

Standardization and quality control of biological products

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Overview of the Presentation



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- Quality Control Tests of Veterinary Vaccines
- ☐ Trends in the Origin of Vaccines Tested
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AU-PANVAC's Mission & Mandates



MANDATES

- 1 INDEPENDENT QUALITY CONTROL of vet. vaccines.
 - 2 Development and Production of **DIAGNOSTICS**
 - TRANSFER OF VACCINE PRODUCTION TECHNOLOGIES
 - STANDARDIZATION of production and HARMONIZATION of the quality control techniques in Africa
 - 5 CAPACITY BUILDING (Training and technical support) to veterinary laboratories.





AU-PANVAC SPECIAL MANDATES



- Maintaining Africa free from Rinderpest: "Sequestration of RP material from African laboratories and maintaining an emergency vaccine stock"
- New Mandate: auditing and certification of vaccine manufacturing facilities in collaboration with National Regulatory Authorities in Africa.





International Recognitions

AU-PANVAC

ETHIOPIA.





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



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



Rinderpest Holding Facility (RHF)
for Africa (among five other RHFs: US, UK,
France, China & Japan)





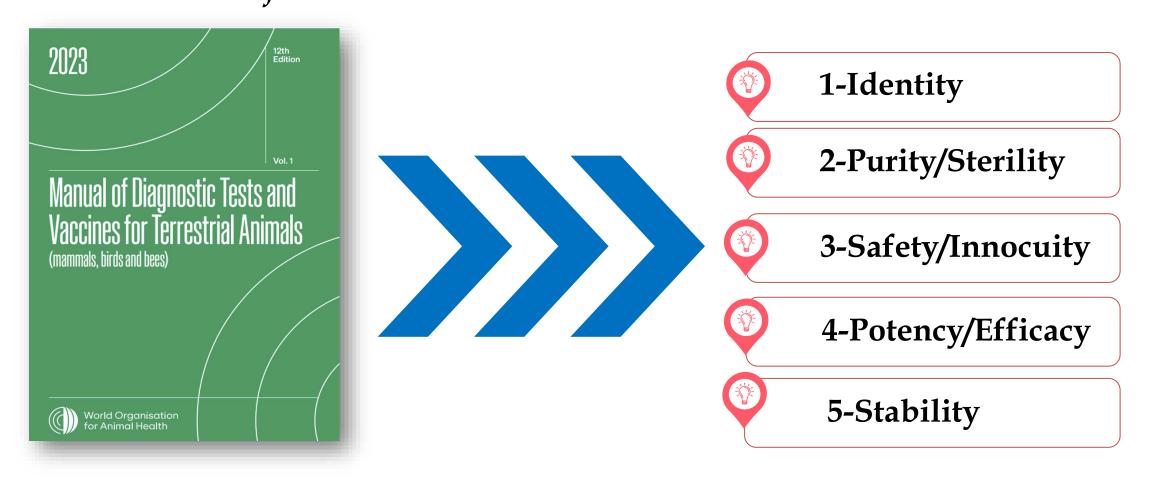




Quality Control Tests of Veterinary Vaccines



Vaccine QC Tests conducted following the World Organisation "Manual of Diagnostic for Animal Health Founded as OIE"



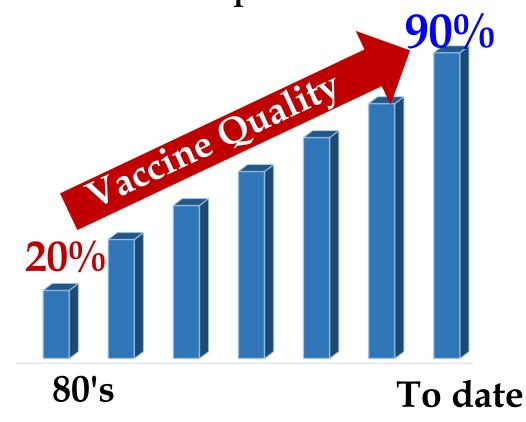
Quality Control Tests of Veterinary Vaccines



□ 300 - 400 vaccine batches (3.5 Billion doses) annually certified by AU-PANVAC for more than 50 types of Vaccines



☐ Vaccine Quality Produced in Africa improved









Quality Control Tests of Vaccines



Quality control test performance 2023-24

In 2023 received 364 biologicals:

- >272 batches of vaccines,
- >79 diluents,
- >8 different vaccine seeds,
- > 2 kits
- ≥2 cells

In 2024 received 405 biologicals

- ➤ 337 vaccine batches,
- > 35 diluents,
- ≥24 vaccine seeds,
- ➤ 3 cell lines,
- ≥3 kits,
- ≥2 sera,
- > 1 GMEM

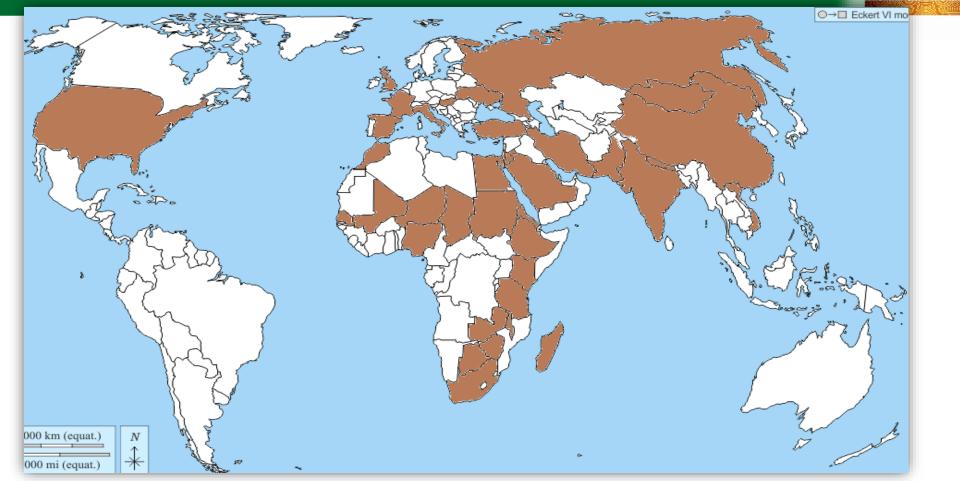






Trends in the Origin of Vaccines Tested





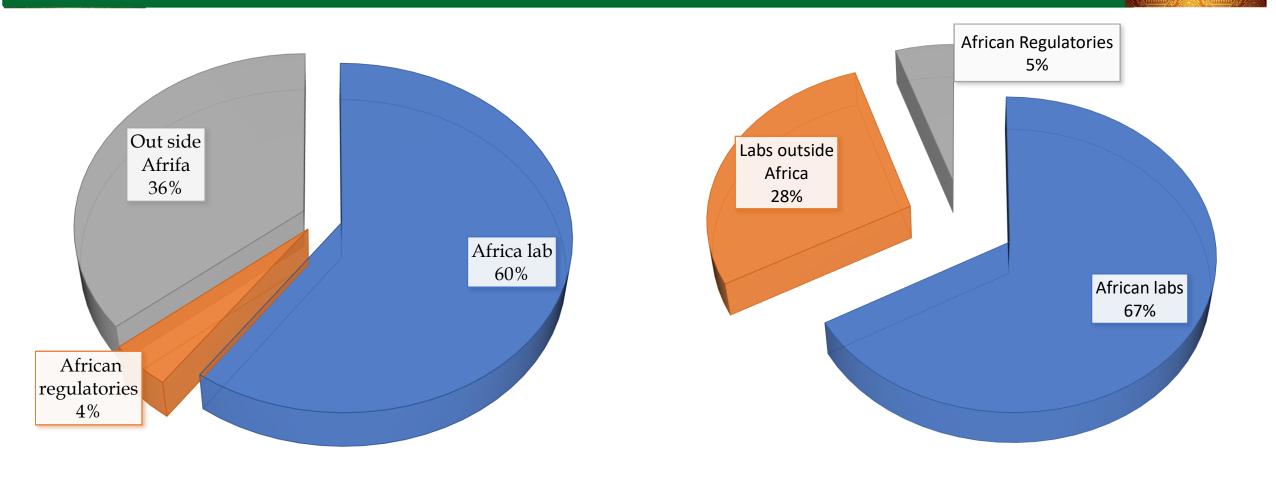
Receiving vaccines from all over the world (except South America & Australia)

- African Manufacturers (25 labs) & Nat. Regulatory bodies
- Over sea Manufacturers (24 labs)



Proportion of vaccines senders in 2023-24





In 2023, 60% and in 2024, 67% of the vaccines received were from AUMS labs





Technical Support in Vaccine Production

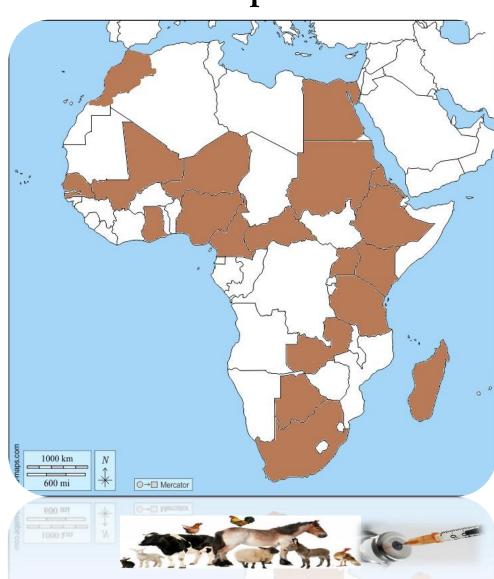




25 Vaccine Manufacturers from 18 AUMS are assisted in vaccine production

- North -Africa: Egypt (VSRVI, MEVAC) & Morocco (MCI & BIOPHARMA),
- West Africa: Senegal (ISRA), Mali (LCV), Niger (LABOCEL), Ghana (CVL, Accra) & Nigeria (NVRI)
- Central Africa: Cameroun (LANAVET), Chad (IRED)
- East Africa: Ethiopia (NVI) & Kenya (KEVEVAPI, INNOVA), Uganda, Tanzania (TVLA, HESTER Africa)
- Souhthen Africa: Botswana (BVI), South Africa (OBP, MSD), Madagascar (IMVAVET), Malawi (CTTBD), Zambia (CVRI), Zimbabwe (CVL)





Technical Support in Vaccine Production



□Harmonising protocol & Support vaccine production with the Continental Vaccine Seed Repository held at AU-PANVAC

□ Training over of 1000 LABORATORY STAFF in vaccine production & quality control

□Introduction of New Technology (Thermostable Technology-THERMOVAX & XEROVAC) for production of more 13 Vet. Vaccines.





Continental Vaccine Seeds Repository



To support production of veterinary vaccines for 13 Priority Animal Diseases.

S/N	Type of Vaccine Seed	Strain Name	Vaccine Strain Origin
1	PPR	Nigeria 75/1	Nigeria
2	ND	• Lasota	US, Australia
		• I-2	
3	Sheep pox	SP 30	Kenya
4	RVF	Smith burn	Uganda
5	SGP	0180, 15LK, IEBL	Kenya/New York, Plum Island
6	LSD	Neethling	South Africa
7	CBPP	T1/SR & T1/44	Tanzania
8	CCPP	F38	Kenya
9	HS A	Pasteurella multocida type A	Ethiopia
10	HS B	Pasteurella multocida type A	Ethiopia
11	Anthrax	Bacillus anthracis	Ethiopia
12	Black Leg	Clostridium chauvoei	Ethiopia
13	Camel Pox	VD 45	Niger



Trainings & Capacity Building of Scientists



☐ Training about 20 Lab Technicians from AUMS annually

☐ Pan African University (PAU) students on Production and Quality Control of Vet.

Vaccines



8-10 students from the PAU for Life and Earth Sciences (**PAULESI**) in Ibadan, Nigeria are received annually



Master Research work at AU-PANVAC for 8 to 10 Months









Interlaboratory comparison test (ILT) for PPR QC



AU-PANVAC participates for PPR QC ILT annually on PPR control (in 2023 with 7 labs & in 2024 with 8 labs)

- Totally 19 samples were properly labeled and sent
- The samples were tested for potency (titration), PPR identity, and sterility(freedom from bacterial/fungi, freedom from mycoplasma and BVDv)
- The ILT result was communicated to respective labs





Harmonisation of Vaccine Registration Standards



- ☐ African Union "Harmonized Guideline for Registration of PPR vaccine in Africa" developed with the support of NRAs and Manufacturers
- □ Support the "Establishment of a Network of African Regulatory Authorities" for exchange information and for capacity building
- □ AU-PANVAC in collaboration with NRAs and RECs to initiate the "Development of a Harmonised Guideline for Audit and Certification of vaccine manufacturers".



Nairobi, Kenya: Dec 2019



Abuja, Nigeria: July 2023



Dar Es Salaam, Tanzania, July 2025





Conclusions



- □ AU-PANVAC, as a central pillar for animal health in Africa, plays a crucial role in assuring the quality of veterinary vaccines through independent and rigorous quality control testing.
- ☐ AU-PANVAC also actively strengthen the continent's vaccine manufacturing laboratories through capacity building:
 - > supplying essential vaccine seeds and cells,
 - > providing technical support to manufacturers,
- ☐ In collaborating with National Regulatory Authorities and various stakeholders AU-PANVAC is actively working on harmonization of regulatory standards.







One Continent, One Market, One Standard for Registration of Vaccines & manufacturers

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