Challenges in ensuring access to new health products in low income countries

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Presentation Outline

1. NEPAD Agency Background
2. African medicines Regulatory Challenges
3. Various Schemes for Strengthening Regulatory Capacity and their benefits
4. Harmonization of Medicines Regulation in Africa
5. Proposed Way Forward
6. Conclusion

NEPAD Agency Background

- NEPAD Agency's vision, values, principles and philosophy, as defined by African leaders at the inception of NEPAD in 2001, constitute an inspirational set of ideas for a new paradigm for Africa's development
- 4 primary objectives
  - to eradicate poverty
  - promote sustainable growth and development
  - integrate Africa in the world economy, and
  - accelerate the empowerment of women.
- It is based on underlying principles of a commitment to good governance, democracy, human rights and conflict resolution; and the recognition that maintenance of these standards is fundamental to the creation of an environment conducive to investment and long-term economic growth
- NEPAD seeks to attract increased investment, capital flows and funding, providing an African-owned framework for development as the foundation for partnership at regional and international levels
- The key primary objectives of NEPAD that have guided its implementation in the past will continue to guide the work of the new NEPAD Agency
- The ultimate impact of NEPAD Agency's work is envisaged to be "an integrated, prosperous and peaceful Africa, driven by its own citizens and representing a dynamic force in global arena", which is the vision of the AU

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NEPAD Agency Background

- NEPAD Agency in February 2009, partnered with the Pan African Parliament Secretariat to forge ahead the agenda for harmonization of medicines regulation across Africa as part of implementation of the AU Pharmaceutical Plan
- Pursuant to the AU Assembly Decision 55 taken at the Abuja Summit in January 2005 which mandated the AU Commission to develop a Pharmaceutical Manufacturing Plan for Africa within the NEPAD framework
- To consult on and enable the technical process, a workshop of Heads of Medicines Regulatory Authorities and REC technicians was held in Johannesburg in February 2009
- As a result, the African medicines regulatory harmonization initiative spearheaded by the Consortium: NEPAD/AU, PAP, WHO, BMGF, DFID and Clinton Foundation was established with a view to improve patient access to quality, safe and efficacious medicines to the African population

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African Medicines Regulatory Challenges

- Pharmaceuticals inextricably linked to economic factors but are not an ordinary commodity of trade that should be left only to market forces
  - many players with diverse objectives and different entry points
  - public health vs economic interest
- Though we may come from different platforms like speedy market authorisation from the industry's side or timely access to essential technologies from a public health perspective, the target area of safety, efficacy and good outcomes is common for all parties
- Common purpose implies timeliness, responsiveness, vigilance, innovation and adaptation to a changing environment. This naturally requires the need for cooperation and different types of partnerships which can optimize efforts to ensure equitable access to quality, safe and efficacious medicines to majority of our populations

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African Medicines Regulatory Challenges

- Each national regulatory authority (NRAs) has an obligation to ensure that the risk benefit balance of every medicine is appropriate for that country's population
- NRAs have an obligation to society to deliver the right medicine at the right time and in an affordable manner and to assist the society to make informed decisions in their choices.
- They have an obligation to guide appropriate policy orientations in the pharmaceutical arena
- The issue to ask ourselves is, are the NRAs in developing countries doing enough? What challenges are they facing in fulfilling their obligation? What can they do differently?

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African Medicines Regulatory Challenges

1. Changes in disease type and patterns

- Climate change with potential changes in disease types and patterns, a quadruple burden of disease (HIV & AIDS, TB, non -communicable diseases and injuries & violence), migration within the continent, all with unintended consequences that require the attention of NRAs

2. Lack of development of appropriate technologies for neglected diseases

- In African continent, the lack of development of appropriate technologies for neglected diseases that are exclusively or predominantly prevalent in the countries has recently been put on a remedial agenda by PDPs, a commendable step indeed
- This however comes with demands on regulatory capacity from the clinical trial stage through market authorization to post marketing surveillance
- In pursuit of timely access to technologies, regulators increasingly tend to concentrate on quality & efficacy and rely on limited data for safety

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African Medicines Regulatory Challenges

3. **Regulatory Human Resource constraint**

- NRAs are constrained with regulatory skills and competencies hence overburdening their already stretched financial resource
- Preliminary results from the NEPAD Commissioned study on African medicines regulatory harmonization (which is still in the data analysis stage) shows varied regulatory capacity among the countries

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NMRA Human Resource in some African countries

Country	Popn (mill)	Regulatory Human Resource				
		Eval Q	Eval S&E	Inspection (GMP)	Inspectors (General)	Lab Analysts
Kenya	38.2	6	6	3	39	28
Lesotho	19				2	
Liberia	3.5	2			1	1
Malawi	13.1	2		1	4	2
Rwanda	9.3	2			2	
South Africa	49.3	40	56	10		
Tanzania	40.2	7	7	23	39	9
Uganda	30.7	10		32	32	11
Zambia	12.8	4		3	6	
Zimbabwe		9	4	1	4	

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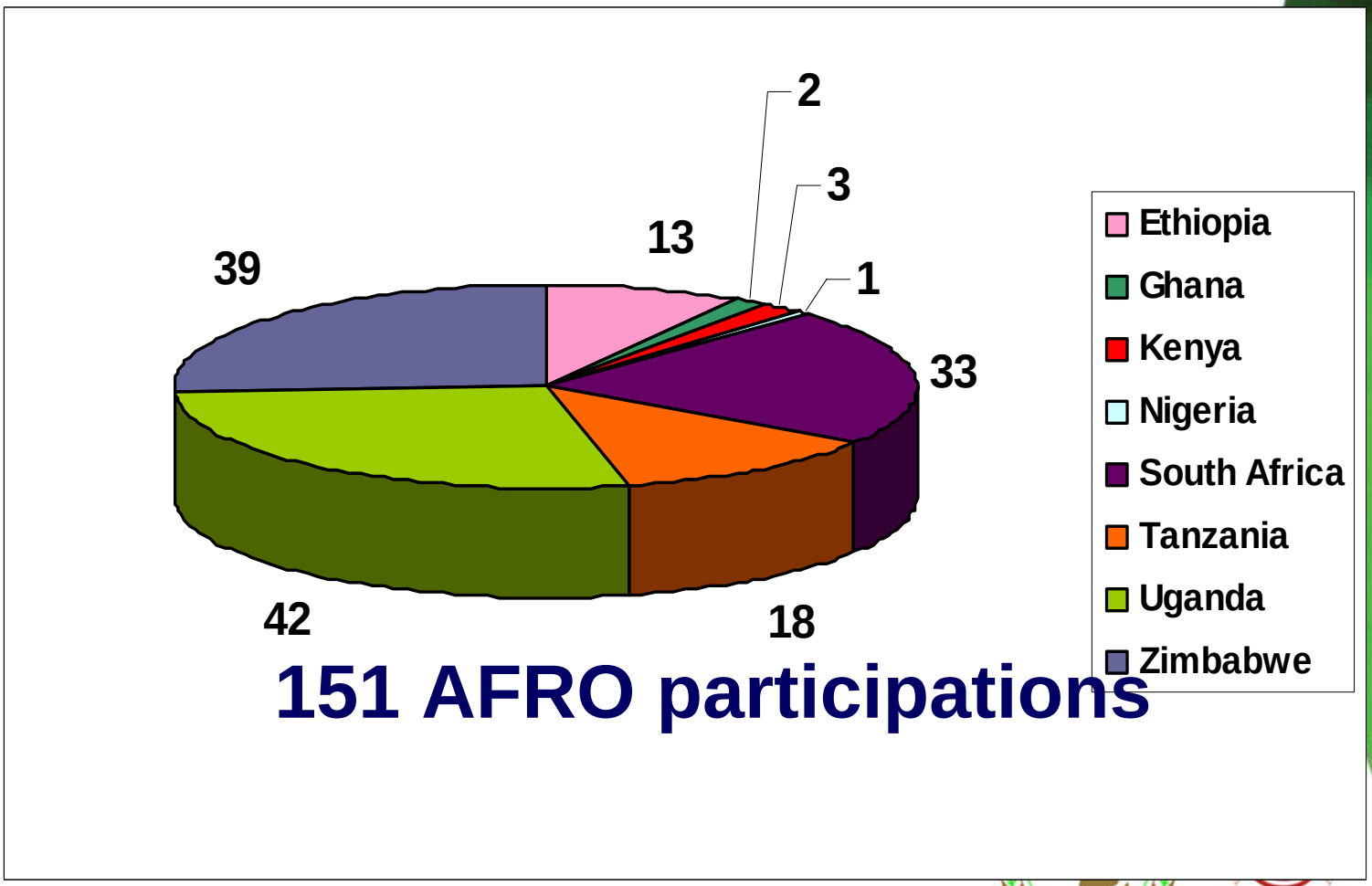
Various Schemes for Strengthening Regulatory Capacity

- WHO Prequalification Programme (PQP) and its linkage to other Stringent NMRA Regulatory Pathways e.g FDA Tentative Approval, EMEA Article 58
- African Vaccines Regulatory Forum (AVAREF)- 19 African Countries involved

Assessors participating in PQP assessment

(all visits in 2001-2008, AFRO countries)



151 AFRO participations

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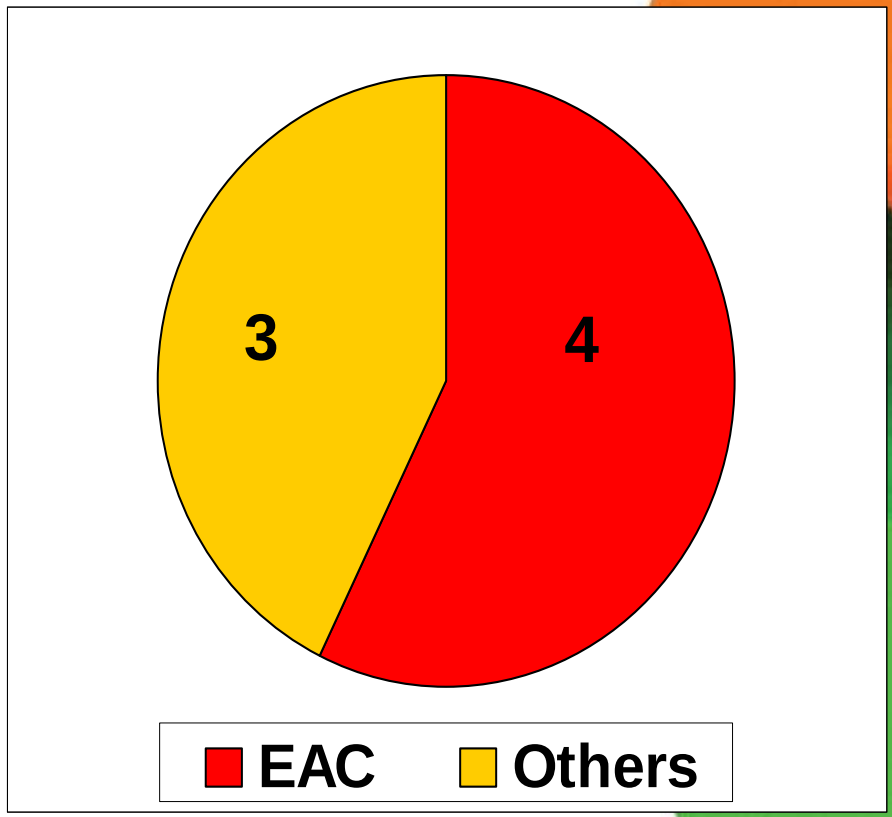
Rotation positions at WHO PQP

2006-January 2009
(including ongoing stays)

- **Zimbabwe 2**
- **Uganda 2**
- **Tanzania 2**
- **Ethiopia 1**

- **Kenya expected**



EAC: 57,1%

Benefits of PQP

- Improved quality of assessment reports through on job training and/or second/peer reviews
- PQP assessors serve as trainers for other medicines evaluators through regional training programme on assessment of dossiers based on WHO PQP guidelines e.g. EAC - Sept 2007 & June, 2008
  - Regional capacity building
- Review of registration guidelines by member states based on WHO PQP guidance documents.
  - Zimbabwe, Tanzania
- PQP – Source of information for pre-qualified API manufacturers, inspected sites including CROs, public assessment and inspection reports etc
- Built in trust and confidence among individual regional assessors participating in PQP
  - Good platform towards harmonization of registration requirements
- Pre-qualified products undergo "abbreviated assessment“
  - Basically looking at country specific requirements
- Information resources available freely
- WHO Public Assessment and Inspection Reports (WHOPARs and WHOPIRs)
  - Used as reference to facilitate and accelerate decision making

Benefits of AVAREF

- Strengthened clinical trial regulatory oversight
  - Development of GCP guidelines
  - Development of template for evaluation/review of CT vaccines & biologicals
  - Training of staff on assessment of CT application, GCP Inspection
  - Improved assessment of CT applications
- Establishment of National Clinical Trial Registries. Pilot in Uganda, Tanzania and plan to link to PACTR (Pan African Clinical Trial Registry which is a designated WHO Primary Clinical Trial Registry for African countries.
- Joint assessment of dossiers

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Harmonization of Medicines Regulation in Africa

- Treaties and protocols for harmonization exist in various RECse.g. EAC, SADC, ECOWAS-WAHO, UEMOA, OCEAC/ECCAS
- Problem in implementing agreed regional decision
- Slow pace in the existing regional harmonization initiatives
  - Limited human and financial resources
  - Regional and national coordination including medicines regulatory harmonization programmes

Harmonization of Medicines Regulation in Africa

- Initial Phase 2009-2010
  - Situation analysis on medicines regulatory harmonization conducted in the East African Community (EAC) and SADC, other RECs to follow
  - RECs project proposals for medicines registration harmonization at different stages: SADC, ECOWAS-WAHO/UEMOA, ECCAS/OCEAC
  - EAC Proposal finalised and ready fro funding by October 2010
  - Plans are underway to start dialogue with RECs, NMRA and industry in the North-North-Eastern Africa
- A comprehensive 5 years programme in response to the political, technical and financial challenges of medicines regulation harmonisation and strengthening is being developed by NEPAD Agency and WHO
  - NEPAD Agency coordination and advocacy role

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Harmonization of Medicines Regulation in Africa

- The primary aim is to reduce time to place a product in a particular market
  - lead-time associated with meeting different country requirements
  - significant cost savings to the pharmaceutical industry
  - Patients' quicker access to new and improved therapies at more affordable prices
- Improved regulation of medicines across borders
  - more streamlined procedures
- Substantial savings for Government budgets
  - high volume, high value essential medicines, speedy registration of generic equivalents
  - additional economies of scale through pooled procurement
  - faster patient access to innovative new products,
  - many patients can be treated at lower costs

Proposed Way Forward

1. An objective assessment of NMRAs in Africa is needed with a view to determine gaps in medicines regulation and harmonization (capacity, infrastructure and legislation gaps) and develop appropriate interventions
   - Establish a data base of pool of African Regulatory Expertise for cross REC sharing of knowledge and skills
   - Joint review which includes those parties who will need to approve a product, including the Western MRA, African MRA/s and WHO.
     - EAC Joint Assessment piloted in March 2010
   - Consider developing a model law to assist countries and RECs in their legislative reviews including mutual recognition

2. A Strategy to streamline the existing regulatory pathways into the existing RECs structures
   - Integrate new regulatory tools and formalise existing capacity building programmes such as DNDi, AVAREF, EDCTP, WHO drug and vaccine Prequalification Programmes into regional training programmes, WHO Regulatory Package e.t.c

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Proposed way forward…

3. A Strategy to Coordinate the RECs harmonization initiative at continental level
   - Need to establish a formal coordination mechanism and structures that takes on board all the key players including NMRAs, Academia, Researchers, Pharmaceutical industry and RECs
   - Develop a robust monitoring and evaluation tool to ensure consistency within and across RECs
4. Identify Centres of Regulatory Excellence in Africa for each Regional Economic Community
5. Identify sustainable financing mechanism for the harmonization initiative

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Conclusion

- Adopt strategies being implemented to address access to medicines that specifically address neglected tropical diseases as they open space for novel policy alternatives that support public health needs. Such policy reforms must prioritize the public good, use innovative policy tools to harness the private sector and academia where possible and create public R&D capacity where market forces and actors are likely to fail.
- There is need to explore new partnerships and regulatory pathways in order to improve efficiency in regulatory work and facilitate access to appropriate technologies.
- Against the backdrop of scarce resources and complex technologies, resources must be efficiently used and duplication of effort avoided. Harmonization of regulatory practices and sharing of information is one of the methods that could be used. We therefore need to investigate what models of harmonization should be implemented and how will they be sequenced and managed.
- Strengthening cooperation and information sharing between regulators and the industry at development phase to understand the science behind the development

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