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Drug Registration procedures in Tanzania

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Presentation Plan

- Tanzania basic facts
- Medicines legislation
- TFDA functions
- Registration of medicines
- Appeals
- References

Tanzania Basic Facts

- Located in East Africa 8-continental-africa-map.gif
- Population 41 million (2009 estimate)
- Gross Domestic Product 16.2 US$ (2007)
- Average economic growth 6% (target 8%)
- Major trading partners: EAC, UK, South Africa, India, Japan, Australia, France, the Netherlands and United Arab Emirates

Medicines Legislation

- Tanzania Food, Drugs and Cosmetics Act,2003
  - Provides for regulation of food, drugs, cosmetics and medical devices
  - Prohibits sale of unregistered drugs
  - Lays down conditions for registration
  - Provides punishment for violations
  - Empowers Director general to make guidelines for registration of product
- Established the Tanzania Food and Drugs Authority (TFDA)

Tanzania Food and Drugs Authority (TFDA)

- Autonomous agency under the Ministry of Health and Social Welfare
- The Authority is responsible for control of quality, safety and effectiveness of
  - food
  - drugs (including herbal drugs)
  - cosmetics
  - medical devices
- TFDA Mission
  - *"to protect and promote public health by ensuring quality, safety and effectiveness of food, drugs, cosmetics and medical devices"*

TFDA HQ in Dar es Salaam

TFDA functions

- **TFDA is an ISO certified semiautonomous agency responsible for regulating:**
  - **all matters relating to quality, safety and efficacy of medicines and medical devices**
  - **all matters relating to quality and safety of food and cosmetics.**

TFDA regulatory activities

- **Pre-market evaluation and market authorization**
- **Licensing and inspection of premises dealing with medicines**
- **Control of importation and exportation of medicines and medical devices**

TFDA regulatory activities

- **Post market surveillance and pharmacovigilance**
- **Control of clinical trials of medicines and medical devices**

Registration of medicines

- Eligible products:
  - **Human medicines (+ biologicals)**
  - **Herbal medicines**
  - **veterinary medicines (+biologicals)**

Registration of medicines

- Eligible products:
  - **Medical devices**
  - **Cosmetics**
  - **Disinfectants for disinfection of premises in which drugs or food are manufactured, prepared or kept, hospitals and equipment and farm houses**

Medicines Registration Process.doc

- Application
- Evaluation
- Technical committees
- Approval letters and Certificates

Application for registration

- **Types of applications**
  - **New application**
  - **Renewal**
  - **Variation**

Application procedures

- **Checklist and index of submitted documents**
- **Filled in Application form**
- **Certificate of a Pharmaceutical Product**
- **Medicinal product dossier**
- **Samples**

Application procedures

- Site master file –first product only
- Evaluation fees-US$ 750.00 Generic, US$1000 NCE
- GMP inspection fees-US$ 3500.00 India sites

Medicinal Product Dossier

- Administrative data
- Summary of product characteristics
- Quality part:
  - Data on quality of API
  - Data on quality of finished product

Medicinal Product Dossier

- Clinical part:
  - Generics medicines -Data on interchangeability with innovators (bioequivalence data)
  - NCE –Pharmacology, toxicology and efficacy data
  - label and package insert

Evaluation

- Evaluation queue:
  - First in first out (FIFO)-review time 12 months
  - Fast track new medicines for diseases without registered medicine- review time 6 months

Evaluation

- Evaluation against legal requirements:
  - Evidence of compliance to standards of quality, safety and efficacy
  - Evidence based Label claims
  - Suitability for intended use
  - Compliance to GMP
  - Availability in public interest

Evaluation

- **Queries issued for non compliance to guidelines**
- **The clock stops till all queries are addressed**
- **Product disqualified and application closed:**
  - Responses not submitted in one transaction within six months
  - failure to fully address queries for 2nd time
  - Non compliance to GMP
- **Approval time includes review time by TFDA and Queries response time by applicant**

Technical Committees

- Human Medicines Registration Technical Committee
- Veterinary Medicines Registration Technical Committee
- Give expert opinion to register, differ or disqualify a product

Approval

- Issuance of approval letter and certificate of registration
- Valid for five years and renewable
- Variations - variation guidelines
- Application for renew-application guidelines

Appeals

- Representations to TFDA
- Minister for Health
- High court

References

- Tanzania Food, Drugs and Cosmetics Act, 2003
- World bank database (www.worldbank.org)
- Encarta (http://encarta.msn.com/fact_631504875/tanzania_facts_and_figures.html

Thank you