AU-IBAR Activities Regarding Regulation/Registration of Veterinary Medicinal Products in the SADC Region

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AU-IBAR
Concern on VMPs

Effective legislation, regulation and enforcement is critically important to protect human health, animal health and the environment..

Veterinary Vaccines and drugs: Essential tools

The AU-IBAR's six interconnected and complementary strategic programmes

- Reducing impact of transboundary animal diseases (TADs) and zoonoses on livelihoods and public health in Africa (*TADs and Zoonoses*);
- Promoting development of, and compliance with, standards and regulations (*Standards and Regulations*);
- Facilitating development of policies and institutional capacities for improved utilization of animal resources in Africa (*Policies and Capacity Building*).

Concerns

- Proliferation of counterfeits; sub-standard/ falsified products on the continent
- Suboptimal performance/poor therapeutic indices:
- Resistance (antimicrobial resistance (AMR), trypanocidals etc)
- Residues in animals and food

These Constitute serious threats to human and animals health from a National and Regional Perspective

Current Legislative & Regulatory environment for VMPs at Continental, Regional and National levels

- National authorization- National authorities with varied capacities undertake registration and regulatory role; sometimes consider authorization results in third countries as applicable;
- In some MS regulation of VMPs and human medicines regulated by same authority
- Regional based approaches
  - ✓ Mutual Recognition of Procedures (MRP) – **EAC model**
  - ✓ Centralised system- **WAEMU Model**

Current Legislative & Regulatory environment for VMPs at Continental, Regional and National levels

- Limited capacity (various) to implement legislation;
- The diversity of procedures and practices for registration of veterinary Medicines;
- Weak laboratory capacities to undertake evaluations (quality control) of products to provide evidence and confidence for approvals by national regulatory authorities;
- Inadequate information sharing
- Limited number of Diagnostic, Quality control and Vaccine Centres of Excellence

Current Legislative & Regulatory environment for VMPs at Continental, Regional and National levels

- Differences in legal frameworks governing the **control of animal diseases in MS**
- Varied and sometimes outdated legislative and regulatory frameworks to guide:
  - ✓ Registration (safety, efficacy)
  - ✓ Quality control),
  - ✓ Distribution, and
  - ✓ Monitoring of products during their use in the field

Regional approach towards effective regulatory environment for VMPs **Advocacy**

- Replicate: West African Economic and Monetary Union (WAEMU) **model**
- Model of economic integration in Africa (multiple/single currency, a customs union and common **(COMESA)** Market
- Advantages of the regional centralized procedures (several)
  - Free (controlled) movement of VMPs within the SADC countries
  - Pooling of resources and expertise for a group of countries in the management and evaluation of VMPs,

SADC, Which way forward?

Improving the National and Regional Institutional Governance for registration, distribution and quality control

- Compliance with OIE International standards governing; legislations, use of VMPs and surveillance of antimicrobial agents
- Effective and enforcement of legislations;
- Leverage resources through cooperation among countries to develop and enforce legislations;
- Decentralized /Mutual Recognition protocols (set of criteria and guidelines) and where possible;
- Central marketing authorization recognised by all member countries

SADC, Which way forward?

Improving the National and Regional Institutional Governance for registration, distribution and quality control

- Improve awareness and involvement of public about veterinary medicine regulation
- Capacity building on core competences with collaboration with the OIE collaborating centres on VMPs and continued capacity building for the National Focal points for Veterinary Products.
- Sharing of information on VMPs
- Prudent to have VMPs and human pharmaceuticals regulation under separate authorities;
- Replicate successful models to and from other **Regions** and **MS** in Africa.

Thank You, Merci, Obrigado, Asante sana