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

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South African Experience on Quality of Veterinary Products

Training Seminar for National Veterinary Products Focal Point: 5-7 September 2023

By Dr Alice T Sigobodhla

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NATIONAL SET UP

Stock Remedies (Act 36/1947)

Stock Remedy' means a substance intended or offered to be used in connection with domestic animals, livestock, poultry, fish or wild animals (including wild birds), ….. *but excluding any substance in so far as it is controlled under the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).*

Veterinary Medicines (Act 101/1965

Any substance or mixture of substances, ***other than a stock remedy or farm feed registered in terms of Act 36***, used or purporting to be suitable for use or manufacture or sold for use in connection with vertebrates, for the treatment, diagnosis, prevention or cure of any disease, infection or other unhealthy condition, or for the maintenance or improvement of health, growth, production or working capacity, or for curing, correcting or modifying and somatic or organic function, or for correcting of modifying behaviour.

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ROLES & RESPONSIBILITIES OF THE AGENCIES

- Assessing veterinary medicine applications in terms of quality, safety and efficacy (Pre-registration and Post-regisration)
- Developing/updating policy and guidance on regulation and control of veterinary medicines
- Authorisation of use of unregistered veterinary medicines
- Authorisation of clinical trial protocols
- Monitoring and acting on reports of adverse drug reactions reported
- Licensing of manufacturers (GMP) and Inspection for regulatory compliance (Law enforcement including import and export controls/recalls) and post-marketing surveillance

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TYPES OF APPLICATIONS OF VMPs RECEIVED IN SOUTH AFRICA

New Chemical Entities

- NCE applications registered by RRAs
- NCE applications of products not registered anyway in the world (Wildlife products)

Generic applications

- Full biostudies
- Requests for biowaivers

Veterinary Biologicals:

Vaccines and Monoclonal Antibodies

Minor use/minor species:

Veterinary Medicines Exemptions from certain Medicine Registration Requirements requests

Clinical trial protocol applications

- Mostly for field trials in target species with the final formulation
- Requests for input on non-clinical safety studies: Postgrad students and some variations

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SUBMISSION OF APPLICATIONS & STAKEHOLDER ENGAGEMENTS

Who can submit applications & location of applicant

- Anyone can apply but must have an office based in South Africa
- Premises must be licensed to operate according to the Act
- Applications are done online (automated) followed by an inspection for compliance: GMP; GDP; GWP; GCP

Stakeholder engagement

- Industry Task Groups for both Agencies: Regular workshops
- Industry Associations: Clinical trials, Generics' companies, Innovator companies, Medical devices, Pharmacovigilance, complementary medicines: meet quarterly
- Various working groups: New applications, variations, clinical trials, complementary medicines
- Other departments and/or in various committees: Environment/DALRRD/GMO/Food Control
- CEOs/Registrar's meetings on a regular basis
- Ministerial Advisory committee on AMR

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HOW WE ENSURE QUALITY DURING THE REGISTRATION PROCESS

- **Assessor templates/Guidances provided to evaluators: full, verified and abridged types of reviews**

Dossier: consists:

- Module 1 – application documentation
- Module2: Expert summaries
- Module 3.2.S – active pharmaceutical ingredient
- Module 3.2.P – pharmaceutical product
- Module 3.2 R – regional information
- Modules 4 & 5 – Non-clinical & Clinical data

Structured review templates

- QOS and QIS
- Bioequivalence studies
- Bio-waiver assessment
- Additional strength biowaiver
- Residue Overall Summary report: MRLs & Withdrawal periods

Guidelines & Standards: VICH/EMA/FDA/WOAH

Peer review system and External Expert Advisory Committees

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MANAGING THE LIFE CYCLE OF VMPs

1. Variations: EMA classification system adapted and adopted

Also looking at the new EMA G/L published in April 2023

- Clinical: Type I and II
- Quality: Type I and II
- Inspectorate and certification variations
- Quality: Additional manufacturers, Labs and Transfer of applicancy

2. Post marketing surveillance and pharmacovigilance

3. Renewal of registrations every 5 years

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Current harmonisation engagements

- Representation of South Africa at VICH as an Observer
- Establishment of the National Veterinary Products Policy Task Team
  - ➢ Constitutes representation from all the Acts (101/1965, 36/1947, 35/1984 and 54/1972)
  - ➢ Has revised all current guidelines by both Acts and adopted most of the VICH guidelines (Q,S,E)
  - ➢ Antimicrobial Resistance Framework – “One Health”. Task Team with DALRRD and Food Control
  - ➢ Vet drug residues in Food: CODEX Alimentarius Committee
  - ➢ MoUs with Recognised Regulatory Authorities (RRAs): sharing of unredacted reports to apply reliance
  - ➢ RRAs: VICH founding members and Observers/Standing members
  - ➢ Focal points: WOAH
  - ➢ Participants of the SADC Vet Zazibona

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Striving for international convergence

Reliance pathway review: Follows WHO good regulatory practices guidance

1. Considers (partly or fully) assessments done by Recognised Regulatory Authorities
2. Agency retains responsibility for its own decisions
3. **Approach: pre and post registration applications**

- Abridged reviews for applications reviewed by a recognized regulator
- Verified reviews for applications reviewed by a recognized regulator
- Recognition: looking forward to adopting this with the upcoming Vet Zazibona initiative

NB: **If an application has not been reviewed by a recognized regulator - a thorough full review is required**

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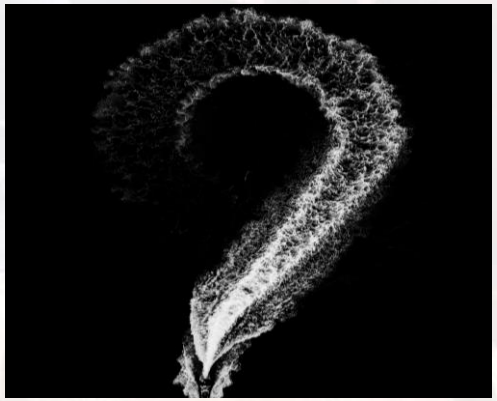
THANK YOU

Questions and Reactions



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