The African Medicines Regulatory Harmonisation (AMRH) Initiative

Prepared by the AMRH Consortium:

NEPAD Agency, WHO, BMGF, WB, DFID, CHAI

November 2010
Presentation Outline

1. African Regulatory Challenges
2. AMRH genesis
3. AMRH Management
1. African Regulatory Challenges
Resource constraints restrict regulators' ability to support access to quality medicines

Countries are obligated to regulate the trade of medical products to ensure access to effective, safe, and high quality treatments...

...But resource constraints make these obligations difficult to fulfill...

1. 90% of African NMRAs\(^1\) lack capacity to guarantee quality, safety, and efficacy\(^2\)

2. Sponsors / mfrs. face a landscape of disparate regulations, frequent delays, and limited transparency

...As a result, needed medicines can lack availability, affordability in low-income countries

- Fewer drugs are available in low-income countries than in the US, EU, etc.
- Cost of inefficient regulatory systems drives up drug prices

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\(^1\) National Medicines Regulatory Authorities
\(^2\) WHO (2006) "Medicines Regulatory Harmonization: Current Status and the Way Forward"
Harmonizing registration addresses resource constraints, enabling accelerated product approval and access

How would harmonization impact the registration process?

<table>
<thead>
<tr>
<th>Today’s current environment</th>
<th>A harmonized future environment</th>
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<tbody>
<tr>
<td>▪ ~ 50 National Medicines Regulatory Authorities (NMRAs) governing drug registration across Africa</td>
<td>▪ Between 5-10 regional economic communities (RECs) covering the entire African continent¹</td>
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<tr>
<td>▪ Paperwork, technical requirements, and other registration steps differ across NMRAs</td>
<td>▪ Common documentation, procedure, and decision-making framework across all RECs</td>
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<td>▪ Manufacturers must invest significant time and effort in each registration, so a limited set of countries are targeted</td>
<td>▪ Low cost to register in each additional country, so coverage is more broad and equitable</td>
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<tr>
<td>▪ No clear timelines for a drug to clear registration and be ready for the marketplace</td>
<td>▪ Streamlined process that is faster and easier... starting first with generics</td>
</tr>
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<td>▪ Little transparency before or during the process</td>
<td>▪ Clear understanding of the process by all parties involved</td>
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1. African regional economic communities (RECs) are regionally focused groups of nations with integrated policies on trade, monetary, customs, or other economic policies. The number of RECs varies depending on the type of classification (e.g. “pillar” blocks vs. “subgroups,” trade blocs vs. monetary unions, etc.).
Harmonization streamlines the registration process for both regulators and manufacturers, leading to increased access.

<table>
<thead>
<tr>
<th>Today</th>
<th>Streamlined (harmonized) future</th>
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<tbody>
<tr>
<td>Regulators’ capacity highly variable, some with almost no capacity at all</td>
<td><strong>Faster registration</strong></td>
</tr>
<tr>
<td>Disparate requirements and formats</td>
<td>▪ Stronger, more consistent capacity</td>
</tr>
<tr>
<td>Lack of clear guidelines, minimal transparency</td>
<td>▪ Streamlined processes and enhanced use of reference evaluations</td>
</tr>
<tr>
<td>Reference evaluations(^1) underleveraged</td>
<td>▪ Resource pooling and information sharing</td>
</tr>
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</table>

**Reduced hurdles for manufacturers**
- Single set of requirements
- Clear guidelines established
- Fewer dossiers to prepare (one per REC)

\(^1\) WHO prequalification, Article 58 positive opinions, stringent regulatory approval, certificate of pharmaceutical product (CPP)
More broadly, AMRH contributes over time to many cross-cutting public health and development goals

<table>
<thead>
<tr>
<th></th>
<th>Prevention and treatment of infections diseases (overall)</th>
<th>Enhanced access to new health technologies</th>
<th>Broad economic development in the region</th>
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<tbody>
<tr>
<td><strong>Short term</strong></td>
<td>Increased access to generics treating many important diseases</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intermediate term</strong></td>
<td>Broader, more rapid access to vaccines and other therapies</td>
<td>More efficient launches for vaccines and other PDP products</td>
<td>Foundation for African pharma industry</td>
</tr>
<tr>
<td><strong>Long term</strong></td>
<td>Extension to all regulatory functions</td>
<td>Greater impact of new life-saving technologies</td>
<td>Healthier, more productive workforce</td>
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</tbody>
</table>

2011-05-27
You may want to use the standard terminologies of ‘quality, safe and efficacious medicines’ instead of adjectives such as ‘superior’ which may need/imply comparison to another standard.

NEPAD, 2010-10-14
2. AMRH genesis
Consortium of key partners established to accelerate and ensure African regulatory harmonization.

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

2011-05-27
Roughly 85% of Sub-Saharan Africa covered by proposals already completed or in process

<table>
<thead>
<tr>
<th>REC</th>
<th>Status</th>
<th>Comments</th>
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<tbody>
<tr>
<td>EAC</td>
<td>Ready for funding</td>
<td>Start 2011</td>
</tr>
<tr>
<td>OCEAC</td>
<td>Being finalized</td>
<td>Expected 2011</td>
</tr>
<tr>
<td>WAHO/UEMOA</td>
<td>In process</td>
<td>Expected 2011</td>
</tr>
<tr>
<td>SADC</td>
<td>In process</td>
<td>Expected 2011</td>
</tr>
<tr>
<td>North/Northeast Africa</td>
<td>In discussions</td>
<td>NEPAD Organizing meeting</td>
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**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>
</tr>
<tr>
<td>EAC, OCEAC, ECOWAS</td>
<td>26 (46%)</td>
<td>26</td>
<td>45%</td>
</tr>
<tr>
<td>EAC, OCEAC, ECOWAS, SADC</td>
<td>41 (74%)</td>
<td>41</td>
<td>72%</td>
</tr>
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</table>

*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
Also enlisting support from likely in-kind donors

Primarily technical assistance from regulators and manufacturer organizations

Monetary contributions

In-kind contributions

Stakeholders likely to provide support

Other stakeholders interested in AMRH

In addition RECs and member countries will be contributing to harmonization plans
<table>
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<tr>
<th>Working independently</th>
<th>Collaborate on selected topics</th>
<th>Harmonised standards and broad collaboration</th>
<th>Recognition of decisions made elsewhere</th>
<th>Centralized regional registration</th>
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<tbody>
<tr>
<td>Member states operate independently and each country has its own technical requirements and format for registration applications</td>
<td>Member states collaborate on selected topics e.g. certain technical guidelines, GMP inspections, information exchange etc.</td>
<td>Member states have common technical requirements and collaborate broadly e.g. sharing assessment and inspection reports, joint evaluations and inspections</td>
<td>National verification based decisions made elsewhere (either within the REC or beyond) and/or mutual recognition agreements</td>
<td>Centralized registration on behalf of participating member states</td>
</tr>
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National sovereignty is respected: medicines registration decisions remaining firmly that of sovereign nations
3. AMRH Management
AMRH Management

- Establishment of AMRH Trust Fund under the World Bank Governance structures
- Estimated US$ 30 million dollars over 5 years project period
- A funding proposal is currently under consideration by BMGF and bilateral donors
- Implementation of part of the proposal for 2 years starting 1st quarter 2011

- Meeting of NMRA Heads and National Focal Points, November 2010
  - Agreed on appraisal of EAC and medicines registration harmonization (MRH) project results matrix
- Expected launch of EAC project 1st Quarter 2011
- Finalization of project proposals with other RECs in 2011
World Bank’s Role in AMRH

• Pending approval of proposal by BMGF, the World Bank will become the fundholder for the pooled funds that go into AMRH, starting with a grant from BMGF
• WB will manage implementation in partnership with NEPAD, WHO and RECs, who will become sub-grantees under the AMRH Trust Fund
• Consortium will transform into broader governance structure to ensure oversight from donors and collaboration with partners, while political ownership remains with African Union
• WB will apply its processes and tools for project management; internally, work will be shared between Africa Region and HNP Anchor (headquarters)
• 5% of funds can be used by other Regions for work to assess and strengthen medicines regulatory functions, exchange knowledge with AMRH countries
Main Roles of Operational Partners

• WHO
  – Technical lead; development of common technical standards, documents, tools and processes
  – Technical support for local and regional capacity building

• NEPAD
  – Create positive political climate for regulatory harmonization at Pan-African and regional level
  – Assist RECs in developing their project plans and monitor project progress at REC and national level (in division of labor with World Bank)
  – Support RECs in regional implementation of plans

• RECs
  – Develop and execute plans for AMRH implementation
  – Develop regional exchange platforms, including a common information management system
  – Coordinate all training and capacity building activities for the NMRAs.
Concluding Remarks

– We, the AMRH Partners, and the broader African health community are very enthusiastic about the AMRH initiative

– We believe we will succeed because we have all of the right stakeholders engaged and supportive of our efforts

– AMRH has the potential for truly transformative impact on the region

Thank you!

Merci!