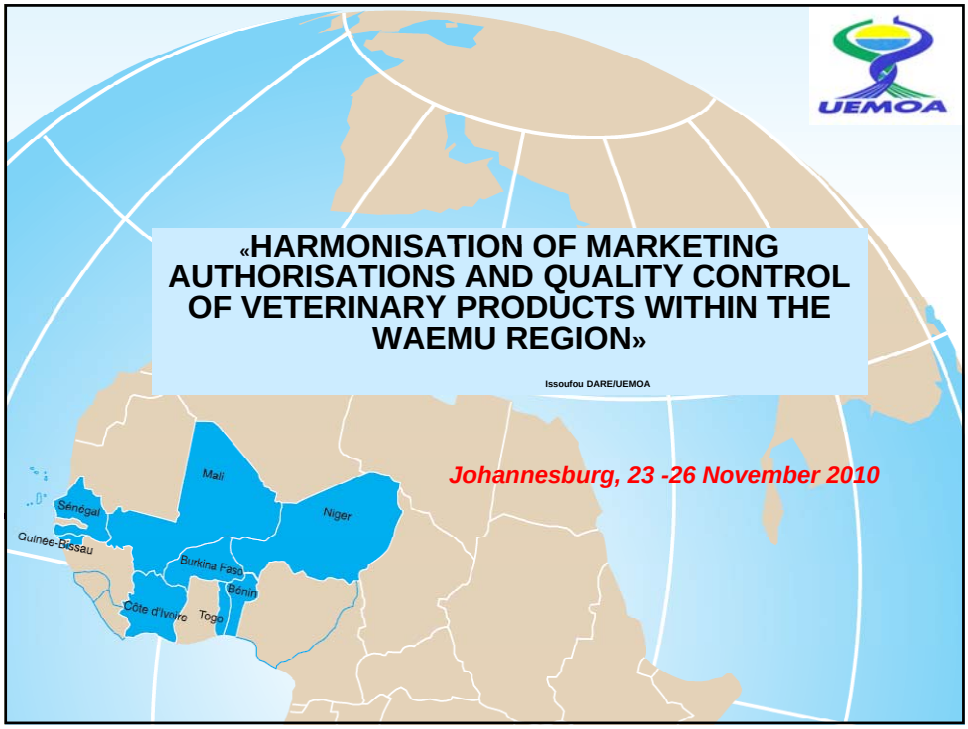
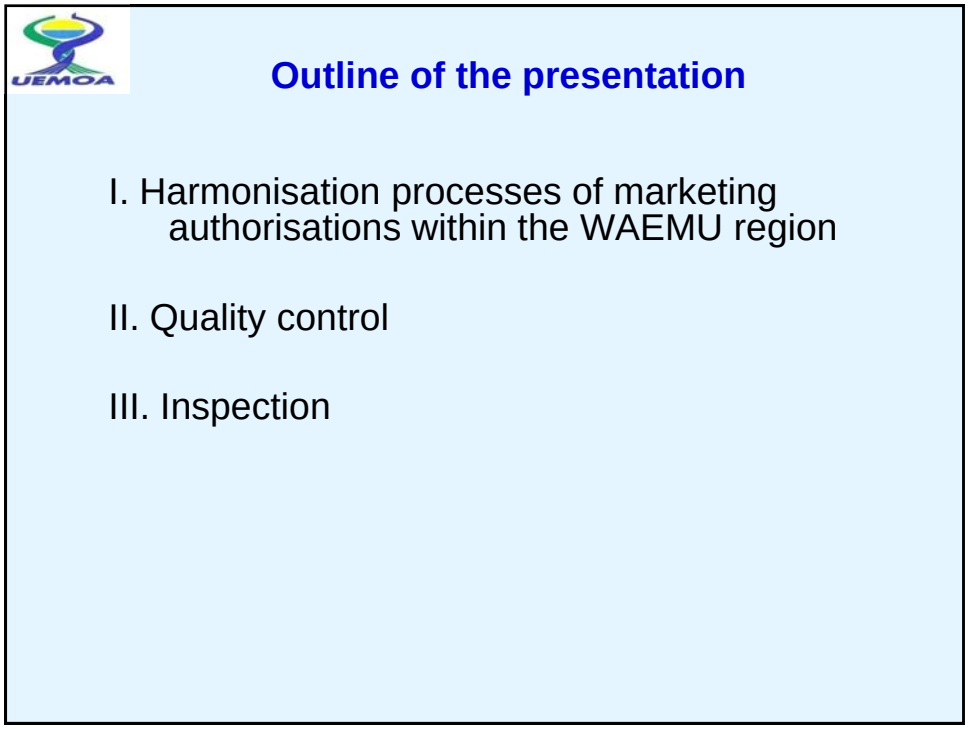
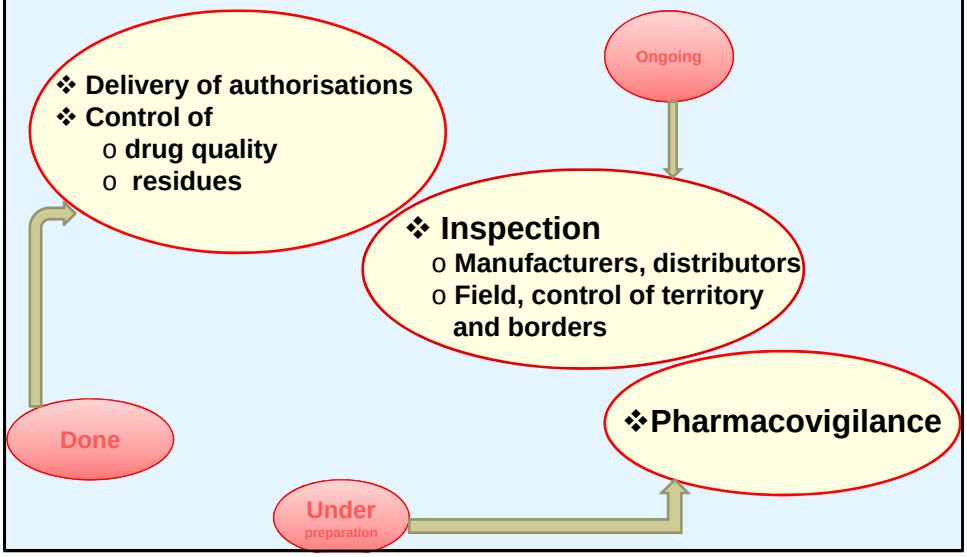

UEMOA
«HARMONISATION OF MARKETING AUTHORISATIONS AND QUALITY CONTROL OF VETERINARY PRODUCTS WITHIN THE WAEMU REGION»
Issoufou DARE/UEMOA
Johannesburg, 23 -26 November 2010
Mali
Sénégal
Niger
Guinée-Bissau
Burkina Faso
Bénin
Côte d'Ivoire
Togo


UEMOA
Outline of the presentation
I. Harmonisation processes of marketing authorisations within the WAEMU region
II. Quality control
III. Inspection

Main pillars of the WAEMU system



I. Harmonisation processes for marketing authorisations within WAEMU

2. The WAEMU approach

Centralised system (community-wide) organised around three complementary processes

- Unified marketing autorisation processes : Regional Committee for Veterinary Drugs (CRMV), attached to the WAEMU Commission.
- Unified quality control processes : Networking of laboratories for the quality control of Veterinary Drugs
- A consultation process by the Commission before taking a final decision : Veterinary Committee (mandate enlarged to other areas)

I. Harmonisation processes for marketing authorisations within WAEMU

3. Unified marketing authorisations processes

The CRMV, ***backbone of the marketing autorisation processes, attached to the WAEMU Commission***

Mandate

- Assess all technical dossiers required for the granting of the various administrative authorisations (granting or refusal of the autorisation, renewal, alteration, suspension, revoking etc…)
- Submission of draft administrative decisions to the WAEMU Commission, resulting from the evaluation of the dossiers

I. Harmonisation processes for marketing authorisations within WAEMU

3. Unified marketing authorisations processes

The CRMV, ***backbone of the marketing autorisation processes, attached to the WAEMU Commission***

Constitution

- Constituted of recognised scientists (10): Galenics/drug analysis (3); Immunology (2); Toxicology-pharmacology (2) Veterinary clinical science (2) and the President
- Seconded by a **Permanent Secretariat** located at the WAEMU Commission

I. Harmonisation processes for marketing authorisations within WAEMU

3. Unified marketing authorisations processes

The CRMV, ***backbone of the marketing autorisation processes, attached to the WAEMU Commission***

Operation

- **The Permanent Secretariat (2)**
  - Receives the requests for marketing authorisations
  - Verifies the administrative eligibility of the dossiers
  - Prepares the meetings of the CRMV
  - Prepares the draft administrative decisions resulting from the CRMV's evaluations

I. Harmonisation processes for marketing authorisations within WAEMU

3. Unified marketing authorisations processes

The CRMV, ***backbone of the marketing autorisation processes, attached to the WAEMU Commission***

Operation

- **The membres of the CRMV** meet several times a year to :
  - Examine the dossiers that have previously been validated by the Permanent Secretariat (technical evaluation)
  - Decide whether additional investigations are required
  - Decide whether the request is technically receivable
  - Draft the decision to be submitted to the WAEMU Commission

I. Harmonisation processes for marketing authorisations within WAEMU

3. Unified marketing authorisations processes

The LEMV, *in support of the CMRV*

- Constituted of reference experts and institutions specialised in veterinary drugs
- May be sollicited by the CRMV, when needed, to assist in the technical evaluation of certain dossiers (assist the rapporteur, technical working groups, etc.)

I. Harmonisation processes for marketing authorisations within WAEMU

3. Unified marketing authorisations processes

THE WAEMU VETERINARY COMMITTEE

- Directors of Veterinary Services of the Member States and observers
- Issues a technical advice to the WAEMU Commission regarding the draft decisions suggested by the CRMV
- *But its mandate is enlarged to other areas : animal health, food safety, veterinary practice, etc.*

I. Harmonisation processes for marketing authorisations within WAEMU

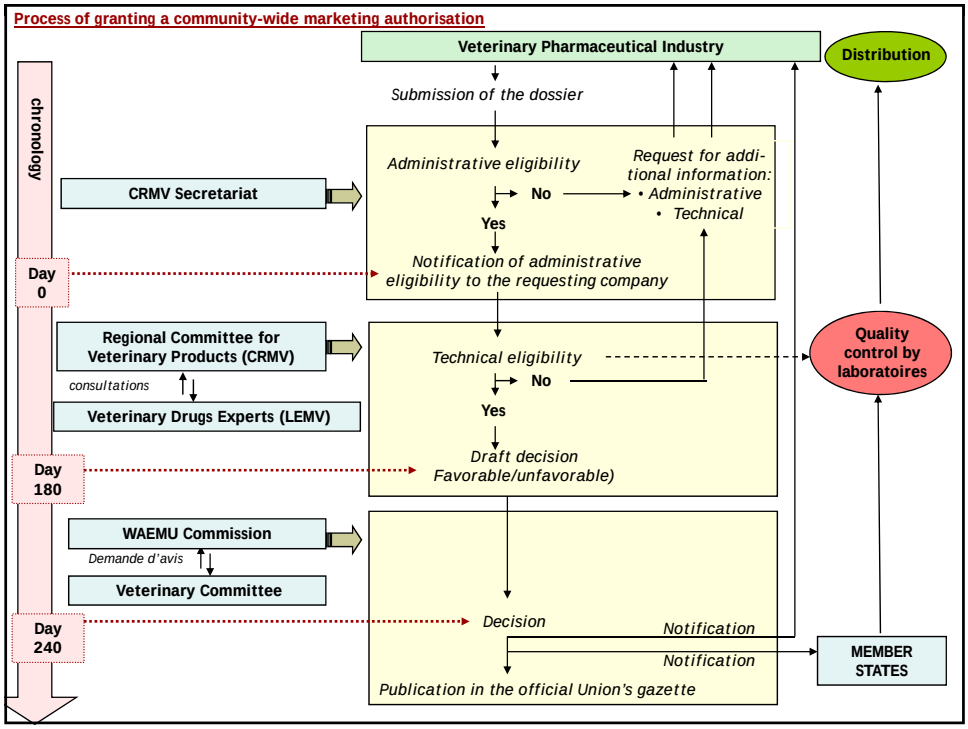
4. marketing authorisations processes (steps and duration)

- Validation (administrative)
- Start the clock (total process = 240 days)
- Duration of the evaluation
  - 240 – 60 = 180 days
- Transfer to the Chairperson of the WAEMU Commission for decision (on day 180)
- Consultation of the Veterinary Committee and decision (duration = 60 days)
- Notification of the decision on day 240 (provided there are no additional requests for information to the companies)

I. Harmonisation processes for marketing authorisations within WAEMU

4. Processes (Notification of the decision)

- The decision is notified to the requesting company, the veterinary authority and the authorities in charge of livestock, trade and customs of the Member States.
  - The decision to grant a marketing autorisation is accompanied by the summary of caracteristics of the product (RCP) and of the draft package insert and label design, validated by this same Committee.
- Decisions regarding marketing authorisations are gazetted in the Union's official gazette.



I. Harmonisation processes for marketing authorisations within WAEMU

5. Legal foundation *(autorisation procedures)*

REGULATION N° 02 /2006/CM/UEMOA

Article 13

- 1. Except for medicated feeds, no veterinary medicine may be marketed in any of the Member States, whether for free or for sale, without having a marketing autorisation, delevered by the WAEMU Commission. Medicated feeds may be manufactured from medicated pre-mixes only, which in turn have received a marketing autorisation in conformity with the present Regulation.

I. Harmonisation processes for marketing authorisations within WAEMU

5. Legal foundation *(authorisation procedures)*

REGULATION N°02/2006/CM/UEMOA

Article 22

- Exceptional authorisation
  - 1. However, in cases of serious epizootics, a Member State may, **provisionally**, allow for the import by a veterinary pharmaceutical company and the use by one or more veterinary surgeons, of veterinary products, on its own national territory, without marketing autorisation as intended under article 13, because of the absence of adequate products and after having informed the WAEMU Commission of the detailed conditions of its use.
  - 2. Within **six months**, the WAEMU Commission, upon recommendation of the Regional Committee, will have to decide whether it allows the continued use of this product, and may deliver a special time-bound autorisation.
  - 3. When needed, the Commission may **extend this autorisation** to other Member States.
  - 4. The Member States will **update** the WAEMU Commission on a quarterly basis on the **epidemiological situation** and the use of the product.

I. Harmonisation processes for marketing authorisations within WAEMU

5. Legal foundations *(the contributions)*

REGULATION N°03/2006/CM/UEMOA INSTITUTING CONTRIBUTIONS WITHIN THE WAEMU

Article 1

- It is instituted within the Union, contributions which have to be paid against the services provided for the issuance and the maintenance of marketing authorisations for veterinary products, as well as for other services rendered within this framework.

II. Quality control of veterinary products

1. Quality assurance process

a. establishment of a accredited laboratory network

9 selected laboratories (technical audit) : 6 for analyses for chemical products and 3 for immunological products

II. Quality control of veterinary products

1. Quality control process

a. Legal foundation (Regulation n°04/2006/CM/UEMOA)

Article 2: objectives of the network

The laboratory network for quality control of veterinary products endeavours to :

- Provide technical assistance to Member States in the field of quality-assurance of pharmaceutical products and vaccines;
- Develop the know-how of participating laboratories……..

II. Quality control of veterinary products

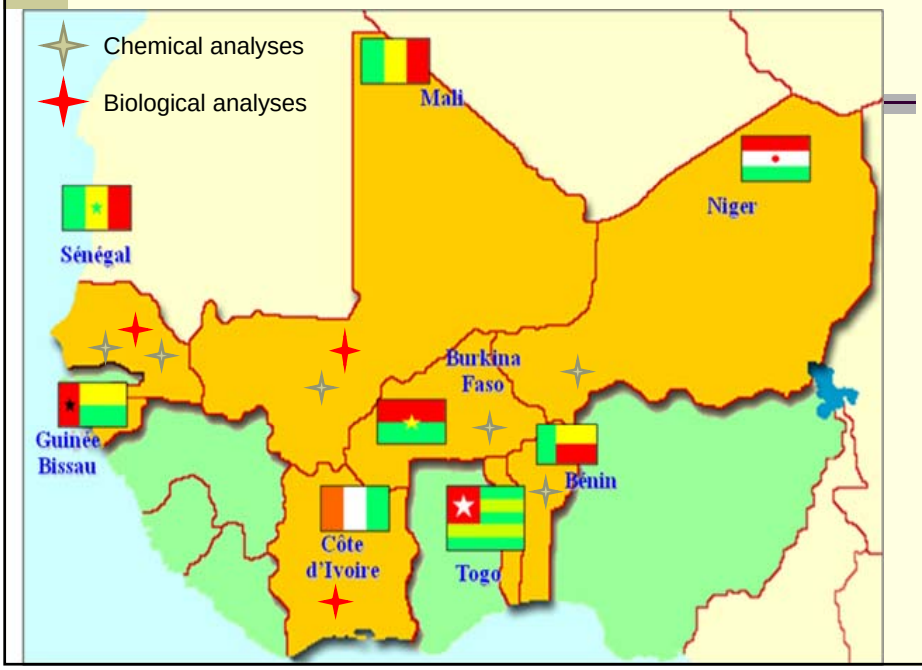
1. Quality control process

a. Interventions

The laboratories conduct quality control analyses for veterinary products within the framework of :

- Marketing autorisation procedures (analyses of samples)
- Importations of veterinary products
- Inspection procedures for the delivery chain from manufacturing to distribution
- Pharmacovigilence procedures

The network of quality control labs



III. Inspection

2. Inspection process *(being developed)*

Objectives

- Establish a uniform and efficient control system for the importation, manufacturing and distribution of veterinary products
- Harmonise national legislation regarding inspection within the WAEMU region
- Pool human resources of Member States in terms of medicines' inspection
- Harmonise inspector's statuses within the region

CONCLUSION

- The reform implemented by WAEMU : delivery of a regional marketing autorisation , following a scientific evaluation process involving the CRMV, the Veterinary Committee and if required the experts of the LEMV
- This regional authorisation replaces the national authorisations, and is recognised by the WAEMU Member States
- This regional authorisation, accompanied by an import autorisation, delivered by one of the Member States, ensures the un-hampered circulation of these products in all Member States, exempt of customs duties and VAT.
- This reform is accompanied by the setting-up of a network of quality control laboratories for veterinary products : expertise for the evaluation of marketing requests, control of the manufacturing processes and the distribution of products.
- For the future, there is the intent to establish a process for communauty based inspections, from manufacturing to distribution of veterinary products

JE VOUS REMERCIE