Harmonizing Regulatory Systems: African Medicines Regulatory Harmonization (AMRH) Programme Progress Update

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Presentation Outline

1. AMRH Programme Overview
2. AMRH Vision, Critical Milestones & Approach
3. AMRH Partnership Model
4. AMRH Programme Progress Update
5. Conclusion

AMRH Programme Overview

AMRH Programme Overview

Pharmaceutical Manufacturing Plan for Africa (PMPA) endorsement by the AU Conference of Ministers of Health in 2007 in response to a call by the African Heads of States in 2005

- Ineffective regulatory systems in Africa
- Technical barriers to the free movement of products within and across regions
- Local production policy priorities
  - Sound medicines regulatory systems
  - Intra regional and intra continental trade
  - Creation of a viable market size.

Where are we coming from?

- A situation of:
  - Inadequate medicines legislations (absent or weak legal and regulatory frameworks)
  - Lack of/limited regulatory capacity to approve medicines in a timely manner and ensuring acceptable quality, safety and efficacy standards
  - Manufacturers confronted with different regulatory requirements, frequent delays, and little process transparency
- Consequently
  - 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

AMRH Critical Milestones, Vision & Approach

Critical Milestones, Vision & Approach

Overall aim

To improve public health by increasing rapid access to safe and effective medicines of good quality for the treatment of priority diseases

Specific aim

To reduce the time taken to register priority medicines

Critical Milestones , Vision & Approach..

Methodology

1. Situation analysis of medicines regulation and harmonization across RECs
2. Support the development of regional project proposals to expedite and strengthen medicines registration through regional harmonization and collaboration
3. Mobilise political support, financial and technical resources

AMRH Vision

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)

Critical Milestones

1. **Harmonised requirements and standards**

Not Harmonised → **Fully Harmonised**

Working independently	Member States Collaborate on selected topics	Harmonised standards and broad collaboration	Recognition of decisions	Centralized Procedure
Member states operate independently and each country has its own technical requirements and format for registration applications	**Regional harmonised guidelines & procedures:** • **Guidelines for registration of medicines** • **Procedures for evaluation of medicines** • **GMP guidelines & Inspection procedures**	• **Joint evaluations and inspections** • **Sharing assessment and inspection reports**	**Mutual recognition agreements**	**Centralized registration on behalf of participating member states**

National sovereignty is respected:
medicines registration decisions remaining firmly that of sovereign nations

Critical Milestones…

2. Regulatory capacity building & systems strengthening

Ad-hoc training programmes → **Institutionalised training programmes**

Working independently	Member States Collaborate on training programmes	Harmonised training standards and broad collaboration	Utilise Existing Regional structures & expertise: NMRAs & Academic institutions
Existing training programmes for NMRA staff based on donor funding	• Evaluation & registration of medicines • GMP Inspections • Quality Management Systems • Management Information Systems	• Harmonised training curriculum • Certification • Evaluation of training programmes	**Short Term:** • Twinning/Exchange programmes among NMRAs within & outside the continent • Regional Centres of Regulatory Excellence (RCORE) **Long-Term:** • Engagement of academic institutions to offer post graduate courses in Regulatory Science

- Increased regulatory workforce in Africa
- Robust & transparent regulatory processes

NEPAD Agency AMRH Partnership Model

Partnership Model

Consortium

Other Stakeholders

COHRED

Major stakeholders convened in February 2009

Country NMRA representatives

RECs

Unanimous consensus emerged: Start now with REC-led efforts, initially focusing on generics registration

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Establishment of the AMRH programme Multi-Donor Trust Fund

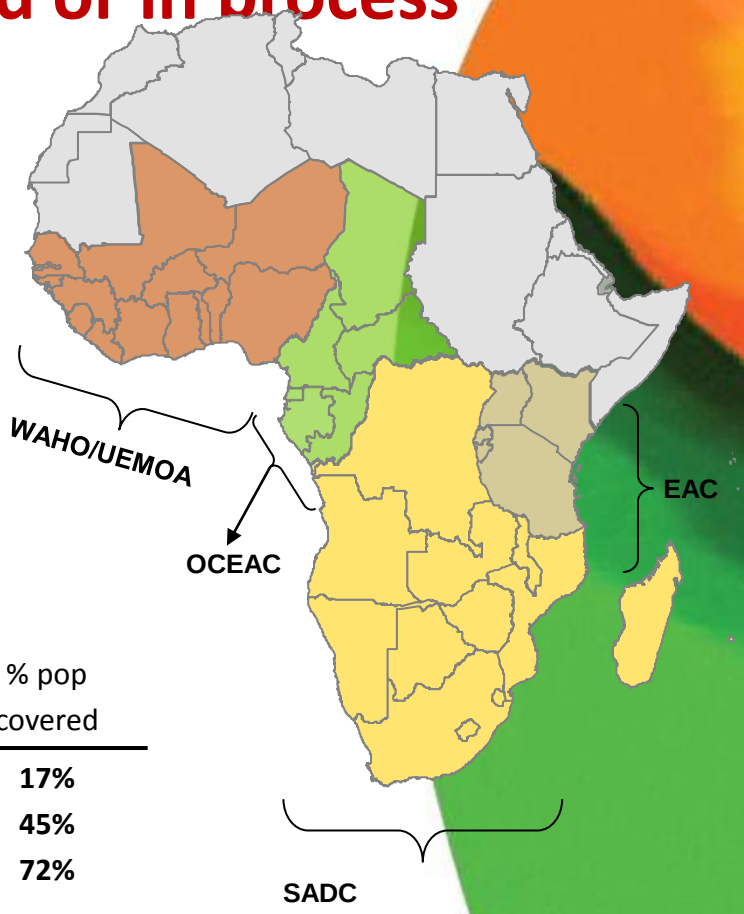
- The World Bank as fund holder for the pooled funds that go into AMRH, starting with a grant from BMGF
- Initial funds to cover EAC Project and AMRH Partners
- Strategically mobilize additional resources to cover other RECs

AMRH Programme Progress Update

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

REC progress

REC	Status	Comments
EAC	MRH Project Proposal finalized 2011	Project launched 30th March 2012
ECCAS/OCEAC	Under consultation	
WAHO/UEMOA	Finalized for AMRH Partners consultation	
SADC		
North/Northeast Africa	Under consultation	



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

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

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Some Lessons Learnt

- EAC MRH Project provides invaluable lessons for other RECs
- However REC contexts, challenges and opportunities differ and this must be taken into account
- Each REC develops its harmonization model based on its context

Other Recent AMRH Activities

- AMRH Initiative Stakeholder Consultation Plenary
- AMRH Advisory Committee Launch & Inaugural meeting
- AMRH Programme Roundtable on Regulatory training programmes
- Model Law on Medicines Regulations Consultations began in April 2012 and involves various stakeholders; Initial consultations recommended Model Law be drafted that will assist regional economic communities (RECs) and countries in their endeavor to enact or review their medicines laws

Conclusion

- There is progress on harmonization made in Africa through RECs
- Several lessons have been learnt in Africa in the harmonization effort: process is slow, requires consultation; harmonization models exist; regulation based on science is key for harmonization; importance of effective regulatory management systems cannot be overemphasized; regulation to take into account issues of globalisation, cross-border trade, cross-border manufacturing should be considered in the harmonization agenda

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Merci!

Thank You!