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Counterfeit drugs: Experience of West Africa

**Regional Seminar for OIE National Focal Points for
Veterinary Products – 4th Cycle,
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Situation of the counterfeiting of the veterinary drugs in West Africa



PLAN(1/2)

INTRODUCTION

- 1.Veterinary drugs: defintion
2. Marketing authorization for a veterinary drug and Procedure
- 3.Counterfeit medicines: definition
- 4.Situation of counterfeiting of drugs in West Africa
- 5.Situation of counterfeiting of the veterinary drugs in West Africa

PLAN (2/2)

6. Factors facilitating counterfeiting of the veterinary drugs in West Africa

7. Risks related to counterfeiting of the veterinary drugs

8. Role of and West African Economic Monetary Union (WAEMU)

9. Recommendations

CONCLUSION

Introduction: importance of veterinary drugs

- **Veterinary medicinal products are essential to animal health, animal welfare and public health.**
- **Animal health professionals in the field and livestock producers need fast access to quality, safe and effective veterinary medicinal products at a reasonable price.**
- **This is vital to ensure the health of herds and to limit epizootic diseases.**
- **They are used to prevent the transmission of zoonotic diseases to humans, either through contact with animals or their environment, via a vector or through the consumption of foodstuffs of animal origin.**

1. Veterinary drugs: legal definition

Any substance or composition presented

□ as having curative properties or preventive effects on animal diseases.

□ which could be administered to an animal in order to:

- establish a medical diagnosis or
- restore,
- correct or
- modify physiological functions in the animal.

2. The marketing authorization (MA) for a veterinary drug and Procedure

MA is only granted if the holder brings evidence that:

- He has a manufacturing method and control procedures guaranteeing the quality of the drug at the level of *the serial production*,
- He has carried out verification of the pharmaceutical properties and that of *innocuousness to animals, humans* (Residues, Withdrawal time), *and the environment*,
- That he has proceeded to the verification of the effectiveness of the drug in light of the *therapeutic indications* he puts forth.

2.The marketing authorization (MA) for a veterinary drug and Procedure (G. Moulin, ANSES)

INDUSTRY

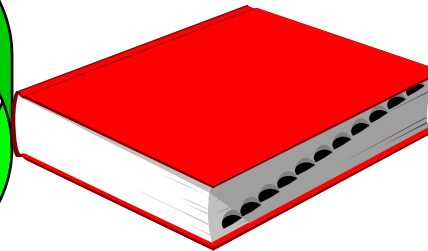
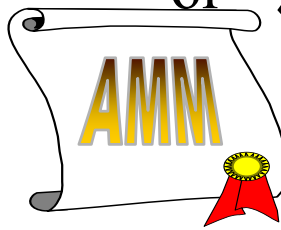


Before MA

AUTHORITIES

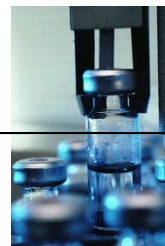


or



MA Procedure

PRODUCT ON THE MARKET



After MA



3. 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 Technical Report Series, No. 957, 2010.

3. Counterfeit medicines: definition

Counterfeit drugs must thus be differentiated from:

- **Defective drugs:** produced legally but with manufacturing defects.
- **Sub-standard drugs:** while genuine and produced by authorized manufacturers, they do not fulfill the associated specifications and quality standards required by the registration specifications.

3. Counterfeit medicines: definition



4. Situation of counterfeiting of drugs in West Africa

<u>1995</u>	Niger : Fake vaccines used in a meningitis epidemic: 2,500 dead
<u>2009</u>	Nigeria: 84 children died after drinking adulterated acetaminophen syrup
<u>9 July 2013</u>	Burkina Faso : Customs officers ” arm themselves ” against counterfeit
<u>November 20th, 2014</u>	The governments of Benin and the U.S. Agency for International Development (USAID) have launched a new campaign against fake products.

4. Situation of counterfeiting of drugs in West Africa

21 October 2015

Counterfeiting is now considered as a customs offence in Senegal

This information is even more important that the seizures value of counterfeit medicines made by Customs in 2014 amounts to US\$ 300,000).

May 23, 2015

Mauritania and Senegal have signed an agreement to strengthen their fight against fake veterinary medicines

5. Situation of counterfeiting of veterinary drugs in West Africa: Role of the LACOMEV

- **LACOMEV (Veterinary Drugs Quality Control Laboratory)**
- **at the Inter States School of Veterinary Science and Medicine of Dakar (Institution of higher education, vocational training, research and expertise)**
- **Members states are: Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Congo, Côte d'Ivoire, Gabon, Mauritania, Mali, Niger, Rwanda, Senegal, Chad and Togo.**

5. Situation of counterfeiting of veterinary drugs in West Africa: Role of the LACOMEV

Survey: Administration of questionnaire and Collection of data from the Vet. Services of the Members States :

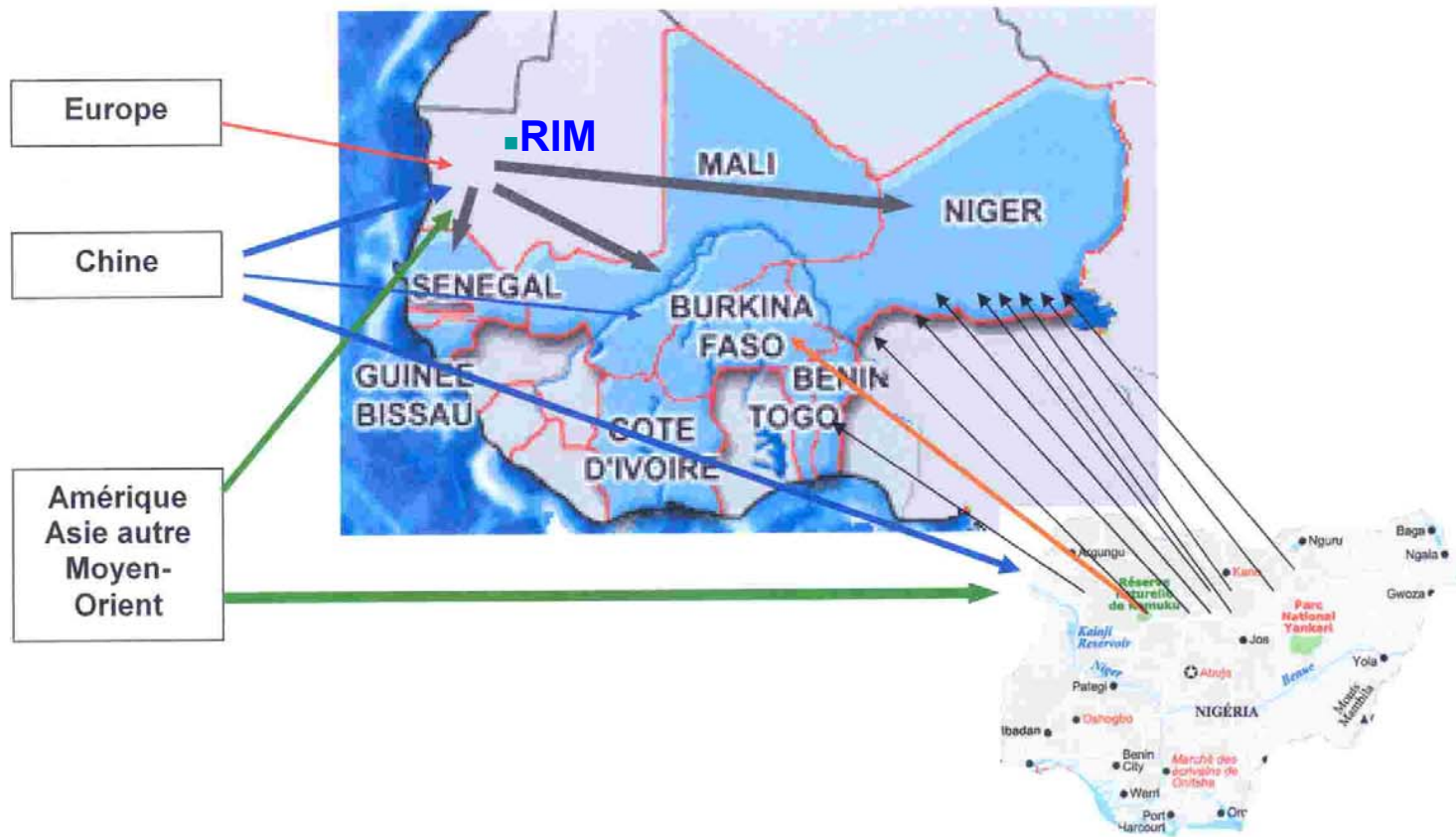
1. System of quality assurance of veterinary drug
2. Local production of veterinary drugs
3. Imports of drugs and veterinary raw materials
4. Distribution of veterinary drugs
5. Pharmacovigilance system

Quality control of veterinary pharmaceuticals collected during the survey

5. Situation of counterfeiting of veterinary drugs in West Africa: Role of the LACOMEV

RESULTS

Sources



NIGERIA



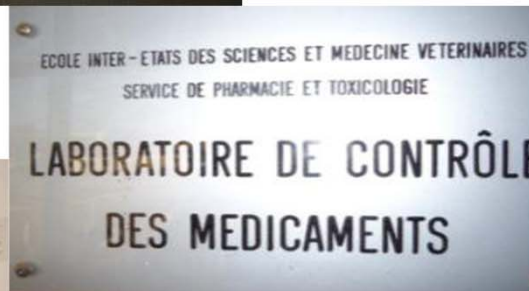
Distribution/Use



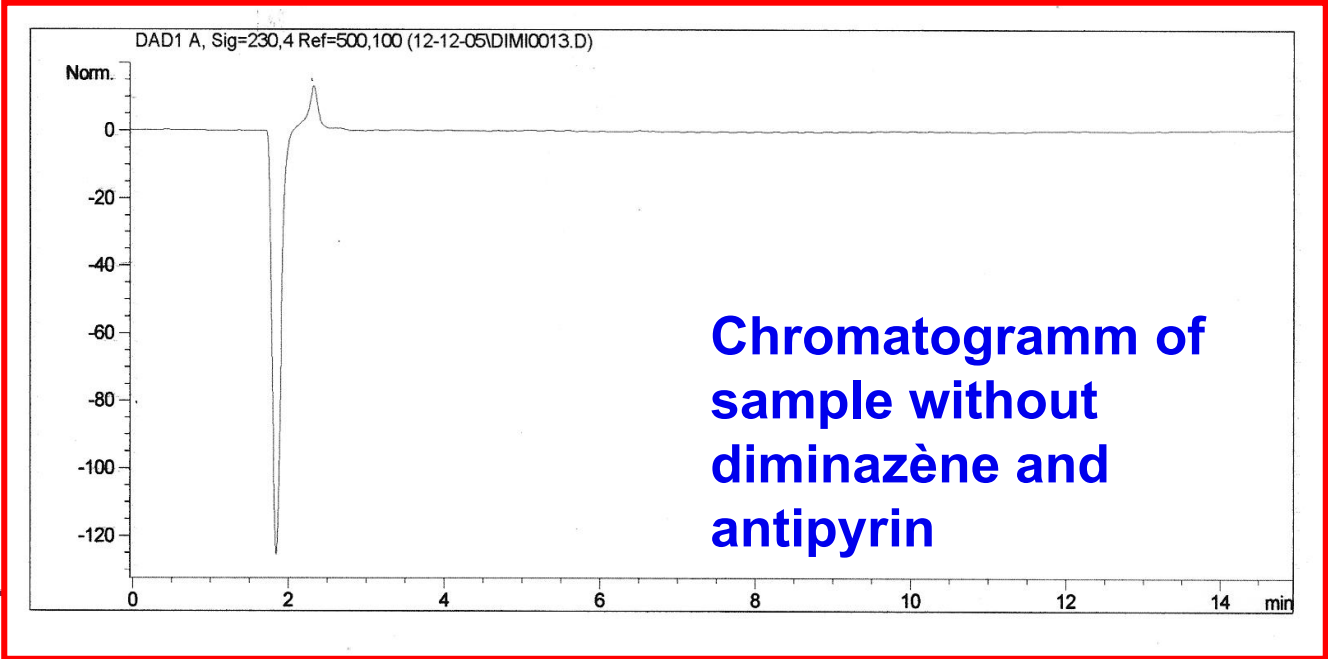
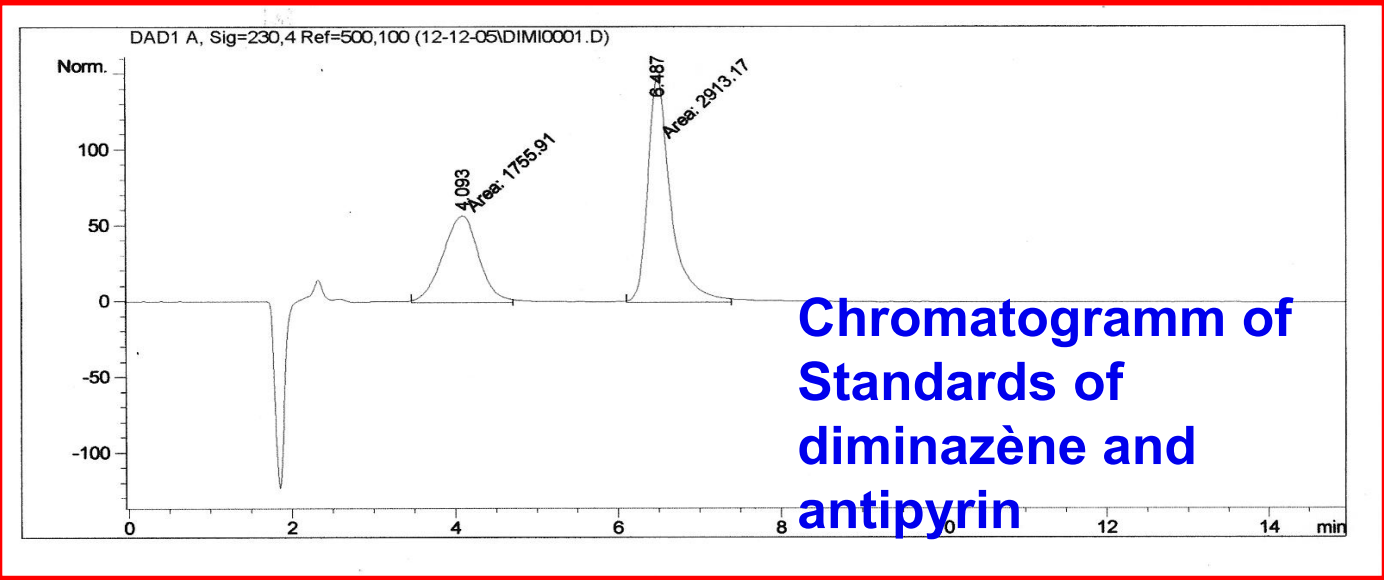
Quality of the drug

Testing protocol

- *Galenics tests*
- *Identification and dosage/
HPLC*



Antibiotics, antiparasitics,
trypanocidal drugs



Quality of the drug

Pays	Proportion of vet.drugs not complies (%)		
	Official market	Illegal market	Total
Bénin-Togo	36 (14/39)	61 (20/33)	48 (34/72)
Burkina Faso	52 (33/63)	53 (36/68)	52 (69/131)
Côte d'Ivoire	43.5 (30/69)	30 (03/10)	42 (33/79)
Mali	19 (04/22)	56 (09/16)	43 (16/37)
Mauritanie	38 (11/29)	64 (9/14)	59 (24/43)
Senegal	69 (20/29)	65 (17/26)	67 (37/55)

6. Factors facilitating counterfeiting of veterinary drugs in West Africa

- **Lack of legislation**
- **Absent or weak national drug regulatory authority**
- **Lack on enforcement of existing legislation**
- **Weak penal sanctions**
- **Corruption and conflicts of interest**
- **Transactions involving many intermediaries**
- **Demand exceeding supply**
- **High prices**
- **Sophistication in clandestine drug manufacture**
- **Inefficient cooperation between stakeholders**

7. Risks related to counterfeiting of veterinary drugs

No or no good EFFICACY => Creation of resistance

=> No Cure



Source: Cirdes, 2015

7. Risks related to counterfeiting of veterinary drugs

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

8.Role of West African Economic Monetary Union (WAEMU)

- Created in January 1994 at Dakar
- 08 countries
- 3,5 millions Km²
- 81 millions inhabitants
- 33% GDP of West Africa
- Common currency: francs CFA



Harmonisation of veterinary pharmaceutical legislations

8. Role of West African Economic Monetary Union (WAEMU)

Regulation N° 02/2006/CM/UEMOA	Establishment of Community procedures for marketing autorisation and surveillance of veterinary medicines
Regulation 04/2006/CM/UEMOA	N° Implementation of a Community system for the quality control of Veterinary Medicines via the creation of a network of 9 national laboratories
Directive N° 07/2006/CM/UEMOA	Harmonisation of national legislations in terms of control of veterinary medicines at import, movements within in the Union, placing on the market, manufacture authorisation and functioning, use for commercial purposes, wholesale and retail marketing

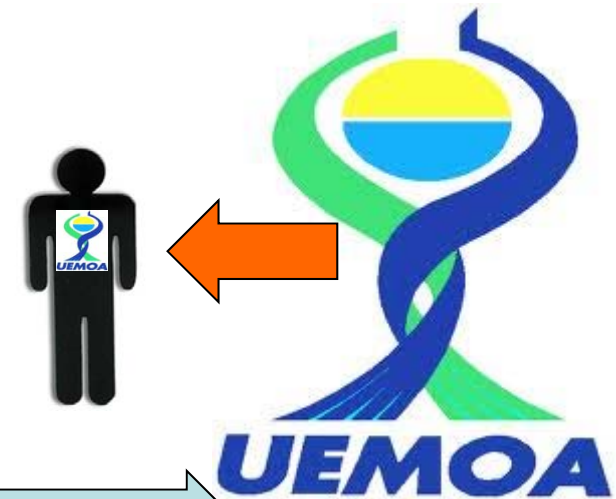
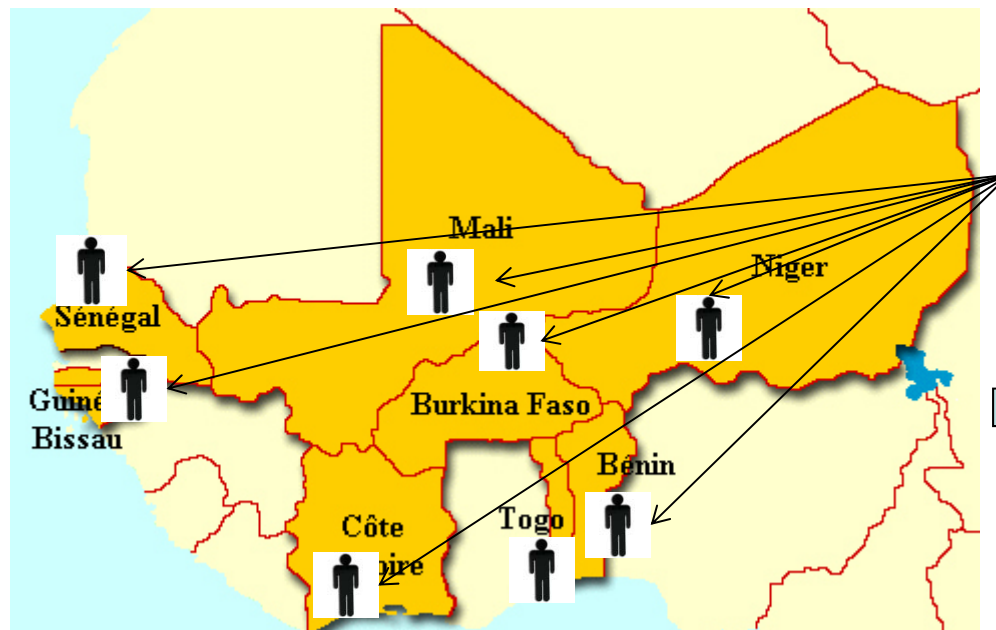
Harmonisation of veterinary pharmaceutical legislations

8.Role of West African Economic Monetary Union (WAEMU)/SURVEILLANCE OF THE VET. MARKET

RECRUITMENT AND TRAINING OF **02 INSPECTORS/COUNTRY** FOR COLLECTING VET. DRUG SAMPLES

RECRUITMENT OF **01 PROFESSIONAL** RESPONSIBLE OF THE INSPECTION SYSTEM AND THE NETWORK OF LABORATORIES
(**Very recent october 2015**)

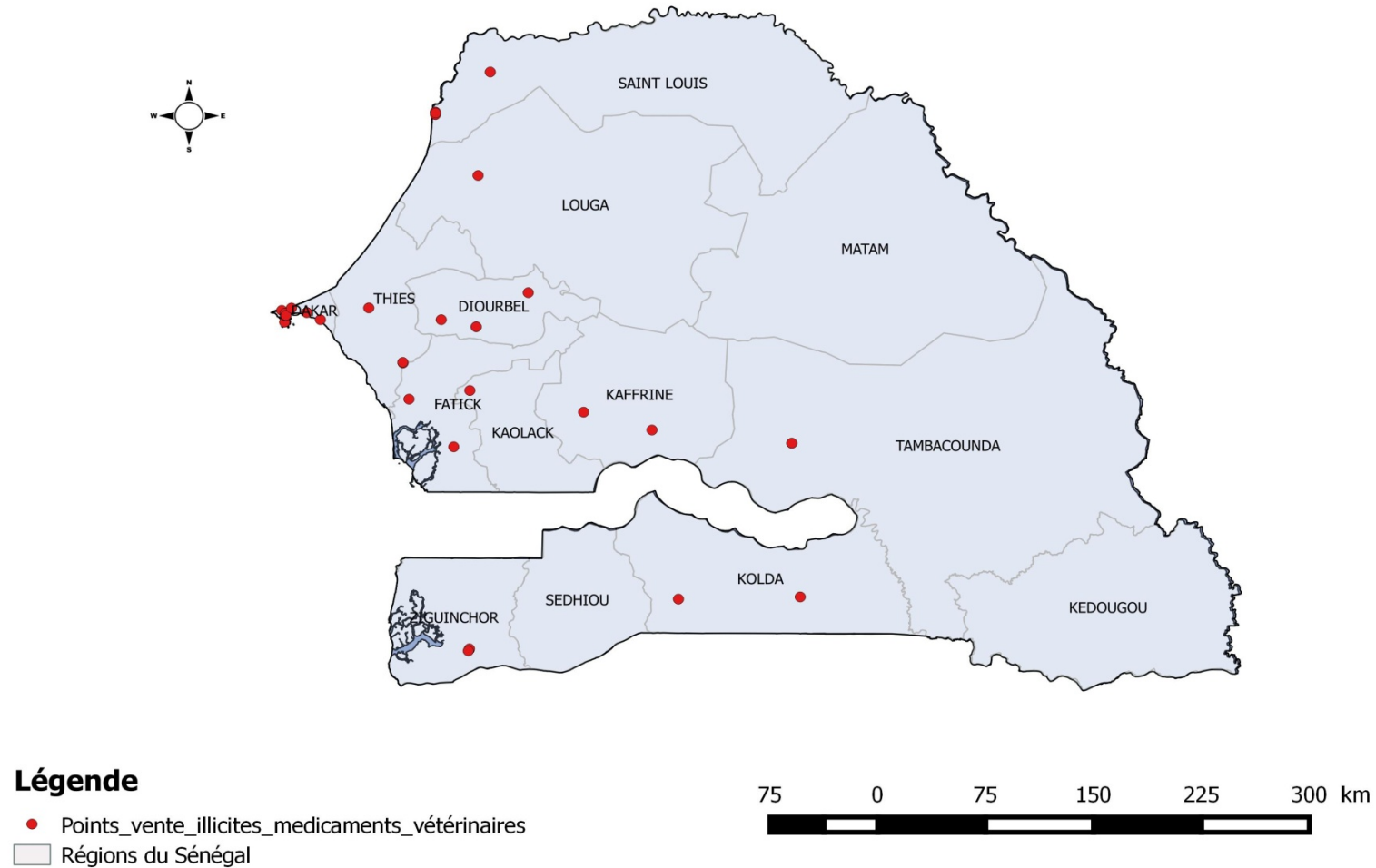
8. Role of West African Economic Monetary Union (WAEMU) / SURVEILLANCE OF THE VET. MARKET



**Report of the
situation of
the
veterinary
drug market**

EXAMPLE: SENEGAL

Figure n°8: Carte de répartition des acteurs illicites de médicaments vétérinaires



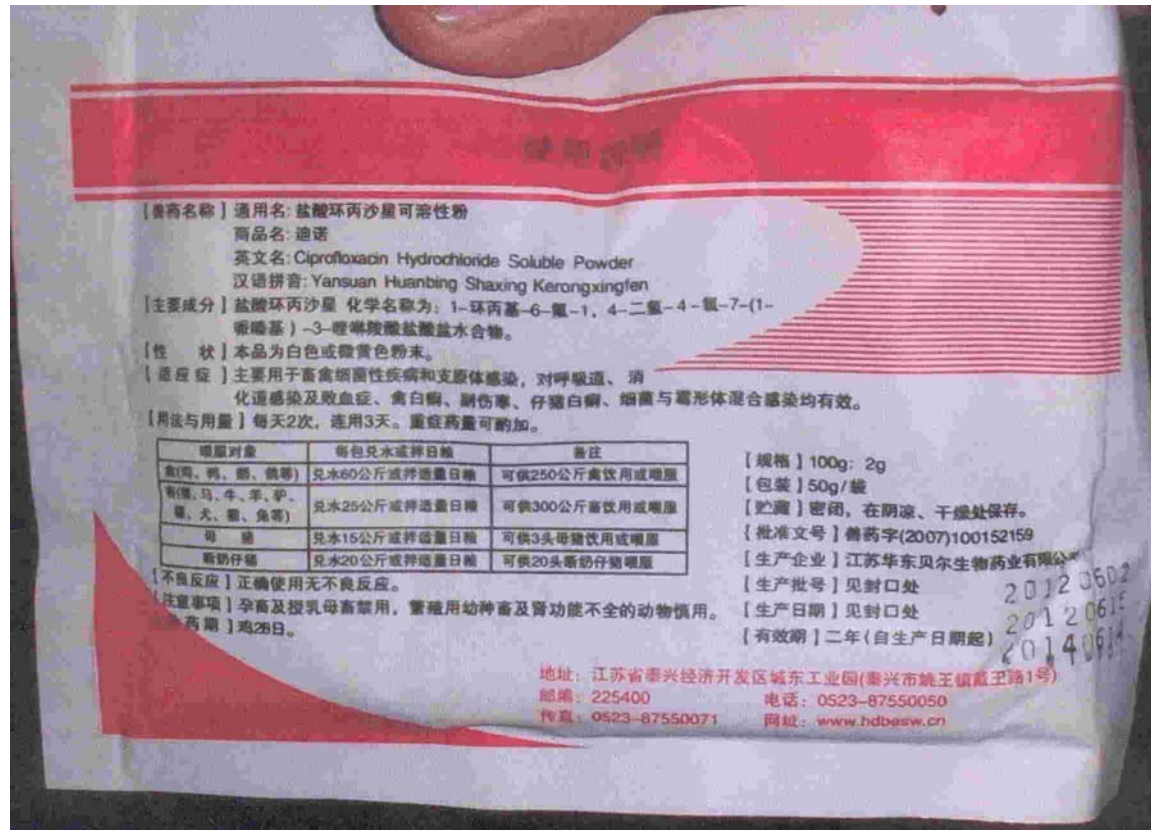
THE FAKES DRUGS FIND DURING THE CAMPAIGN IN THE WAEMU MEMBERS STATES



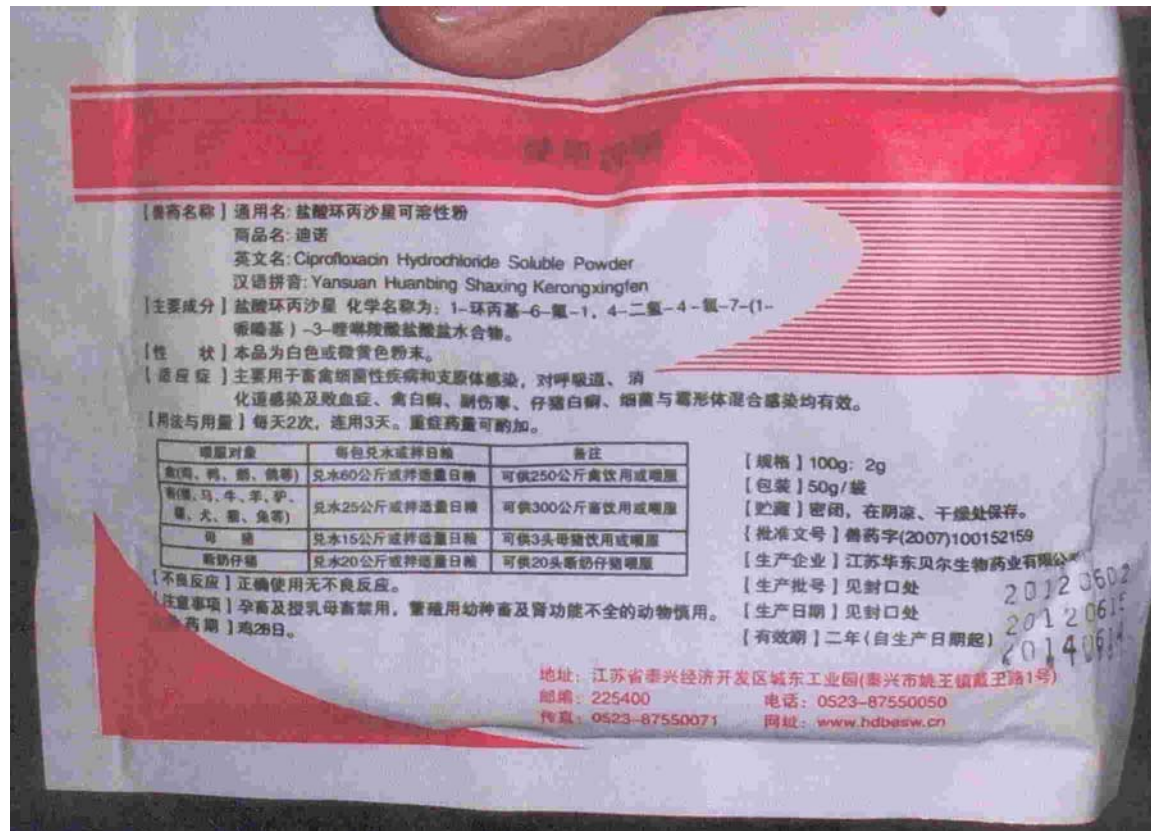
THE FAKES DRUGS FIND DURING THE CAMPAIN IN THE WAEMU MEMBERS STATES



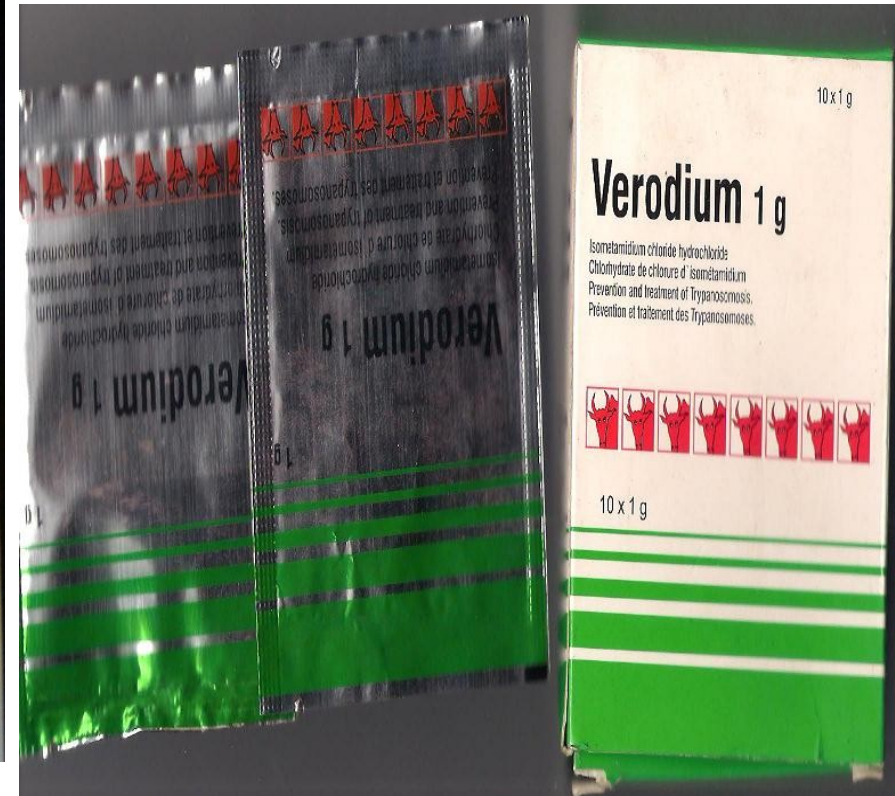
THE FAKES DRUGS FIND DURING THE CAMPAIN IN THE WAEMU MEMBERS STATES



THE FAKES DRUGS FIND DURING THE CAMPAIN IN THE WAEMU MEMBERS STATES



THE FAKES DRUGS FIND DURING THE CAMPAIGN IN THE WAEMU MEMBERS STATES



9. Recommendations

**Informing, training and advising healthcare professionals.
Securing the supply chains.**

Organizing vigilance, monitoring incidents and systematizing feedback.

Facilitating access to authentic medicines in developing countries.

Educate and communicate to the general public.

Harmonize the legislation.

Conclusion



Thank you for your attention

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