The African Medicines Agency: Accelerating Regulatory System Strengthening in Africa

We need to raise awareness of what's happening in the regulatory field

in Africa at regional and continental level

highlighting the recent processes implementing

RELIANCE and collaboration mechanisms

Let's see how the experts believe we can achieve this!

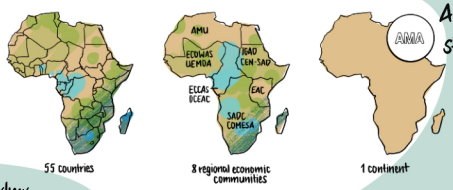
Paul Tanui (AUDA NEPAD)

Progress of the signing and ratification process of the treaty

- 28 states signed the AMA treaty
- 3 signed and ratified but not yet deposited the ratification
- 19 member states have signed, ratified and deposited the instrument of ratification at the commission
- 25 member states that have neither signed nor ratified

After signing an interim governance for partners' support was established

46 Partners



A unified and strong continental regulatory framework

Workplan for Partner Support to operationalize AMA is set up

- (A) Build up to the first meeting of the COSP
- (B) Operationalizing AMA and build up to day 1 of AMA
- (C) Priority activities and tasks for year 1

Martin Harvey Allchurch (EMA)

Improving **GLOBAL HEALTH** via 3 pathways

1. EU-M4all
   collaboration of the EMA with WHO, on medical products intended for markets outside of the EU
2. WHO CRP
   accelerates national approval where resources are limited
   active capacity-building for local NRAs
3. OPEN initiative at EMA to NON-EU authorities
   enables to share scientific expertise
   enhancing transparency

> accelerate medicines access at a global scale

regular workshops and trainings

Training Center open to non-EU regulators

Capacity building outside of EU

Supporting creation of AMA

Network support

Support by funding

Using existing models as an actual model not a template

Hiiti Sillo (WHO)

> 70 % of countries have a weak national regulatory system

WHO support via

- Benchmarking
- Capacity building
- Promoting "smart regulation"

- Building up NRAs
  - providing technical support
  - providing financial support

Applying GOOD regulatory practices

Applying Good reliance practices

strong NRAs will support AMA

AMA will expand timely access to medicines for patients

AMA will lead to an optimization of patient care, and enhanced impact of the patient voice, at all levels of care, in Africa.

Patients have convened the AMA Treaty Alliance (AMATA) to catalyse meaningful engagement of all stakeholders.

AMA promotes collaboration between regulators and industry:

- complementing and steamlining existing systems, giving help and support
- avoiding duplication of work

? potential collaboration between Ghana FDA and AMA
- sharing of expertise
- complementing each others duties
- work sharing

AMA's role in transforming the African regulatory ecosystem

- belief and trust in AMAs Vision
- AMA as a catalyst to build up reliable mechanism

trying to implement new training courses
- giving them dossiers

building up competence

sharing knowledge

? How can the European training Academy for Regulators support regulators in Africa?

? The role of AMRH partners in the operationalization of AMA is seen on three levels

capacity building + advocacy + financial ressources

? attractive factors for the Industry by the regulatory system

+ having a system that allows to provide the patients with the medicine fast ← implemented by AMA!

? challenges and opportunities for the industry are
- speedy access of products for patients
- products that are save!

- different legal systems cause different processes and timelines

lack of harmonization or guidelines → but a lot has been done

Reliance is the 21th century tool to move forward