World Organisation for Animal Health

Training Seminar for National Veterinary Products Focal Points

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

05 – 07 September 2023 Lilongwe, Malawi

The Fleming Fund

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Global Information & Alert System for Substandard And Falsified Veterinary Products (SFVPs) Pilot Project – Eswatini Experiences - *"Major Highlights"*

English Speaking Africa Training Seminar for National Veterinary Products Focal Points
5th – 7th September 2023
Lilongwe, Malawi

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ESWATINI VMPS REGULATORY LANDSCAPE

- Responsibility of Department of Veterinary & Livestock Services
- Animal Disease Act 7, 1965 – Principal Act
  - Animal Disease (Amendment Act), 1990 – restriction of importation, distribution and usage of VMPs
  - Prohibition of use of Anabolic Hormones, Thyrostatic Substances & Growth Promoters Regulations, 2006
  - **Regulation & Control of Veterinary Drugs and Medicinal Substances Regulations, 2012**
- Medicines and Related Substances Control Act 9, 2016 - MoH
  - Specifies some shared responsibilities between Health Services & Veterinary Services (e.g. highly regulated VMPs – e.g. Game capture/Euthanasia)
  - Regulations still at drafting stage

ORGANISATIONAL SET UP FOR VMP REGULATION

- VMP Responsibilities
  - Veterinary Medicinal Products Only – pharmaceuticals & biologicals
- Staff Compliment (with some roles in relation to VMP Regulation)
  - Veterinary Directorate – Headquarters
    - HQ Veterinarians – 4
    - (National Focal Point for VMPs – based at a Regional Level) – 1
  - Veterinary Field Services – Regional level
    - Public Service Field Veterinarians – 8 in four regions
    - Subregional Animal Health Inspectors – 28 in four regions
    - Frontline Veterinary Assistants – +/- 240 in four regions, at Dip tank level
  - Private Sector Veterinarians
  - Veterinary Public Health Unit – National Residue Monitoring mandate
    - Veterinarians – 2
    - Meat Inspectors – 12
    - Food Hygiene Lab Techs – 3

ULTIMATE REGULATION IN SIMPLICITY

- Regulation and Control of Veterinary Drugs and Medicinal Substances Regulations No. 1, 2012
  - The Regulations provide for and/or specify:
    - Recognition of certain Regulatory Authorities & authorizing the use of VMPs sourced directly from these Territories – **VMPs MUST HAVE MA in country of origin**
    - The listing of authorized VMPs – Compendium of Registered Veterinary Products
    - The categorization/classification of listed VMPs to regulate & restrict distribution and usage (Category 1 – 4)
    - The criteria for authorization of retailers and specifying the category of products they are allowed to distribute based on facility's technical capacity/competency
    - empowering the DVLS to conduct retailer inspections, and impose sanctions as necessary
  - All VMP imports are regulated through a strict paper-based import permit control system implemented by the DVLS (since 2007)
  - There is no form of local manufacturing practiced currently; all imports are for "final or ready to use packs"

ESWATINI PARTICIPATION IN SFVP PILOT PROJECT

- Participated since inception of Phase 1 of the Project in 2021
- Major benefits:
  - Mainly being able to make in depth analysis and assessment of our own performance and gap analysis in the surveillance and monitoring of our Veterinary Medicinal Products (VMPs) supply chain supervision – mapping of supply chain; linking importing distributors with retailers
  - Identification of implementation gaps in the passive surveillance system through Competent Authority monitoring of the VMP supply chain
    - Need for strengthening awareness and sensitisation of field surveillance teams (field veterinarians and paraprofessionals) on the importance of inspections and/or information gathering in the whole supply and use chain – strengthening of regulatory legal obligations

BENEFITS OF PROJECT TRANSITION TO PHASE 2

- Comparison of Phase 1 and Phase 2

Phase 1

- Excel based Questionnaire
- Relatively cumbersome to complete, particularly the Immediate Notification Form, which was rather too big and possibly difficult to send

Phase 2

- Web-based on SharePoint
- Less cumbersome & much more user friendly
- Caters for all three forms on one platform (Baseline/ Immediate/ Monthly Declaration of Absence

Great Features of the New Web-based Platform

- Provides three reporting forms with fixed reporting time lines
  - Baseline Data (Blue) – 15 January to 31 March (Q1)
  - Immediate Notification (Green) – anytime of suspected SFVPs
  - Monthly Notification for Absence (Pink) – within first 7 days of the following month
  - All supported by reporting email reminders by the WOAH SFVP Team
  - Provides access to links for publicly available national databases of VMPs
  - Provides an Alert Platform for SFVP Notifications made publicly available by the reporting Member States (MS)
  - Provides a Feedback platform for MS interaction with WOAH SFVP Team

POSSIBLE CONSIDERATIONS FOR THE FUTURE

- Future digital platform could consider additional resources
  - Database of Member States Regulatory Authorities or SFVP Focal persons or possible collaborations to provide links to other already existing database initiatives e.g. VMD-UK; Global Database of Veterinary Regulators
  - Database of Laboratory expertise per Regional Economic block to support SFVPs testing for surveillance
  - Availability of the downloadable versions of the reporting forms for in-country team trainings/ capacity building platforms

Thank You!