EDCTP Regulator Forum

The African Medicines Regulatory Harmonization Programme: Continental Progress Update

Presentation Outline

- The AMRH Background & Vision
- Strategic Directions & Expected Outcome/Results
- Progress to Date
- Way Ahead

The AMRH: Background

- **Implementation of Pharmaceutical Manufacturing Plan for Africa (PMPA) – AU Decision 2015**
  - support African countries in improving public health by increasing access to good quality, safe and effective medical products and technologies
    - Ineffective regulatory systems in Africa
    - Technical barriers to the free movement of products within and across regions
    - Local production policy priorities
  - Harmonizing regulation of medical products and technologies through the regional economic communities (RECs) and countries

Consortium of key partners established to accelerate and ensure African Medicines Regulatory Harmonization (AMRH)

Consortium Partners

Other Stakeholders

NMRA Representatives

Consortium and major stakeholders convened in February and November 2009

Regional Economic Communities and Organizations (RECs)

Unanimous consensus emerged: now is the right time to push for regulatory harmonization in Africa

AMRH VISON

Today

- ~ 54 National Medicines Regulatory Authorities (NMRAs) governing medicines regulation across Africa
- Regulators' capacity highly variable, some with almost no capacity at all
- Different requirements and formats, lack of clear guidelines
- Minimal transparency, No clear timelines
- Reference evaluations[1] underleveraged

Streamlined (harmonized) future

- Between 5-7 regional economic communities (RECs) covering the entire African continent[1]
- Stronger, institutionalized regulatory capacity & systems strengthening programmes
- Single set of requirements, Clear guidelines, Fewer dossiers to prepare (one per REC)
- Transparent regulatory processes with clear timelines
- Resource pooling and information sharing

Earlier approval of more medicines & vaccines

1. WHO prequalification, Article 58 positive opinions, stringent regulatory approval, certificate of pharmaceutical product (CPP)

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AMRH creates a platform on which to build African regulatory capacity

Initial focus

Registration platform

- Common requirements / guidelines
- Common dossier
- Common assessments / inspections
- Streamlined decision processes
- Strengthened capacity and infrastructure
- Work sharing / pooling of resources

Accelerated registration...

...initially for generics

...extending to all product types with time

Future: broaden regulatory functions

Regional regulatory platform

- Organization and infrastructure
- Political commitment
- Common processes and frameworks
- Trust and relationships
- Momentum

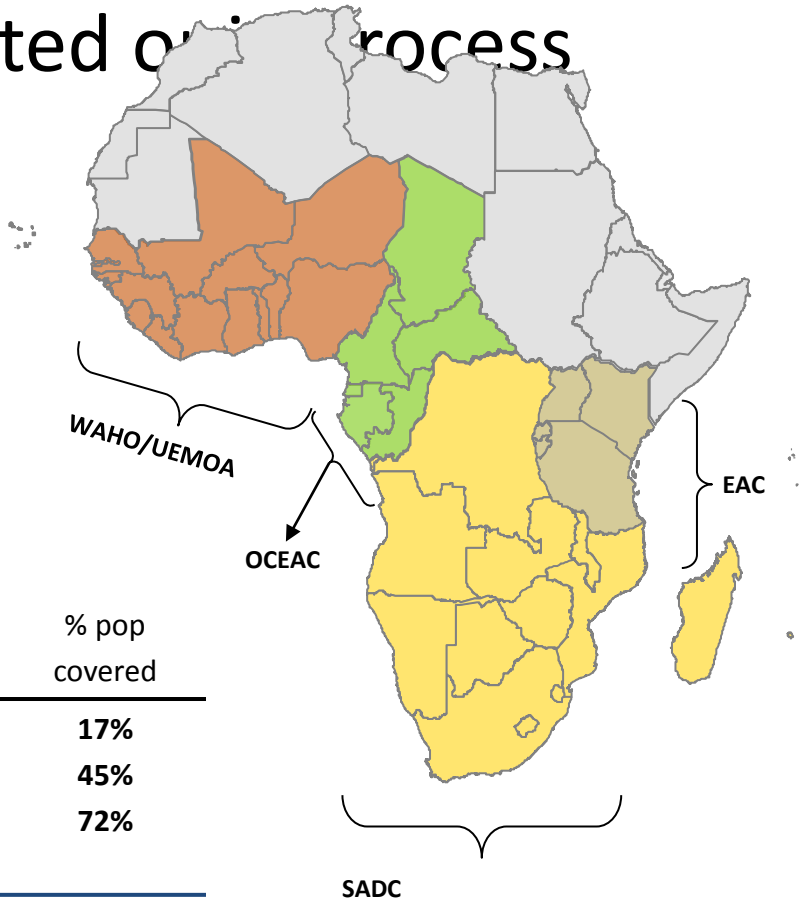
Capacity building across all regulatory functions:

Clinical trials regulation
Adverse event surveillance
Market control
etc...

Roughly 85% of Sub-Saharan Africa covered by proposals already completed or in process

REC progress

REC	Status	Comments
EAC	Ready for funding	Start 2011
OCEAC	Being finalized	Expected 2011
WAHO/UEMOA	In process	Expected 2011
SADC	In process	Expected 2011
North/Northeast Africa	In discussions	NEPAD Organizing meeting



Completed or in-process RECs	Countries covered	Total members*	% pop covered
EAC & OCEAC	12 (20%)	11	17%
EAC, OCEAC, ECOWAS	26 (46%)	26	45%
EAC, OCEAC, ECOWAS, SADC	41 (74%)	41	72%

*Tanzania in both EAC and SADC (but will go with EAC); UEMOA/ECOWAS are working out overlap

We are pushing forward those RECs that are ready while continuing to work with the remaining regions

Source: BCG analysis

AMRH STRATEGIC DIRECTIONS

1. **Policies and Regulatory Reforms**
2. **Regulatory Capacity Development**
3. **Knowledge Generation & Leveraging**
4. **Governance, Management & Partnerships**

REGULATORY CAPACITY DEVELOPMENT

AMRH Result Area	Progress

1. Regulatory capacity building & systems strengthening	• 2012: Technical Working Group on Regulatory capacity Development operational with focus on:
	  • Establishment of Regional Centers of Regulatory Excellence (RCOREs)
	  • Work in progress on baseline data on competences for NMRA in their respective RECs
	  • Expression of Interest for establishment for RCOREs
	  • Expression of Interest for establishment regulatory pool of experts in Africa and Diaspora to support RCORE
	  • Sub-working groups on curricula development and regulatory capacity development strategy established
	  • Need based training for RECs, NMRAs & industry to be offered

KNOWLEDGE GENERATION & LEVERAGING

AMRH Result Area	Progress

2. Access to knowledge and skills for regulatory science	• 2010-2012: Studies conducted on regulatory systems & harmonization in EAC, SADC, ECOWAS, ECCAS
	• 2011: AMRH Advocacy & Communication Strategy developed and operational (newsletters, Information, Education & Communication (IEC) materials, AMRH website (www.amrh.org)
	• 2-3 Dec 2013: 1st AMRH Scientific Conference
	  • NEPAD Agency, WHO,US-FDA, DNDi
	• 4-6 Dec 2013: 3rd Sub-Saharan African Regulators conferences & 1st African Regulators Conference
	  • WHO-AFRO, WHO-EMRO, NEPAD Agency
	  • Birchwood, Johannesburg, RSA

POLICY & REGULATORY REFORMS

AMRH Result Area	Progress

3. Policy, Legal & regulatory framework for harmonisation	• 2012: Consultations & drafting Model Law on Medicines Regulation and Harmonization in Africa
	• June 2013: TWG on Medicines Policy and Regulatory Reforms (MPRR) established and operational
	  • Model Law on Medicines Regulation and Harmonization in Africa
	  • Based on 2010 study findings
	  • validated ready for wider stakeholders consultation
	  • Sub-Committees for Finalization and Implementation of the Model Law established & Operational
	• From Feb-March 2014: Regional consultation and advocacy meetings for endorsement & adoption of the AMRH model law at country, regional and continental levels

AMRH GOVERNANCE, MANAGEMENT & PARTNERSHIPS

AMRH Result Area	Progress
4.AMRH Governance and Management; and Partnerships	• AMRH Advisory Committee established in 2012, meetings conducted annually • 2012-2013: RECs MRH Steering Committees & Technical Working Groups (Evaluation & Registration, GMP, QMS, IMS) established in EAC and ECOWAS-WAHO regions • Oct 2013: Draft AMRH monitoring and evaluation (M&E) framework and AMRH Implementation Tool Kit validated by EAC NMRA Partner States

GOVERNANCE, MANAGEMENT & PARTNERSHIPS…

AMRH Result Area	Progress
4…..AMRH Governance, Management & Partnership	• MRH Project proposal frameworks for Western, Central and Southern African regions at different levels of development • AMRH Partners providing regular implementation support to RECs and countries including resource mobilization • Active AMRH Partners: AUC, PAP, WHO, WB, Bill & Melinda Gates Foundation, UNAIDS • Potential Partners: US-FDA, USP, EDCTP

Thank You