

# Training Seminar for National Veterinary Products Focal Points

**Veterinary Products: A Vital Tool for Improving Animal Health and Welfare**

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EXPERIENCES ON QUALITY OF VMPS IN KENYA

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**Veterinary Medicinal Products Focal Points**

# Outline

- ❖ Background
- ❖ Medicinal products
- ❖ Quality of Veterinary Pharmaceuticals
- ❖ Quality of Veterinary Immunological products
- ❖ Quality of alternative/Traditional Medicinal Products
- ❖ Conclusions & Recommendations



# BACKGROUND

- ❖ Kenya is an East African country
- ❖ Borders: Uganda, Tanzania, Somalia, Ethiopia, Sudan, Indian Ocean
- ❖ Quality of VMPs influenced the quality in neighboring countries
- ❖ Currently the Regulation of VMPs is done by Veterinary Medicines Directorate (VMD) established in 2011 and operationalized in 2016
- ❖ VMD took over from Pharmacy & Poisons Board (PPB) that regulates Human Medicines
- ❖ Poor Quality of VMPs was the main reason for creation of VMD
- ❖ A study conducted by Kenya KVA in 2008



# VETERINARY MEDICINAL PRODUCTS IN KENYA

- ❖ VMD regulates veterinary pharmaceuticals, Pest Control products and immunological products

- ❖ Ministry responsible for culture regulates alternative medicines

NATHEPA: Natural Traditional Healers and Practitioners Association

# Veterinary Medicines Directorate

- ❖ The Veterinary Medicines Directorate (VMD) regulated manufacture, importation, exportation, registration and distribution VMPs
- ❖ Objective regulation is to achieve the highest standards of safety, efficacy and quality of VMPs
- ❖ VMD ensures the integrity of medicines: Registration, post-registration, Pharmacovigilance & Post Market Surveillance.

# EXPERIENCES ON QUALITY OF VMPS

- ❖ Pharmacy & Poisons Board was established in 1944
- ❖ Veterinary Medicines Directorate (VMD) was established in 2011
- ❖ VMD has recognized labs for VMPS and issuance of Certificate of analysis (CoA).
- ❖ Laboratories recognized by VMD for determination of quality of VMPS
  - ✓ University of Nairobi, Faculty of Vet. Med. (PHPT Laboratory)
  - ✓ University of Nairobi, School Pharmacy (DARU)
  - ✓ National Quality Control Laboratory (NCQL)
  - ✓ Mission for Essential Drug Supply (MEDS)

# Sample analysis

- ❖ Name and address of manufacturer

- ❖ Brand Name

- ❖ Active ingredient

- ❖ Strength e.g. mg/ml

- ❖ Dosage form e.g. Oral suspension

- ❖ Specification e.g. Broad spectrum Anthelmintic

- ❖ Standard e.g. USP 45NF/USP

- ❖ Laboratory Number

- ❖ Date of manufacture

- ❖ Date of expiry



# Pre-registration Certificate of Analysis

Testing item	Standards	Results	Conclusion
Characteristics	An off-white to blue colored viscous suspension with no visible impurities	An off white viscous suspension with no visible impurities	Conforms
Identification	The principal peak relative retention time in the sample must correspond to that of Albendazole reference standard by HPLC assay	e.g.The principal peak relative retention time of (trade name) corresponds to that of albendazole RS by HPLC assay	Conforms
pH	4.5 - 5.5	4.92 at 22.5°C	Conforms
Sterility	No growth [ USP 34 ]	No growth [USP 34 ]	Conforms
Fill Volume	1000 ml	1000ml	Conforms
Assay	e.g. Albendazole : 90 - 110%w/v (label claim)	Albendazole : 95.3%w/v (label claim)	Conforms
Conclusion	The sample complies with the above standards		

# POST MARKETING SURVEILLANCE

- ❖ Post Market Surveillance: Continuous assessment of the safety and efficacy of VMPs post-registration.
- ❖ VMD has the responsibility of regulating the quality of medicines circulating to minimize falsified and substandard medicines

# CURRENT POST-MARKET SURVEILLANCE

- ❖ VMD in collaboration with FAO has recently carried out a survey on quality of selected VMPs circulating in Kenya.
- ❖ The broad objective was to determine the quality of selected veterinary medicines circulating in the year 2022/2023.
- ❖ Laboratory testing of selected VMPs at UoN,
- ❖ Results will inform strategies and implementation plans to address the problem identified by the survey,
- ❖ Stakeholder including the public to be informed on the quality status of circulating VMPs

# QUALITY OF VACCINES

- ❖ Kenya relies on AUPANVAC (Ethiopia) to determination of quality of Vaccines
- ❖ VMD in collaboration with University of Nairobi exploring possibility of analysis of vaccines

# QUALITY OF ALTERNATIVE MEDICINES

- ❖ UoN has developed a Centre for Natural Products and bio-prospecting (CENBIO)
- ❖ CENBIO in collaboration with National Traditional Healers
- ❖ National Traditional Healers & Practitioner Association (NATHEPA)
- ❖ CENBIO & NATHEPA are planning studies to determine the quality of alternative medicines in Kenya



# CONCLUSIONS & RECOMMENDATIONS

- ❖ In the last 6 years there has been improvement in assessment of the quality of VMPs in Kenya
- ❖ Kenya should continue building build capacity in determination of the quality of veterinary pharmaceutical products
- ❖ Kenya is the process of developing capacity for analysis of veterinary immunological veterinary products (initiative at UoN)

END OF PRESENTATION

❖ Thank for listening to me