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GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF VETERINARY VACCINES IN ZIMBABWE

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PURPOSE

- Provides guidance on information that must be submitted for all applications for registration of veterinary vaccines in Zimbabwe
- MCAZ/EVR/GL-13 will be used to facilitate screening and review
- To ensure that only vaccines proven to be safe, effective and of good quality are authorized for use

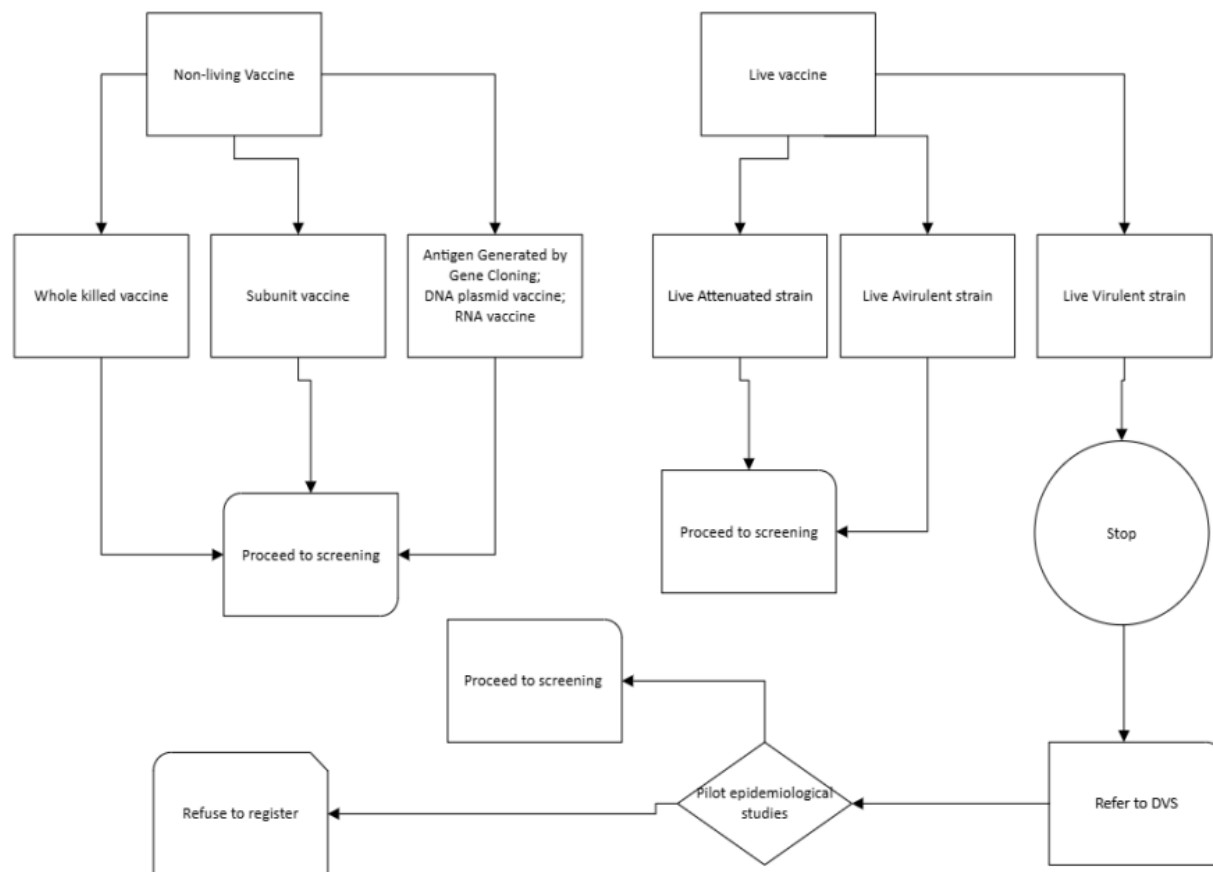


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BACKGROUND

- Zimbabwe is a member of the World Organization for Animal Health (WOAH)
- MCAZ developed these guidelines based on the WOAH terrestrial manual and those developed by the East African Community (EAC), as well as VICH
- The guidelines include a matrix for handling live and non-living vaccines

RISK-BASED MATRIX





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STRUCTURE OF THE GUIDELINES

- Part 1- Product information
- Part 2- Manufacture and control
- Part 3- Safety
- Part 4- Efficacy



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PART 1 – PRODUCT INFORMATION

- Administrative information
- Proof of registration in the country of origin
- Samples
- SmPC
- Labelling and PI to comply with the MASCR of Zimbabwe



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PART 2 –MANUFACTURE AND CONTROL

- Table of qualitative and quantitative composition
- For FMD vaccines, justification for the choice of vaccine strains should be included or cross-referenced to the section of the dossier where it is located
- Details of container closure system – signed, dated and version-controlled specifications
- Flow chart & detailed description of manufacture
- Inactivation kinetics, detoxification, purification, stabilisation
- Formulation of finished product – sterilisation processes, aseptic processing, filling etc.



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CONTROL OF STARTING MATERIALS

- Control of starting materials listed and not listed in pharmacopoeias
- History of cell line (origin, number of passages, media used in multiplication, storage)
- MCS and WCS should be reserved for testing by MCAZ or AUPANVAC
- Embryonated eggs must be obtained from an SPF flock (COAs to be provided)
- Information on Virus seed and bacterial seed to be provided
- BSE/TSE free certification for starting materials of animal origin



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Batch data and stability studies

- Batch to batch consistency data – table of results for 3 batches of the vaccine should be provided
- Stability data for **at least 3 representative** consecutive batches
- Stability indicating tests – (sterility, potency/virus titre/bacterial counts, bacterial endotoxins, physical and chemical tests)
- Data for in-use shelf life to be provided for 2 batches
- For live vaccines, in-use shelf life for 8-10 hours to be supported by stability data
- Shelf-life post reconstitution should be provided



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Part 3 – Safety & Part 4 – Efficacy

Safety

- Laboratory tests – VICH GL44
- Field safety
- Other safety issues – Safety to the user, safety to the environment, safety of residues, interactions

Efficacy

- Laboratory efficacy
- Vaccination-challenge studies
- Compatibility studies
- Field efficacy



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Common deficiencies

Part 1- Administrative

- Incorrectly completed MC8 forms
- Labelling and package inserts that do not comply with the MASCR of Zimbabwe
- Samples
- Proof of registration in the country of origin

Part 2- Manufacture and control

- Flow diagram and narrative description of manufacture
- Inactivation kinetics
- BSE/TSE free certification for starting materials of animal origin
- Specifications devoid of critical tests
- Batch to batch consistency data
- Lot release protocols not provided
- Stability data



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Common deficiencies

Part 3- Safety

- Safety studies representative of all target species for which the product is intended

Part 4- Efficacy

- Laboratory efficacy
- Vaccination-challenge studies
- Compatibility studies
- Field efficacy
- Number of unvaccinated and vaccinated animals not specified



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THANK YOU

Protecting your right to quality medicines and medical devices