Regional Centres of Regulatory Excellence (RCOREs) In Africa

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Presentation Outline

1. Background
2. RCORE Definition
3. Categories of RCOREs
4. Eligibility criteria
5. Selection Process
6. Conclusion
Background

• **2001 - 2010:** NEPAD Planning and Coordinating Agency
  ➢ Technical arm of the African Union (AU)
• **2005:** AU Decision on Pharmaceutical Manufacturing Plan for Africa (PMPA)
• **2009:** African Medicines Regulatory Harmonization Initiative
  ➢ Systemic regulatory capacity limitation
• **AMRH Partnership:** AUC, PAP, WHO, WB, UNAIDS, DFID, BMGF, CHAI
Background...

• Regional Economic Communities (RECs) & countries involvement
  – Medicines Registration Harmonization Projects
    • Pathfinder for harmonization of other regulatory functions and products e.g. clinical trial oversight, pharmacovigilance, generic vs new drugs e.t.c.
  – Harmonization of regulatory standards
    • CTD, GMP, QMS, IMS, Regulatory Capacity Building, Mutual Recognition

• East African Community (Launched March 2013), West Africa (WAHO/UEMOA); SADC, Central Africa (ECCAS/OCEAC), IGAD
Background...

- The roundtable discussion on 30th March, 2012 in Arusha, Tanzania
  - Institutionalization of regulatory training programmes in existing institutions in Africa
  - Establishment of Technical Working Group on Regulatory Capacity Development in Africa (TWG-RCD)
  - Sustainability of regulatory training programmes
  - Regulatory training curriculum and a certification scheme
  - Establishment of Regional Centres of Regulatory Excellence (RCOREs)
  - Pre-test the RCORE scheme in one REC before scaling up
Background...

• TWG-RCD Established
  – 1\textsuperscript{st} meeting; 15-16 November 2012
    review the first draft criteria for establishing RCOREs
  – 2\textsuperscript{nd} meeting; 6 June 2013
    • Endorse the revised criteria and the application process
    • Call for bids and submission of expression of interest
RCORE Defined

• Institution or partnership between institutions with specific regulatory science expertise & training capabilities
  • NMRA, University Faculty, National/Regional training Centre, Scientific/Research institution, Quality Control Laboratory, Pharmacovigilance Centre, and/or Drug Information Centre

• RCORE Mission:
  i. To provide academic and technical training in regulatory science applicable to different regulatory functions; and
  ii. To provide skills enhancement through hands-on training
RCORE defined..

Harmonised Curricula & Certification Scheme

National Medicines Regulatory Authorities (NMRAs)

RCORE

Academic/Research institutions

Specialised regulatory function
Categories of RCOREs

• Based on regulatory functions:

  ➢ Assessment of safety, efficacy and quality of medicines, and issuing marketing authorization

  ➢ Clinical trials oversight

  ➢ Licensing of the manufacture, import, export, distribution, promotion and advertising of medicines
Categories of RCOREs..

- Post marketing surveillance (monitoring the quality and safety of medicines)
- Inspecting and surveillance of manufacturers, importers, wholesalers and dispensers of medicines
- Providing independent information on medicines to professionals and the public
- Quality Control
Eligibility criteria..

• Capabilities:
  ➢ Regulatory capability
  ➢ Training capacity
  ➢ Governance & management systems
  ➢ Infrastructure
Selection process

• Application: Call for bids and submission of expression of interest

• Assessment: assessment of expressions of interest, short-listing and audits

• Approval & Selection: Based on the eligibility criteria

• Performance Evaluation/Review: monitoring for continued performance
Conclusion

- RCOREs intended to address systemic regulatory capacity challenges in Africa
  - Practical/hands on training experience
  - Structured competence assessment and certification
  - Ensure sustainability of regulatory training programmes through institutionalized and structured formal curriculum

- Increased regulatory workforce to facilitate quality review of medical products and clinical trials conducted in Africa
Thank You!!