4TH ANNUAL **SADC** INDUSTRIALISATION WEEK

Engagement Plan for African Medicines Agency

Catherine Grant Makokera

Director, Tutwa Consulting Group

Wednesday 7 August 2019

Context

- **Major problem in many African countries - proliferation of substandard and falsified (S&F) medical products**
  - Serious adverse health effects (including disabilities and deaths)
  - Availability of these products poses a threat to regional manufacturing and trade in medicines.
- **Difficult to introduce new products into the African market due to cumbersome regulatory procedures**
  - Delays access to innovative quality, safe and efficacious medical products.

Context

- **These factors considerably impede Africa's ability to respond appropriately to the health challenges the continent faces.**
- **Regional harmonisation of standards under African Medicines Regulatory Harmonisation (AMRH) Initiative and Africa Vaccine Regulatory Forum (AVAREF).**
- **Feeds into the Intellectual Property Rights chapter of the African Continental Free Trade Agreement, still to be negotiated under Phase 2.**

Role of AMA

Aspiration: the African Medicines Agency (AMA) will help Africa achieve a safe medicines market that is quality-assured, well-regulated, participatory, transparent and accountable.

- AMA will be a force for inclusion and growth
- Promote regulatory harmonisation across Member States and RECs
- Provide support (technical, legal) for Member State governments
- Encourage alignment amongst RECs

Why AMA?

- **A continental regulatory body will complement and leverage regional initiatives to address capacity constraints in individual member states through economies of scale, information sharing and skills transfers.**
- **Regulatory stability and harmonisation will attract FDI into the pharmaceuticals sector.**
- **Good quality and safe medicines will be more widely available in Africa's fight against disease.**
- **The AMA meets economic development imperatives as well as public health priorities.**
- **Its efficient and participatory institutional architecture ensures inclusivity of all African countries.**

How will AMA operate?

- **AMA will coordinate on-going regulatory systems, strengthening and harmonizing efforts of the AU, RECs, Regional Health Organizations (RHOs) and Member States.**
  - AMA will complement national and regional processes to ensure better coordination of stakeholders undertaking medicines regulation across the continent.
- **Sustaining the AMRH and AVAREF momentum and a smooth transition into AMA will contribute to reducing technical barriers to trade especially at this time when the RECs are rapidly moving towards stronger economic integration**

How will AMA be funded?

- **Since AMRH is already in existence, and will transition to AMA, no substantial start up funding requirements. The existing AMRH staff can be considered as the core team.**
- **AMA's financing model is based on diversified funding to ensure ownership and sustainability. The financial mechanisms are**
  - direct contributions from Member States through the AUC
  - direct contributions from partners
  - revenue generation
  - innovative financing mechanisms (endowment fund and use of social impact bonds). It is expected that contribution from the endowment fund and social impact bonds will reach 25% by 2022.

Current Status of AMA

- April 2014: AU Ministers of Health recommend the establishment of a regulatory continental body
- January 2016: AU Model Law officially endorsed by African Heads of State and Government at the AU Summit
- May 2018: AU Ministers of Health adopt the Treaty for the establishment of the AMA
- November 2018: AU Ministers of Justice & Legal Affairs adopt Treaty for the establishment of AMA
- February 2019: AMA Treaty adopted by the AU Assembly
- June 2019: Rwanda became first AU Member State to sign the Treaty, followed by the Sahrawi Arab Democratic Republic and Algeria in July 2019 and Madagascar in August 2019 (first SADC member state to sign)

What Next?

- **AMA needs 15 AU member states to ratify the Treaty**

- **RECs are at different stages of adoption of the AMRH. AUDA is currently working closely with**
  - EAC
  - ECOWAS
  - ECCAS
  - IGAD
  - SADC

What Next?

- **Engagement Strategy under way –**
  - Knowledge and information sharing - facts are important, looking beyond ratification
  - Evidence based – case study approach
  - Focus on capacity/knowledge and skills transfer opportunities
  - Targets RECs and individual countries
  - Emphasis on the trade/economic benefits (AfCFTA link) as well as the health benefits

4th ANNUAL **SADC** INDUSTRIALISATION WEEK

https://www.youtube.com/watch?v=SiSqCdljJs8

HOSTED BY

Ministry of Industry and Trade

CO-ORGANISED BY

NEPAD BUSINESS FOUNDATION

As the host of the SADC Business Council

SPONSORED BY