

#### **Ethel Chitsungo**

AU-PANVAC Laboratories

African Union

#### **Brief Recall on AU-PANVAC**

- □ 1980's-Resurgence of Rinderpest
- 1983-Audit on Vaccine Quality (FAO):
   Only 20% Good Quality Vaccines
- 1986-92 QC centers established to support the PARC
- □ 1993- the 2 Centers merged (PANVAC)
- □ 2004- became AU Technical Centre
- □ Mandates expanded to other activities









#### **AU-PANVAC's Mission**



AU-PANVAC is the only African Union Organization mandated to provide **International Independent Quality Control** of all veterinary vaccines produced or imported into Africa

#### MISSION:

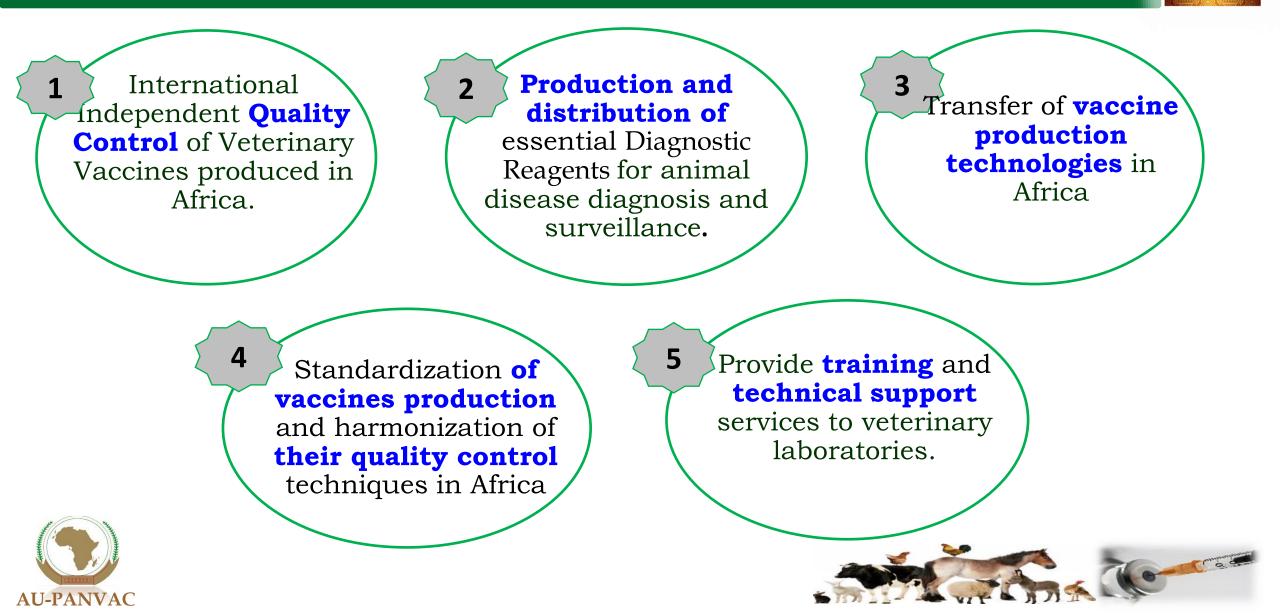
"To promote the use of **Good Quality Vaccines** and **Diagnostic Reagents** for the control and eradication of animal diseases in Africa."





#### **AU-PANVAC: Core Mandates**





### **AU-PANVAC: Special Mandates**



- **Maintaining Africa free from Rinderpest:** "Sequestration of all Rinderpest material from African laboratories and maintaining an emergency vaccine stock"
  - Rinderpest holding facilities for Africa designed by FAO and the World Organisation for Animal Health (WOAH).

*The Only Centre in the world holding Rinderpest field and vaccine strains in the same facility.* 

Maintaining Continental vaccine bank as emergency preparedness

Harmonization of Veterinary vaccine registration on the continent





#### AU-PANVAC: Quality Management System (QMS) 20



#### **ISO/IEC 17025 Accredited** □ ISO 9001:2015 Certified CERTIFICATE R እትዮጵያ ብሔራዊ አክሬዲቴሽን ጽ/ቤት THE INTERNATIONAL CERTIFICATION NETWORK This is to certify that UL CERTIFICATE **Pan-African Veterinary Vaccine Centre** ETHIOPIAN NATIONAL ACCREDITATION OFFICE IQNet and DQS GmbH Deutsche Gesellschaft zur Zertifizierung von Managementsysteme (AU-PANVAC) Debre Zeit hereby certify that the company P.O. Box 1748 **ACCREDITATION CERTIFICATE** Pan-African Veterinary Vaccine Centre (AU-PANVAC) has implemented and maintains a Quality Management System Debre Zeit P.O. Box 1748 PAN AFRICAN VETERINARY VACCINE CENTRE (AU-PANVAC) Ethiopia has implemented and maintains a Quality Management System Debre zeit Ethiopia Provision of Quality Control Service for veterinary vaccines, and production and distribution of essential biological reagents for animal disease diagnosis Facility Accreditation No: T0025 Scope Provision of Quality Control Service for veterinary vaccines, and production and distribution of essential biological reagents for animal disease diagnosis Is accredited by the Ethiopian National Accreditation Office (ENAO) to perform tests in accordance with the attached Scope of Accreditation in the Through an audit, documented in a report, it was verified that the management system Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard: fulfills the requirements of the following standard field of Veterinary Vaccine Testing (Molecular Biology a Testing) ISO 9001 : 2015 ISO 9001 : 2015 The facility is accredited in accordance with the requirements of ISO/IEC 17025:2005 The tacility is accredited in accordance with the requirements or isO/IEC 170252000 General requirements for the competence of testing and calibration laboratories. The accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system. While this certificate remains valid, the Accredited Facility name above is authorized to use the relevant ENAO accreditation symbol to issue Valid from 2017-02-22 Valid until 2020-02-21 Date of certification 2017-02-22 Certificate registration no. 40100077 QM15 Registration number: DE-40100077 QM15 Valid from 2017-02-22 DAkkS Date of issue: 16/11/2018 Valid until 2020-02-21 Expiry date: 15/05/2023 freed Maul Gil Date of certification 2017-02-22 Michael Drechsel Frank Graichen Managing Director of DQS GmbH QNet Partners\*\* DQS GmbH Ato Arava Fesseha Lady CGC Chine CQM Chine CQS Creen Republic Cro Cent Create DQB Holding GmHH Germany MDDNORMA Wereuske is ICONTEC Contra link ML Mercion Inspecta Certification Finited INTECC Contra Ric na. JQA Jupan KFQ Kores MIRTEC Greece MST Hungary Nemito AS Norway NSAI Instand PCBC Poland Austin Autoria Martina Russis SIGE Mercion SII Intera SIG Soveria SIRIM ASIA International Melloyaia SQS Subtrafinad SRAC Romania TEST SI Petersburg Russis TES Tarley YUQS Serbie Itable in expensember in the USA yx ArROR Certification, CIBC, DQB Holding Green Land Nucl. **Director General** Naul Lill Ethiopian National Accreditation Office Frank Graichen Managing Direg \* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone \*\* The lat of IQNet perform is valid at the time of issue of this certificate. Under a directly interview inner Page 1 of 3 - IQNet -Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany Administrative Office: DQS Holding GmbH, Konrad-Adenauer-Allee 8-10, 61118 Bad Vilbel, Germany

AU-PANVAC



### Vaccine Quality Control Activities



# **Vaccine QC Tests are based on the Oife** 'Manual of Diagnostic Tests and Vaccines for Terrestrial Animals"





#### **QC** Testing of vaccine at AU-PANVAC



- 1. **CERTIFICATE AND REPORT:** If vaccine complies
- 2. **REPORT ONLY:** If vaccine does not comply
- 3. **TURN-AROUND TIME**: 1-2 months (Rabies 1 month)

Publication of batches passed QC tests on the AU-PANVAC website:

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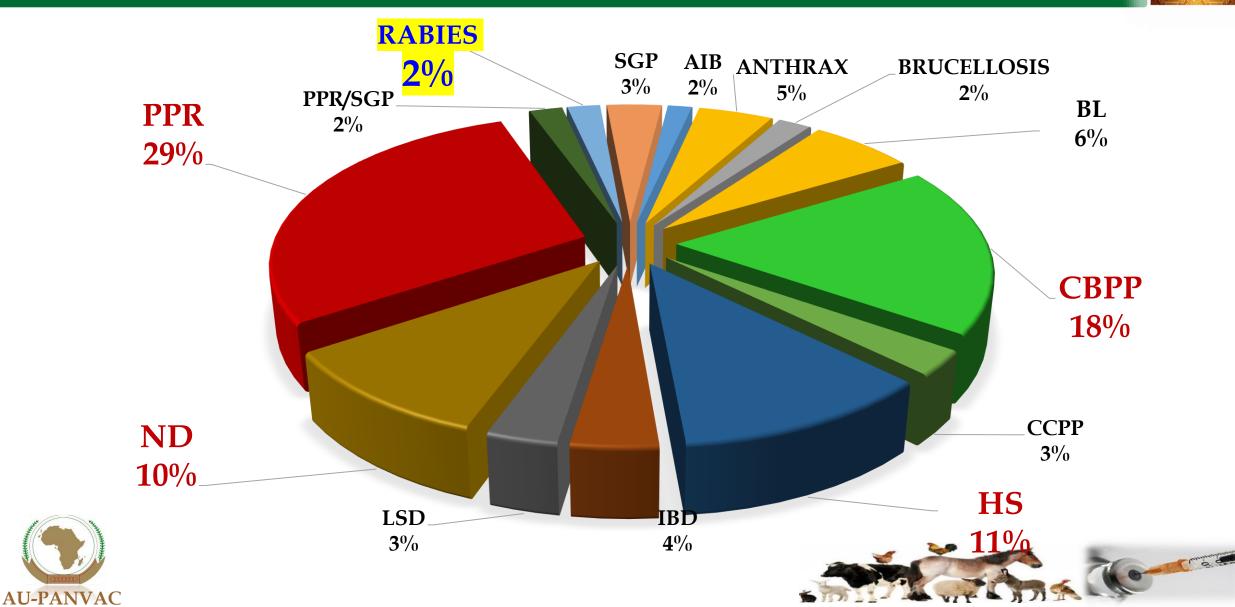
#### Vaccine Quality Control Activities 2018-2020 **Outside of Africa Countries** Africa 18% 82% Vaccine Producers: **African Vaccine Labs** Middle-East, Asia, Europe & USA



**CVOs**, **Drug authorities & NGOs** 

#### VACCINES RECEIVED FOR QC (2018-2020)





# **Rabies Vaccine Submitted for QC**



- 2 African producers submit their vaccines for QC
  - NVRI, Nigeria live attenuated vaccine
  - NVI, Ethiopia inactivated vaccine
- Non-producers
  - DVS, Benin,



BVI, Botswana – Boehringer Ingelheim vaccine,



# **Rabies Vaccine Submitted for QC**



- Non-African producers
  - Merial/Boehringer, France,
  - Indian Immunologicals, India
  - LLP Biotron, Kazakhistan
  - Zoetis, USA





#### **RABIES VACCINE QUALITY CONTROL**



#### **4 tests based on the OIE Manual**

	Sterility	Safety	Potency	Identity
Rabies	Liquid and Solid Media/ Mycoplasma (PCR)& BVD (Real time PCR) for Live Vaccines		<ul> <li>On BHK cells for live Vaccines</li> <li>Challenge Test being implemented for inactivated Vaccines</li> </ul>	





#### **Rabies Vaccination Partnership in Ethiopia**



Ethiopian Wolf Conservation
 Programme

 Virbac's Rabigen SAG2 oral vaccine bait vaccine administered to wolves in the Ethiopian highlands









#### **Rabies Vaccination Partnership in Ethiopia**



- Quality control conducted at AU-PANVAC
- The vaccine stock stored in AU-PANVAC vaccine bank





#### Conclusion



• AU-PANVAC available to support rabies vaccine QC











**OIE Collaborating Center for Quality Control Of Veterinary vaccine** (OIE Gen. Ass. Resolution 32, May 2013)



FAO Reference Centre for Technical Assistance in Quality Control of Veterinary Vaccines (11<sup>th</sup> May 2015)



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