

African Union
Pan African Veterinary Vaccine Centre
AU-PANVAC

PPR Vaccine Certification and Procurement Guideline in Africa

Dr Charles BODJO, Director AU-PANVAC

AU-PANVAC's Mission & Mandates

MISSION: "To promote the use of **GOOD QUALITY VACCINES** and **DIAGNOSTIC REAGENTS** for the control, eradication and surveillance of animal diseases in Africa."

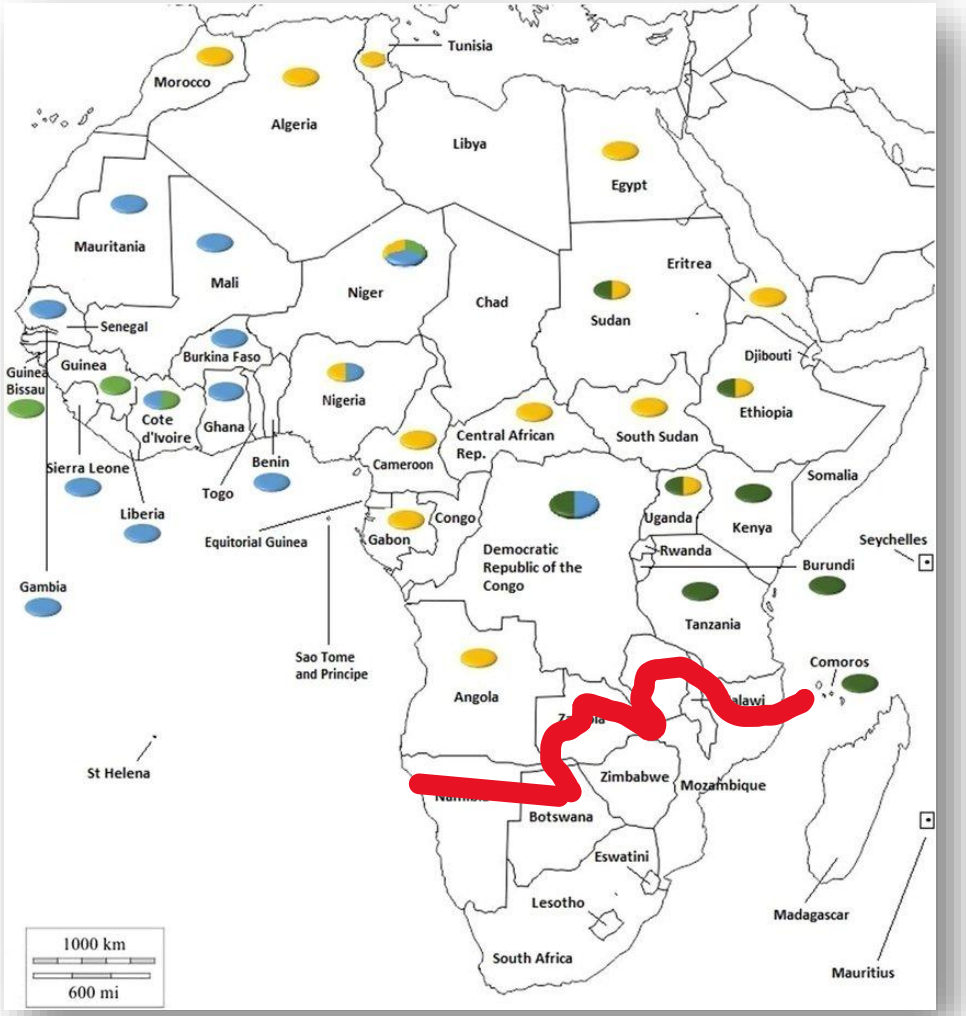
MANDATED to act as CONTINENTAL REFERENCE CENTRE for:

- **Independent quality control and certification of veterinary vaccines** produced in or imported into Africa.
- **Produce, maintain, and distribute biological reference materials** to support disease surveillance and diagnosis.
- **Provide training and technical assistance** to laboratories and national vaccine production facilities to build capacity for quality assurance.
- **Auditing and certification of vaccine manufacturing facilities** *in collaboration with National Regulatory Authorities in Africa.*
- Maintaining **Africa Free from Rinderpest**

AU-PANVAC's Contribution AU Flagship Programme

- **: The Africa We Want**
  - Strategic Objective : **Increased Agricultural Production & Productivity**
- CAADP COMPREHENSIVE AFRICA AGRICULTURE DEVELOPMENT PROGRAMME Kampala Summit
  - Enhance sanitary and phytosanitary standards (SPS) and implement One Health protocols to safeguard food safety and protect human, animal, plant and environmental health.
  - Invest in disease surveillance and reporting, **STRENGTHEN VETERINARY LABORATORIES, INCREASE VACCINE PRODUCTION**, prioritize eradication of peste des petits ruminants (PPR) by 2030, and improve cooperation on transboundary animal diseases.

PPR Virus in Africa



- **PPR Virus (genus of Morbillivirus) with Four Lineages** endemic in most Africa (Except the SADC region)
  - Lineage 1 (Green)
  - Lineage II (Blue)
  - Lineage III (Dark green)
  - Lineage IV (Yellow)
- But only **one Serotype**

Dundon et al. 2020. Arch Virol ***165****, 2147–2163 (2020).*

PPR Vaccines

- **PPRV Nigeria 75/1 Strain** (*Diallo et al. 1989; Diallo 2004*): Lineage II, **Most widely used in the world (ONLY currently used in AFRICA)**
- **PPRV Sungri/96** (*Singh et al. 2009; Saravanan et al. 2010*): Lineage IV, **used only in India**
- **Duration of immunity**: **immunity for at least 3 years**.
- **Vaccine produced in freeze-dried form,**
  - Heat sensitive.
  - Need to **maintain cold chain** to guarantee vaccine efficacy for field use.

Peste des Petits Ruminants Vaccine (Nigerian Strain 75/1) Confers Protection for at Least 3 Years in Sheep and Goats

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Abstract

The present study reports the duration of immunity and protective efficacy of Peste des Petits Ruminants (PPR) vaccine (Nigerian strain 75/1) in sheep and goats. A total of 105 sheep and goats were divided into three groups A, B and C. Group A received normal recommended dose (1.0 ml) of PPR vaccine, group B received half dose (0.5 ml) of PPR vaccine and group C was kept as unvaccinated control group in contact with vaccinated animals. The post vaccination dynamics of antibodies against PPR virus was studied. It was found that significant antibody titres persisted for 3 years post vaccination in sheep and goats vaccinated with either full dose or half dose of PPR vaccine. The challenge protection studies were carried out in experimental animals at 24 and 36 month post vaccination. The vaccinates withstood challenge and were found completely resistant clinically and virologically to virulent PPR virus for 24 and 36 months post vaccination. The unvaccinated control animals developed typical clinical signs of PPR and the challenged virus was detected in ocular, nasal and oral secretions of these animals. This study demonstrated that a single immunization with PPR vaccine conferred solid protection in sheep and goats for 3 years.

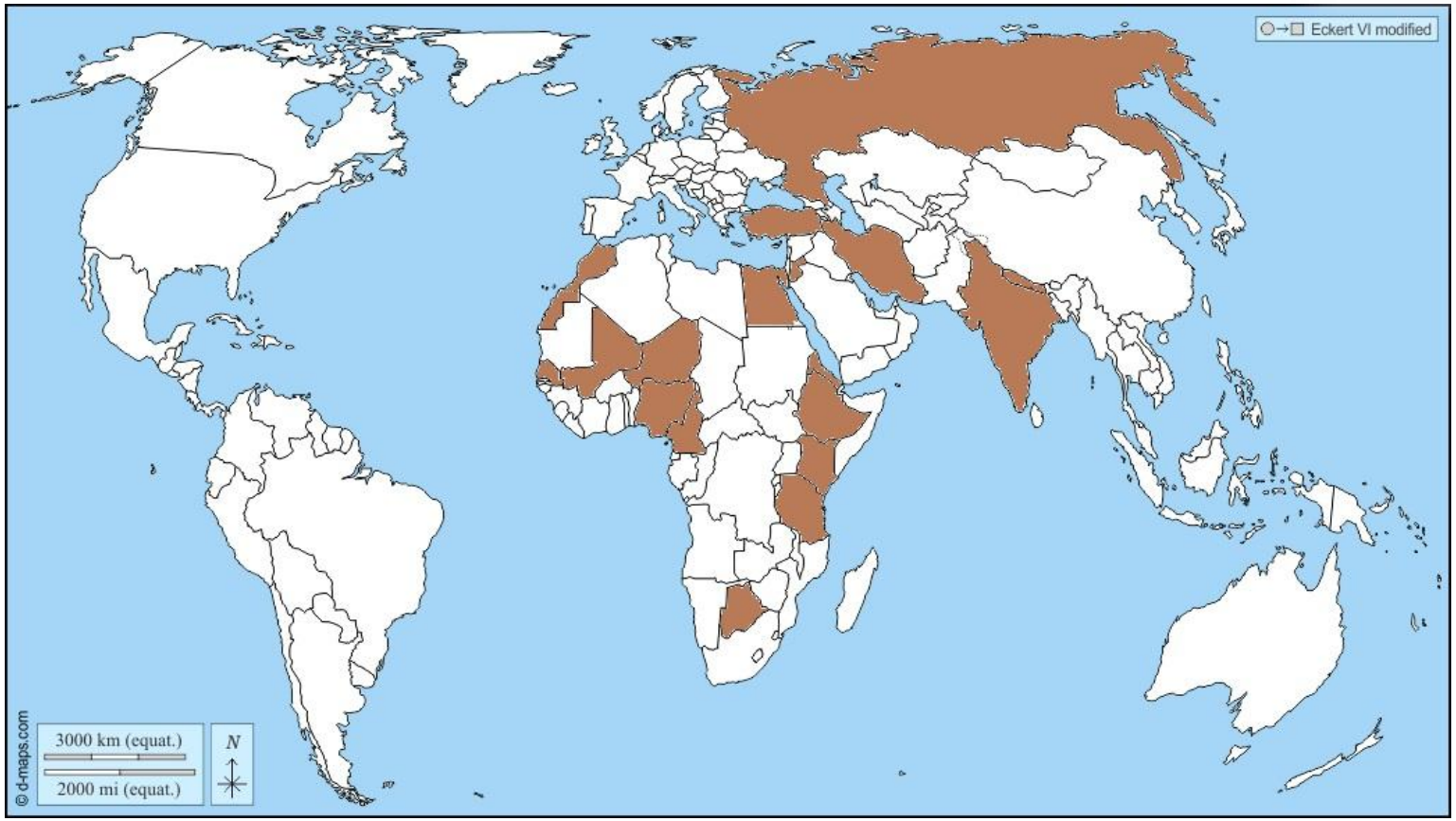
Keywords

PPR Vaccine, Small Ruminants

PPR Vaccine Received for Quality Control

❑ 12 AFRICAN LABS

- ✓ MEVAC & SRVI (Egypt),
- ✓ MCI & BIOPHARMA (Morocco)
- ✓ ISRA-Production (Senegal),
- ✓ LCV (Mali),
- ✓ NVRI (Nigeria),
- ✓ LANAVET (Cameroun)
- ✓ NVI (Ethiopie),
- ✓ NAPHL (Eritrea),
- ✓ KEVEVAPI (Kenya)
- ✓ BVI (Botswana)

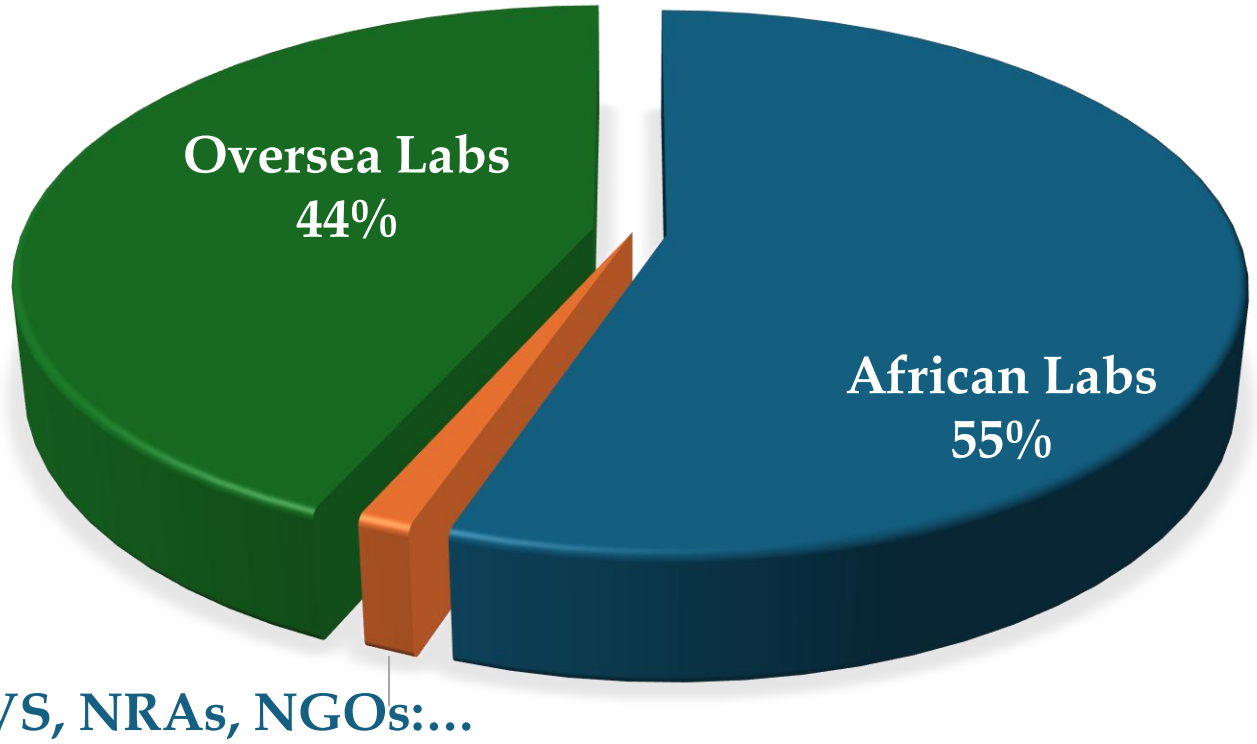


❑ 9 OVERSEA LABS

- ✓ HESTER (Nepal),
- ✓ JOVAC (Jordan),
- ✓ VETAL & DOLLVET (Turkey)
- ✓ FGBI ARRIAR, (Russia)
- ✓ RaziVSRI & Vira Vaccine Shaya (Iran),
- ✓ Indian Immunologicals & BIO-MED (India): PPRV Sungri/96 Vaccine

PPR Vaccines Received for QC

- Total of **442 PPR Vaccine Batches** tested from 2020 to 2025
- In 2025 the total batches of PPR vaccines correspond **~ 231 Million Doses**
- Origin of PPR Vaccines



PPR Vaccine Production Capacity in Africa

- 2024: Joint Online Meeting **AU-PANVAC & AU-IBAR** with African PPR Vaccine Labs to:
  - Assess the current capacities of laboratories for PPR vaccine production.
  - Discuss challenges and barriers for effective collaboration.
  - Identify opportunities for resource sharing and joint ventures.
  - Identify strategies/actions for enhanced collaboration and coordination, to implement the PPR Eradication from Africa.

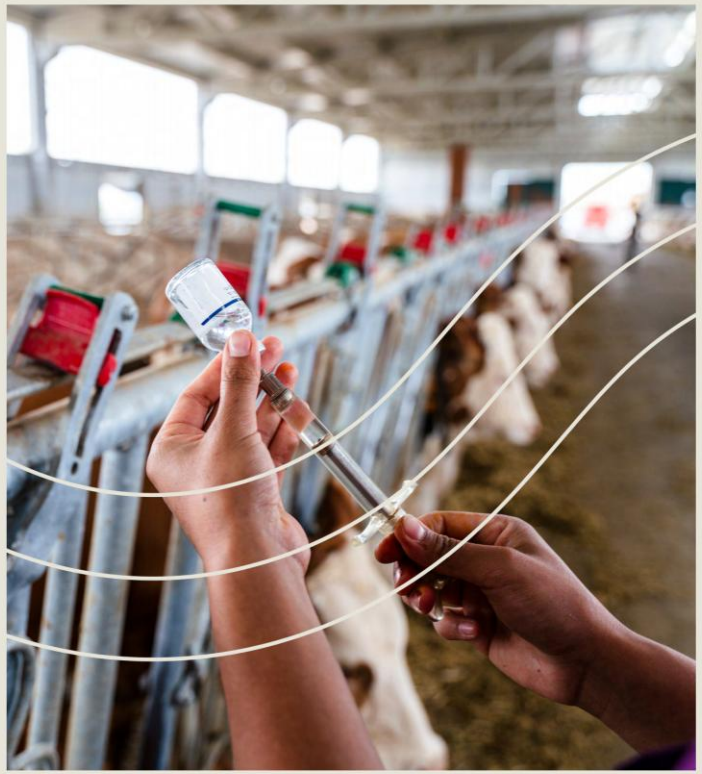
- **9 Vaccine Labs** participated to the meeting (*BIOPHARAMA-Morocco; MCI-Morocco; ISRA-Senegal; NAPHL-Eritrea; HESTER-Tanzania; CVRL-Sudan; NVRI-Nigeria; SRVI-Egypt; CVL-Mali*)

- Outcome from this assessment: 8 Vaccine Labs production labs indicated a capacity for production of **587 million doses/Annually** (which can be increased)

WOAH Guideline on Procurement of Vaccines

Practical Guidelines for National Procurement of Veterinary Vaccines

February 2024



World Organisation for Animal Health
Founded as OIE

https://www.woah.org/en/what-we-offer/veterinary-products/

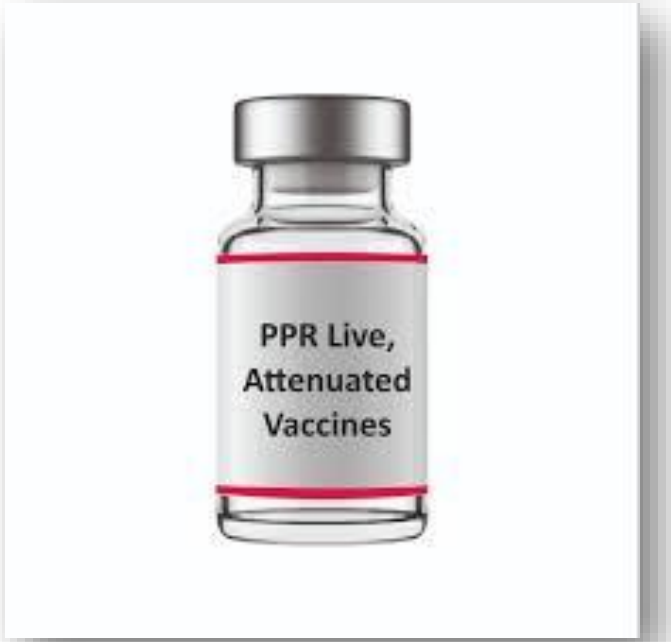
Figure 2: Six key questions surrounding the selection of a vaccine



PPR Vaccine Technical Requirements

❑ Vaccine characteristics

- ✓ Vaccine Strain: **Preferred PPRV Nigeria 75/1 Strain**
- ✓ Vial size (Doses)
- ✓ Stability and Shelf-life data
- ✓ Formulation: Freeze-dried (lyophilised) vaccine supplied in sterile glass vials.



❑ Labelling and packaging conditions

- ✓ Product information "Directions for Use"
- ✓ Delivery conditions (supply of cold chain to ensure that vaccines remain effective during shipment)

❑ **Diluent:** sterile diluent supplied in matching volumes

PPR Vaccine Technical Requirement…

- **Standard storage conditions: +2°C to +8°C.**
- **Dosage and Administration**
  - ✓ Recommended dose volume per animal shall be stated.
  - ✓ Route of administration (e.g. subcutaneous) shall be specified.
  - ✓ Stability after reconstitution and maximum usable time shall be stated.
- **PPR Vaccine Quality Control**
  - ✓ Proof of the use of a quality-assured vaccine
  - ✓ Requirement of **AU-PANVAC Certificate**

Quality Control Tests of Veterinary Vaccines

Vaccine QC Tests conducted following the "*Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*"

World Organisation for Animal Health
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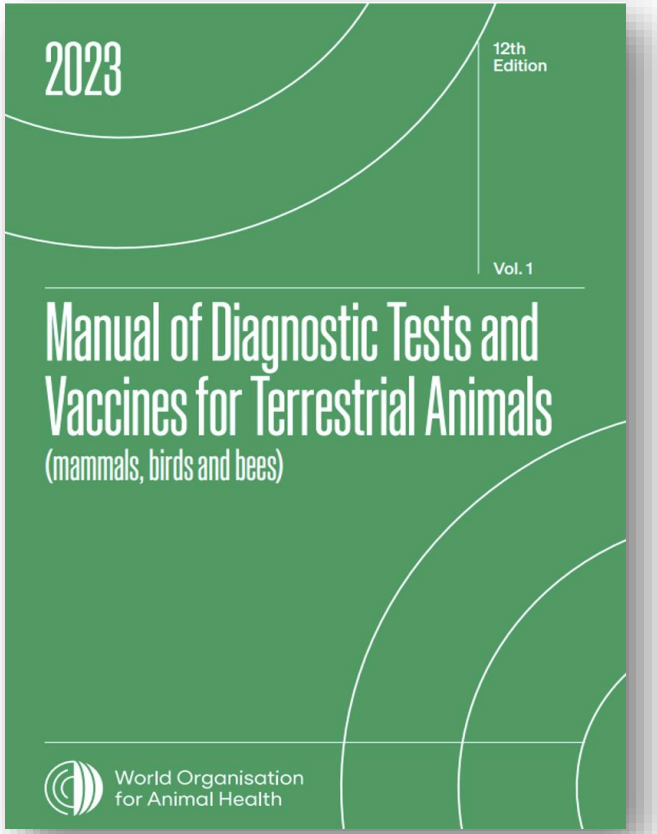


1-Identity

2-Purity/Sterility

3-Safety/Innocuity

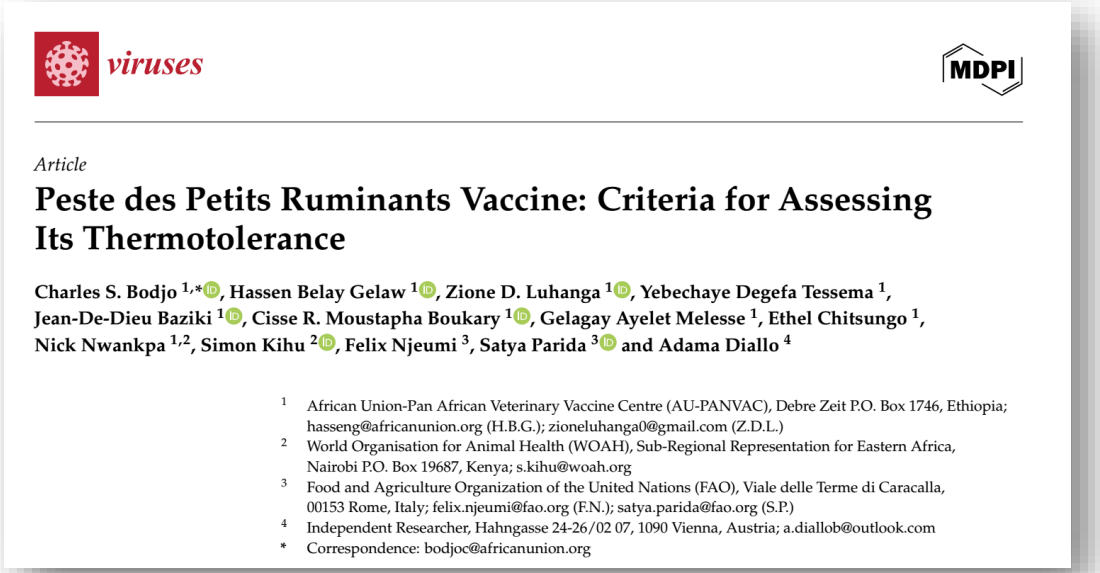
4-Potency/Efficacy

5-Stability

PPR Thermotolerant Vaccine

❑ Criteria of PPR Thermotolerant Vaccine

1. Incubation **Day5 / 40°C**
2. Post Incubation
   - Titer maintained **≥ 2.5log10** (TCID50/ml)
   - Titer Loss **≤ 1 log10**



viruses MDPI

Article

Peste des Petits Ruminants Vaccine: Criteria for Assessing Its Thermotolerance

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❑ Similar Criteria were used for Thermostable Viral Vaccines:

- *Rindertest Thermostable vaccine: minimum titer* **2.5 log10** (TCID50/ml) after exposure at **45°C/14 Days** & **Titer loss ≤ 1.6 Log10**

- *Measles-Mumps vaccine:* **3 log10** (TCID50/ml) after post exposure at **37°C/7Days** & **Titer loss ≤ 1 Log10**

Criteria for Thermotolerant PPR Vaccine adopted by the WOAH Biological Standard Commission

- Presentation on the Criteria and the Standard Operating Procedure (SOP) for testing thermotolerant PPR vaccines was made on Sept. 2025 to WOAH Biological Commission.

- The WOAH Biological Commission agreed on the following

  - Incorporation of the criteria for assessing thermotolerant of PPR vaccines in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Chapter 3.8.8 (Section C.2.2.4 or C.2.3.3 on batch release).

  - Detailed SOP for testing thermotolerant PPR vaccines should be maintained through the WOAH PPR Reference Laboratory Network website."

Quality Control Test Report & Certificate

Vaccine Batch **FAILS** Quality Control → QC Test Report

Vaccine Batch **PASS** Quality Control → QC Test Report & Certificate

Publication Certificates of batches PASS QC tests :

WWW.AUPANVAC.ORG

BATCH RELEASE

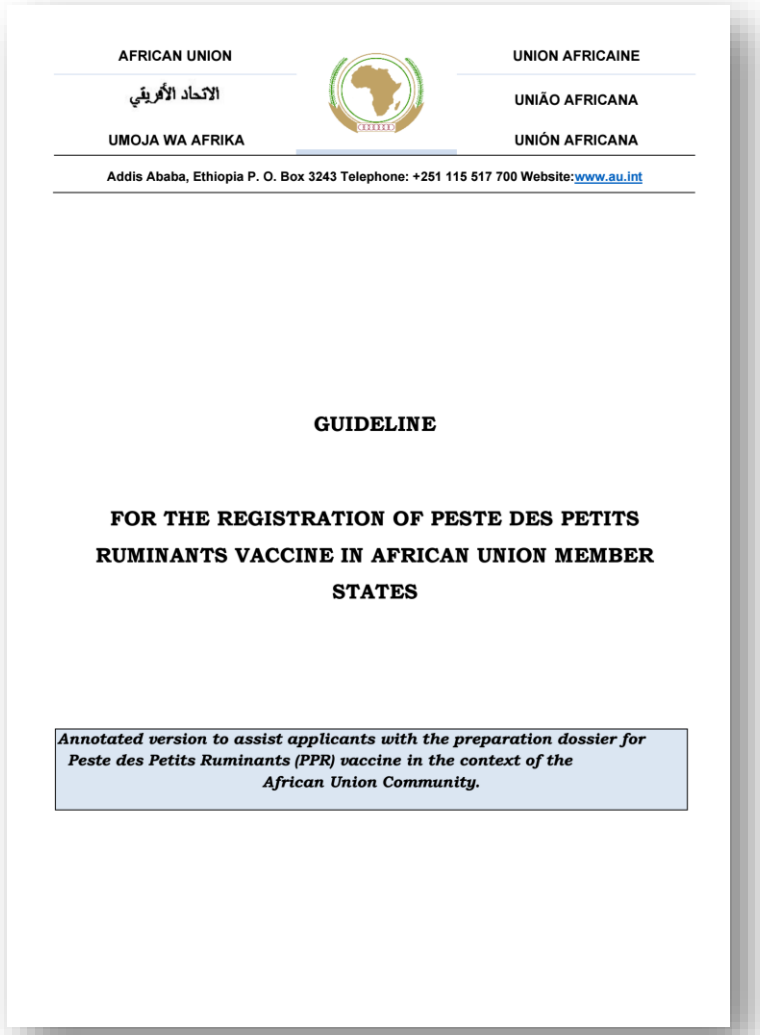
Regulatory Requirement: Market Authorisation

- Market authorization: **registration/licensing in the corresponding country** (including the number of the marketing authorisation and holder).

Or

- Justification and supporting documentation for emergency or special import authorisation.

Guideline for PPR Vaccines Registration



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GUIDELINE

FOR THE REGISTRATION OF PESTE DES PETITS RUMINANTS VACCINE IN AFRICAN UNION MEMBER STATES

Annotated version to assist applicants with the preparation dossier for Peste des Petits Ruminants (PPR) vaccine in the context of the African Union Community.

Harmonised Guideline (*developed with the Technical support of the GALVmed)* aimed to facilite the registration of PPR vaccine across Africa

GUIDELINE CONTENTS

1. PART 1: PRODUCT INFORMATION AND LABELLING
2. PART 2: QUALITY-MANUFACTURE AND CONTROL
3. PART 3: SAFETY
4. PART 4: EFFICACY
5. ANNEXES

- **Application form for registration of PPR vaccine in Africa member state**
- **Templates for leaflet/insert, the summary of product characteristics and labelling for ppr vaccine.**

Harmonisation of Standard for PPR Vaccine Registration Initiatives

"Socialization of the African Union Harmonized Guideline for Registration of PPR vaccine in Africa", workshop organized, June 2025, Dar Es Salaam



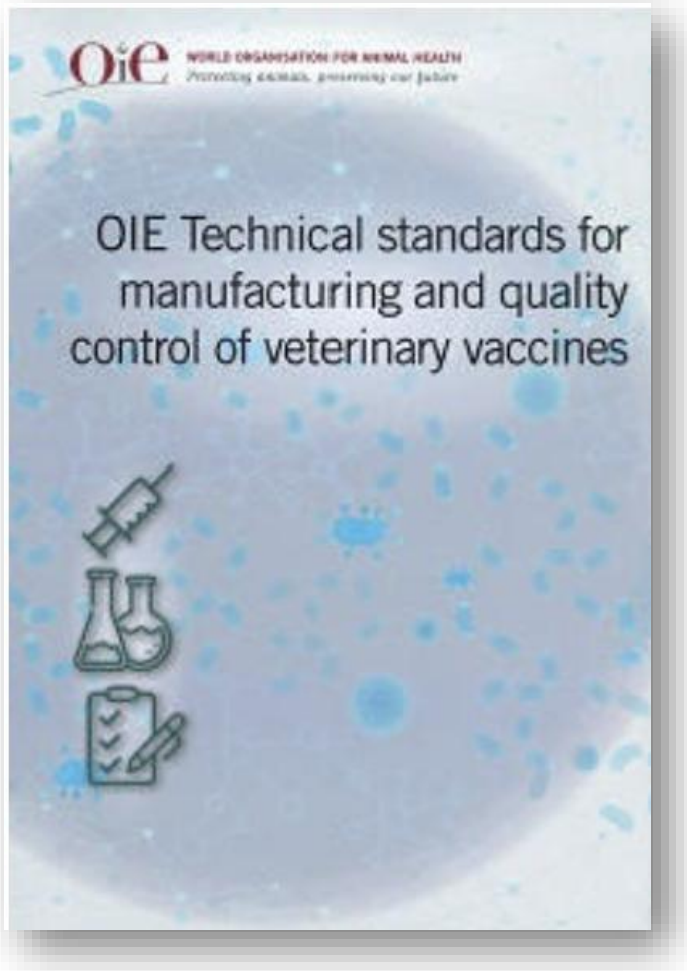
June 2025: *Dar Es Salaam, Tanzania*

- Familiarize Stakeholders with the harmonized guidelines for the registration of PPR vaccine

- To facilitate PPR Vaccine Registration across Africa

Manufacturer - Supplier

- Good manufacturing practices (GMP) certificate provided by a relevant authority.
- Compliance with relevant quality assurance programmes and procedures based on international standards for all vaccines to be delivered: ISO Certification
- WOAH technical standards for manufacturing and quality control of veterinary vaccines
- Description of the manufacturer's Pharmacovigilance, adverse event reporting procedures, and batch recall mechanisms.



Call for Tender

- **Operated by AU-IBAR:** Invitation for Bids
- **Section 1: Introduction (Short introduction on the country)**
- **Section 2: Background and context** (objectives, duration of the vaccination campaign, estimated start date and duration, estimate of quantities of vaccines needed for the duration of the campaign, etc.)
- **Section 3: Scope of services**
- **Section 4 (Evaluation of Technical Offers):** Compliance with
  - ✓ Vaccine specifications
  - ✓ GMP
  - ✓ Quality Control: AU-PANVAC Certification
  - ✓ Cold chain and logistics arrangements





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