Regulatory Enforcement and the Risk of Counterfeit and Substandard Medicines in Africa

The case of Tanzania

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Outline

• Tanzania Food and Drugs Authority
• Counterfeit and substandard medicines in Africa
  – The case of Tanzania
• Challenges in combating counterfeit medicines
• Challenges in the supervision of overseas vs local manufacturers
• Examples of cases of counterfeit medicines cases in Tanzania
• Combating counterfeit medicines
• Conclusions & Way Forward
Tanzania

• Located in **Eastern Africa**, sharing borders with 8 countries
  – Burundi, Rwanda, Uganda, Kenya, Malawi, Mozambique, Zambia, Democratic Republic of Congo
  – & the Indian Ocean with a coastline of 1,424km
• The largest nation in East Africa, both in land area and population *(44, 929,002 million - 2012 census)*
• Many tourist attractions
  – National parks
  – Mount Kilimanjaro (highest peak in Africa)
1. Serengeti National Park  
2. Ngorongoro Crater  
3. Manyara National Park  
4. Mt. Kilimanjaro
Medicines Regulation in Tanzania

- Tanzania Food, Drugs and Cosmetics Act, No.1, 2003
  - Provides for regulation of food, medicines, cosmetics and medical devices
  - Prohibits sale of unregistered products
  - Lays down conditions for registration of regulated products
  - Provides punishment for violations
  - Empowers the Ministers to make regulations & the Director General to make guidelines

- Established the Tanzania Food and Drugs Authority (TFDA)
Tanzania Food and Drugs Authority

► Tanzania Food and Drugs Authority (TFDA) is an Executive Agency under the MoHSW established in 2003.

► Headquarters in Dar es Salaam & 5 zone offices across the country.

► TFDA is a regulatory body mandated to regulate safety, quality and effectiveness of food, medicines (including veterinary, vaccines and herbal medicines), cosmetics and medical devices.
Tanzania Food and Drugs Authority (TFDA)

- **TFDA Mission** - “to protect and promote public health by ensuring safety, quality and effectiveness of food, medicines, cosmetics and medical devices”.

- **TFDA Vision** – “to be the leading African Regulatory Authority in ensuring safety, quality and effectiveness of food, medicines, cosmetics and medical devices for all”.

- **Key milestones achieved (2003 – 2012)**
  - Key regulatory systems, processes and procedures in place
  - Medicines testing laboratory WHO Prequalified since January, 2011.
TFDA HQ in Dar es Salaam
Counterfeit and Substandard Medicines

- Medicines save lives and prevent diseases and epidemics only when they are efficacious, safe, of good quality and rationally used.
- However, counterfeit and substandard medicines circulate alongside approved quality medicines.
- Counterfeiting of medicines is a serious global public health problem.
- Counterfeit medicines resemble a silent murderer when they are used to treat life threatening conditions e.g. malaria.
- *is a national problem with “international dimensions”*
Impact of counterfeit medicines

• On Public Health
  – Counterfeit medicines have potential to kill
  – They are dangerous to patients as:
    • they may not respond as quickly to treatment
    • counterfeit antibiotics can increase resistance
    • counterfeit vaccines do not immunize
    • direct harm if they contain impurity or poisonous substances
• On Health Systems
  – Erosion of public confidence
  • Healthcare professions
  • National Medicines Regulatory Authorities
  – Public money is used to buy medicines of unknown safety and quality

• On Economy
  – Legitimate sale and tax revenue lost
  – Reduction on economic growth (reduce financial returns on investment in innovation)
Challenges in combating counterfeit medicines

- Inadequate legal framework and weak penal sanctions
- Un-harmonized regulatory systems with bordering countries
  - Many porous borders between countries
- Limited number of drug inspectors vs. the size of the country and number of ports of entry.
- Inadequate access to essential medicines including insufficient coverage of health insurance schemes
- Wide price gaps or extremely high prices since many countries do not regulate medicines prices
Challenges on supervision of overseas vs. local manufacturers

- Costs involved in conducting and follow GMP inspections.
- Limited number of qualified GMP inspectors to conduct regular inspections of overseas manufacturers.
- Policies in producing countries that promote exports vs. compliance to regulatory requirements e.g. GMP
- Lack of harmonized GMP requirements and inspection procedures among NMRAs in importing and exporting countries.
- Contract (third-party manufacturing) that is difficult to monitor
- Capacity to inspect all batches imported at port of entries
Examples of counterfeit medicines cases in Tanzania

• Tanzania has experienced a number of cases of counterfeit medicines

• Documented cases from 1999 onwards

• Actions have been taken to address the public health challenge.

• Five examples outlined in the next slides
Counterfeit Chloroquine in 2001

Expired Chloroquine Injection (from an unregistered manufacturer) was relabeled as Quinine Dihydrochloride Injection 600mg/2ml purported to be from a manufacturer in Cyprus.

- Culprit prosecuted but case abetted due to death of culprit
Counterfeit Metakelfin tablets in March 2009

• Counterfeit anti-malarial, Metakelfin tablets were found on the market.
  – Lab analysis confirmed lack of Pyrimethamine 25mg, one of the active ingredients while Sulphamethoxypyrazine was available at 0.4% (acceptance limits 90-110%)
  – Several batches were confiscated from the private pharmacies

• Suspended importation, distribution and use of Metakelfin in Tanzania.

• Recalled all batches of Metakelfin from the market and disposed off all stock

• 5 prosecutions – court cases ongoing.

• Manufacturer changed packaging and re-introduced the product.
Metakelfin 500 mg

COMPOSITION:
Each tablet contains 500 mg of metakelfin, a non-steroidal anti-inflammatory drug (NSAID).

INDICATIONS:
- Treatment of acute musculoskeletal pain.
- Relief of headache.
- Treatment of pain and inflammation.

ADVERSE EFFECTS:
- Common: nausea, vomiting, abdominal pain, constipation, diarrhea.
- Rare: dizziness, flushing, rash, allergy.

CONTRAINDICATIONS:
- Hypersensitivity to metakelfin or any component of the formulation.
- Patients with a history of peptic ulcer disease.
- Children and adolescents under 12 years of age.

DOSAGE:
- Adults: 1 tablet every 6-8 hours as needed, maximum of 6 tablets per day.
- Children: 1 tablet per day, divided into 3 or 4 doses.

PRECAUTIONS:
- Use with caution in patients with a history of cardiovascular disease.
- Avoid prolonged use and high doses.
- Discontinue use if symptoms persist or worsen.

Manufactured by: [Manufacturer Name]

Batch No.: [Batch Number]
Expiration Date: [Expiry Date]
Counterfeit **Laifin** (with Sulphamethoxazole) was being sold/dispensed as **Laefin** (with Sulfametopyrazine) in September, 2011.
Ibuprofen tablets was found being sold/dispensed as Erythromycin tablets in August, 2011
Metronidazole tablets were found being sold as Antimalarial Quinine Sulphate tablets in February, 2012.
Substandard Medicines: Operation Mamba 2008
Combating counterfeit medicines

• Combating counterfeit medicines requires collaboration at national, regional and international level
  – Political will and commitment
  – Legal framework that clearly defines counterfeit medicines and recognizes it as a crime that is different and more serious than counterfeiting other kinds of goods e.g. t-shirts, cassettes
  – Strong medicines regulatory framework backed by legislation
Combating counterfeit medicines (2)

• Collaboration at regional and international level
  – Bordering countries
  – New Member State Mechanism established by WHA in 2012

• Role of pharmaceutical manufacturers and their associations in identifying counterfeited products

• Pharmaceutical distributors, wholesalers, importers, exporters – apply principles of good distribution practices
Efforts in Tanzania

- Implementation of Medicines Quality Assurance program with primary screening at ports of entry (PoEs) and at identified centres using Minilab Kits
- Establishment of the Drug Quality Control Laboratory
  - WHO Prequalified in January, 2011
- Implementation of structured Post-Marketing Surveillance Programme
  - Surveillance of a basket of medicines annually
- Implementation of Accredited Drugs Dispensing Outlets (ADDOs)
  - Conversion of poorly regulated small drug outlets into ADDOs
Efforts in Tanzania --- (2)

- Establishment of **joint TFDA – Police and Customs taskforce** on counterfeit medicines.
  - Tasked to carry out regular joint operations to identify and confiscate counterfeit medicines.

- Combating counterfeit and substandard medicines is one of TFDA’s priority areas in its 5-year Strategic Plan (20012/13 – 20116/17).

- Public education programs on public health implications of counterfeit and substandard medicines on TVs, radio, exhibitions.

- Launch of the EAC medicines regulatory harmonization project, in March 2012
  - Harmonized medicines regulatory systems, processes and procedures.
Conclusions and way forward

• Counterfeit medicines is a real and serious public health problem
  – affects both developed and developing countries
  – collaboration and co-operation among NMRAs and law enforcement agencies at national, regional and international levels is the only way to win this war
  • Especially in Africa where regulatory systems are still weak or non-existent in some countries coupled with limited skilled human resources

• New Member State Mechanism established by WHA in 2012
• Improved co-operation among law enforcement agencies at national and regional levels (NMRA, Police, Customs)
Thank you