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

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

Consortium Partners

Other Stakeholders

Regional Economic Communities and Organizations (RECs)

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

- ~ 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

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

**Future focus**
- Regional regulatory platform
  - Organization and infrastructure
  - Political commitment
  - Common processes and frameworks
  - Trust and relationships
  - Momentum

Accelerated registration...

...initially for generics

...extending to all product types with time

Capacity building across all regulatory functions:

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

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

**Completed or in-process RECs**

<table>
<thead>
<tr>
<th>REC</th>
<th>Countries covered</th>
<th>Total members*</th>
<th>% pop covered</th>
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<tbody>
<tr>
<td>EAC &amp; OCEAC</td>
<td>12 (20%)</td>
<td>11</td>
<td>17%</td>
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<tr>
<td>EAC, OCEAC, ECOWAS</td>
<td>26 (46%)</td>
<td>26</td>
<td>45%</td>
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<tr>
<td>EAC, OCEAC, ECOWAS, SADC</td>
<td>41 (74%)</td>
<td>41</td>
<td>72%</td>
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*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

<table>
<thead>
<tr>
<th>AMRH Result Area</th>
<th>Progress</th>
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<tbody>
<tr>
<td>1. Regulatory capacity building &amp; systems strengthening</td>
<td>• 2012: Technical Working Group on Regulatory capacity Development operational with focus on:</td>
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<td>• Establishment of Regional Centers of Regulatory Excellence (RCOREs)</td>
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<td></td>
<td>• Work in progress on baseline data on competences for NMRA in their respective RECs</td>
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<td>• Expression of Interest for establishment for RCOREs</td>
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<td>• Expression of Interest for establishment regulatory pool of experts in Africa and Diaspora to support RCORE</td>
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<td>• Sub-working groups on curricula development and regulatory capacity development strategy established</td>
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<td>• Need based training for RECs, NMRAs &amp; industry to be offered</td>
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| 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](http://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

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| 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

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| 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 |
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| 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