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Fast-tracking health R&D, innovation, and access.

POLICY BRIEF

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# Evaluation of Health Products Regulatory Process in Kenya

***A Summary of Progress, Challenges, and Opportunities***

## Executive Summary


The processes by which countries regulate medical products and health technologies can have a profound impact on whether high-quality vaccines, devices, diagnostics, and drugs are accessible to those who need them most.

The government of Kenya has demonstrated commitment to strengthen its regulatory environment and support the efficient evaluation of medical products and health technologies. The government has developed a robust regulatory framework, which includes a number of regulatory agencies, each overseen by various government ministries. Despite this progress, there are many bottlenecks in the regulation of medical products.

The Coalition of Research and Development (CHReaD) together with its partners undertook an evaluation to assess the relevance, efficiency, effectiveness, and sustainability of the health products' regulatory review pathway and identify opportunities and challenges that hinder or enable efficient review and turnaround time of products and innovations in Kenya.

The rapid evaluation has shown successes and milestones achieved as well as areas for improvement required for the Pharmacy and Poisons Board (PPB) to be more effective and efficient, and to have a major influence in Kenya Health Products and Technologies (HPTs) evolution and become the best HPTs regulatory body in the region. PPB needs to rapidly address human resources gaps to onboard well-trained evaluation assessors, more financing to underfunded regulatory functions, an IT infrastructure that is fit for purpose and set up a robust regulatory Monitoring and Evaluation (M&E) and research platform. Going forward, there is need to embed agilities identified during the pandemic into the new normal, innovative HPTs' to encourage PPB, private sector and other relevant public entities within the Ministry of Health and other ministries to be an enabler of new technologies and promote co-creation of new policies and approaches.

## Introduction

The concept of essential medicines was birthed in 1977 by World Health Organization. Kenya has since recognized it as an essential to primary health care. Today's regulatory framework for pharmaceutical sector in Kenya is provided by the Pharmacy and Poisons Act of 1957 (CAP 244) as well as the Health Act, 2017 and the Kenya National Pharmaceutical Policy— Session Paper No.4 of 2012. The Acts and policies define procedures for pharmaceutical and other health products regulation, selection, quantification, procurement, storage and distribution, rational use and quality control. They have given PPB the regulatory mandate over Kenya's HPTs. PPB is responsible for the regulation of pharmaceutical products, registration of HPTs and clinical trial approvals. PPB has four directorates under the new organization structure; Medical Products and Health Technologies, Pharmacy Practice, Laboratory Services and Corporate Services. There are regional offices in Nairobi, Central, Eastern, Coast, Garissa, Eldoret, Kisumu and Kakamega regions, carrying out inspections, pharmacovigilance and examinations. Drug or HPT registration is not decentralized but officers in regional offices are involved in the assessment process. The combination of regulation of profession and medical products by PPB is not the norm globally and the functions are normally separately undertaken by different entities, there is need for PPB or the new Kenya Food and Drug Authority (KFDA) proposed bill to rethink this model. PPB is expected to foster pharmaceutical innovations, promote cutting edge research, integrate technological advancements and facilitate curriculum transformation as well as best practices in the manufacture, trade and distribution of HPTs in tandem with global trends. However, the board remains at crossroads. It's workforce is considerably small and it's approach still has some inefficiencies compared to other National Medicines Regulatory Authority (NMRA's) in the region like Ghana, Tanzania and Rwanda.

## Findings

In 2020, Kenya, like other countries, was faced with the Covid-19 pandemic, in the first phase the PPB was actively involved in the pandemic owing to Covid PCR kits required for Covid-19 testing.

The Kenya HPT regulatory systems continue to be challenged in supporting the pandemic response. With introduction of new Covid-19 vaccines, medical oxygen utilization, there has been increased stakeholder dialogue to identify where flexibilities are possible and can be enacted within PPB's legal framework. These have covered areas such as: supply chain; conduct and reporting of clinical trials; manufacturing, inspection, and quality audits; authorization review processes; post-authorization activities.

The pandemic has created both opportunities and challenges for new ways of working and accelerating the assessment of HPTs, both in clinical trials and approval settings. The situation has resulted in increased collaborations between PPB, development partners and inter-ministerial entities on technical and policy fronts.

## 1. Need for Action and Policy Solutions

Kenya now has a robust policy framework for HPTs regulation with a high number of government entities playing in the regulatory arena leading to a longer regulatory pathway. This has caused delays as research institutions, the private sector, and other innovators strive to navigate the bumpy path toward the registration of health products.

a. **Pharmacy and Poisons Board is a semi-autonomous Medicines Regulatory Authority, operating under the haziness of laws that have failed to clearly distinguish the responsibilities of the Board from other agencies.**

b. **There is a need for more expertise at the PPB who can analyze vaccine manufacturing and evaluate a lot of summary protocol and grant lot release. Capacity building is urgently required in lot release protocols with local manufacturing of human vaccines underway.**

c. **Regulation of health products and technologies such as vaccines, diagnostics, and blood and blood products are lagging. This is attributed to the complexities of lack of evaluation, manufacturing capacity in Kenya, and reliance on stringent regulatory agencies based in the US, Europe, and Asia for recognition of approval such as the CE mark as a proxy.**

## 2. The Need for Concerted Efforts

Global trends of continuing pressure on National Regulatory Authorities (NRAs), of all sizes and capacities, have been noted, due to the increased volumes of applications received, the complexity of the submissions and the increased categories of medical products. Efforts to address these challenges, especially for NRAs in low and middle-income countries, have focused on strategies for identifying and performing core regulatory functions, that are undertaken directly by NRAs, to meet country or regional needs. WHO has encouraged NRAs to consider regulatory convergence and to collaborate with and recognize the work carried out by other agencies to ease the regulatory burden. African Medicines Agency (AMA) is expected to contribute to the improvement of regulation of medicines, medical products and technologies and to advance the implementation of the Pharmaceutical Manufacturing Plan of Africa. As of April 2022, up to 25 African countries ratified the African Medicines Agency (AMA) treaty, marking the entry of the second specialized health agency of the African Union, Kenya is yet to ratify AMA.

## 3. The Journey towards WHO Global Benchmarking Tool (GBT) Maturity *Level 3*

The last WHO benchmarking process ranked level I in 2014, and 2018 with the main bottleneck to advance this maturity forward being the updated legislative instruments. A number of African countries including Kenya due to Covid-19 pandemic and huge interest in human vaccine manufacturing are increasingly pressuring their country national medicine regulatory authority to progress further in the maturity scales for vaccine manufacturing to take place.

This is a great push and nudge in ensuring strengthening of regulators on quality assurance and capacity as more advanced local manufacturing of complex molecules happens in the local private market. PPB is working towards the attainment of WHO Maturity Level 3 (ML3) in 2022 (Generally for Kenya to manufacture vaccines, PPB needs to be at ML3 especially with Kenya Biovax and Moderna vaccine manufacturing plant investment announcements).

### 4. Kenya's Journey to Vaccine Manufacturing

Kenya is taking initiative to build capacity for human vaccine production. This has been catalyzed by the COVID-19 pandemic due to the inability to access adequate supplies of the COVID-19 vaccine. Additionally, this Project will support Kenya in preparing for its exit from GAVI support that begins in 2023. The establishment of the Kenya Biovax Ltd, and the formation of a National Multi-Agency Committee of Human Vaccine Production by the Government of Kenya was one of the first steps towards realizing human vaccine manufacturing in Kenya. While the Moderna Vaccine manufacturing plant will be the first of its kind in Kenya, it is noteworthy that Kenya has been manufacturing animal vaccines through the Kenya Veterinary Vaccines Production Institute. This experience can be leveraged in setting up and running the proposed COVID19 manufacturing plant.

### 5. Metrics for Regulatory Efficiency

At the PPB, a monitoring and evaluation tool exists for monitoring the institution's strategic plan. The stra¬tegic plan is under implementation and key performance indicators have been listed in the strategy. The current structures for monitoring and evaluation are still at nascent stages within the corporate services directorate under a planning and M&E unit.

## Challenges

**a. Inadequate human resources especially on evaluation of product dossiers & other core departments as required for increase in number of applications. There is need to undertake a proper review of current HR core tasks and reduce duplication/redundancy and focus on application of reliance principles**

**b. Funding challenges; there is need for more resources allocated to PPB.**

**c. Renewal of software licenses used by the board even as we shift to digitalization of all systems require a significant operational cost**

**d. There is inadequate monitoring and evaluation functions**

**e. Investment in technology is not integrated/not interoperable systems under PRIMS (PPB's Online Services Portal) and no tracking and tracing capacity for applications**

**f. FIFO for product submissions is not fully observed and the query/feedback system still a challenge.**

**g. Numerous guidelines which are not harmonized and not speaking to each other leading to human resource burden to implement the guidelines.**

h. Duplication of importation rules and fees between KEBs and PPB for food supplements, nutrition products and borderline products. There is need for stream- lining to avoid increasing product prices.

i. Accountability challenges.

## Opportunities

Covid-19 pandemic has underscored the importance of PPB having agile mechanisms in product evaluation and registration pathways. PPB through the current strategic plan has committed to advancing regulatory science and looking at other regulators that have experience with novel regulatory models. PPB aims to transition in future to a more mature regulatory authority and a clear investment roadmap by PPB should be developed and linked to the new development of the Africa Medicines Agency which leverages heavily on previous investment by countries on the National Regulatory Authorities and regional regulatory blocks such as the East African Community. The following are some key lessons learnt and key messages which form part of the conclusions in this rapid evaluation, we recommend regular bi-annual evaluations (internal and external facing) to be undertaken for PPB to be a patient focused, evidence-based, risk-orientated, transparent, effective and a flexible regulator:

a. PPB has made major milestones in the last decade and continues to set the bar high for medicines regulatory agencies in the region. For instance, being the Africa Centre of regulatory excellence on Pharmacovigilance is a remarkable initiative for ensuring patient and product safety is continuously monitored.

b. Kenya is a major powerhouse with regards to local manufacturing of medicines and other health products. In addition, with the recent announcement of vaccine plants development by Kenya Biovax, Konza Technopolis and Moderna and other innovators are set to be game changers and PPB needs to provide a more advanced and enabling regulatory environment for new investors in the HPT space.

*- PPB strategic involvement in the Covid vaccine deployment process and providing consistent advisory to the Covid-19 pandemic earlier response and vaccine taskforce position PPB as a public health focused, science-based medicines and health products regulatory agency especially to the newly formed National Public Health Institute based at the Ministry of Health*

*- As economic growth continues in Kenya towards a middle-income country, and spending priorities expand to regular procurement of more innovative HPTs, regulatory oversight will also grow in importance. A careful balance of regulations that improve patient safety and transparent processes that do not excessively hinder market entry is needed.*

c. PPB has now additional mandate of regulating medical devices, diagnostics and broadly all HPT's in Kenya. Additional mandate comes with mounting pressure to deal with larger volumes of market authorization applications, complex submission and increased product categories.

d. The ICT investments done by PPB towards bolstering better systems and openness/ transparence to enhance regulatory review processes the last five years and building in-house capabilities to manage the IT systems and upgrade has been a sustainable move by PPB and encouraging feedback from stakeholders to continuously improve the systems towards being user friendly and responsive is the future.

e. PPB participation in international bench-markings such as the WHO Global Benchmarking Tool (GBT) and allowing this independent evaluation is a clear statement of building more evidence-based assessment of PPB's strengths and weaknesses to address regulatory inefficiencies.

f. Kenya has participated actively in the AUDA/NEPAD and IGAD Medicines Harmonization process and improved work-sharing through shared knowledge and skills has resulted in faster regulatory approvals and improved availability of safe, efficacious, and quality medicines to EAC block. Evaluation of the AMRH initiative has demonstrated that policy and legal frameworks provide a foundation for effective regulation and reliance and cooperation are key factors for building trust and capacity among NMRAs.

g. Stakeholder interviews from private and health research institutions had consistent key messages including need for effective and efficient application screening and review tracking mechanisms, transparency on market authorization review decision making.

PPB should be more relevant, transparent, monitor their performance and create an internal culture of continuous improvement through an elaborate M&E system.

h. Government should invest more on PPB's efforts which have proven to facilitate effective and efficient utilization of already limited resources while at the same time reducing the time taken for applicants to put the product on the market. "The increasing demand for medicines in Africa including the EAC region attributed by population and economic growth as well as raising consumer awareness warrants Kenya Governments' investment on regulation of medical products"

Finally, Amref Health Africa and CHReaD provide a great advocacy platform for Pharmacy and Poisons Board to leverage in positioning Kenya as a leader in HPT regulation and providing solutions to the current challenges. CHReaD could provide an engagement platform (new/ existing) with industry (private sector, researchers, innovators, academia etc.) as open dialogue is becoming increasingly important considering scientific innovation and development pathways to move beyond traditional engagements. We believe this evaluation is an unprecedented step by Amref, CHReaD and development partners towards better collaborative efforts with PPB and support the regulatory advancements in Kenya HPTs and become an anchor agency forming the scientific and implementation backbone of the new Africa Medicines Agency.


**The Coalition of Research and Development (CHReaD)**
Wilson Airport, Lang'ata Rd,
P.O. Box 30125–00100
Nairobi, Kenya.
Telephone: +254- 20 699 4000
**Email: Maureen.Awuor@Amref.org**