THE ROLE OF TFDA IN ENSURING QUALITY AND SAFETY OF MEDICINE, MEDICAL DEVICES & DIAGNOSTICS

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DODOMA

Outline

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3. Vigilance on quality and safety of medicine, medical devices and diagnostics
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6. Examples of Counterfeited Medicines, Medical Devices & Banned Cosmetics
7. Illicit transport of Medical Devices
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1: INTRODUCTION

- Establishment of TFDA (Sect.4, CAP219 of TFDC Act)
- Responsibility: To control quality, safety and effectiveness of food, medicines, cosmetics, medical devices and diagnostics
- Vision, Mission, Philosophy
- Quality Management Systems, ISO 9001:2015; ISO 17025:2005(Laboratory Services)
- Delegation of Powers and Functions Order 2006, GN. 162 and its amendment by GN. 165, 2007 and GN. 476, 2015).

2. ROLES OF TFDA (Sect.5,Cap219)

- (a) regulate all matters relating to quality, and safety of food, drugs,herbal drugs, medical devices, poisons and cosmetics;
- (b) regulate in accordance with this Act, the importation, manufacture,labelling, marking or identification, storages, promotion, sale and distribution of food, drugs, cosmetics, herbal drugs and medical devices or any materials or substances used in the manufacture of products regulated under this Act;

Roles…cont

- (c) ensure that evidence of existing and new adverse events, interactions and information about pharmacovigilance of products being monitored globally, are analysed and acted upon;
- (d) ensure that, clinical trials on drugs, medical devices and herbal drugs are being conducted in accordance with prescribed standards;
- (e) Public Education

3. Vigilance on quality and safety of medicine, medical devices and diagnostics

(i) Product evaluation and registration

- Human Medicine 2015/16(1,593); 2016/17 (1,163); 2017/18(738)
- Medical Devices 2015/16(124); 2016/17 (76); 2017/18(101)
- Diagnostics 2016/17(75); 2017/18(78)

(ii) Import/Export Control

(iii) Establishment of 7 Zones

(iv) Premise Inspection, Registration and Licensing

(v) Post marketing surveillance (Quality Monitoring) of medicines

- Conducted in two (2) approaches:

► Primary screening of medicines done during routine inspection(QA Centres in 7 Zones).

► Structured PMS Programmes with focus on sampling and testing products based on risks

PMS Programme 2007 – 2009 focus products

- Selected ARVs,
- Anti-malarials - ALu, Quinine and SP tablets,
- Selected analgesics and
- Antibiotics - Cloxacillins & others

- PMS Programme has proven to be successful as a number of SF medical products including Cloxacillin dry syrups and capsules were removed from the market
- The survey of Cloxacillin was conducted between September 2011 and March 2012 in 11 regions of Tanzania
- 86 and 52 samples of Cloxacillin capsules and syrups respectively were collected at different geographical locations

Regulatory actions on SF

- Product registrants were informed on the outcome of the survey for them to comply registration requirements
- Substandard products were recalled and manufacturer directed to investigate and submit CAPA
- Cloxacillin formulations were withdrawn from the market due to high failure rate
- Results of the survey were disseminated to the public and in scientific conferences

(vi)The use of mobile phone technology in reporting SF

- Experience is showing that healthcare professionals are one of the most reliable sources of reports, but tend to report the least
- Mobile technology solutions could greatly simplify reporting and are successfully used in other health related and non-health related fields
- TFDA with the support of WHO has started a smart phone application (MPRO5) for reporting SF
- User asked to submit photographs of suspect product and reporting completed in under 90 seconds

(vii)Pharmacovigilance: ALU (94%) 2009-2012; Chloramphenicol injection(Lincolin) 2016; Ketoconazole Tbs; ADR 234 (2017/18)

(viii)Public awareness campaigns

- Use of media: Press conferences, TV and radio programmes in urban and rural areas
- Conducting awareness programmes in schools and local communities (**Aflatoxin** 9,550 participants in 48 villages and 7 schools; **Rational use** 65,753 participants from colleges & schools 2017/18)
- Use of printed information materials: bronchures
- Sharing the outcomes in seminars and workshops

(ix) Inspection and Enforcement

- GMP Inspections
- Routine Inspection and law enforcement (7 Zones).

  Disposals: 2015/16(92T:80T reported + 12T confiscated);2016/17(78T:77T reported+1T confiscated); 2017/18(149T: 144T reported + 5T confiscated)
- Special Inspections(Manufacturing & Warehouses)
- Inspections at PoE (32)

(x)Regional collaboration on PMS

- Formation of EAC Technical Working Group on PMS and Pharmacovigilance
- Assessment has been done in EAC on existing PMS capacity
- Conducted joint operations: Pangea V(3.7 mil Tablets= 10.5mil.$; 18,000 websites closed down, 80 culprits in 100 countries in 2012)Mamba Operation (EAC) and Giboia Operation (SADC),Operation AFYA(SADC).

(xi) Control of Clinical Trials(15-20 trials/Ebola/HIV

(xii) Control of advertisements(POM not allowed)

4.Situation Analysis

1.Unregistered Medicine

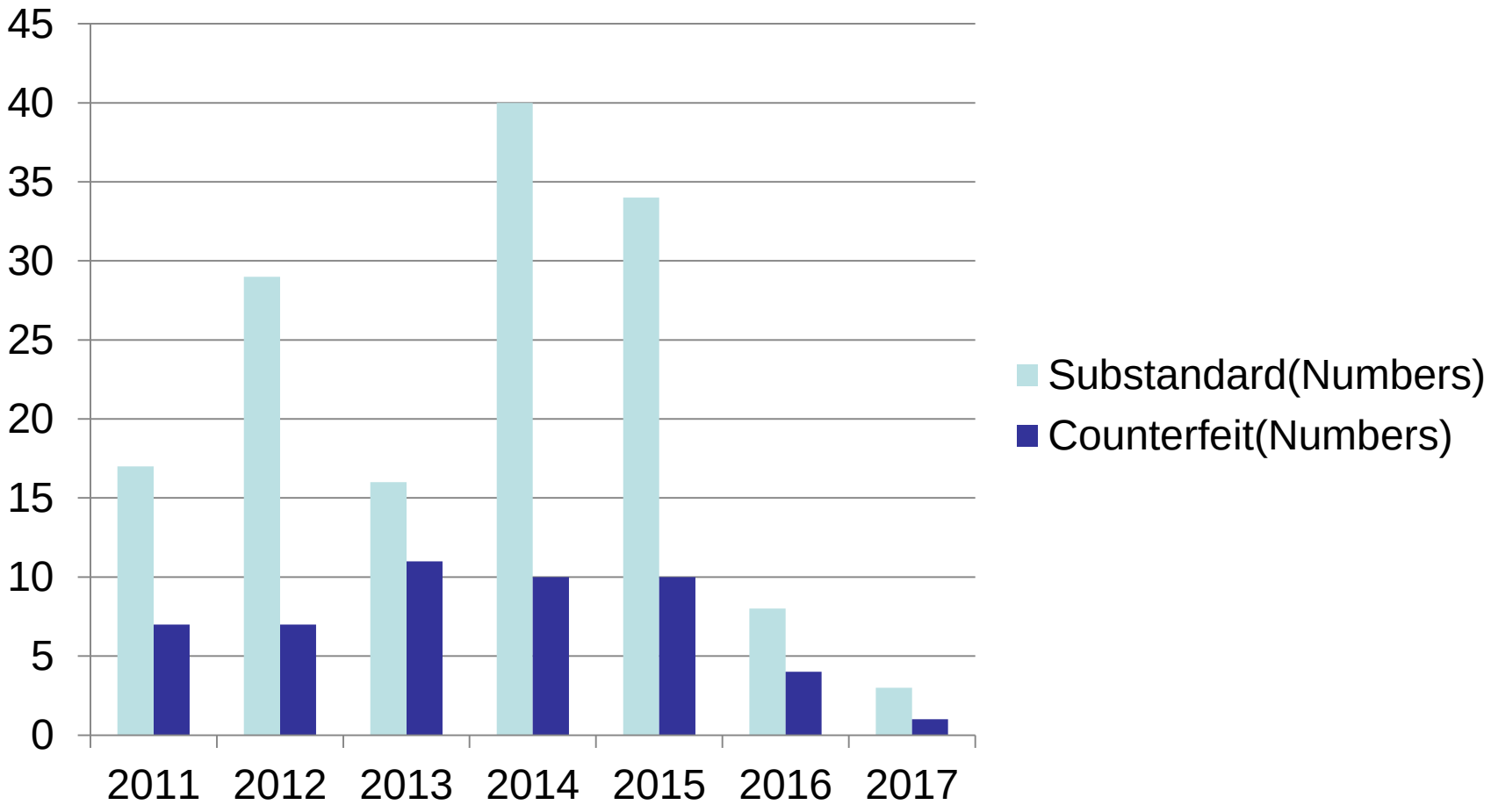
- **Unregistered/unlicensed** medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

- Trend on unregistered medicines 2016/2017(8),2017/2018(3) Ex Uganda and Zambia

2.Counterfeit Medicines

	Substandard	Counterfeit	Percentage	
			Substandard	Counterfeit
2011	17(3772)	7(3772)	0.4507	0.1856
2012	29	7	0.7688	0.1856
2013	16	11	0.4242	0.2916
2014	40	10	1.0604	0.2651
2015	34	10	0.9014	0.2651
2016	8	4	0.2121	0.1060
2017	3	1	0.0795	0.0265

Current Situation/Trend



List of Counterfeit Medicine 2016/2017

Year	Trade Name	Generic Name	Manufacturer
2016	Nicardia Retard	Nifedipine 200mg	Unique Pharmaceuticals
2016	Ergovita inj.	Ergometrine	Vital Healthcare PVT Ltd
2017	Rabipur	Inactivated rabies virus(Rabie vaccine)	GSK Chiron Behring Vaccine Ltd,Ankleshwar India Site
2017	Albendazole Bolus	Albendazole 300mg	Ashisha Lifescience, PVT India
2017	Quinine 300Tablets	Quinine Sulphate 300mg	Keko Pharmaceutical Industries (1997) Ltd

Counterfeit/Substandard Medicines 2017/18

- 1 Human medicine: Ampicillin (Ascillin)
- 1 Veterinary Medicine: Ivermectin 1%

Substandard Medical devices& Diagnostics 2017/18

- 1 Medical device
- 8 Diagnostics

5. Counterfeit /SF/Medicine/Identification

- Ilicit trade of counterfeit medicine is estimated to be US$ 75 billion (http://www.who.int/bulletin/volumes/88/4/10-020410/en/).

- Southern Sahara 25-30% of medicines are counterfeit/falsefied.

- In Tanzania (2016/17) the total of 1.68 tonnes (8500USD) of substandard medicines were seized and disposed of(0.07%).
- In Tanzania (2017/18) 1 counterfeit medicine (0.02%)

Identification of Counterfeit Medicine …TFDCA, 2003 (Sect. 76)

- It is manufactured under a name which belongs to another medicine
- It is an imitation of, or substitute for another medicine, resembles another medicine likely to deceive or bears upon its label or container the name of another medicine unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other medicine.
- The label or container bears the name of an individual or company purporting to be a manufacturer of the medicine; which individual or company is fictitious or does not exist.
- It has been substitute wholly or in part by another medicinal substance;
- It purports to be a product of manufacturer of whom it is not truly product.

(i) Sophisticated production facilities

- All processes in control
- Good label appearance
- Little API
- No API

A perfect counterfeit product (i.e. well made & well-labeled) is very difficult to detect.

6.EXAMPLES
Falsified Medical Products

FALSIFIED

Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

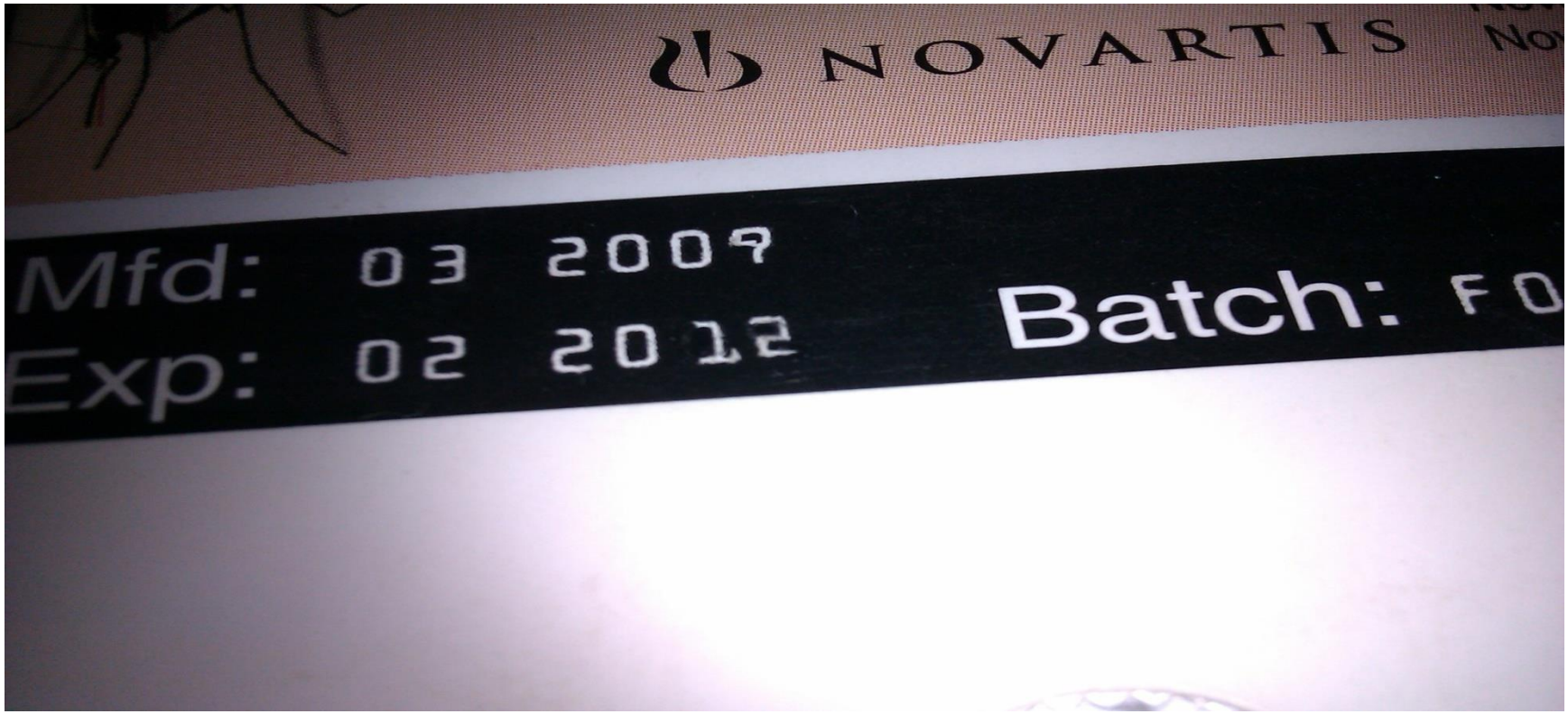
Falsified Antimalarial in Tanzania, **Laifin** (with Sulphamethoxazole) being sold as **Laefin** (with Sulfametopyrazine), Antimalarial in Sept., 2011

Genuine Product

Falsified Antimalarial in Tanzania

(ii) **Hacker manufactured counterfeits**

- Poor quality
- Non-uniform Colors
- Poor labels
- Poor compression – powder, capping
- No API



Genuine manufactured on 03/200**7** and expiring on 02/200**9**. **Falsefied** indicated to have been manufactured on 03/200**9** and exipiring on 02/20**12**

(iii) Sub-Standard Products

- Substandard products are those whose composition and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient.

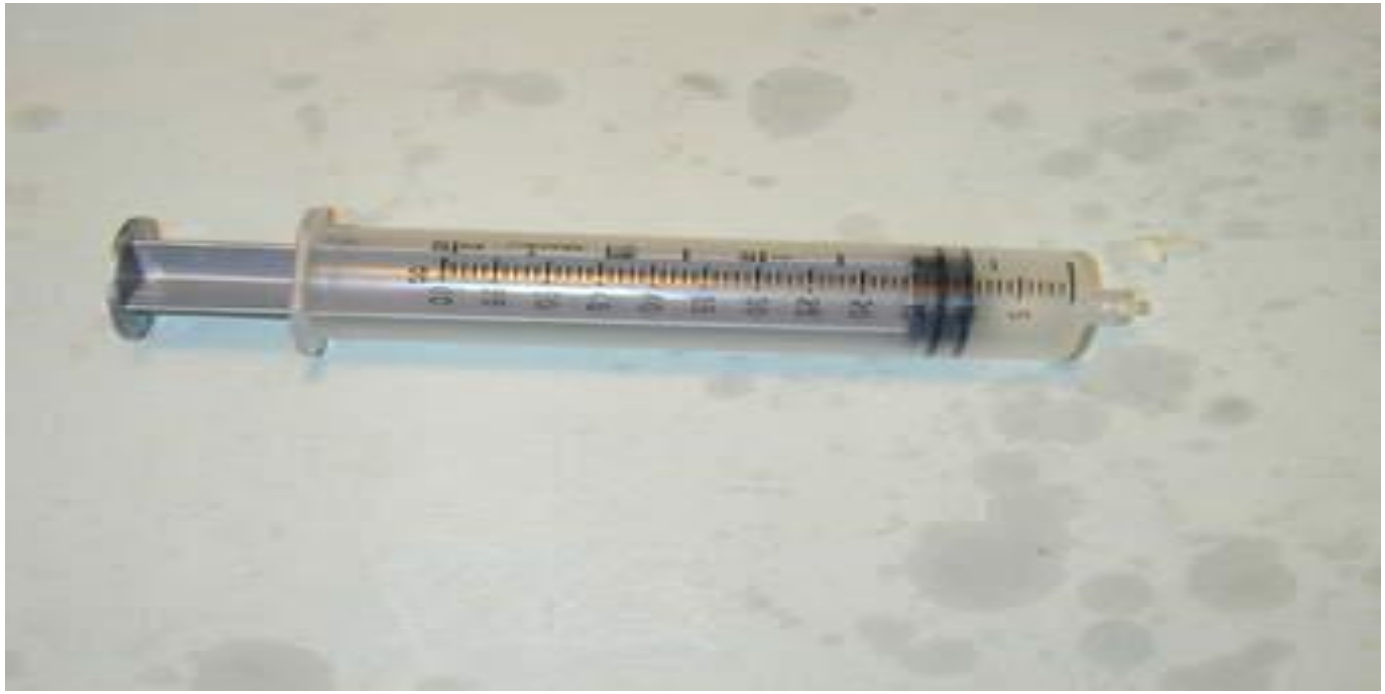
- Substandard products may occur as a result of negligence, human error, insufficient human and financial resources or counterfeiting.

Diazepam changing from yellow colour to black colour

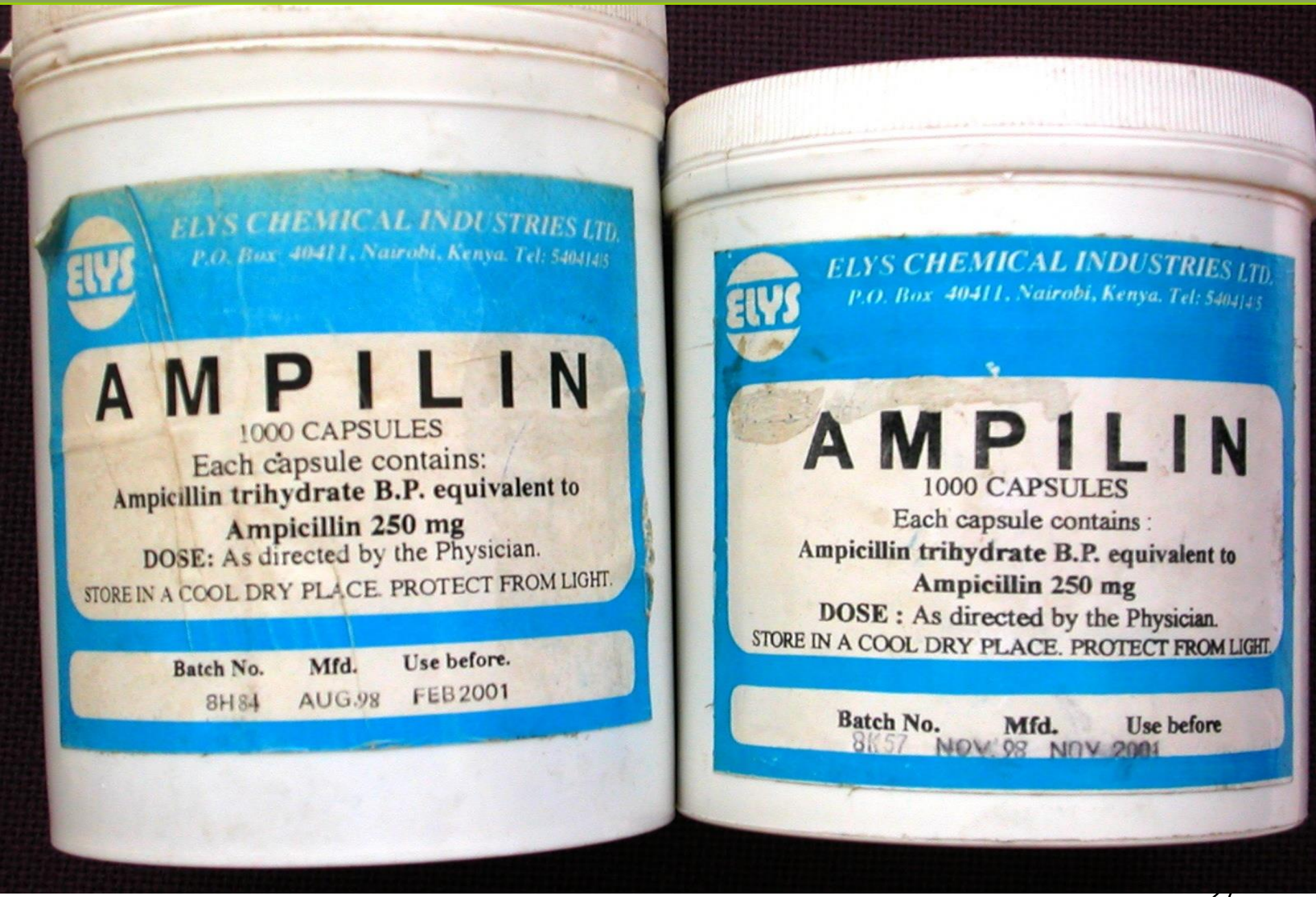
Counterfeit Ampicillin (Seized from market during Special Operation Feb 2018)

Substandard medical devices

- Syringe with easily broken plunger:



Substandard Diagnostics


ELYS CHEMICAL INDUSTRIES LTD.
P.O. Box 40411, Nairobi, Kenya. Tel: 5404145
ELYS
AMPILIN
1000 CAPSULES
Each capsule contains:
Ampicillin trihydrate B.P. equivalent to
Ampicillin 250 mg
DOSE: As directed by the Physician.
STORE IN A COOL DRY PLACE. PROTECT FROM LIGHT.
Batch No. Mfd. Use before.
8H84 AUG.98 FEB 2001
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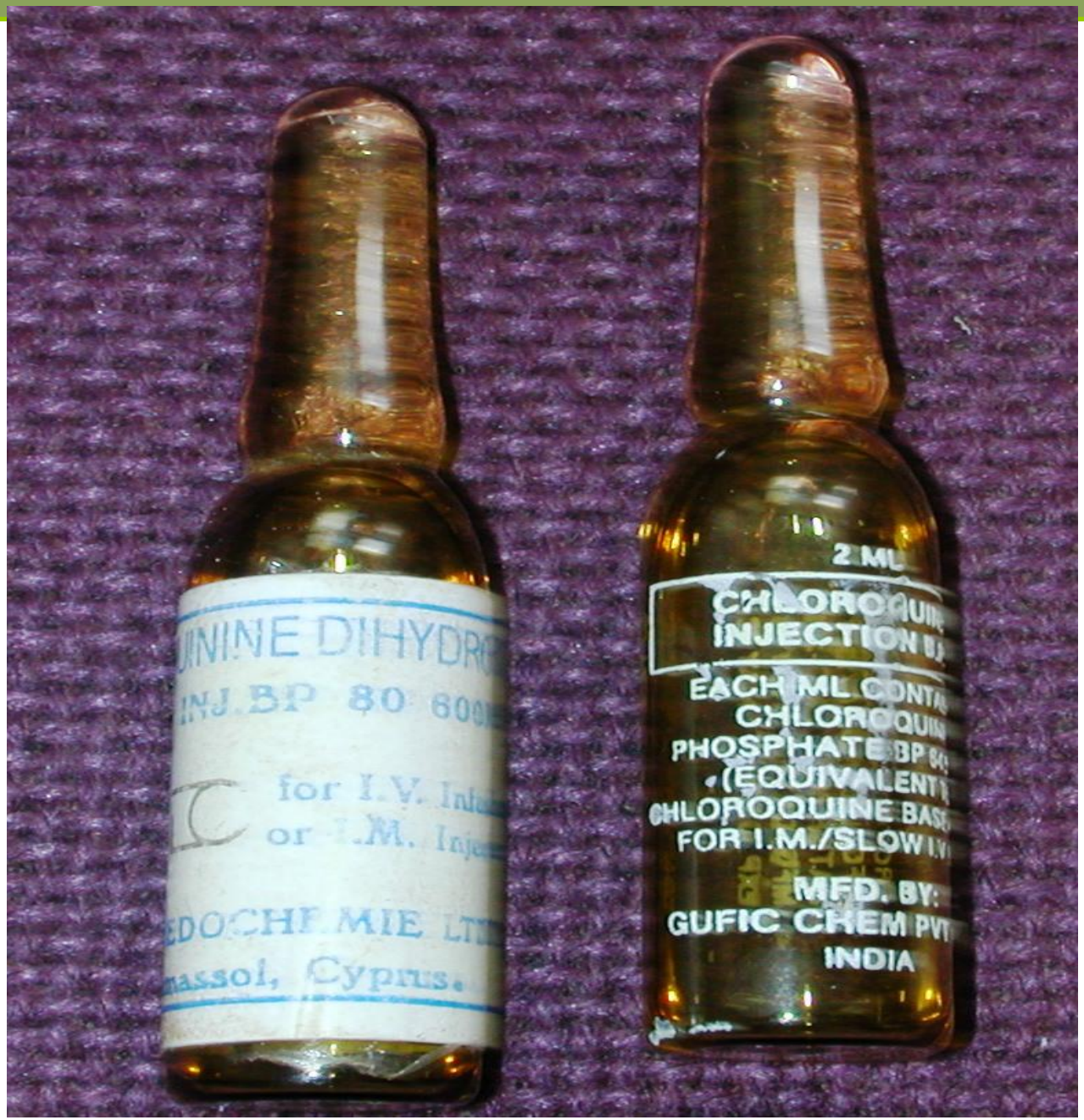
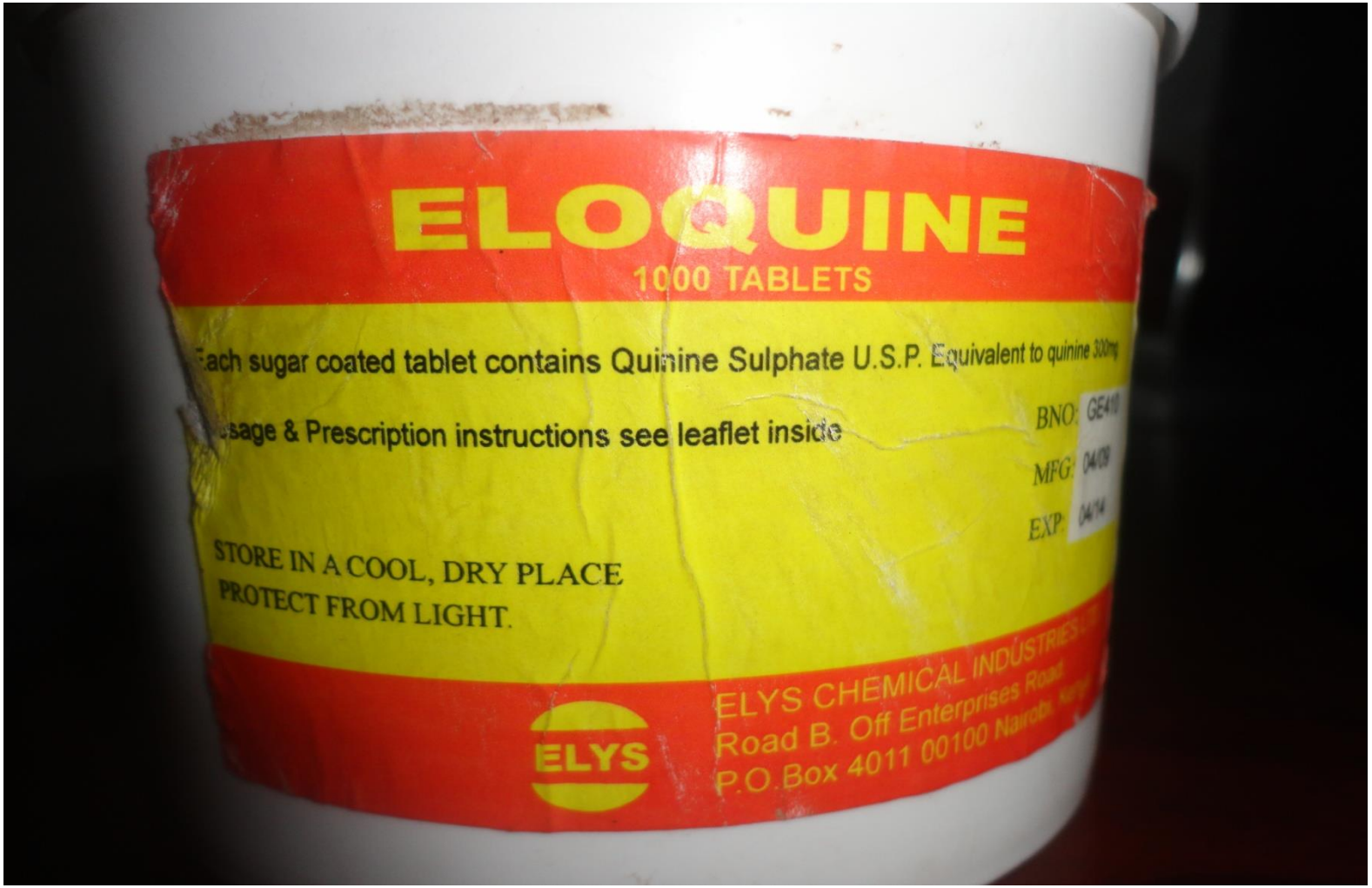

INJ. BP 80
for I.V. Inf
or I.M. Inje
nassol, Cyprus.
2 ML
INJECTION
EACH ML CONTA
PHOSPHATE BP
(EQUIVALENT
FOR I.M./SLOW I.V
MFD. BY:
INDIA

1: Elphedren: Purported to have been manufactured by N& Bulk, India

4: Elphedrin: Purported to have been manufactured Fortes, India

Ibuprofen tabs sold as Erythromycin tablets

FEB, 2012: Counterfeit Quinine Sulphate (ELOQUINE) purported to have been manufactured by Elys, Kenya???

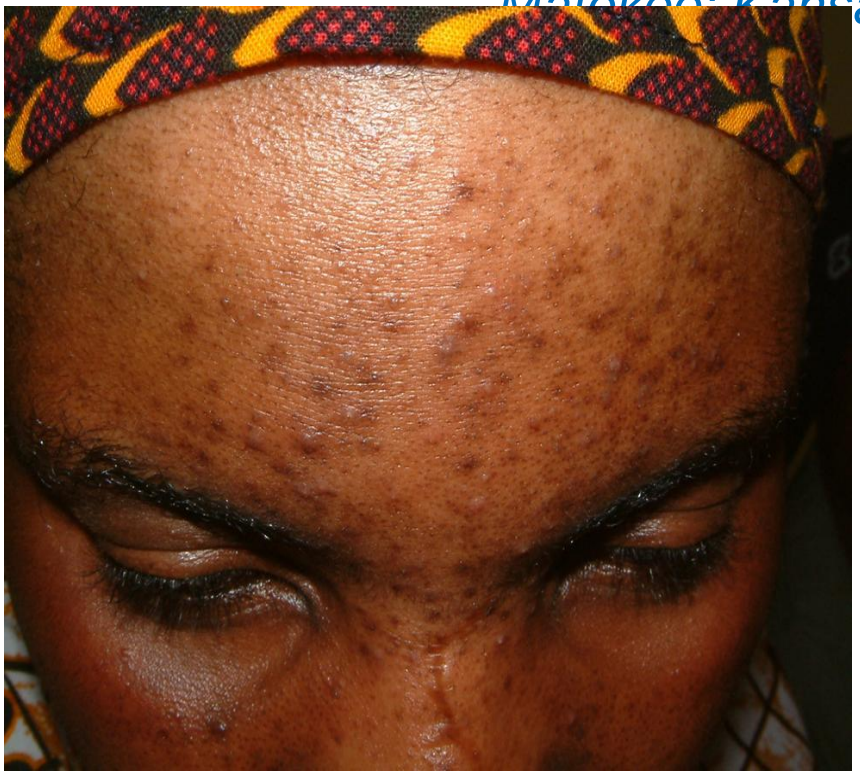


EXAMPLES OF BANNED COSMETICS

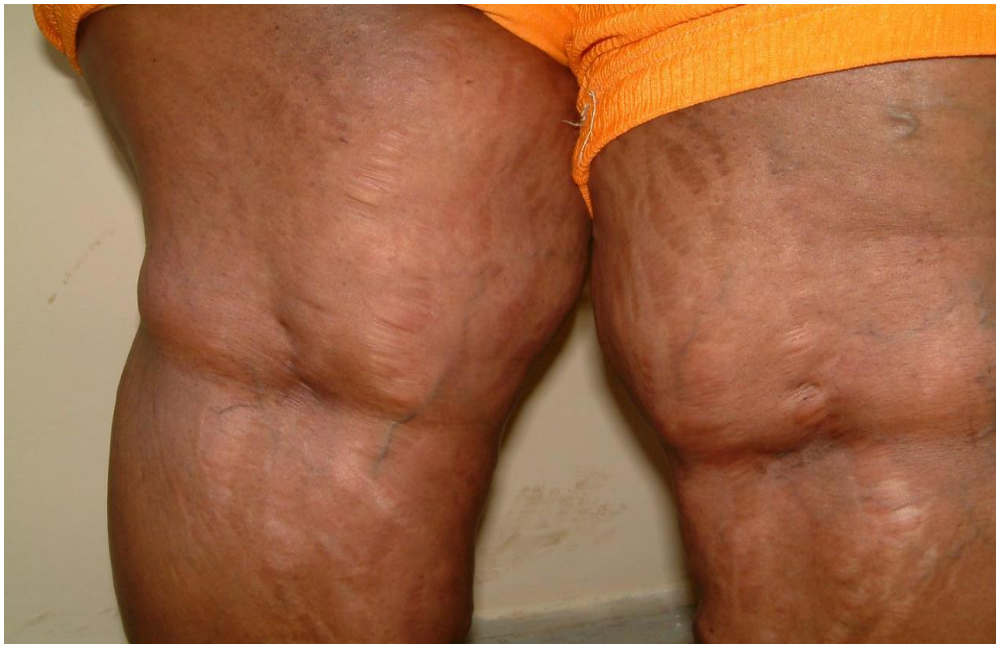
Mercury:Jaribu, Mekako+ k **clobetasol and betamethasone; like.**

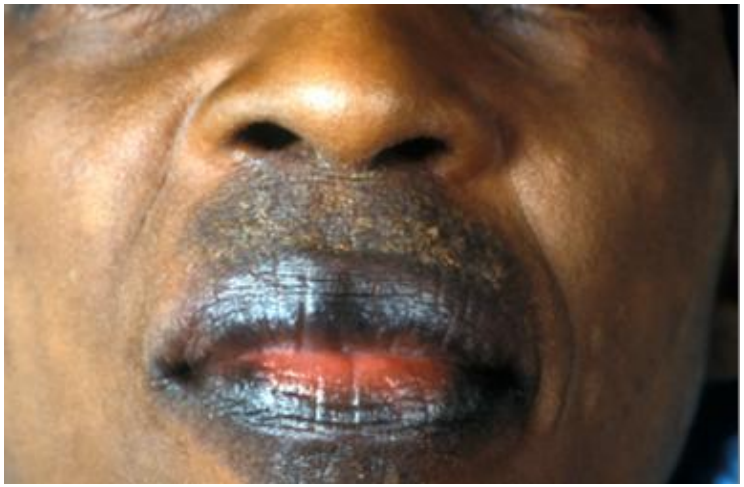
Amira cream, Betasol cream, skin success cream nk.

Matokeo: Kansa ya ngozi, mzio

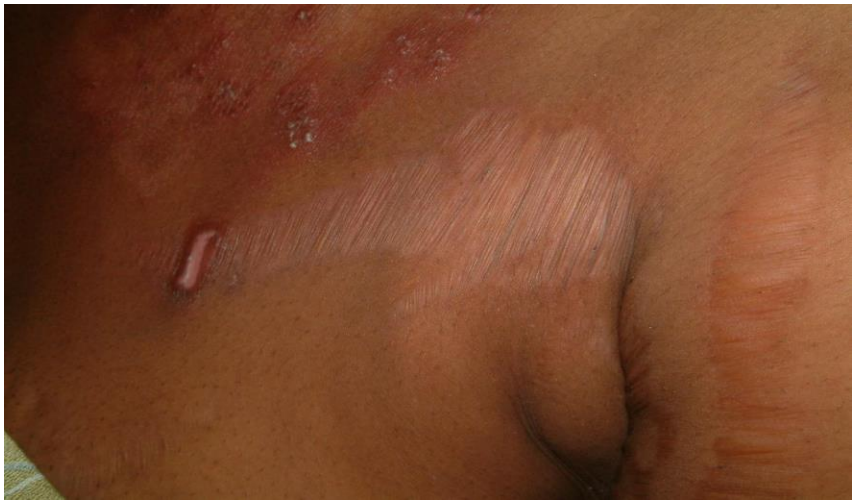


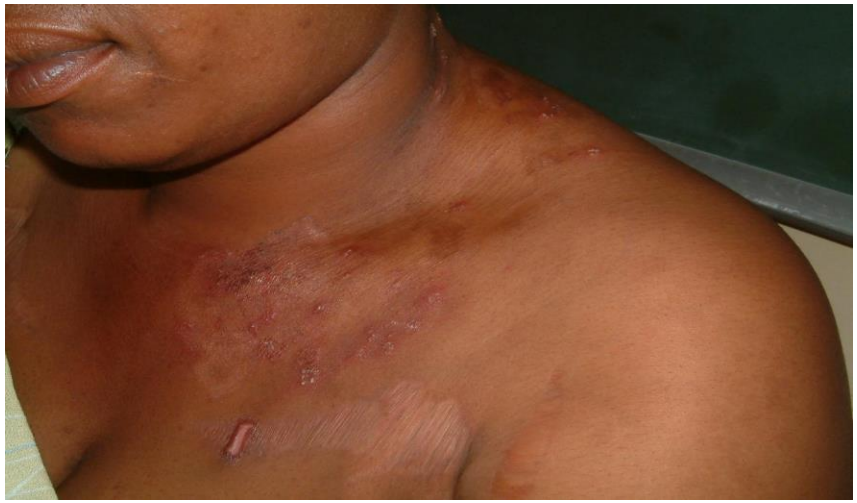
Hydroquinone, *e.g Caro Light and G&G Cream :*
Impacts: *Skin bleaching, Allergy (mzio), Skin cancer, Teratogenic effects, Renal & Liver failure*



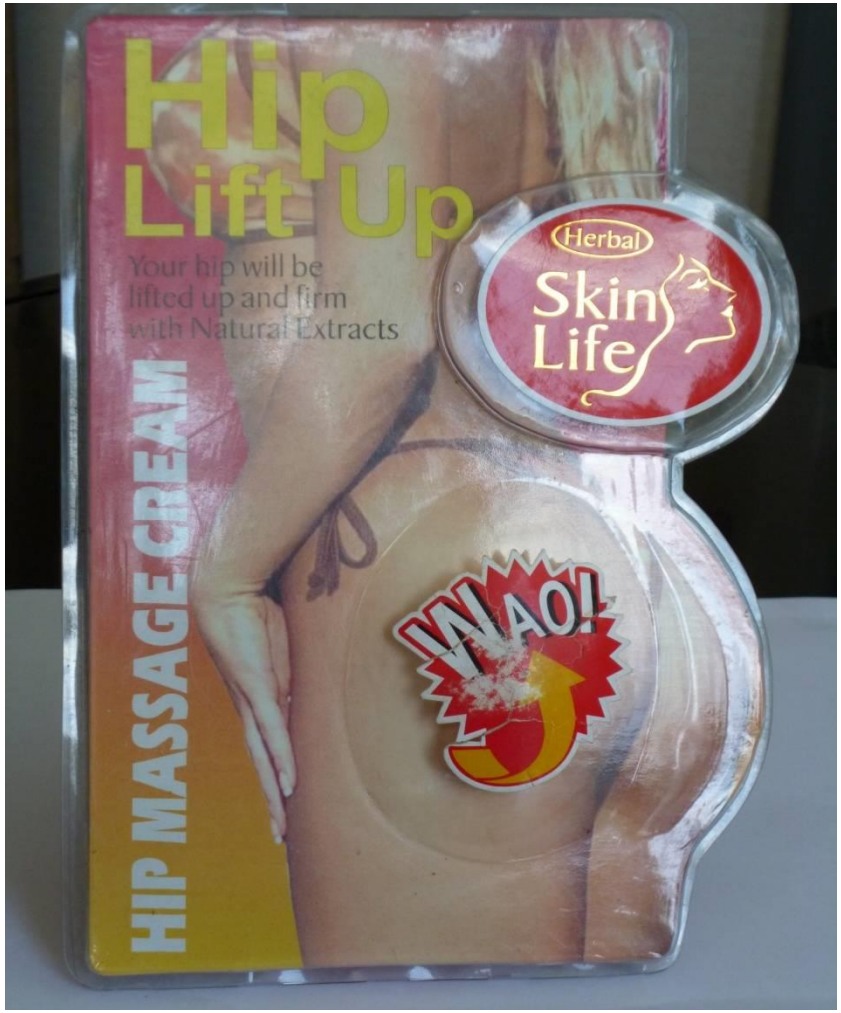


Steroids:e.g Movate, Lemonvate
Impacts: Allergy, Fungus, skin cancer, renal failure





Cosmetics believed to increase hips
HIP LIFT UP MASSAGE CREAM: Your hip will be lifted up and firm



Hip Up CREAM: TOUCH ME

YOU WILL LOOK, YOUNG AND BEAUTIFUL

COSMETICS

- Registered **3,078** products
- Registered Manufacturing industries **28**

- Banned Cosmetics **242**
- **Way forward**

➢ Inspect our dressing tables

➢ Morning prayer

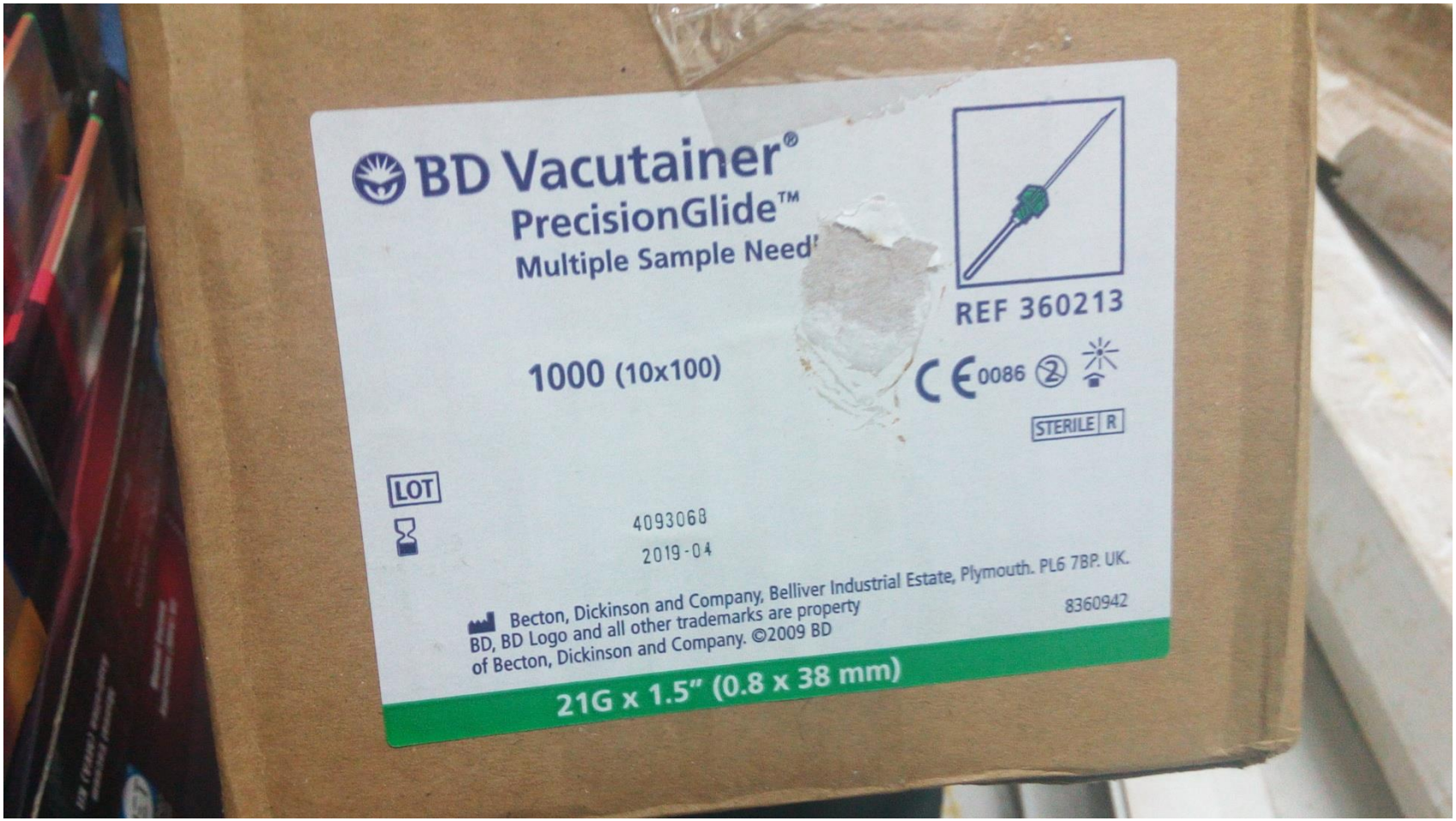
➢ Change of attitude towards light skin

➢ Report to DMOs immediately when you see these products

7. Illicit transport of Medical Devices (from Malawi) seized in Morogoro 2016

MVA Kit soaked in Fuel (Seized in Morogoro)

Vacutainer Needles(ex Mozambique) 2017



8. SUCCESS OF TFDA

1. Control systems are compliant with ISO 9001:2015 (clearly defined and written regulatory processes and procedures)
2. Attainment of Maturity Level 3 after inspection by WHO
3. Registration of Medicines increased from 3,120 up to 3,858 (738 for 2017/18)=24%
4. Competence of TFDA Laboratory

- **Medicine Analysis**: WHO Prequalified (2011), among 23 lab in the world and 7 in Africa, TFDA Lab is the only one Africa(RA

Success …cont

- **Food Analysis:** Accredited to ISO 17025:2005 since 2012 by SANAS(RSA); 1 out of 4 Labs in Africa

5. Because of good control systems, TFDA has conducted training to 13 countries:Kenya, Ghana, Nigeria, Zambia, Botswana, Msumbiji, Burundi, Ethiopia, Liberia, Cameroon, Uganda, Rwanda and Southern Sudan

Modern Lab TFDA

Success…cont

6. TFDA is the leading Organization in the EAC Medicine Registration Harmonization Project
7. Through control systems, Counterfeit and SF were seized from the market and legal actions taken.

These achievements are due to Ministry,PS,MAB,TFDA, TAMISEMI/RMOs,DMOs,UTUMISHI and other stakeholders.

9. Challenges& Way forward

- Porous borders
- Inefficient/Weak legal system (CAP 219(76)(1,2)
- Scarce Human Resource
- Over reliance on imported products(Local 14 Medicine Factories, 1 Medical device)
- Internet Marketing/Social Media(Cyber, 4)
- Failure of some of Councils to inspect routinely
- Unharmonised regulatory initiatives btn EAC&SADC

Thank you