

**OIE REGIONAL SEMINAR ON VETERINARY
PRODUCTS
JOHANNESBURG – SOUTH AFRICA 23 – 26
NOVEMBER 2010**

**PAN AFRICAN VETERINARY VACCINE
CENTRE OF AFRICAN UNION
(AU/PANVAC)**

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BACKGROUND



BACKGROUND

- ❑ Rinderpest situation in Africa in 1980s
- ❑ Request for 2nd Continental campaign: Pan African Rinderpest Campaign
- ❑ 1983 – 1986: Inventory and audit of 12 vaccine producing laboratories in Africa. Concept of the idea of (PANVAC).
- ❑ 1986 – 1988: Regional Vaccine Quality Control and Training Centre: in Dakar (Senegal) for Central and Western Africa and in Debre Zeit (Ethiopia) for Eastern and Southern Africa: FAO TCP respectively TCP/RAF/6766 and TCP/RAF/6767.



BACKGROUND (Cont'd)

- ❑ 1989 – 1993: UNDP assumed responsibility for funding the centers.
- ❑ 1993: The two centers were combined into one at a single site at Debre Zeit (Ethiopia) and became the Pan African Veterinary vaccine Centre (PANVAC).
- ❑ 1994: Interim funding of the European Commission (GCP/RAF/305/EC) and two FAO TCP: (TCP/RAF/2265 and TCP/RAF/4565) until 1995.
- ❑ 11 – 15 April 1994: Addis Ababa, Ethiopia: 4th Conference of African Ministers responsible for Animal Resources: PANVAC as a technical center of the OAU.
- ❑ FAO: \$ 125 000 to PANVAC to ensure the resumption of activities until the middle of 1996 (TCP/RAF/4565) and the establishment of a system of cost recovery.



BACKGROUND (Cont'd)

- ❑ April 1997: PANVAC component B began funded (\$1.5 million) for 5 years by the government of Japan (Reinforcement of Veterinary Vaccine Production and Quality Control by PANVAC, GCP/RAF/377/JPN).
- ❑ 23-27 February 1998: Addis Ababa: 67th Ordinary OAU Council of Ministers decided to elevate PANVAC to the level of a Centre of Excellence for vaccines productions and Quality Control in Africa with a status of an OAU Specialized Agency.
- ❑ September 1999: Appreciating the encouraging decisions of 67th OAU Council of Ministers, EU granted about 1 million ECU through OAU/IBAR to support PANVAC QC for 5 years.
- ❑ 18-22 March 2002: Addis Ababa: 6th Conference of Ministers responsible for Animal resources recommended the immediate resumption of PANVAC QC activities.



BACKGROUND (Cont'd)

- 12th March 2004: The Centre was officially launched as an AU Regional centre at Debre Zeit (Ethiopia) and the Department of Rural Economy and Agriculture of the AU Commission included PANVAC's strategic plan into its 2004 2007 Strategic Plan.
- 6-7 December 2004 Addis Ababa : Approval of PANVAC structure within DREA by The 6th Extraordinary Session of the AU Executive Council.



VISION AND MISSIONS



VISION AND MISSIONS

- ❑ Founded in the belief that, with respect to the major vaccine Preventable infectious diseases (Rinderpest, CBPP, PPR, FMD, ND etc), the health of livestock in Africa can be drastically improved by the use of good quality vaccines and good diagnostic biologicals.

- ❑ **VISION:**

“Build a Recognized in the international arena, Reference Centre for Vaccine quality control, technology transfer, production of diagnostic and surveillance reagents and capacity building, driven by and for African professional.”



VISION AND MISSIONS (Cont'd)

- ❑ **MISSIONS:**
 1. Provide International Independent Quality Control of Veterinary Vaccines
 2. Facilitate the standardization of Veterinary vaccines production and harmonization of their QC techniques
 3. Promote the transfer of appropriate vaccine production technologies
 4. Provide training and technical support services to Veterinary vaccines and Quality Control laboratories
 5. Produce and distribute essential biological reagents for animal disease diagnosis and surveillance



QUALITY CONTROL OF VACCINES



QUALITY CONTROL OF VACCINES

Definition

Part of GMP which is concerned with sampling, specifications and testing, and with the organization, documentation and release procedures which ensures that the necessary and relevant tests are actually carried out and that products are not released for sale or supply, until their quality has been judged satisfactorily.

- In-process QC: Producers
- QC on final product: In house and Independent
- Essential Requirements for a vaccine of good quality:
PURITY; SAFETY; POTENCY; EFFICACY



QUALITY CONTROL OF VACCINES (CONT'D)

LIVE ATTENUATED VACCINES QC

- Submission to PANVAC: Freeze dried: 20 vials
- Quality Control tests
 - * Vacuum test (qualitative test)
 - * Residual moisture
 - * Freedom from contamination:
 - Bacterial and Fungi contaminants: Media inoculation and incubation + subculture;
 - Mycoplasma contamination: ELISA and PCR;
 - BVD contamination: IP and PCR
 - * Identity: ELISA, IF, PCR
 - * Safety tests: Lab. Animal and host animals (CBPP T144)
 - * Potency/Efficacy (in vitro): Titration
 - * Stability tests: validity of the expire date
 - * Interference test: 2 or more antigen components



QUALITY CONTROL OF VACCINES (CONT'D)

INACTIVATED VACCINES

- Submission to PANVAC: Liquid form: 10 bottles
- Quality Control tests
 - * Level of residual inactivant (Formalin)
 - * Completion of inactivation: Culturing
 - * Identity: PCR / Efficacy
 - * Safety tests: Lab. Animal and host animals
 - * Efficacy: Vaccination/challenge
 - * Stability tests: Adjuvant
 - * Interference test: 2 or more antigen components (FMD vaccines)



REAGENTS PRODUCTION



Reagents Production

❑ **Objective:** To build in Africa a Reference Center for Animal Disease Diagnosis

❑ **Activities will focus on:**

- ✓ The production and distribution of reagents (Kits) for animal disease diagnostic
- ✓ The implementation of latest molecular technologies for disease diagnosis
- ✓ Training veterinarian labs technicians to the latest laboratory diagnosis techniques
- ✓ Provide assistance to national veterinary laboratories in animal disease diagnosis.



PANVAC Biological Reagents Production laboratory

□ Planning of Biological Reagents Production activities: 3 phases.

- ✓ **Phase 1 (2 Years: 2010 to 2011).** Establishment of biotechnologies for:
 - Recombinant protein expression
 - Baculovirus system using insect cells,
 - Establish stable cells line producing protein need.
 - Monoclonal antibodies production technology
 - Proteins analysis: Immunoprecipitation, SDS-PAGE, Western blot.
 - Strength PANVAC capacity in diagnosis of animal disease:
 - Molecular biology (Real-Time PCR) technology
 - All serology test such ELISA



PANVAC Biological Reagents Production laboratory

□ Planning of Biological Reagents Production activities: (cont'd)

- ✓ **Phase 2 (from January 2012):** Involve PANVAC in project the development, production and validation of diagnosis test kit:
 - iELISA PPR
 - iELISA NSP-FMD.
- ✓ **Phase 3 (in 3 years) :** recognize PANVAC as Reference Center for Animal disease Diagnosis in Africa.



ACHIEVEMENTS



ACHIEVEMENTS

➤ **Vaccine Quality Control fully operational:**

❖ Diseases: RP, PPR, CBPP, RVF, SGP, AHS, HS, BL, Anthrax, ND, IBD, AI, IB.

❖ Vaccine Received From producing Lab:

- Africa: Mali, Niger, Senegal, Cameroon, Chad, Sudan, Ethiopia, Kenya, Botswana, Mozambique, Egypt & South-Africa.
- Middle East: Jordan and Turkey
- Europe (France): LAPROVET.
- Vaccines tested in 2009: 55 batches (67 % pass)
- Vaccines tested in 2010: 93 batches



ACHIEVEMENTS (cont'd)

➤ Harmonization of vaccine production in Africa:

- ✓ Repository of Biological materials for vaccine production:
 - Vaccine Seeds: 30 (8 Type of vaccine)
 - Cells: cells lines (Vero, BHK & MDBK)
 - Challenge Strain: Brucella Strain.
- ✓ QC manuals produced



ACHIEVEMENTS (cont'd)

- ✓ Trainings & Technology Transfer:
 - Workshop on the use of new adjuvants for the production of inactivated vaccines: Jointly with SEPPIC .
 - ND vaccine I2 strain (thermostable): Jointly with GALMED, Maputo 2009.
 - Vaccine Quality Control & Laboratory Quality Assurance.
- ✓ Technical assistance in:
 - Maintenance and Calibration of Lab. Equipment
 - To Laboratories and Veterinary Services in animal health.



ACHIEVEMENTS (cont'd)

- ❖ Meetings: Pan African Meeting of Vaccine Lab. Directors.
 - Debre Zeit;
 - Pretoria
 - Cairo
- ❖ Establishment of Biological Reagents Production Laboratory:
 - Essential Laboratory Equipment in place
 - In 2010 Establishment of the basic biotechnologies for production and analysis of biological reagents.



PANVAC FACILITIES





PAN AFRICAN VETERINARY VACCINE CENTER



➤ PANVAC Laboratories: 3 physical separated



❖ Vaccine Quality Control Laboratory



❖ Training Center Molecular Biology



❖ Reagent Production Laboratory



PANVAC Biological Reagents Production laboratory activities.





Biological Reagent Production Laboratory



Section for cleaning, sterilization and preparation of distilled water



Biological Reagent Production Laboratory



Section for Buffers Preparation.

Centrifuges.



Biological Reagent Production Laboratory



Serology



ELISA Reader.



Biological Reagent Production Laboratory



Cells culture and storage.



Biological Reagent Production Laboratory



Section for virology and Recombinant Proteins Expression.



Biological Reagent Production Laboratory



Section for bacteriology/DNA cloning.



Biological Reagent Production Laboratory



Section for Recombinant DNA/Vector Preparation for protein expression



PANVAC Training Center laboratory for Molecular biology.



PANVAC/Biological Reagent Production.



PANVAC Training Center laboratory for Molecular biology.



Section for Preparation of PCR reagent

PANVAC/Biological Reagent Production.



PANVAC Training Center laboratory for Molecular biology.



Section for Nucleic Acid extraction / cDNA preparation.

PANVAC/Biological Reagent Production.



PANVAC Training Center laboratory for Molecular biology.



Section for Nucleic Acid extraction / cDNA

PANVAC/Biological Reagent Production.



PANVAC Training Center laboratory for Molecular biology.



Section for Protein Electrophoresis

PANVAC/Biological Reagent Production.



PANVAC Training Center laboratory for Molecular biology.



Section for DNA amplification

PANVAC/Biological Reagent Production.



PANVAC Veterinary Vaccine Quality Control laboratory.



PANVAC/Biological Reagent Production.



PANVAC Veterinary Vaccine Quality Control laboratory.



Section for cleaning, sterilization and preparation of distilled water

PANVAC/Biological Reagent Production.



PANVAC Veterinary Vaccine Quality Control laboratory.



Section for cells culture and storage.



PANVAC Veterinary Vaccine Quality Control laboratory.



Section for cells culture storage



PANVAC Veterinary Vaccine Quality Control laboratory.



Section for Viral Vaccines



PANVAC Veterinary Vaccine Quality Control laboratory.



Section for Bacterial Vaccine

CHALLENGES



Establishment of Pan African Repository of Vaccines Strains at PANVAC: The BSL3 laboratory



THE BSL3 LABORATORIES: mains features

- Risk Group 1 (no or low individual and community risk)
- Risk Group 2 (moderate individual risk, low community risk)
- Risk Group 3 (high individual risk, low community risk): i.e.
 - ✓ FMD virus
 - ✓ Rinderpest virus
- Risk Group 4 (high individual and community risk)



MOBILE LAMM : BSL3 AIRLOCKS VIEWS



ENTRANCE
AIRLOCK



SERVICE HATCH
(P3 LAB SIDE)



WASHBASIN

MOBILE LAMM : BSL3 LABORATORY INTERNAL VIEWS



MOBILE LAMM : BSL3 LABORATORY INTERNAL VIEWS



INDEPENDENT HUSBANDRY FOR LABORATORIES ANIMALS



□ 2 Husbandries:

- ✓ Animals breeding
- ✓ Inoculation laboratory animals.



Establish Quality System for accreditation

- ✓ Apply for PANVAC accreditation (ISO 17025 standards) for vaccine (CBPP, PPR and ND) QC



THANK YOU