Experience of Nigeria in Application of VICH Guidelines

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Outline

- Introduction
- Applicable Guidelines
- Nigeria Situation
- Challenges
- Way Forward

Introduction

- **VICH** – International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
- Members – EU, Japan and USA. Australia, Canada, New Zealand and South Africa have observer status

Introduction (contd)

- It establishes and implements harmonized technical requirements (guidelines) for the registration of veterinary medicinal products in the VICH regions,
- This ensures high quality, safety and efficacy standards and
- Minimizes the use of test animals and costs of product development

Introduction (contd)

- **Veterinary Products** – are important tools in the prevention and control of animal diseases. These include vaccines, veterinary medicines, such as antimicrobial agents, and diagnostic kits.

Registration of Veterinary Products

- The Regulatory Authority (RA) assesses data of studies carried out on the VMP during development and production from the manufacturer to ensure it is safe and efficacious for use in animals
- The product when it has passed the test is registered for marketing.
- The RA still carries out post marketing survey to track the distribution and use of the VMP

Process of developing guidelines

Step 1	▪ Concept paper to propose issue ▪ Review by SC ▪ Appointment of Topic Leader/Chairman
Step 2	EWG to produce draft Guideline
Step 3	SC to review draft Guideline
Step 4	Official consultation in three regions
Step 5	EWG to review comments
Step 6	SC to adopt final Guideline
Step 7-8	Implementation of Guideline
Step 9	Recommendation for review
→	9 step procedure repeated

VICH Guidelines

- 56 guidelines for Industry and Regulatory Authorities
- 6 guidelines have been revised
- 2 guidelines are under revision
- Focus is on – pharmaceuticals, biologicals, pharmacovigilance and general aspects

Guidelines (contd)

- The VICH guidelines are used by industry and regulatory bodies for technical requirements in registration of veterinary products
- Guidelines are administrative tools that do not have the force of law
- Alternative approaches to the principles and practices described in the guidelines may be acceptable but must be supported by adequate scientific justification.

Relevant Agencies

- In the Nigeria context the focus for implementation of the VICH guidelines will be on the National Agency for Food and Drug Administration and Control (NAFDAC) and the National Veterinary Research Institute (NVRI)
- NAFDAC gives marketing authorization, conducts post-market surveys and carries out parmacovigilance. The Directorate of Veterinary Medicines and Allied Products (VMAP) has been newly established
- NVRI produces veterinary vaccines and other biologicals

Applicable guidelines in the Nigeria situation

- **Regulatory Authority**
  - GL24 – Pharmacovigilance of veterinary medicinal products: Management of Adverse Event Reports (AERs)
  - GL27 – Guidance on pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance
  - GL29 – Pharmacovigilance of veterinary medicinal products: Management of periodic summary update reports
  - GL30 – Pharmacovigilance of veterinary medicinal products: Controlled list of terms

- **Industry**
  - GL9 – Good clinical practice, this is to

provide guidance on the design and conduct of clinical studies of veterinary products in the target species.

  - GL17 – Stability testing of new biotechnological/biological products
  - GL25 – testing for residual formaldehyde in inactivated veterinary vaccines
  - GL26 – testing for residual moisture in freeze dried veterinary vaccines

- GL34 – Testing for detection of Mycoplasma contamination
- GL41 – Target animal (TA) safety: Examination of live veterinary vaccine in TA for absence of reversion to virulence
- GL44 – Target animal safety for veterinary live and inactivated vaccines
- GL50 – Criteria to waive target animal batch safety testing for veterinary vaccines

Current Situation

- **NVRI**
  - GL9 – For Good Clinical Practice – the Institute produces all its veterinary vaccines and other biologicals in accordance to the "Manual of Diagnostic Tests and Vaccines for Terrestrial Animals" by the World Organisation for Animal Health (OIE). *http://www.oie.int/manual-of-diagnostic-tests-and-vaccines-for-terrestrial-animals/*

- GL17 – Stability testing of new biotechnological/biological products is not carried out in the Institute due to the unavailability of the relevant equipment and associated materials
- GL25/26 – testing for residual formaldehyde in inactivated veterinary vaccine and residual moisture in freeze dried veterinary vaccines is not done in the Institute due to the unavailability of the relevant equipment and associated materials

– GL34 – Testing for detection of Mycoplasma contamination is done using the relevant primers in collaboration with the Molecular Biology of the Institute.

- **NB:** batches of vaccines produced are tested at PANVAC for quality control purposes

- GL41/44 – Target animal (TA) safety: Examination of live veterinary vaccine in TA for absence of reversion to virulence and Target animal safety for veterinary live and inactivated vaccines are not done due to the unavailability of an animal experimental house and the required specific pathogen free experimental animal species required for the procedure

- GL50 – Criteria to waive target animal batch safety testing for veterinary vaccines is done based on the OIE guidelines for vaccine production in consonance with Good Laboratory Practice as governed by the ISO 17025 Standards for Testing and calibrating laboratories . The Institute is presently implementing a Quality Management system (QMS) in accordance with the ISO 9001 in general and specifically working towards an ISO 17025 accreditation for the production of veterinary vaccines.

- **NAFDAC**
  - Not using the VICH guidelines
  - Agency has developed guidelines for monitoring the adverse event of veterinary medicinal products
  - that the Agency has established an information data bank on adverse events for human drugs (yet to be done for VMP)

Challenges

- Lack of clear knowledge and understanding of VICH guidelines and activities by Regulatory Authority and Industry
- Weak capacity of regulatory body (VMAPD) to apply VICH guidelines or other requirements
- Infrastructure deficit within industry for implementation of VICH guidelines or other requirements

Way Forward

- Greater awareness drive for stakeholders especially industry and regulatory authorities
- VICH to explore means to assist NAFDAC and NVRI find funding for implementation of VICH guidelines
- Advocacy to Regional Economic Communities (RECs) should be made

Acknowledgements

- National Agency for Food and Drug Administration and Control (NAFDAC)
- National Veterinary Research Institute (NVRI)
- Federal Ministry of Agriculture and Rural Development
- World Organization for Animal Health (OIE)

THANK YOU FOR LISTENING