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# Counterfeit drugs : experiences from the African continent

**Regional Seminar for OIE National Focal Points for  
Veterinary Products (5th Cycle)**

***EZULWINI, SWAZILAND, 6-8 December 2017***

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# PLAN

1. Conterfeit medicines : defintion

2. Situation of counterfeiting drugs in Africa

3. Situation of counterfeiting of the veterinary drugs in Africa:

Example of Trypanocides

4. Risk related to counterfeiting of veterinary drugs

(Trypanocides)

5. Recommendation

# 1. Counterfeit medicines: definition

- *A counterfeit medicine is one that has been deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product.*
- *Counterfeit products include drugs with no active ingredient, drugs that are super potent, and drugs with dangerous impurities.*

**\*Source: WHO**

# 1. Counterfeit medicines: definition

***IMPACT (International Medical Products Anti-Counterfeiting Task force:***

***“The term counterfeit medical product describes a product with a false representation of its identity or its source. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products.***

***“Counterfeits may include products with correct ingredients/components or with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients or with fake packaging.”***

# 1. Counterfeit medicines: definition

**What is a falsified medicine?**

- **Forgery is the « voluntarily action to alter a substance or any other element with the intent of misleading».**
- **When dealing with the risks to public health, the term “forgery” will be preferred to that of “counterfeiting” (“counterfeiting” has a legal connotation, indicating a violation of intellectual property rights).**

## 2. Situation of counterfeiting of drugs in Africa

### What do we know?

- Counterfeiting is criminal activity - difficult to detect, investigate, quantify
- Information we do have is based on 2 types of sources:

### Law enforcement actions (and media coverage thereof)

### Some testing in some markets – extrapolation

## 2. Situation of counterfeiting of drugs in Africa

Law enforcement actions (and media coverage thereof)

<http://www.iracm.com/en/geographic-observatory/country-info/>

Country	Actions
Angola:	More than 2000 illicit boxes of medicines seized in 2016
Algeria	Algerian customs seized 17,272 boxes of medicines in 2016. This illicit market is mainly linked to smuggling.
Egypt	On 17 October, the Egyptian pharmaceutical industry called for a new legislation to combat fake medicine trafficking and to step up sanctions in order to protect the public.
Ethiopia	On October 28, 2015, a team of pharmaceutical experts from Ethiopia has visited the facilities set up in Nigeria by the health authority <a href="#">NAFDAC</a> to build on actions against fake medicines and secure drugs.

## 2. Situation of counterfeiting of drugs in Africa

<http://www.iracm.com/en/geographic-observatory/country-info/>

Country	Action
Ghana	The Center for Pharmaceutical Advancement and Training (CePAT) trains professionals to ensure compliance with the quality of pharmaceutical products in 2015
Nigeria	Almost 400 pharmacies sealed in Edo in 2017
Uganda	In Arua, police confiscate fake medicines worth more than 20 million Ugandan Shillings
Tanzania	Tanzania: government appeals for falsified medicines actions in 2017



# 3. Situation of counterfeiting of veterinary drugs in Africa: Trypanocides

## Some testing in some markets

Testing in:

Veterinary Drugs Quality Control Laboratory  
LACOMEV/

Tanzania Food and Drugs Authority

**GALVmed**

- A trypanocide drug/ Animal Trypanosomosis?

# 3. Situation of counterfeiting of veterinary drugs in Africa : Trypanocides

## Control Methods of **Animal Trypanosomosis**

Vector Control - spraying, dipping, trapping and elimination of habitat

Constraints: cost, sustainability, contamination of milk and meat and environmental damage

Elimination of reservoir hosts Constraints: cost and environmental damage

Trypanotolerant livestock Constraints: distribution, productivity and breakdown of tolerance

Vaccine: Problem of antigenic variation

Integrated Control is important

# 3. Situation of counterfeiting of veterinary drugs in West Africa: Trypanocides

Chemotherapy - prophylactic or curative Constraints:

- ❑ >50 million doses of trypanocides administered annually
- ❑ Drug resistance, limited number of drugs available, toxicity
- ❑ Counterfeit problems????

QUALITY OF THESE DRUGS?

# 3. Situation of counterfeiting of veterinary drugs in Africa: Trypanocides

- A trypanocide drug sampling protocol was developed at **LACOMEV/ Tanzania Food and Drugs Authority/GALVmed**
- Collection of commonly used trypanocide brands at different sites in Benin, Burkina Faso, Cameroon, Ivory Coast, Mali, Niger, Togo, Senegal, Ethiopia & Tanzania
  - Diminazene
  - Isometamidium
- Categories of sites:
  - Legal market: Wholesaler, Pharmacy & Vet shop
  - Illegal market (informal market)

# Test Protocol

- **Galenic tests**
  - Limpidity (Solubility) of reconstituted solution
  - pH of reconstituted solution (Isometamidium samples)
  
- **Identification & dosage**
  - HPLC techniques
  
- **Tolerance intervalles (requirements)**
  - Isometamidium samples: requirements in the SOPs & Monographs
  - Diminazene samples: 10% stated amount

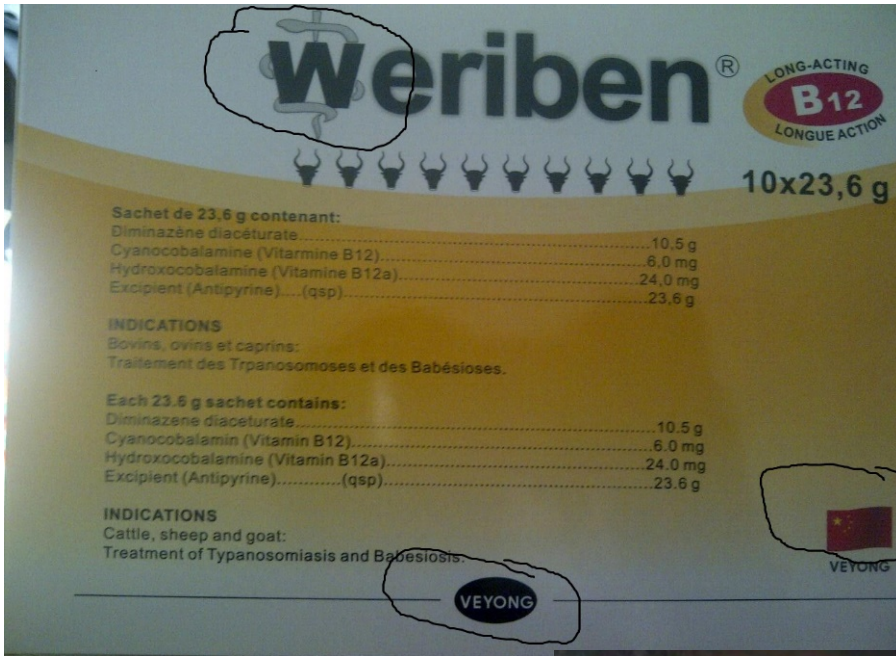
## Results Summary- Overall samples (Teko A., 2015, Charys, 2015)

Country	Number Tested	Non-compliance
Benin	55	34 (61.82%)
Burkina Faso	49	16 (32.63%)
Cameroon	33	21(63.4%)
Ethiopia	50	13 (27%)
Mali	52	28 (53.84%)
Niger	38	18 (47.36%)
Senegal	56	26 (46.4%)
Tanzania	61	13 (21.3%)
Togo	49	31 (63.27%)

## Observations from field survey outcome

- **Many substandard trypanocide drugs in African markets leading to under dosing and undermining confidence in their efficacy**
- **Field study shows substandard trypanocidal drugs; proportions varying between 21-63% depending on countries**
- **All manufactures are concerned**

# Observations from field survey outcome/ Counterfeit drugs



Purchase at Ethiopia



Purchase at Burkina Faso

Purchase at Tanzania





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**COMPOSITION**

Isometamidium chlorhydrate de chlorure / 1g  
Chloride hydrochloride  
Excipient (antipyrine) q.s.p / s.q.f. 6.2g  
8 doses bovins standards 8 standard cattle doses

Boite de 10 sachets de 6,2 g  
Box of 10 x 6.2 g sachets

## 4. Risks related to counterfeiting of veterinary drugs (Trypanocides)

- No or no good **EFFICACY** => **Creation of resistance**

**=> No Cure**

- **SAFETY PROBLEMS** => **Toxic “chemical by-products”**

- **Loss of money** for the farmer: **Loss of Milk** and/or **meat** production, loss of **weight gain**

- **Loss of the animal** for the farmer

- **Reproduction** problems (non-fertile , abortus, very low weight at birth, weak offspring)

- **FOOD SAFETY**

- Dangerous for **consumers**: - bad milk quality and bad meat quality  
(residues, toxic products)

**=> Allergies, Diseases**

## 5. Recommendations

- **Extend field trypanocide Quality Control (QC) to some other countries**
- **Awareness, visibility and communication**
  - **Engage discussions with national regulatory authorities through OIE /FAO and RECs (EAC, SADC, UEMOA, ECOWAS and ECCAS) with the support of UA-PATTEC**
- **To initiate & implement QC in trypanocide registration processes**
- **To criminalize non-compliant products: police should be involved in enforcement**
- **Sustain the testing of trypanocides**

# Conclusion





# Thank you for your attention

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