The African Medicines Regulatory Harmonisation (AMRH) Initiative

Presented By:
Margareth Ndomondo-Sigonda
AMRH Programme Coordinator
NEPAD Agency
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Presentation Outline

1. What are the regulatory challenges facing African countries today?
2. How can regulatory harmonization improve access to medicines?
3. What is the AMRH initiative?
4. What are the harmonization challenges, critical success factors and AMRH initiative Vision?
5. AMRH Current status
6. Conclusion
Regulatory challenges facing African countries today
Many countries in Africa face challenges that jeopardize timely access to essential medicines

• Every country is obliged to regulate the pharmaceutical products sold within its borders
  – This includes licensing of premises, practises and persons, inspection of manufacturing sites and distribution premises, product assessment and registration, market control (quality, safety, promotion)
  – The mission of medicines regulation is to ensure citizens use medicines of acceptable standards in terms of safety, quality, and efficacy
  – National Medicines Regulatory Authorities are legally mandated to perform these functions

• But constraints exist that make these obligations difficult to fulfill
  – Inadequate medicines legislations (absent or weak legal and regulatory frameworks)
  – Lack/limited regulatory capacity to approve medicines for sale (both in a timely manner and in terms of ensuring acceptable quality, safety and efficacy standards)
    • Financial and human resource constraint to perform specialised legal, administrative and technical functions
    • WHO Report 2004: 90% of African countries lack capacity to guarantee the quality, safety and efficacy of medicines in their countries
  – Manufacturers on their part are confronted with different regulatory requirements, frequent delays, and little process transparency

• As a result, much needed medicines lack availability in many African countries
  – Fewer medicines are available to the majority of the African population
  – Prices remain higher for longer as competition is introduced more slowly and scale of economies including cross-country pooled procurement is delayed
Low regulatory capacity and a lack of harmonisation may limit patient access to life-saving health interventions

- Historically, health interventions have seen delayed access between the originating high-income countries and low/middle-income countries
- Access problems are marked by slow uptake and limited coverage

1. Source: WHO/UNICEF; World Bank; BCG analysis

Long regulatory approval times contributes to this slow product uptake
How can regulatory harmonization improve access to medicines?
By improving medicines regulatory processes by NMRAs

Today's current environment

• ~ 50 different National Medicines Regulatory Authorities (NMRAs) working independently to register medicines across Africa
• Different administrative and technical requirements, processes and procedures for medicines registration across NMRAs
• No clear indication of the time taken, or the maximum times allowed, for regulators to assess and register medicines
• Limited transparency before or during the registration process

A harmonised future environment

• Approx. 5 or 6 regional groups each with harmonised technical requirements coordinating registration across the entire African continent
• Common (harmonised) registration documentation (format and technical requirements), procedures, and decision making processes across African regional groups
• Streamlined processes that are faster, more predictable and better aligned to public health needs (in terms of prioritization, condition approvals etc.)
• Transparent and clear procedures, and a good understanding of registration requirements and processes by all stakeholders
What would successful harmonization look like?

• Increased capacity
• and more efficient resource use

• Increased applications to register medicines from manufacturers

• Cost savings

• Greater access to quality and safe essential medicines

NMRAs benefit from capacity building, regional sharing of regulatory resources through the best use of limited skilled resources including leveraging the potential of well established NMRAs. Industry benefit from common registration documentation and increased transparency as incentives for submission of more applications. Governments, donors and patients can achieve savings from lower priced medicines through enhanced competition and pooled procurement. Communities get quicker access to essential medicines of assured quality, hence greater progress towards achieving the three health related Millennium Development Goals (MDGs 4, 5 and 6).
What is the AMRH initiative?
The AMRH initiative builds on the existing political mandates, plans and progress at continental and regional levels

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<th>Overall aim</th>
<th>Improve public health by increasing access to safe and effective medicines of good quality for the treatment of priority diseases</th>
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<td>Specific aim</td>
<td>To reduce time taken to register priority medicines</td>
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<td>Methodology</td>
<td>1. Support the development of regional project proposals to expedite and strengthen medicines registration through regional collaboration and harmonization</td>
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<td>2. Mobilise financial, technical and political support</td>
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AMRH is backed by a Consortium of partners

- Consortium partners
  - Political/Technical Organizations
    - New Partnership for Africa’s Development (NEPAD Agency)
    - African Union Commission
    - Pan African Parliament
    - World Health Organization (WHO)

- Donors & NGOs
  - Bill & Melinda Gates Foundation
  - UK Department of International Development (DFID)
  - Clinton Health Access Initiative (CHAI)

- Objectives
  - Mobilise political support and financial and technical resource for AMRH
  - Promote and facilitate inter-REC communication, coordination, technical consistency and shared learning
  - Build a continental initiative, assist in priority setting and plans for regulatory harmonization

- Funding
  - Both financial and in-kind support is needed to fully operationalize the AMRH initiative
AMRH Approach

A step-wise approach that commits to the most logical and realistic steps first (medicines registration, starting with generics/new chemical entities depending on need of each region) and expanding to encompass other products and regulatory functions at a later date)

Enlisting the support of all regions and countries, as a truly continental effort that will promote and enable inter-REC communication and collaboration

Creating a supportive community, with the right partners already cooperating and a high level of donor interest (the Bill & Melinda Gates Foundation and DFID are committed in principle and Consortium partners are actively engaging other interested donors to solicit their support)
A NMRA consultation meeting in Feb 09 agreed unanimously that now is the right time to push for regulatory harmonization.
Four regional project proposals are currently in development involving 75% of African countries.

**Southern Africa: SADC – 15**

- Angola
- Botswana
- DRC
- Lesotho
- Madagascar
- Malawi
- Mauritius
- Mozambique
- Namibia
- Seychelles
- South Africa
- Swaziland
- Tanzania
- Zambia
- Zimbabwe

**East Africa: EAC – 5**

- Angola
- Burundi
- Cameroon
- Chad
- Congo
- DRC
- Equatorial Guinea
- Gabon
- Rwanda
- Sao Tome & Principe

SADC = South African Development Community; EAC = East African Community; ECCAS = Economic Community of Central African States; ECOWAS = Economic Community of West African States; UEMOA = Union Economique et Monétaire Ouest Africaine
What are the harmonization challenges, critical success factors and AMRH initiative Vision?
## Challenges facing AMRH

- **Situation analysis of medicines regulatory harmonization preliminary study report on EAC shows that:**

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<tr>
<th>Country</th>
<th>Legislation/Policy</th>
<th>Findings</th>
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<tr>
<td>Burundi</td>
<td>No specific law on medicines regulations- Public Health Law used instead</td>
<td>Rwanda and Burundi do not have required pieces of legislation</td>
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<td>Kenya</td>
<td>The Pharmacy and Poisons Act, Cap 244</td>
<td>Variant medicines policies and laws with different levels of comprehensiveness e.g. clinical trials in Kenya administered under national medicine policy vs legislative framework</td>
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<td>Rwanda</td>
<td>The National pharmaceutical policy of May, 2009</td>
<td>National laws no provision for domestication of regional decisions</td>
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<td>Tanzania-Mainland</td>
<td>The Tanzania Food, Drug and Cosmetics Act 2003</td>
<td>Absence of recognition of decisions made by other partner states in all NMRAs</td>
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<td>The Traditional and Alternative Medicines Act 2002</td>
<td>Variable commitment to speedy domestication of decisions made under the EAC Treaty</td>
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<td>Tanzania-Zanzibar</td>
<td>The Zanzibar Food, Drug and Cosmetics Act 2006</td>
<td></td>
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<td></td>
<td>The Traditional and Alternative Medicines Act 2002</td>
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<tr>
<td>Uganda</td>
<td>National Drug authority and policy Act (1993)</td>
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Planned to scale up the study to cover all REcs and countries in Africa
Challenges facing AMRH...

• Most of the RECs Treaties and Protocols provide for standardisation and harmonization of pharmaceutical market
  – However, implementation by member states is slow as such Treaties and protocols are non-self-executing hence rely on county domestication of regional decision in their national laws
  – Example: EAC Council of Health Ministers decision in 2000 for all Partner States to establish autonomous NMRAs and integrate food and drug laws only implemented by one country to date

• Most of African countries belong to more that one REC hence posing problem for NMRAs to decide on which harmonization scheme to adopt

• Lack of appropriate Governance structure for AMRH
  – Needed to guide development of appropriate policies & strategic vision
  – Needed to minimise risk of various players acting in an uncoordinated manner
Critical success factors and roles of key players

Joint decision by key parties on African Health Strategy, Pharmaceutical Manufacturing Plan for Africa, Strengthening Pharmaceutical Innovation in Africa

— African Union Commission - Provide policy guidance on AMRH as part of implementation of the AU Pharmaceutical Plan for Africa (PMPA)

— Pan African Parliament - Provide political advocacy on AMRH through legislative reviews at continental, regional and national levels

— AU NEPAD Agency
  • Coordination and implementation of AMRH through AU decision 55 on PMPA which identifies medicines regulation as a critical factor in pharmaceutical research and development and hence promotion of local pharmaceutical production in Africa
  • Call from 2nd African Medicines Regulators Pre-Conference held in November 2009, Maputo-Mozambique for establishment of Secretariat at NEPAD to coordinate AMRH

Real political commitment at continental level is vital for success
Critical success factors and roles of key players...

Regional Economic Communities provide a structure for harmonisation
- Recognized by the AU
- Functioning trade agreements & activities already in place
  - Progress on common pharmaceutical policies, operational plans, common medicine registration standards etc.
  - Previously planned common standards failed due to a lack of technical, financial, human resources and effective coordination at national, regional and continental levels

Real political commitment at regional and national levels
The Consortium is committed to mobilizing resources in partnership with African countries and REC's

All key players must be taken on board
- WHO – Technical support
- World Bank – AMRH Fund and Project Management
- Functional NMRAs – US-FDA, EAM, TGA e.t.c
- Product Development Partnership (TB Alliance, DNDi, Concept, Aeras, IPM, MMV, MVI, MVP e.t.c)
- COHRED

Donors: Pool AMRH fund
## AMRH Vision

### AMRH Regional Project Proposals

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<th>Not Harmonised</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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<td><strong>Working independently</strong></td>
<td><strong>Member states operate independently and each country has its own technical requirements and format for registration applications</strong></td>
<td><strong>Member states collaborate on selected topics e.g. certain technical guidelines, GMP inspections, information exchange etc.</strong></td>
<td><strong>Member states have common technical requirements and collaborate broadly e.g. joint evaluations and inspections, sharing assessment and inspection reports</strong></td>
<td><strong>Centralized registration on behalf of participating member states</strong></td>
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**National sovereignty is respected:** medicines registration decisions remaining firmly that of sovereign nations
AMRH Current status

• EAC MRH proposal ready for funding, implementation expected to start early 2011
  – Ongoing discussions between NEPAD Agency, WHO, WB, BMGF and EAC on AMRH fund and project management
  – Areas of focus:
    • To implement an agreed common technical document for registration of medicines in EAC Partner States
    • To implement a common information management system for medicines registration in each of the EAC Partner States’ NMRAs which are linked in all Partner States and EAC Secretariat
    • To implement a quality management system in each of the EAC Partner States’ NMRAs
    • To build regional and national capacity to implement medicines registration harmonization in the EAC
    • To create a platform for information sharing on the harmonised medicines registration system to key stakeholders at national and regional level
    • To develop and implement a framework for mutual recognition based on Chapter 21, Article 118 of the East African Community Treaty
  – Lessons learnt to be used in replicating to other RECs
AMRH Current status...

• SADC, ECOWAS/UEMOA, OCEAC/ECCAS draft MRH project proposal to be finalized by end 2010

• Plan to hold consultation meeting with RECs, NMRAs and Industry in North/North-Eastern Africa by November, 2010
Conclusion

• Medicines regulation is an important and strategic component of public health promotion and sustainable economic development

• African medicines regulation harmonization is attainable given cooperation, collaboration and commitment of all the key players including the policy makers and politicians; the public; academic and research institutions; industry; national, regional, continental and international organizations; PDPs e.t.c.

• Patient access to essential medicines is critical to MDG attainment
It Can Be Done......!

• Thank you!

• Shukran!

• Ahsanteni sana!

Merci!

.........Play your part!!!!!