African Union

AU-PANVAC Laboratories

World Organisation for Animal Health
Founded as OIE

Increasing the Adoption of Quality Vaccines for Livestock Diseases in Africa

Workshop on Vaccines and Substandard and Falsified Veterinary products

Dr Charles BODJO, Ag Director AU-PANVAC

Overview of the Presentation

- Brief recall on AU-PANVAC's Mission & Activities
- Quality Control of Veterinary Vaccines in Africa
- Support for Veterinary Vaccines Registration
- Effort for Securing of the QC Test Certificate
- Guideline for Risk-Based Post Market Surveillance
- Guideline for GMP and GDP
- Surveillance of the Veterinary Vaccines Genetic Stability

Recall on AU-PANVAC's Mission & Activities

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MISSION:

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

ACTIVITIES:

- **INTERNATIONAL INDEPENDENT QUALITY CONTROL** of all veterinary vaccines produced or imported into Africa.
- **PRODUCTION AND DISTRIBUTION OF DIAGNOSTIC REAGENTS** for surveillance of animal diseases
- **TRAINING AND TECHNOLOGY TRANSFER** in vet. vaccine production

AU-PANVAC International Status

World Organisation for Animal Health
Founded as OIE

- **Collaborating Center For Quality Control of Veterinary Vaccine** (*WOAH Gen. Assembly Resolution 32, Paris, May 2013*)

Food and Agriculture Organization of the United Nations

- **Reference Centre for Technical Assistance in Quality Control of Veterinary Vaccine** (11th May, FAO Rome, 2015)

GF-TADs
GLOBAL FRAMEWORK FOR THE PROGRESSIVE CONTROL OF TRANSBOUNDARY ANIMAL DISEASES

Food and Agriculture Organization of the United Nations

World Organisation for Animal Health
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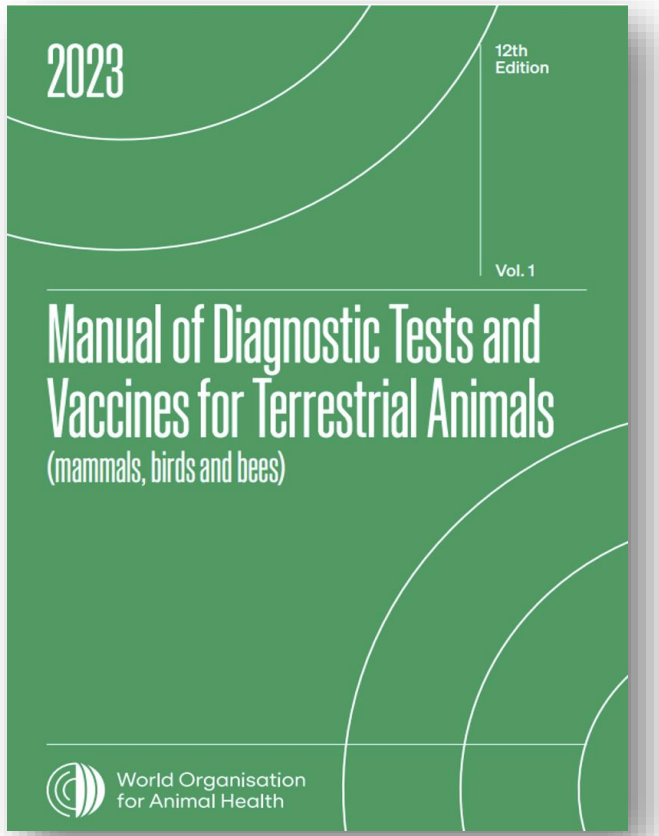
- **Rinderpest Holding Facilities (to maintain Africa Free from Rinderpest)**

Quality Control Tests of Veterinary Vaccines

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



1-Identity

2-Purity/Sterility

3-Safety/Innocuity

4-Potency/Efficacy

5-Stability

Trend of Vaccines Tested at AU-PANVAC

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- **1986 - 1996: 2 Vaccines**
  (RP and CBPP for cattle)

- **To date : More than 50 types of Vaccines**
  - **All Animal Species** (*except Fish*)
  - *300 - 400 batches annually*

- *Bacterial & Viral Vaccines*
- *Live & Inactivated vaccines*

Trends in the Origin of Vaccines Tested

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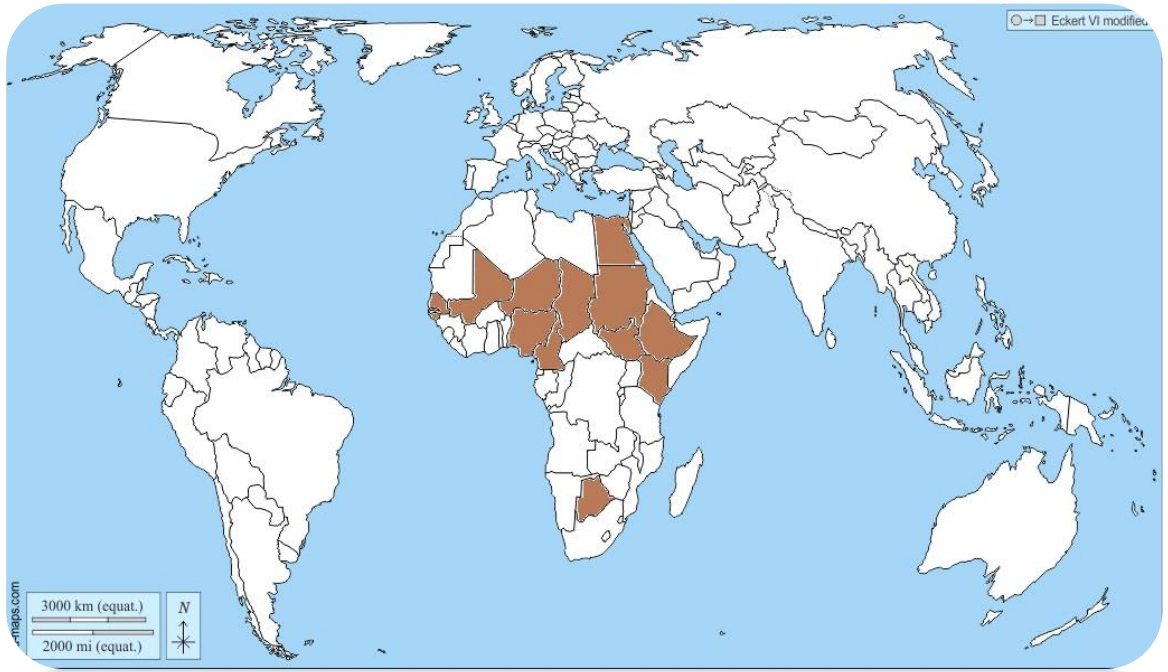
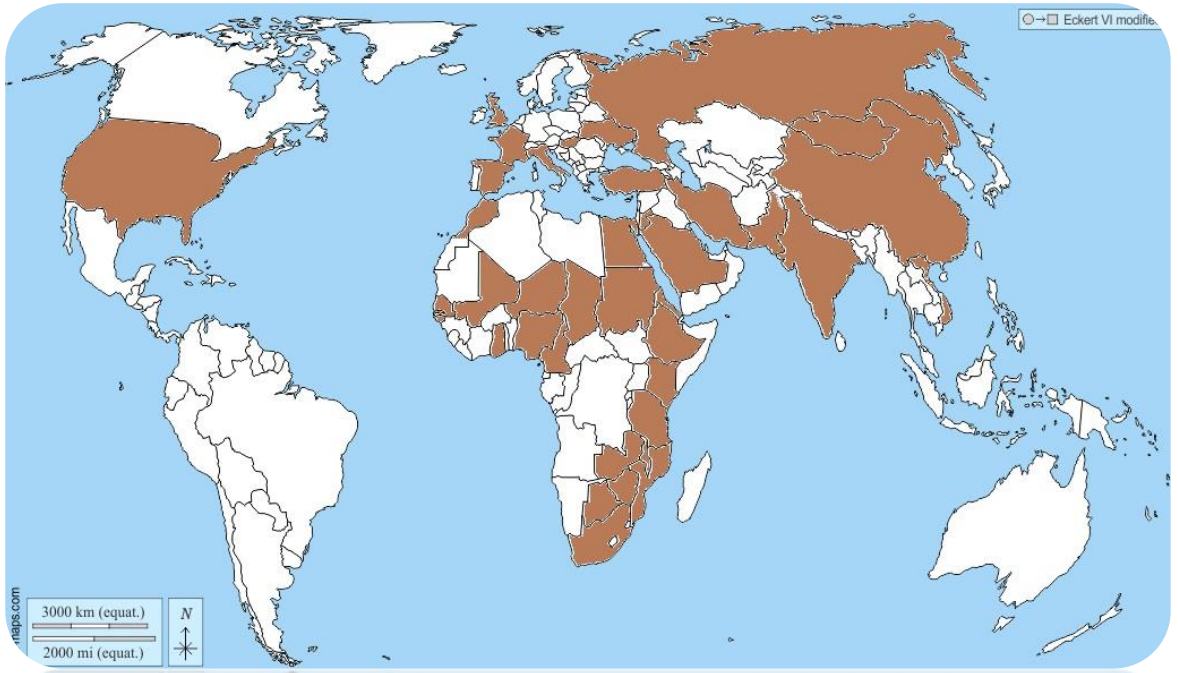
❑ 1986 - 1996



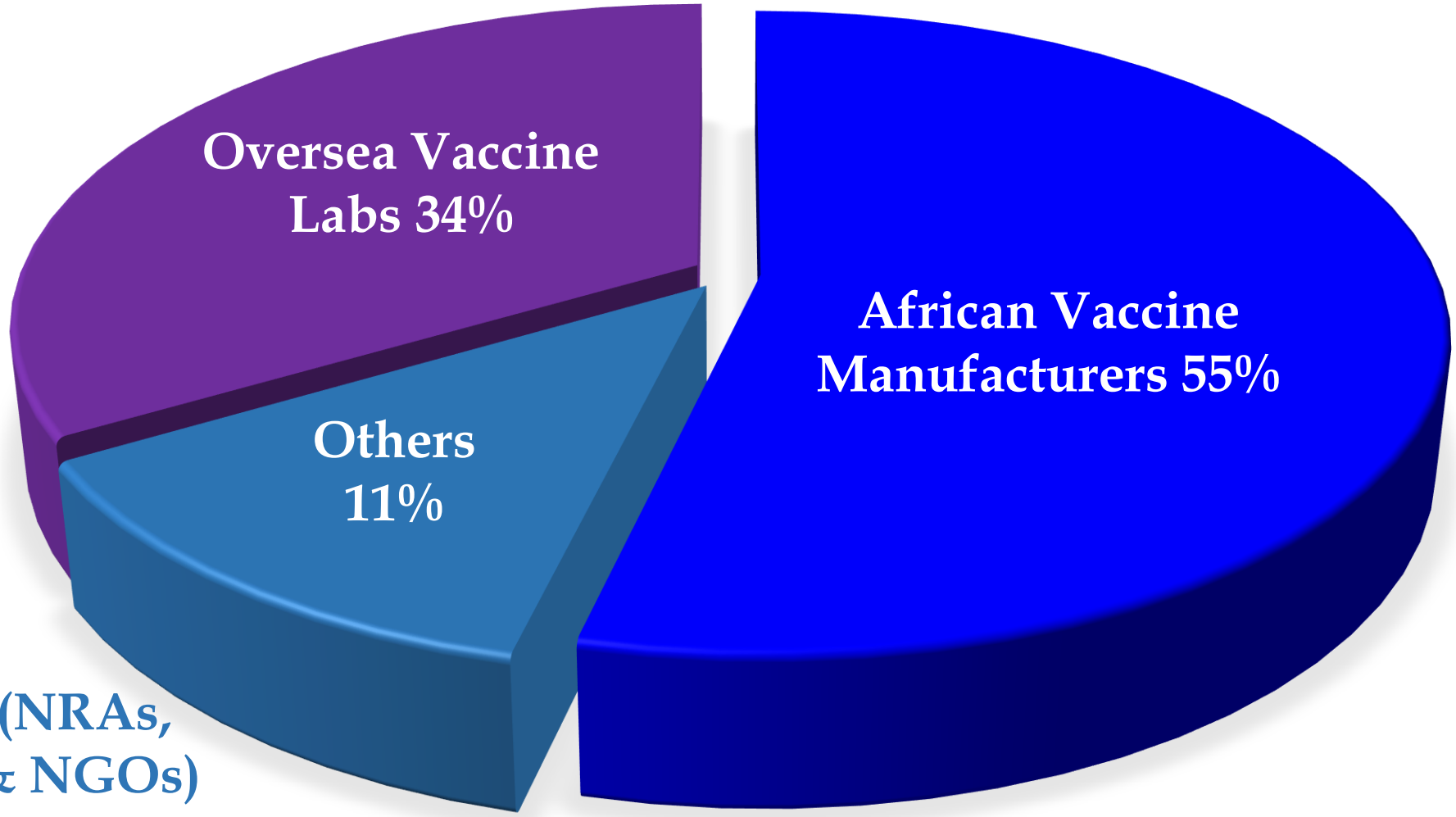
- African Manufacturers (11 countries)

❑ To date



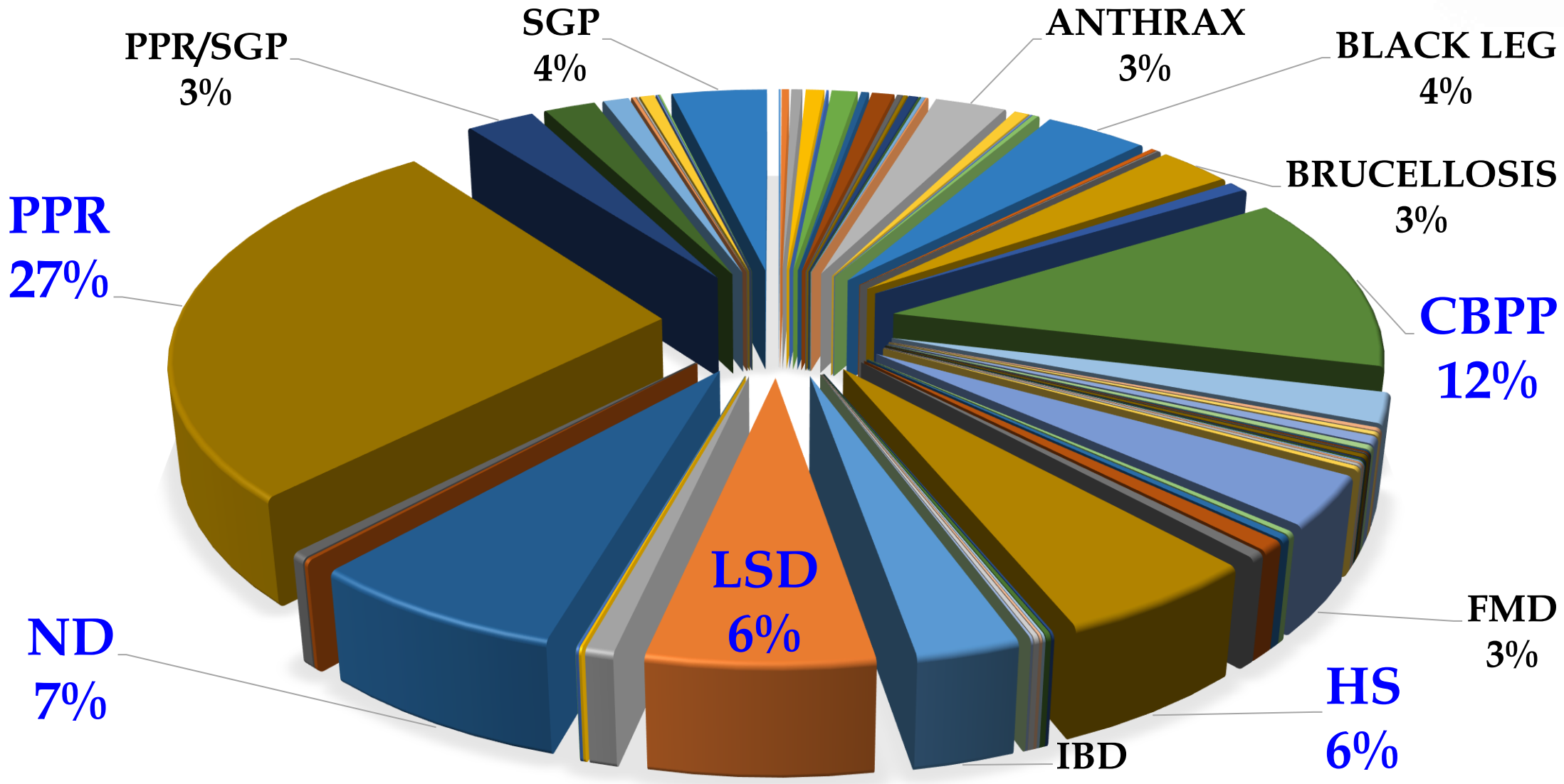
- African Manufacturers (20 countries) & Nat. Regulatory bodies
- Oversea Manufacturers (24 countrries)

Origin of Tested Vaccines: 2019 - 2023

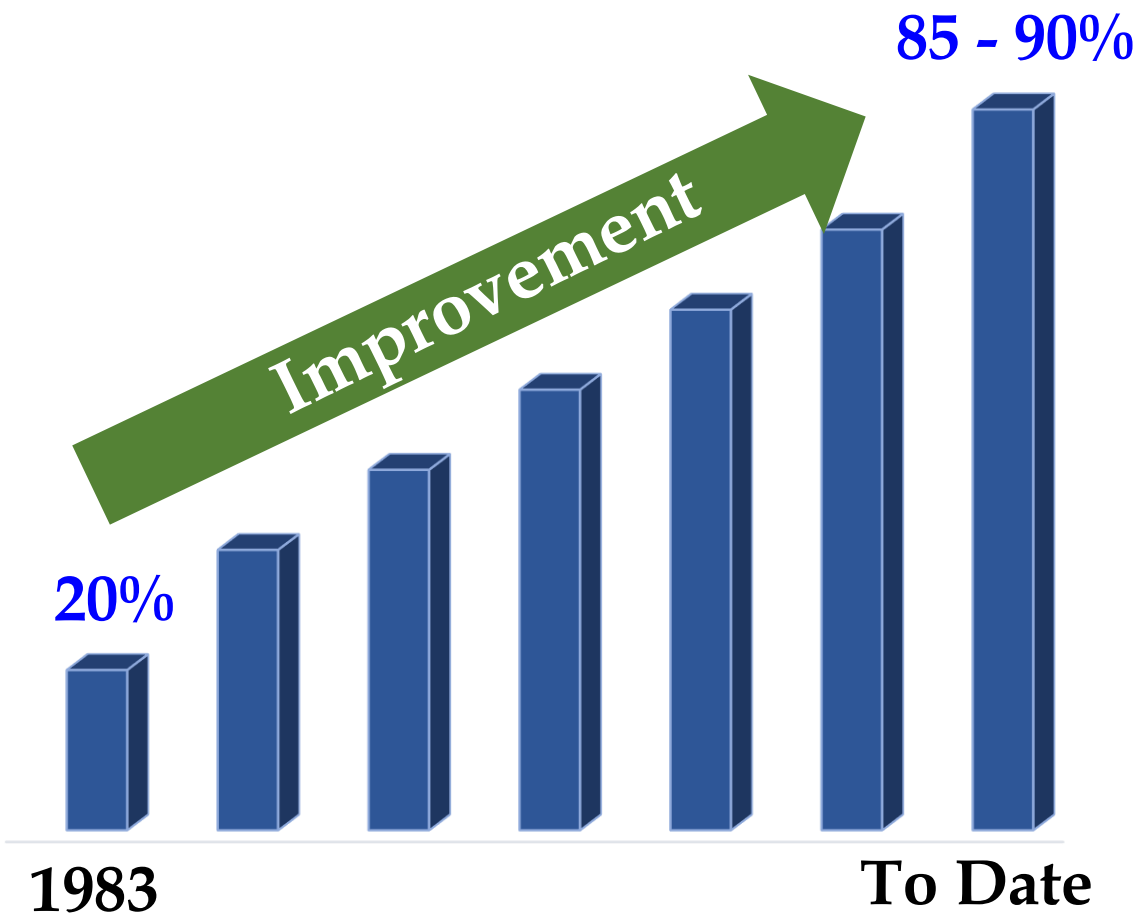


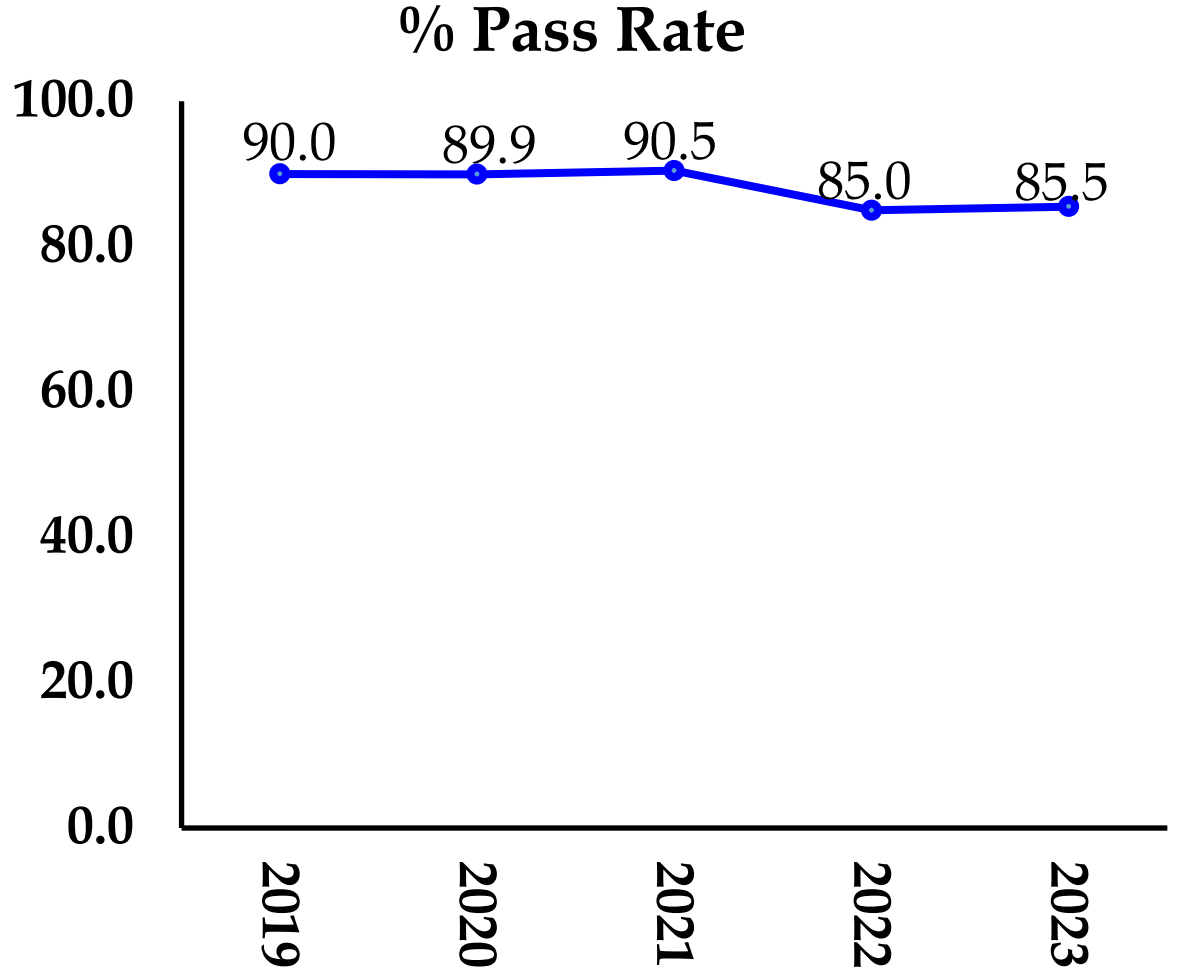
Other (NRAs, DVS & NGOs)

Main Types of Vaccines Tested: 2019-2023

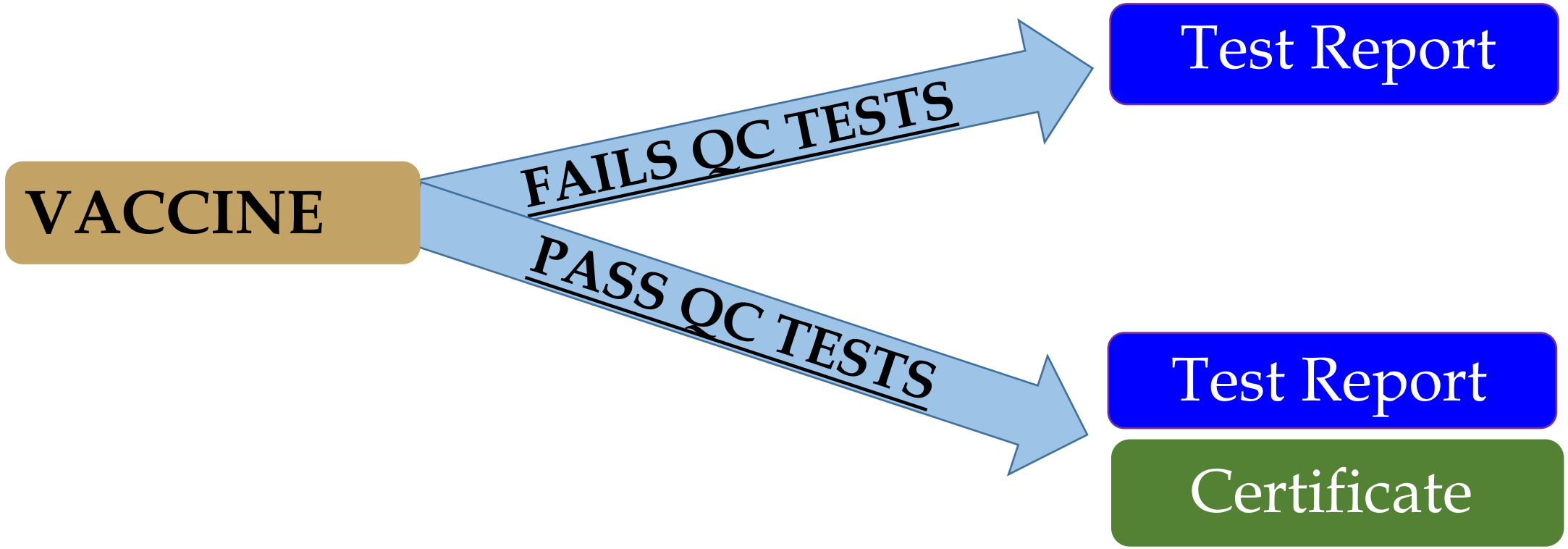


Vac. Quality Control Pass Rate: 2019 - 2023





Quality Control Test Report & Certificate



Forgery of QC Test Report & Certificate

- **2019: Sub-standard/falsified FMD vaccine**
  - Contacted by WOAH for certificate verification
  - The vaccine was on Uganda market. The National Competent Authority has been informed by WOAH and PANVAC for appropriate action to be taken.

- **2016: Sub-standard/falsified Rabies vaccine**
  - Contacted by FAO for certificate verification
  - Rabies vaccine for use in South-Sudan

Effort for Securing of the QC Test Certificate

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- Publication of vaccine QC Certificates on Website:

WWW.AUPANVAC.ORG

- New report with QR Code under process to:

- **Improve Accessibility**
- **Enhance Integrity**

Support for Vaccine Registration

AU-PANVAC QC Test Report is used to support the Registration of Veterinary vaccines and immunologicals to ensure that products are in

GOOD QUALITY:

PURE, SAFE and **EFFICACIOUS**

Support for Vaccine Registration…

PART 1 SUMMARY	PART 2 QUALITY	PART 3 SAFETY	PART 4 EFFICACY
1.A: Application form	**2.A:** Composition	**3.A.1 – A2:** **Safety, Single Dose, Overdose, Repeated Dose**	**4.A Lab Efficacy**
1.B:SPC	**2.B:** Method of Manufacture	**3.A.3: Other Safety Studies, e.g. Reversion to Virulence.**	**4.B: Field Efficacy**
1.C: Packaging	**2.C:** Control of SMs	**3.B: Field Safety**	**4.C** Bibliographical references
	2.D: In-Process Controls	**3.C: Safety to user and environment; residues, interactions.**	
	2.E: Controls on Finished Product		
	2.F: Batch consistency		
	2.G:Stability		

Harmonization of Standards for Vaccine Registration in Africa and Auditing of Facilities

- *Nairobi (Kenya) meeting* ***Nov. 2019***
- *Abuja (Nigeria) meeting* ***July 2023***

Participants: RECs, NRAs of AUMS, Vet. Vaccine Manufacturers, CVOs, AU-IBAR, GALVmed, Secretariat African Continental Free Trade Area (AfCFTA) & WOAH.

Workshop Recommendation from Harmonization of Standards for Vaccine Registration

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❑ Abuja Meeting Report Recommendation

- ➢ Use of the **Guideline developed for vaccine registration for the EAC** "*Technical Documentation Required in the Dossier for Registration of Immunological Veterinary Product*" as **Harmonised Template for PPR Vaccine Registration in Africa**
- ➢ Support (*with AU-IBAR & GALVmed*) the **"Establishment of a Network of African Regulatory Authorities"** for information exchange and capacity building on vaccine registration
- ➢ In collaboration with NRAs and RECs to initiate the **"Development of a Harmonised Guideline for Audit and Certification of vaccine manufacturers".**

❑ Endorsed by the Executive Council 44th Ordinary Session (AU Summit 2024): Decision EX.CL/Dec.1234(XLIV)

Surveillance the Quality of Vet. Vaccines

- **Substandard and Falsified Veterinary Products (SFVP)**
  - **Substandard veterinary products:** Vet. medicines that do not meet quality standards due to manufacturing or storage conditions.
  - **Falsified veterinary products:** Fraudulent products whose identity, composition or source are deliberately misrepresented.
- **Objective**
  - Detect and eliminate SFVP in the market
  - Strengthen regulatory enforcement and compliance
  - Enhance reporting and data collection mechanisms

Guideline for Risk-Based Post Market Surveillance

- Draft Document under development by the WOAH Electronic Experts Group (EEG) for Substandard & Falsified Veterinary Products (SFVP)
- Establishing Guidance for risk-based Post-Marketing Surveillance (rb-PMS) of Veterinary Products (VPs)
- The objectives is to monitor the quality of VPs in the market (focus on the quality, safety and efficacy of VPs after they have been approved and made available on the market)
- Components of Risk-Based Post-Marketing Surveillance
  - Establishment of a reporting system for stakeholders, especially veterinary specialists and NRA, to report concerns of SFVP and unregistered VP.
  - Establish a pharmacovigilance system for collecting reports on adverse events
  - Batch quality and consistency control system to assure uniformity and consistency in product quality across all batches produced and detecting any deviations
  - Risk Mitigation Strategies

Guideline for Post Market Surveillance…

❑ Stakeholder Roles and Responsibilities

- The country NRAs as the primary governmental agency responsible for overseeing the implementation of rb-PMS for VPs and liaison with PhV systems
- Field Inspectors or sampling teams as the NRA personnel authorised to collect samples from various points in the supply chain (e.g., manufacturers, distributors, retailers, or farms).
- Accredited laboratories responsible for analysing the samples collected during PMS.
- Importers, distributors, wholesalers and retailers of veterinary medicines
- Veterinarians, veterinary paraprofessionals, and End-Users such as farmers and animals' owners
- Stores and warehouses for VP
- Marketing authorisation holders (MAHs) play an important role in guaranteeing the quality, safety and efficacy of the VMP they are selling.
- Manufacturers are responsible for ensuring their products comply with Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), and Good Pharmacovigilance Practices (GVP) throughout the product lifecycle
- International organisations

Guideline for GMP and GDP

- The purpose of this guideline is to establish best practices and standards to address the manufacturing and distribution challenges associated with substandard and falsified veterinary products (SFVP).
- This guideline aims to provide a practical framework for ensuring that veterinary products meet consistent quality standards from production through distribution.
- It seeks to assist manufacturers, distributors, regulators, and veterinary professionals in identifying and mitigating risks associated with SFVP, thereby supporting the safe and effective treatment of animal diseases.
- It emphasizes the importance of international cooperation and harmonization in combating these issues, recognizing the global nature of veterinary supply chains.

Guideline for GMP and GDP…

- **Responsibilities of Manufacturers**
  - as the origin of VPs, manufacturers are the first line of defence in ensuring that products entering the supply chain meet quality, safety and efficacy standards.
  - MUST adhere to GMP standards to ensure that VPs are manufactured according to rigorous quality protocols, *(starting from sourcing quality raw materials, maintaining clean and controlled production environments, and conducting thorough quality testing)*
- **Distributors and wholesalers** are critical in maintaining the integrity of VMP post-manufacture and ensuring that only high-quality, verified products reach veterinarians and end-users.
- **Regulatory bodies**, oversee compliance with GMP and GDP standards, play a central role in monitoring the market, and provide the legal framework for enforcement and international collaboration

Surveillance of Genetic Stability of PPR Vaccine

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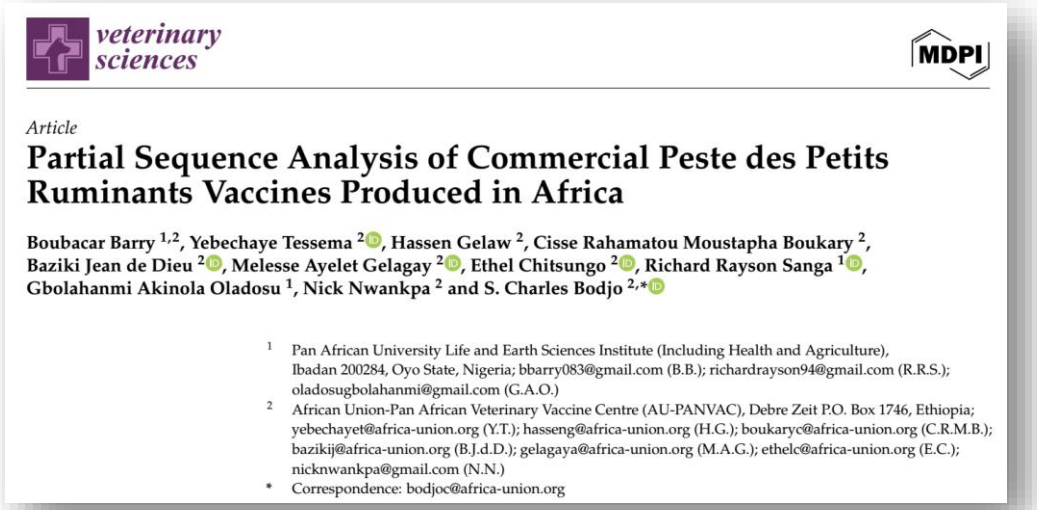
- Partial Sequence analysis of the hypervariable region (C-terminus domain) of the nucleoprotein of PPR Vaccine75/1 strain from 10 African vaccine manufacturers were analysed.



veterinary sciences

MDPI

Article

Partial Sequence Analysis of Commercial Peste des Petits Ruminants Vaccines Produced in Africa

Boubacar Barry [1,2], Yebechaye Tessema [2], Hassen Gelaw [2], Cisse Rahamatou Moustapha Boukary [2], Baziki Jean de Dieu [2], Melesse Ayelet Gelagay [2], Ethel Chitsungo [2], Richard Rayson Sanga [1], Gbolahanmi Akinola Oladosu [1], Nick Nwankpa [2] and S. Charles Bodjo [2,*]

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- Sequence data analysis revealed **100% homology** between commercial vaccines and the seed in PANVAC.
- Indicating the **genetic stability of the PPR vaccine Nigeria 75/1** over decades

- The full genome sequencing (*using NGS NextSeq 2000, Illumina Inc*) confirmed the **100% homology** of PPR vaccines from the 5 manufacturers.

Characterization of RVF Vaccines

- RVF vaccine seed (at AU-PANVAC repository) and 2 commercial vaccines were sequenced for comparison with RVF Vaccine Smithburn Reference sequence.

	Production date
AU-PANVAC RFV Vaccine seed (A) PANVAC RVF01_1197	MAY 1997
Commercial RVF Vaccine (B): PANVAC RVF02_109	01/08/2012
Commercial RVF Vaccine(C): PANVAC RVF03_010	17/11/2010

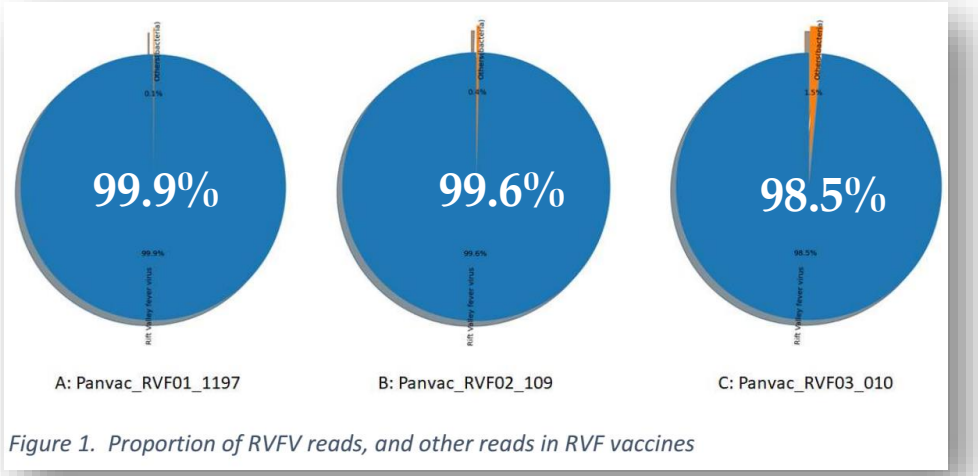

Figure 1. Proportion of RVFV reads, and other reads in RVF vaccines

*The RVF vaccine seed (A), commercial RVF vaccines (B) & (C) showed **99.9%, 99.6% and 98.5% homology** respectively with the RVF Smithburn vaccine reference sequence.*

Need to review production and assist manufacturers to minimise mutations in RVF vaccines

AU-PANVAC !

ADDING VALUE TO ANIMAL HEALTH AND HUMAN LIVES!!

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