Registering New Drugs: The African Context

African Medicines Regulators Perspective

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Presentation Plan

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2. Various Schemes for Strengthening Regulatory Capacity
3. Benefits of the various Schemes
4. Harmonization of Medicines Regulation in Africa
5. Paradigm Shift in medicines regulation in Africa
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Regulatory Capacity in Africa

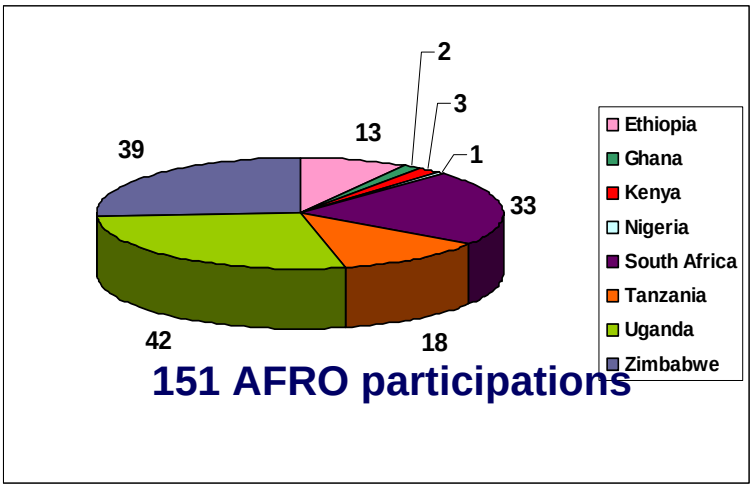
- Over years we have heard of the limited capacity of developing countries National Medicines Regulatory Authorities (NMRAs) to evaluate new chemical entities let alone to perform core medicines regulatory functions (DNDi Report, 2009).
- According to a study conducted by WHO in 2004, African regulatory capacity overall is below that of Europe, Latin America and much of Asia, with a 2004 WHO study reporting that 90% of African MRAs lacked sufficient capacity to guarantee the quality, efficacy and safety of medicines in their country (WHO/AFRO/EDP, 2004).

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
- WHO Regulatory Package: Piloted in 7 Adrican Countries
- African Vaccines Regulatory Forum (AVAREF)- 19 African Countries involved

Assessors participating in PQP assessment

(all visits in 2001-2008, AFRO countries)



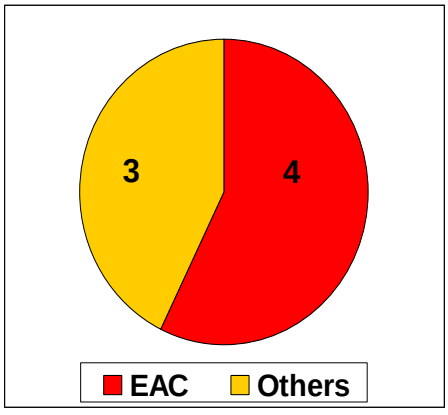
151 AFRO participations

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 served 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

Benefits of PQP

- 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

Benefits of PQP

- Information resources available freely
- WHO Public Assessment and Inspection Reports (WHOPARs and WHOPIRs)
  - Used as reference to facilitate and accelerate decision making
- US FDA and EMEA assessment reports – rarely used
- Other information sources especially from "stringent" NMRAs not readily available

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

WHO Regulatory Package

- WHO Project on Registration Summary for Pharmaceutical Products initiated in 2006 in order to:
  - increase the capacity of the national NMRAs by provision of administrative and technical instruments for establishment of their own decision-making processes on the marketing authorization of medicines
  - ensure that registration summary is a compilation *of scientific information, discussions and conclusions* on the quality, safety and efficacy of a particular pharmaceutical product, reached at the end of the process of evaluation of marketing authorisation application
- Seven pilot countries - Ghana, Kenya, Nigeria, South Africa, Uganda, United Republic of Tanzania and Zimbabwe which have been selected based on their comparable levels of “maturity" to perform main regulatory functions
  - Evaluation of Project recommended scaling up to other African countries

Harmonization of Medicines Regulation in Africa

- Existing some harmonization initiatives through sub-regional harmonization platforms e.g. EAC, SADC, ECOWAS-WAHO, UEMOA, OCEAC
- No formal agreement on exchange of regulatory information with other NMRAs
  - No impact on marketing authorisation and acceleration of approvals
- Information exchange done on request and given on good will only
  - Not binding
  - formal agreement good idea for consideration
- Slow pace in the existing regional harmonization initiatives

Expected benefits of harmonization

- 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

Expected benefits of harmonization (2)

- 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

Challenges of Harmonization

- Striking the right balance between regional rationalisation and national level capacity building
  - One African expert noted: "While efforts are made to harmonise medicines regulation in the region, they should at the same time be geared towards assisting countries with limited resources to build their regulatory capacity as this will be the foundation for building trust among different MRAs and eventually lead to mutual recognition of regulatory decisions."
  - Harmonisation without strengthening will be short-lived and ineffective
- Commitment at National, Regional and Continental levels
  - commitment at every level i.e. political commitment, economic commitment and a fully functioning Secretariat
- Driver of the harmonization process
  - role of external donors in driving harmonisation has received a mixed response
  - Need a the bottom-up approach e.g. the African Drug Registration Harmonisation consortium led by NEPAD/AU, the Pan African Parliament (PAP), the Bill & Melinda Gates Foundation, DFID, the Clinton Foundation and the WHO
    - RECs submit Medicines Registration Harmonization Proposals for Funding

Paradigm Shift in medicines regulation in Africa

- Integration of new regulatory tools for building African NMRAs regulatory capacity as proposed by DNDi report
- Advocate for and support the African Medicines Registration Harmonization (AMRH) initiative under the leadership of AU/NEPAD and WHO in collaboration with Bill and Melinda Gates Foundation and DIFID and other interested Partners

Proposed Way Forward

1. An objective assessment of NMRAs in Africa is needed with a view to determine existing regulatory capacity including expertise and infrastructure
    - Call from 2nd African Conference for Medicines Regulatory Authorities held in Maputo, Mozambique from 24th – 26th November, 2009
    - establishing with confidence the actual status of NMRAs in Africa with a view to determine the level of development whether a fully functional MRA, moderately functional or insufficiently functional and needing significant capacity building to perform fundamental regulatory tasks

Proposed way forward…

2. Identify Centres of Regulatory Excellence in Africa for each Regional Economic Community
    - Fund Centres of Regulatory Excellence in each of Africa's main sub-regions: West, South, East, Central and North Africa.
    - The Centres would training on regulatory science to support African MRAs in meeting their immediate regulatory challenges; as well as providing an institutional pathway for professional training to build and retain African regulatory capacity in the mid-to-long term.
    - Centres would provide "Regulatory Fellowships"

Proposed way forward…

3. A Strategy to streamline the existing regulatory pathways into the existing RECs structures
   - 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 pilot planned for march 2010
   - Exploit the potential of the WHO-AFRO Pilot of the Drug Registration Package (WHO 2007-1, WHO 2008-2) and expand it to cover other African countries.
   - Formalise the WHO drug and vaccine Prequalification Programmes into regional training programmes for evaluators with a view to build African regulatory capacity in a predictable and structured way.
   - Integrate other initiatives for building African regulatory capacity such as:
     - Clinical trial regulatory initiatives e.g. AVAREF
     - DNDi Capacity building initiatives
     - Existing Centres of Excellence for clinical trial capacity building e.g. the EDCTP "Regional Network of Excellence for Conducting Clinical Trials" and/or the Wellcome Trust "Capacity Strengthening in African Institutions for Endemic Diseases Research Initiative"
     - African academic centres of excellence in pharmacology

Proposed way forward…

4. 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
   - Establish a data base of pool of African Regulatory Expertise for cross REC sharing of knowledge and skills
   - Identify sustainable financing mechanism for the harmonization initiative
   - Develop a robust monitoring and evaluation tool to ensure consistency within and across RECs

Conclusion

- Africa has some regulatory capacity built over time
- Need to take stock of existing capacity: identify pool of expertise and regulatory centres of excellence
- Formalize WHO and Other SRA Regulatory Schemes using the existing regional structures
- Advocate and support the on-going medicines regulation harmonization initiative spearheaded by the Consortium: NEPA/AU, PAP, WHO, BMGF, DIFID and Clinton Foundation
- It can be done if we all decide towards a common vision of building African Regulatory Capacity