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)

Tanzania (2)


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
  - Quality Management System certified to ISO 9001:2008 since June 2009.
  - Medicines testing laboratory WHO Prequalified since January, 2011.
  - Food and Microbiology laboratories accredited to ISO/IEC 17025:2005 since September, 2012.

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
  - affects both developed and developing countries
  - 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

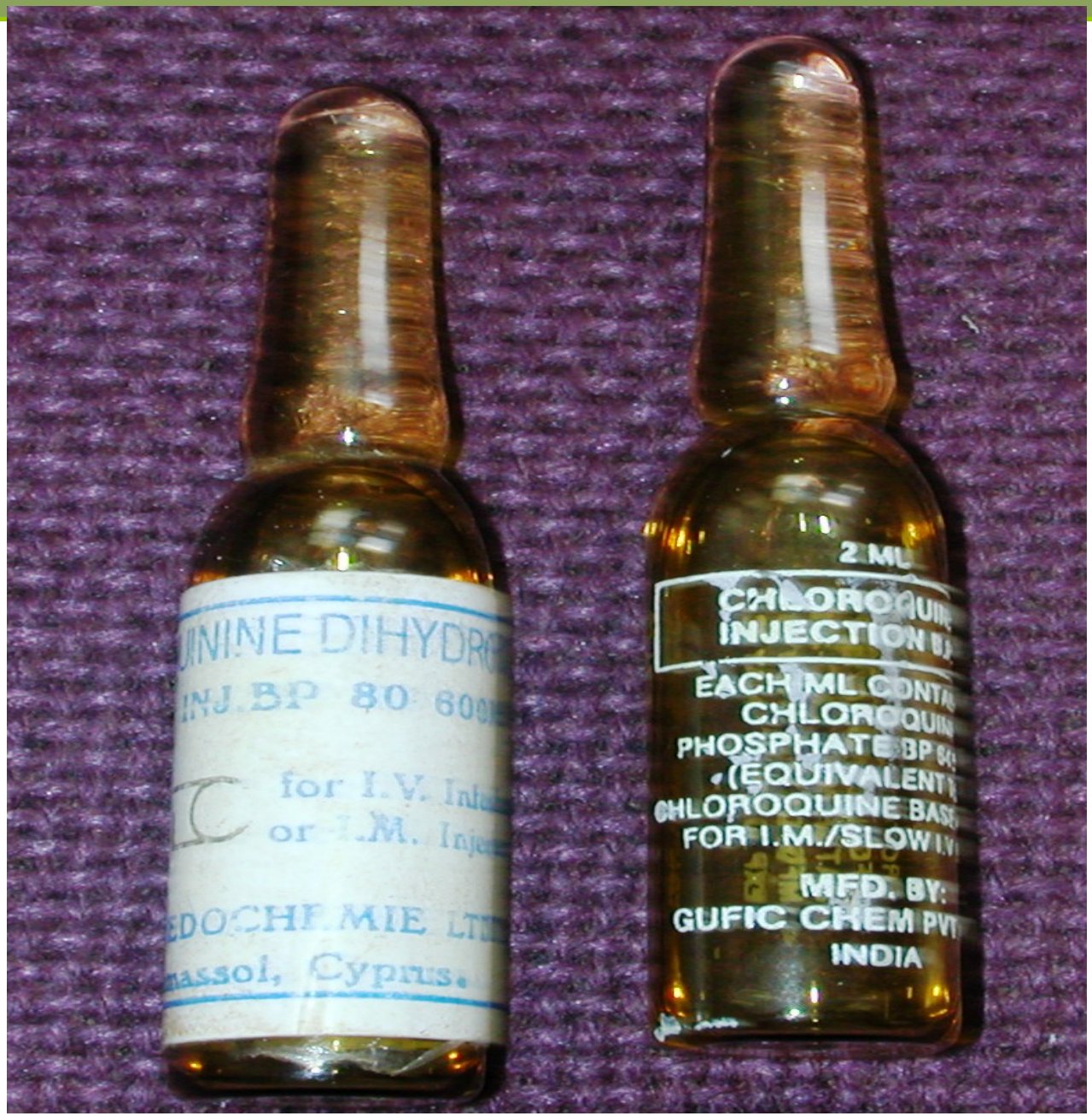
Examples of counterfeit medicines cases in Tanzania

- 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

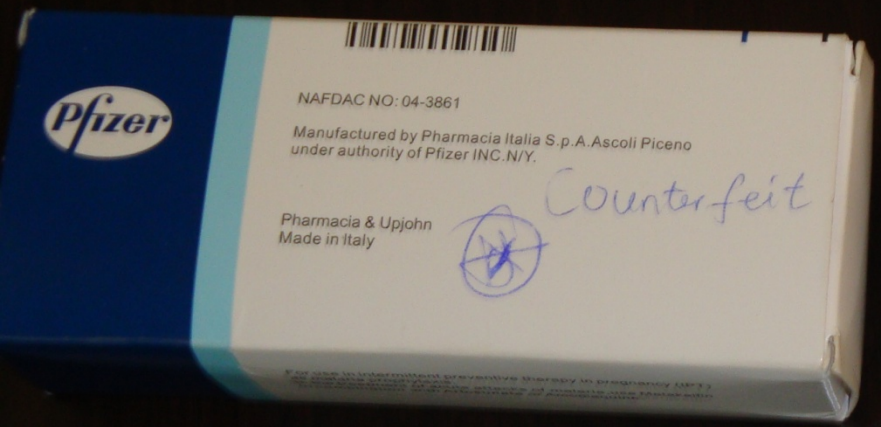
Expired Chloroquine Injection (from an unregistered manufacturer) was relabeled as Quinine Dihydrochloride Injection 600mg/2ml purported to be from a manufacturer in Cyprus.

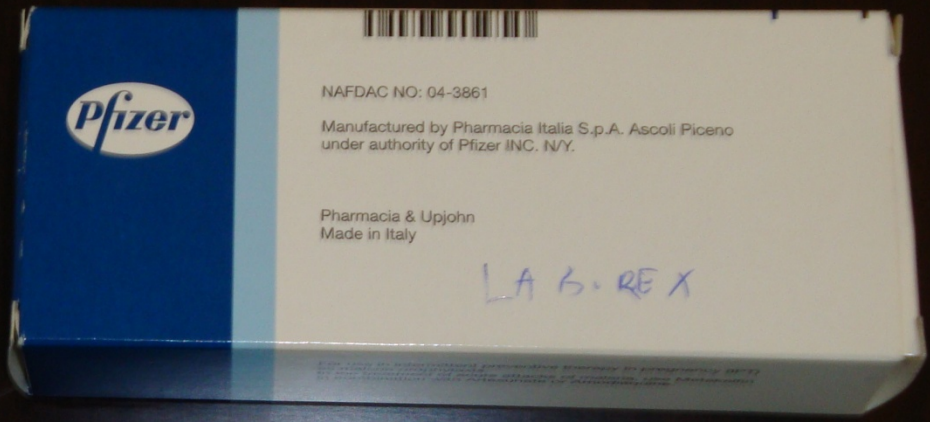
- Culprit prosecuted but case abetted due to death of culprit


2 ML
INJECTION
FOR I.M./SLOW I.V.
MFD. BY:
INDIA

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.


Pfizer
NAFDAC NO: 04-3861
Manufactured by Pharmacia Italia S.p.A.Ascoli Piceno
under authority of Pfizer INC.N/Y.
Pharmacia & Upjohn
Made in Italy
Counterfeit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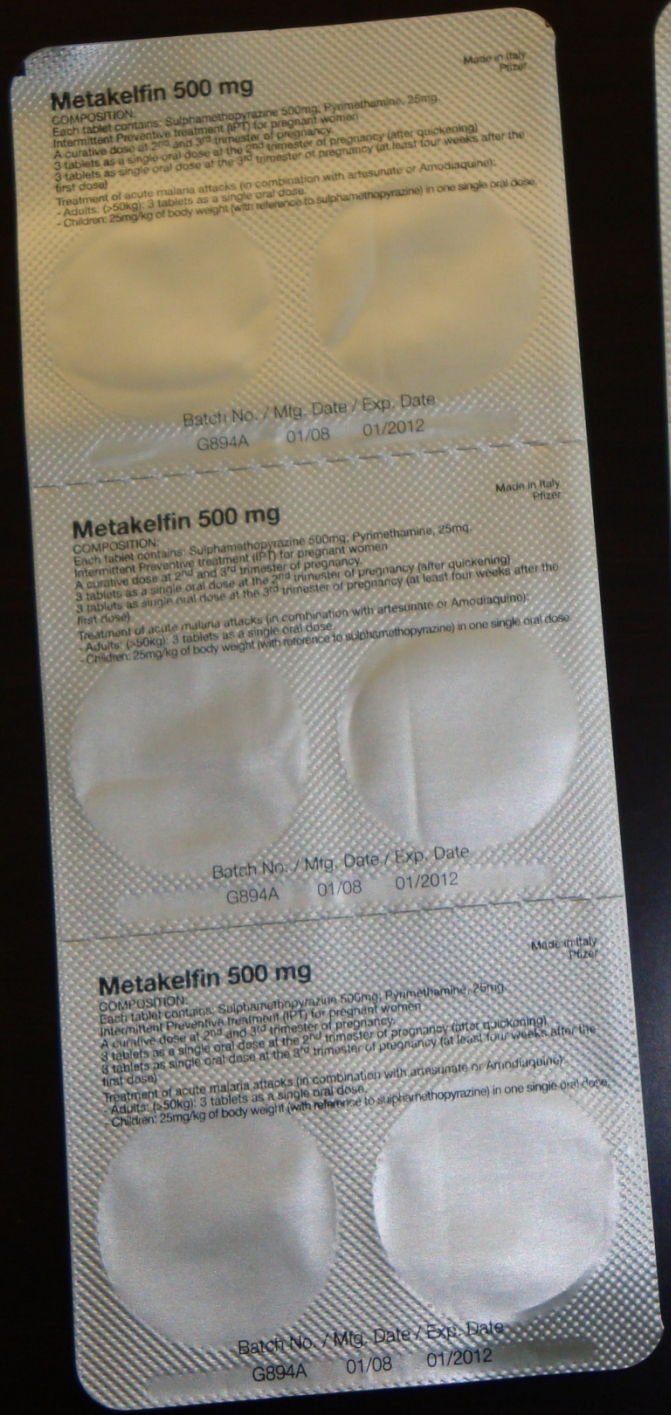
LAB. REX



Made in Italy
Pfizer

Metakelfin 500 mg

COMPOSITION:
Each tablet contains: Sulphamethopyrazine 500mg; Pyrimethamine, 25mg.
Intermittent Preventive treatment (IPT) for pregnant women
A curative dose at 2nd and 3rd trimester of pregnancy.
3 tablets as a single oral dose at the 2nd trimester of pregnancy (after quickening)
3 tablets as single oral dose at the 3rd trimester of pregnancy (at least four weeks after the first dose)
Treatment of acute malaria attacks (in combination with artesunate or Amodiaquine):
- Adults: (>50kg): 3 tablets as a single oral dose.
- Children: 25mg/kg of body weight (with reference to sulphamethopyrazine) in one single oral dose.

Batch No. / Mfg. Date / Exp. Date
G894A 01/08 01/2012

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Therapy and prophylaxis of malaria caused by P. falciparum, P. vivax, P. malariae, P. ovale. SINGLE DOSE THERAPY - Adults: 2-3 tablets - Adolescents: 1-2 tablets - School-age: ½-1 tablet - PROPHYLAXIS: half therapeutic single dose, administered weekly. COMPOSITION - Each tablet contains: 2-sulphanilamido-3-methoxy-pyrazine 500 mg; pyrimethamine 25 mg. **Traitement curatif et prophylaxie du paludisme provoqué par P. falciparum, P. vivax, P. malariae, P. ovale.** TRAITEMENT A DOSE UNIQUE - Adultes: 2-3 comprimés - Adolescents: 1-2 comprimés - Age scolaire: ½-1 comprimé. PROPHYLAXIE: Administrer une fois par semaine la moitié de la dose unique thérapeutique.

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Pfizer

Store below 30°C - Conserver à température inférieure à 30°C.

G043A 07/07 07/2011

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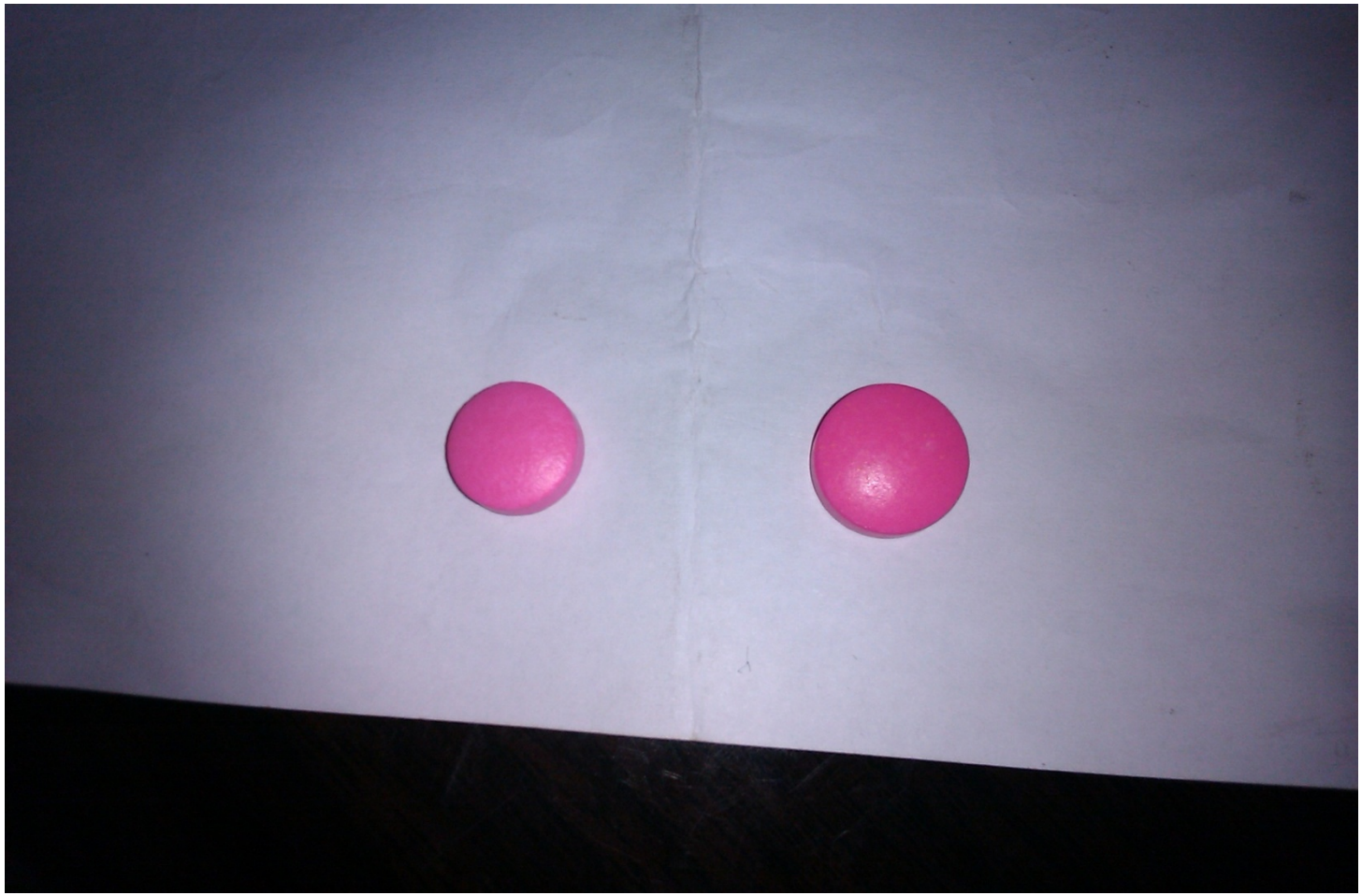
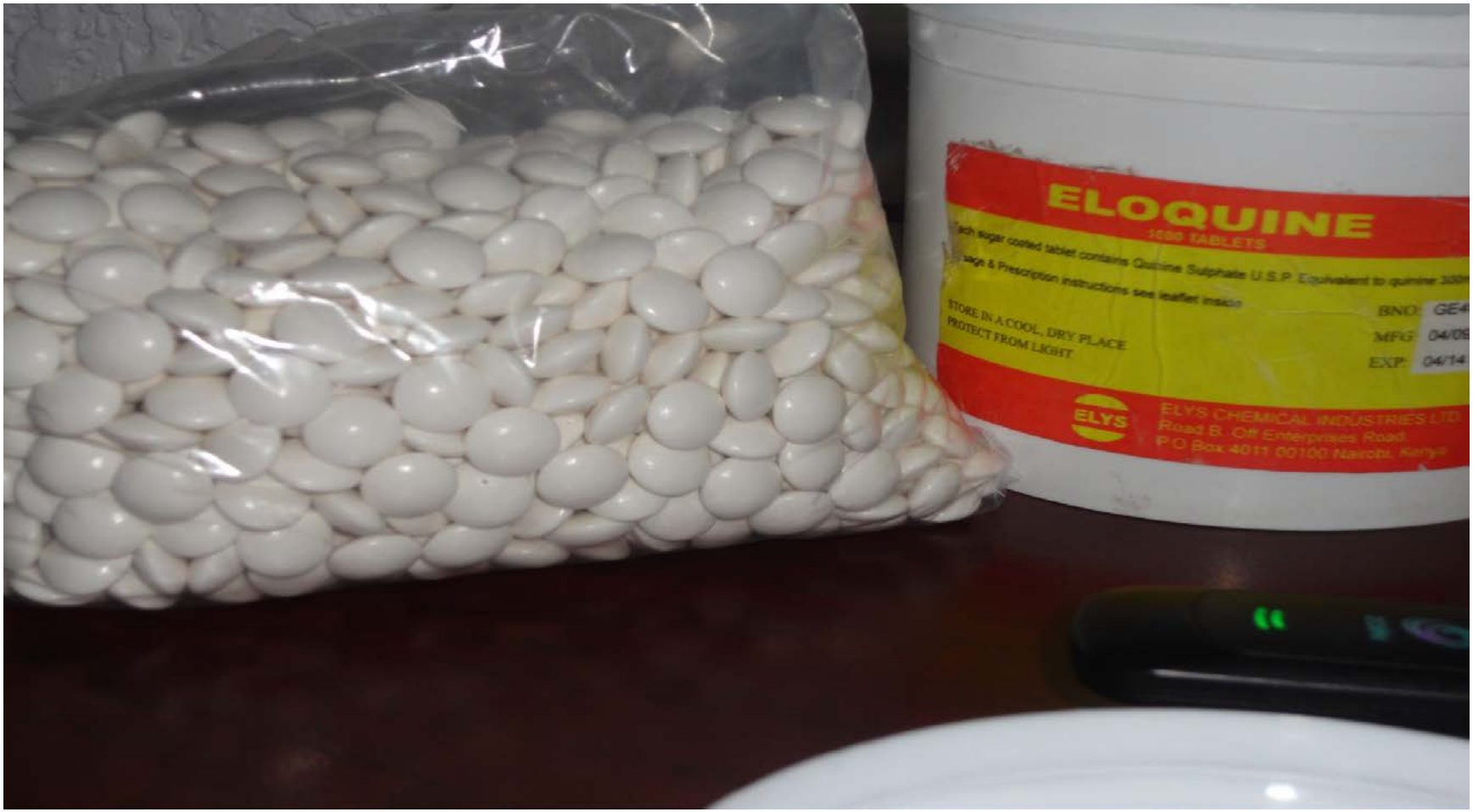
G043A 07/07 07/2011

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 Dispending 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