The proposed value proposition and operating model for the African Medicines Agency

Gugu Mahlangu¹, and Luther Gwaza²
1. Medicines Control Authority of Zimbabwe
2. World Health Organization

A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
Discuss value proposition and an operating model of the African medicines Agency.
Introduction

• No single national regulatory authority has the ability and resources to perform all the regulatory work independently
• Collaboration is not optional for Africa given the high burden and mortality from curable and preventable diseases
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**Context**

54 | Number of countries in African Union

1.13 billion | Number of people on the African Continent

8 | # of Regional economic groups recognised by African Union

“achieve access to safe, effective, quality and affordable essential medicines and vaccines for all”.

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Methodology

1. Developed a **conceptual framework** for medicines regulation in regional and continental context
2. Developed a **theory of change model** for AMA
3. Propose a **social enterprise business model** for AMA
   - Literature review and analysis of existing regulatory models
   - Survey of key stakeholders and feedback from several meetings of the AMA task force
Conceptual framework for medicines regulation in a networked community
If you want to go quickly, go alone. If you want to go far, go together. ~ African proverb
Shared responsibility model is the characteristics of a modern regulator or smart regulation built on key aspects such as reliance, collaboration, work sharing. What this means in real life is differentiating regulatory aspects that cannot be relied on another agency. These functions form the minimum that every country should have in place. Things such as licensing of premises, controlling import and exports, vigilance. Other functions such as review of applications for marketing authorizations, GMP inspections of foreign facilities for example, can be relied on work done by others. However, the key issue is that regardless of the model, the size of the agency – the outcomes should be the same – which is access to safe, effective, quality medicines and health technologies.
Root Cause Analysis: It is based on a literature review and focus group discussion with regulators in SADC. The grey shaded boxes highlight the root causes targeted by the African Medicines Agency.

The greyed boxes are the interventions that AMA targets e.g. advocacy to decision makers and political leaders to priorities medicines regulation by providing sufficient legal frameworks, institutional arrangements and financial resources. Challenges of fragmented markets addressed through promoting harmonization, lack of training opportunities addressed through regional centers of regulator excellence.
Key Activities in Figure 4
1. Advocacy to AUC, RECs, partners and stakeholders for the policy, regulatory and legal reforms at continental, regional and national levels.
2. Coordinate, designate and monitor the regional centres of regulatory excellence (RCOREs)
3. Governance, partnerships and resource mobilisation for regulatory activities including sustainable finance mechanisms at all levels
4. Custodian of the Model Law, development of policies, legal and technical standards in collaboration with WHO.
5. Regulatory guidance for AMA:
   • regulatory guidance and the continent’s voice on emerging issues and pandemics particularly with respect to investigational therapies
   • regulatory guidance on complex molecules (biotherapeutics, innovative new therapies, vaccines)
   • coordination of GMP inspections of API manufacturing sites, complex molecules and priority products
   • GCP of contract research organizations
   • coordination and provision of regulatory guidance as required by RECs
and Member States where capability at national or regional level is lacking, e.g. emerging issues such as regulation of e-commerce businesses

6. Coordinate and facilitate regional harmonization activities and strengthen NMRAs as requested by Member States, where applicable.

7. Establishment and maintenance of accurate information and market intelligence on regulatory and pharmaceutical market (knowledge and information management).
Social enterprise business model

- Deliver measurable social and economic impact in return for financial investments.
- Mix of financing options, fees, direct contributions from member states, partners and innovative funding mechanisms (SIBs and endowment fund).
“Just because we cannot see clearly the end of the road,... that is no reason for not setting out on the essential journey. On the contrary, great change dominates the world, and unless we move with change we will become its victims”

The Future .....