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PERSPECTIVES ON TWINNING ON VETERINARY PRODUCTS

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**REGIONAL SEMINAR ON THE OIE TWINNING PROGRAMME:
CONCEPTS AND PERSPECTIVES**

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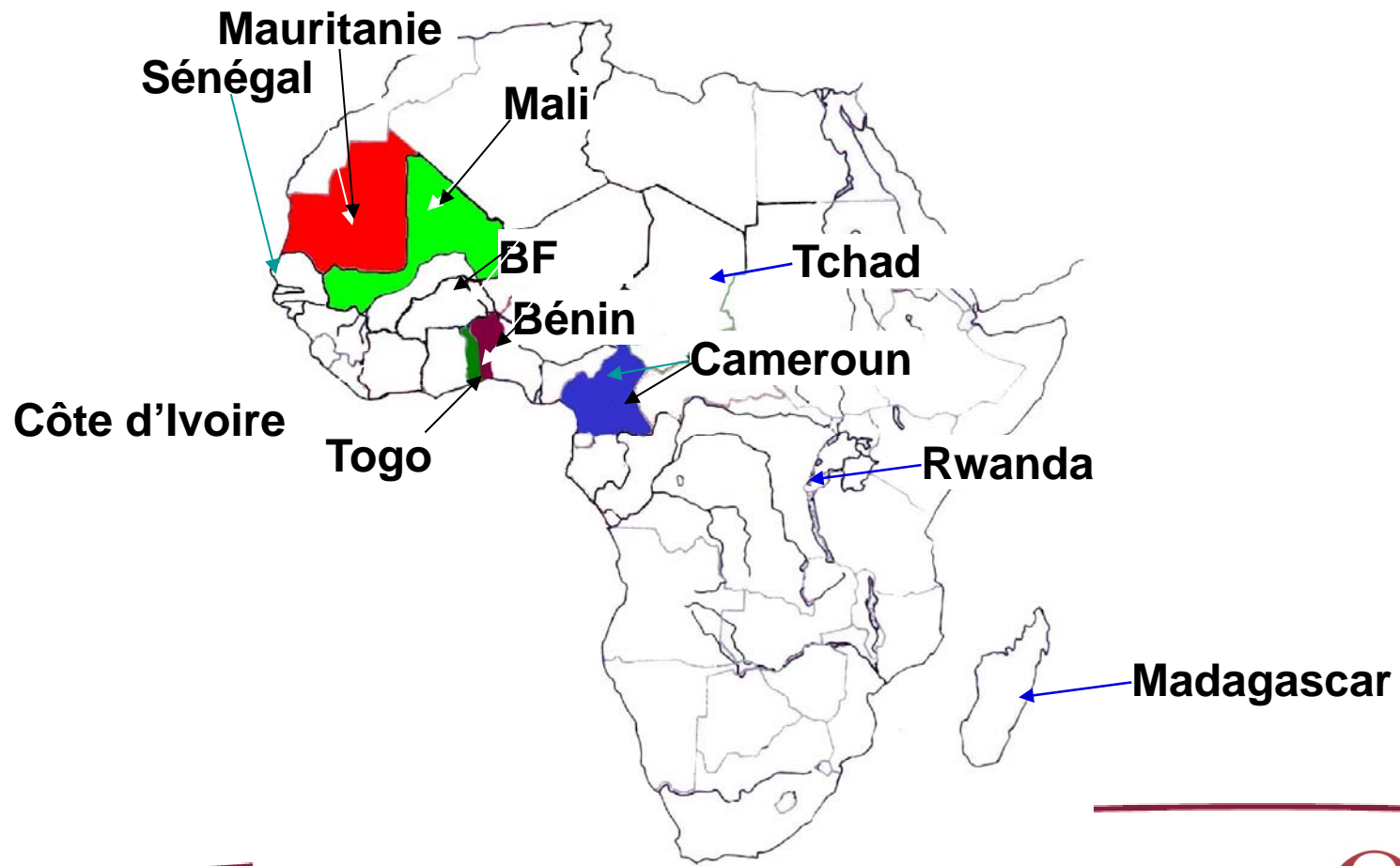
PLAN

- SITUATION OF THE QUALITY CONTROL OF VETERINARY MEDICINES IN AFRICA
- TWINNING PROJECT BETWEEN LACOMEV (Veterinary Drugs Quality Control Laboratory) and ANMV (French Agency for Veterinary Medicinal Products)
- PERSPECTIVES

SITUATION OF THE QUALITY CONTROL OF VETERINARY MEDICINES IN AFRICA

- Almost complete absence of quality control mechanisms for medicines
- In countries having laboratories : most of them face problems of insufficient financial and human resources as well as inadequate equipments (**DARE, 2010**)

Studies conducted on veterinary drugs quality in Subsaharan Africa

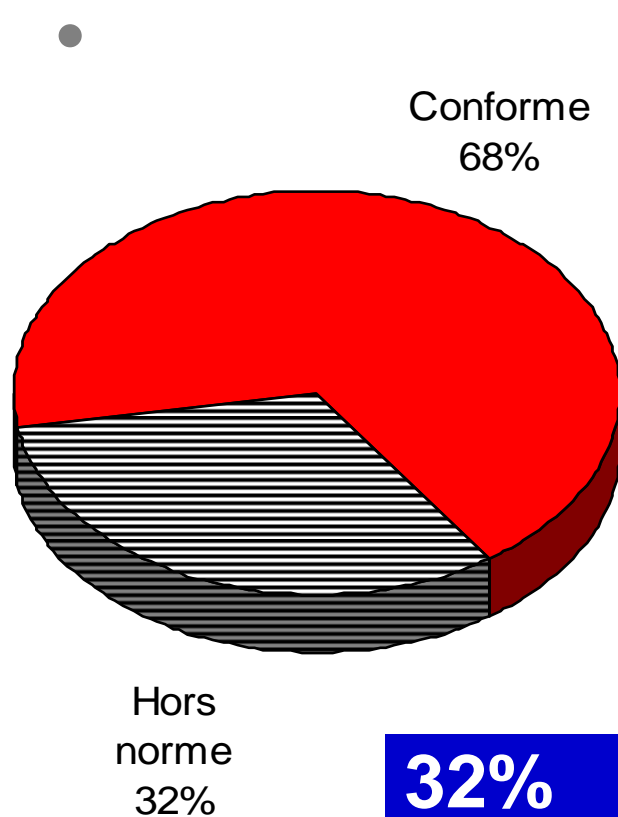


Quality of veterinary products in Africa

Teko-Agbo and al, (2001-2008); Ndottiwa, (2008)

- Studies in various countries of sub-saharan Africa indicate that 42 to 70% of veterinary drugs circulating in these countries are non – conforming/ none complaint

Quality of veterinary products in Africa



FAO, 2001

- 104 samples of Diminazene
- 11 countries (Angola, Central African Republic, Democratic Republic of Congo, Ivory Coast, Malawi, Mali, Mozambique, Namibia, Nigeria, Senegal, Togo)

32% of diminazene sold in the countries do not comply

TWINNING PROJECT BETWEEN LACOMEV (Veterinary Drugs Quality Control Laboratory) and ANMV (French Agency for Veterinary Medicinal Products)

- ANMV



The ANMV is the French Agency for Veterinary Medicinal Product, Responsibilities in assessment, Authorisation, Monitoring, Control, Inspections

ANMV is the OIE collaborating centre for VMP

ANMV

1. INTERNATIONAL HARMONISATION

2. RESEARCH and EXPERTISE

3. TECHNICAL ASSISTANCE

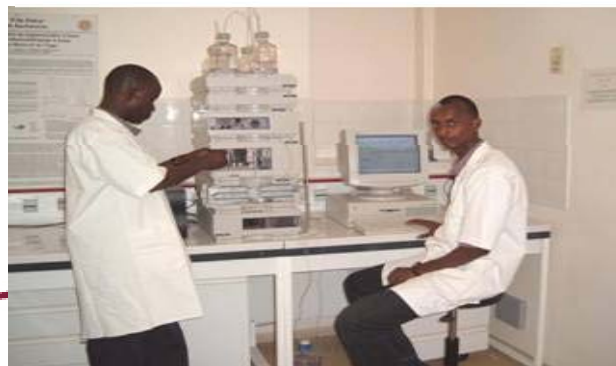
Bilateral and multilateral cooperation and assistance
to OIE member countries (especially developing countries)

Twinning

TWINNING PROJECT BETWEEN LACOMEV-ANMV

- LACOMEV was created in February 2001 at the Inter State School of Veterinary Science and Medicine of Dakar
- Specialised in analytical drug expertise
- World Organisation for Animal Health (OIE) Reference Laboratory since 2004
- Member of **the Network of laboratories** in charge of quality control of veterinary drugs in the West African Economic Monetary Union (UEMOA)

TWINNING PROJECT BETWEEN LACOMEV- ANMV



ECOLE INTER-ETATS DES SCIENCES ET MEDICINE VETERINAIRES
SERVICE DE PHARMACIE ET TOXICOLOGIE
LABORATOIRE DE CONTRÔLE
DES MEDICAMENTS

History of the twinning: December 2006



TWINNING PROJECT BETWEEN LACOMEV- ANMV

- History of the twinning
 - Following technical support committed since 2007 by ANMV with the LACOMEV, the OIE has accepted the twinning project plan written by ANMV and LACOMEV.
 - This twinning began in February 2010 for a period of two years.

TWINNING PROJECT BETWEEN LACOMEV- ANMV

- Objective:
 - Help LACOMEV to strengthen its expertise, reliability and optimize its capabilities in quality control of veterinary drugs.
 - Pairing relates to methodological and pedagogical aspects, engaged in a process of quality management according to NF EN ISO/CEI 17025 for chemical drugs.

- **Specific objectives**

1/the creation of a relevant organization, methods of analysis and operational procedures according to NF EN ISO/CEI 17025 ensuring the quality analysis and traceability.

2/ the routine application of methods and procedures for internal audits.

3 / carrying out laboratory tests for the performance of methods and qualification of the staff on these methods.

4 / conducting an external audit of quality management system.

Relevant activities :

- Technical and scientific support to the drafting and implementation of methods and quality documents on items 4 and 5 of the standard NF EN ISO / CEI 17025
- Training
- Workshops
- Conference calls
- Review Project

Benefit

- *Progress in organizational aspects*

For the implementation of organizational requirements, the laboratory has developed with the support of ANMV Experts several quality documents including:

- ❖ a new quality manual that includes the different chapters of the standard
- ❖ a functional organization
- ❖ procedures, instructions, registration forms, operating protocols.

Benefit

Progress on the technical aspects

LACOMEV staff has been trained on:

- ❖ NF EN ISO / CEI 17025 in Fougères in 2010 and Dakar in 2011;
- ❖ Techniques Audit in Dakar in 2011 and 2012;
- ❖ The estimated uncertainties in test results in Dakar in 2010 and 2011;
- ❖ Methods of analysis in Cotonou in 2011.

Perspectives: 27 march 2012



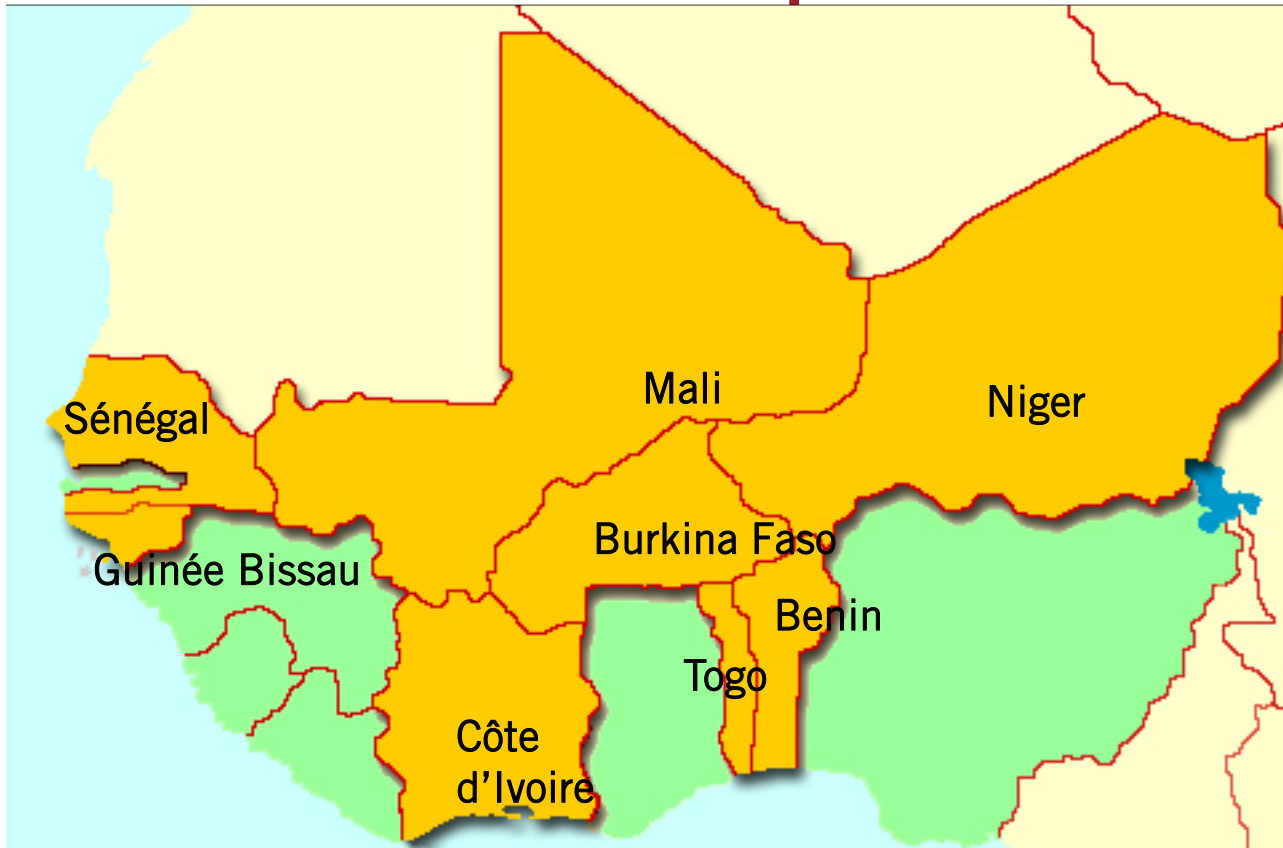
Perspectives

- ❑ LACOMEV began the process of developing a strategic plan to consolidate its gains from this pairing for institutional development.
- ❑ One of the objectives in the medium and long term is to get the LACOMEV accreditation according to NF EN ISO / CEI 17025
- ❑ To achieve this, the LACOMEV needs to be accompanied by ANMV.

Perspectives

- LACOMEV is a Member of the Network of laboratories in charge of quality control of veterinary drugs in the West African Economic Monetary Union (UEMOA)
- **REGULATION N°04/2006/CM/UEMOA** INSTITUTING A NETWORK OF LABORATORIES IN CHARGE OF THE QUALITY CONTROL OF VETERINARY DRUGS IN THE UEMOA ZONE
- **DECISION N°010 2009/COM/UEMOA** APPOINTING THE NETWORK LABORATORIES IN CHARGE OF THE QUALITY CONTROL OF VETERINARY DRUGS IN THE WAEMU

Perspectives



LNCQM (Bénin)
LNSP (Burkina Faso),
LNS (Mali),
LANSPLEX (Niger),
LNCM (Sénégal),
LACOMEV (EISMV Dakar)

FOR THE CONTROL OF CHEMICALS DRUGS

Perspectives

- The Comparative test of ability organised by ANMV for UEMOA's veterinary drug quality control laboratories Network
- Maintain the relationship between LACOMEV and ANMV.

Perspectives

LACOMEV would continue studies on the quality of veterinary medicinal products in the Economic and Monetary Community of Central Africa (CEMAC).

- ❑ This may be done with the technical assistance of ANMV.
- ❑ OIE can help us for this project to find funding

Perspectives

The ANMV recommends at the end of the project:

- The routine application of the quality system,
- Realize a mock audit
- The ANMV in the continuation of this work, will continue to provide scientific and technical assistance as needed from LACOMEV.

Perspectives

Twinning projects can be initiated in the following areas:

- ❑ Evaluation of Dossiers for Veterinary Medicinal Products (VMPs) Authorisation
- ❑ Surveillance for adverse effects arising for the use of VMPs (Pharmacovigilance)
- ❑ Market surveillance of VMPs
 - ❑ Consider the guidelines of the OIE Veterinary Legislation (**OIE Guidelines for legislation for VMPs**
http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/docs/pdf/A_Guidelines_VetLeg.pdf Part 9

Conclusion

- ❑ The OIE twinning project between ANMV and LACOMEV was successfully conducted

- ❑ The closing meeting held in 27 march 2012 was an opportunity to express the great satisfaction of the Twinning partners for:
 - ❑ the results obtained, despite the delay in achieving some activities dues to a technical problem

 - ❑ the excellent cooperation of all partners.

Conclusion

The OIE Member countries need a strong legislation and regulatory framework for VMPs in order to:

- Safeguard human and animal health
- Comply with animal health policies
- Guarantee **efficacy**, **safety** and **quality** of VMPs
- To face new disease threats.

Thank you for your attention

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