Comments on the report on Pharmaceutical Regulatory System in Africa

DNDi Meeting
Nairobi - Kenya

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Tanzania Food and Drugs Authority (TFDA)

- Autonomous agency under the Ministry of Health and Social Welfare
- TFDA was established under the Tanzania Food, Drugs and Cosmetics Act No.1, 2003
- The Authority is responsible for control of quality, safety and effectiveness of
  - food
  - drugs (including herbal drugs)
  - cosmetics
  - medical devices

TFDA HQ in Dar es Salaam

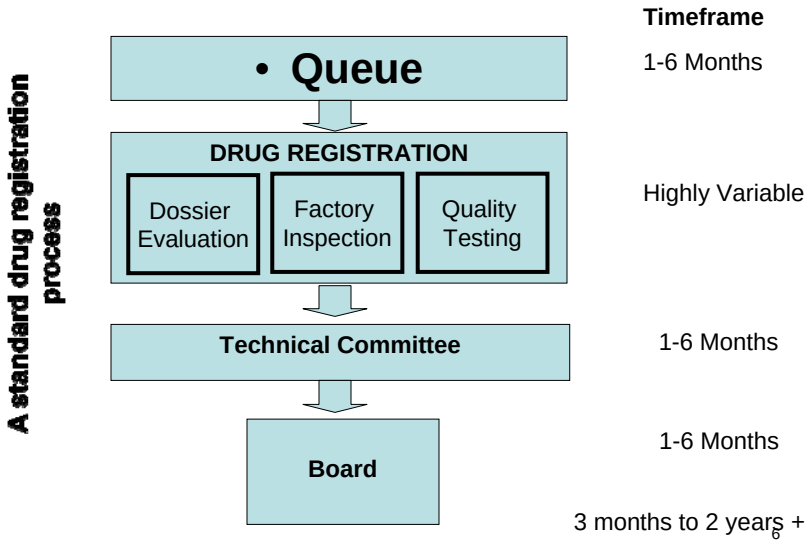
Medicines Control Functions

- Evaluation and Registration of medicines
  - Human & veterinary
- Inspection and Enforcement
  - Market control + QC testing of drug samples
  - Import control
  - GMP inspections
  - Licensing importers and medicines distributors
- Clinical Trials Control
  - Assessment of trial applications
  - Trial site inspections
- Pharmacovigilance
  - Spontaneous reporting
  - Cohort Event Monitoring for ACTs – launched in March 20094

Marketing authorization

- The Tanzania Food, Drugs and Cosmetics Act No.1, 2003 provides requirements
  - Guidelines in place (2008) to submit documentation by manufacturers
- Regulators as obstacle to access
  - Perceived or real??
- Regulatory approvals (registration, MA)
  - based on science – not easy to understand
  - Need considerable scientific and administrative capacity, if done properly
  - Relative lack of transparency (not easy to understand for a lay person, but also increasingly difficult for HC professionals)
  - Takes time

Marketing authorization…….



Comments on the report

- A good report - Critical review of the challenges of medicines regulation in Africa
- Registration of generic medicines
  - Preparing quality dossiers a challenge
  - BE studies not well accepted by domestic manufacturers ~ poor documentation
- WHO PQ
  - Unique training opportunity for many African regulators- assessments, inspections, quality monitoring projects (market control)
  - WHOPARs and WHOPIRs facilitates decision making

Comments on the report (2)

- Clinical trials of products
  - Legal mandates
  - Guidelines for CTAs and trial inspections
  - Independence from ethical committees
- Manufacturers view of registration
  - Tough requirements to meet
  - Delays in approvals
  - Different sets of requirements among neighbouring countries e.g. EAC region

Comments on the report (3)

- Coordination and harmonization of medicines regulation
  - Only way to go; but it takes time (EU ~40yrs)
  - Discussions started in many RECs e.g. EAC, SADC, COMESA, ECOWAS
  - Progress made so far supported by WHO e.g. EAC
  - Needs strong Secretariat and funding to succeed

Some practical challenges

- Access to regulatory information
  - Guidelines to recognize decisions made elsewhere e.g. WHOPARs and WHOPIRs and EPARs
    - How to access info from other Western DRAs
- Weak market controls
  - Counterfeit and substandard medicines on the market
  - Unlicensed drug distribution outlets
    - Part II Drug Outlets in Tanzania

Moving forward

- Centres of excellence – great idea!
  - Clinical trials – harmonize technical requirements first!
    - Training staff to assess dossiers and inspect trials
  - Conduct joint reviews and inspections with experienced assessors and inspectors e.g. WHO PQ
    - Hands on training
- DNDi to join WHO to support medicines regulation harmonization in Africa

Thank you
Ahsanteni