of harmonisation across Africa, sustained commitments—including political, technical, and financial—will be required from policymakers and donors alike.

4-7
years

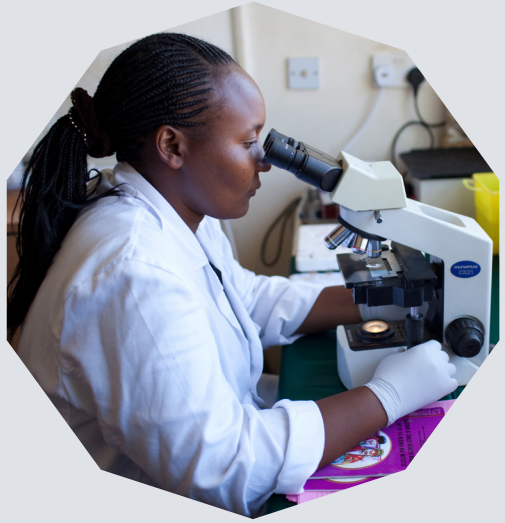
4-7 years average lag time in regulatory approval of new health products in sub-Saharan Africa after first regulatory submission in high-income countries

40-60%

40-60% faster evaluation processes have been achieved in the East African Community due to joint assessments of health products

220
products

220 products have been assessed in a joint review process by the Zazibona initiative since 2013



Progress on Regulatory Harmonisation in Africa

In January 2016, the African Union Heads of State recognised the importance of regulatory harmonisation by adopting the Model Law on Medical Products Regulation (AU Model Law). A critical first step, the AU Model Law is a frame for countries and regional economic communities (RECs) to increase collaboration and more efficiently evaluate products. Full implementation will require adoption into the legal structure in each country.

At the REC level, notable progress has been achieved. For example, the East African Community was the first REC to begin implementation of the African Medicines Regulatory Harmonisation initiative, and notable achievements include the development of joint dossier assessments and registration of new products. Similarly, the Zazibona initiative* has already jointly reviewed 220 health products and registered more than 150.

*A collaboration between national medicines regulatory authorities in Botswana, Namibia, South Africa, Zambia, and Zimbabwe.

Photo: PATH/Eric Becker

Regulatory harmonisation has been endorsed at the highest political levels within the AU, yet progress continues to be slow. To accelerate regulatory harmonisation efforts and improve access to essential health products for underserved populations, political commitment must be paired with assurance of resources. Sustainable funding must be mobilised from donor and domestic funders; harmonisation efforts must be expanded to cover different types of products and across regulation phases; and the AU Model Law should be adopted and converged into law by each member state. Without tangible commitments, current efforts will not overcome regulatory challenges sustainably.

Fund regulatory harmonisation to enable scale-up

Lack of sustained funding for regulatory strengthening, overreliance on a small number of external donors for core funding, and limited domestic investment because of competing priorities limit the ability to make large-scale impact. The lack of a long-term vision for more varied funding, particularly amongst African countries, is a major roadblock to sustainability. This funding deficit is further compounded by limited technical expertise and bandwidth. Funding from international donors must be leveraged for greater domestic investment, which is required to bring harmonisation to scale across Africa.

Ensure all regulatory phases and functions are harmonised across products

Initiatives in the East African Community and Zazibona have demonstrated the impact that harmonisation can have on accelerating access to lifesaving medicines. However, these initiatives—and others across Africa—must be broadened and strengthened to address harmonisation holistically. For example, there is currently a gap in the regulation of diagnostics, critically important to ensuring timely and accurate treatment, as well as medical devices. Harmonisation efforts should also expand across all regulatory phases—including clinical trials, pharmacovigilance, and post-marketing quality assurance. Accelerating access to lifesaving products requires a sustained commitment to building out the scope of ongoing initiatives, including a commitment to sufficiently staffing and building technical expertise.

Domesticate the AU Model Law in all AU member states

The AU Model Law is the framework upon which countries can model their participation in regional regulatory activities. However, to have any impact, the legislation must be adopted and enforced by each country. To date, only 12 of the 54 AU countries have used the AU Model Law to review or amend their national medicines laws.

To overcome barriers and accelerate access to safe and effective products, the public and private sectors must work together to close the funding gap; strengthen regulatory capacity and infrastructure; and prioritise regulatory systems as drivers for economic growth and wellbeing. While regulatory harmonisation efforts may not initially come to mind when discussing universal health coverage, these efforts will have a tremendous impact on our ability to collectively meet our promise to achieve health for all by 2030.

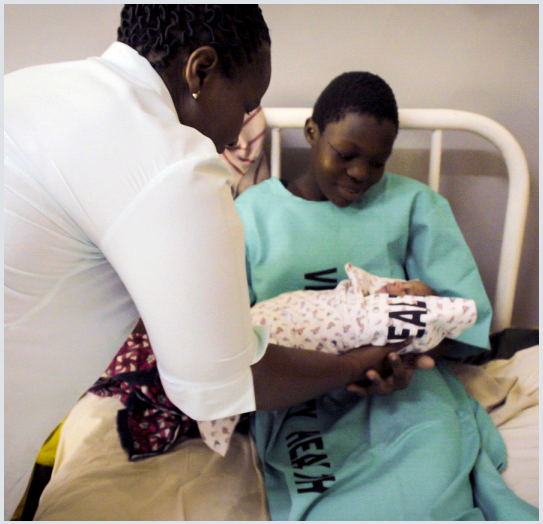


Photo: PATH/Andrew Berends

Making the Case for Regulatory Harmonization

An analysis by PATH demonstrates the potential impact of regulatory harmonisation in real terms—lives saved. The analysis models how many lives could be saved as a result of accelerated access to new or improved drugs aimed at treating postpartum haemorrhage and pneumonia—two leading causes of death among women and children in Africa. The study found that harmonisation of regulatory approvals for just these two medicines could contribute to more than 23,000 lives saved in eastern and southern Africa.

Website: www.path.org/advocacy-policy
Email: advocacyandpolicy@path.org
Twitter: @PATHadvocacy

PATH is a global organization that works to accelerate health equity by bringing together public institutions, businesses, social enterprises, and investors to solve the world's most pressing health challenges. With expertise in science, health, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales solutions—including vaccines, drugs, devices, diagnostics, and innovative approaches to strengthening health systems worldwide.

path.org

Mailing Address
ACS Plaza, 4th floor
Lenana Road
PO Box 76634-00508
Nairobi, Kenya

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