21ST CONFERENCE OF OIE REGIONAL COMMISSION FOR AFRICA, RABAT, MOROCCO.

AFRICAN UNION PAN AFRICAN VETERINARY VACCINE CENTRE

(AU-PANVAC): Ensuring Vaccine quality, Producing basic diagnostic reagents and Maintaining Africa free from Rinderpest.

NICK NWANKPA

AND

CHARLES BODJO

16-20 February 2015

PRESENTATION OUTLINE

- INTRODUCTION
- ESTABLISHMENT OF AU-PANVAC
- AU/PANVAC MANDATES– MISSION – VISION
- ACTIVITITIES OF AU-PANVAC
- CONCLUSION
- ACKNOWLEDGEMENT

INTRODUCTION

AU-PANVAC - Background

- AU/PANVAC is the only organization in Africa Mandated to provide International Independent Quality control of Veterinary vaccines
- One of the three specialized Technical Centers of the African Union – animal disease control
- With regards to vaccine preventable diseases, Animal health can be substantially improved with the use of good quality vaccines and diagnostic support

INTRODUCTION

EARLY ANIMAL DISEASE SITUATION IN AFRICA

- Rinderpest and other major diseases almost controlled by early 60s
- The 1970's witnessed a general decline in the quality of vaccines produced in the continent
- Lack of effectiveness of disease diagnostic laboratories and non-existence or inefficient National Quality control Authorities
- Led to a major resurgence and spread of rinderpest in many African countries in the early 1980's

INTRODUCTION

EARLY ANIMAL DISEASE SITUATION IN AFRICA

- Losses of up to US$ 100 million in direct losses and more than US$ 1 billion in indirect losses.
- This caused great concern for the African Heads of State and Governments
- Inter African Bureau for Animal Resources of the then OAU (OAU/IBAR) was instructed to take necessary actions to control the epidemic

ESTABLISHMENT OF AU-PANVAC

ESTABLISHMENT OF QC & TRAINING CENTRES

- An audit demanded by donors as prerequisite for support in a 2nd Campaign
- 1983 : Audit by FAO on Rinderpest (RP) Vaccines produced in Africa showed only 20% were of good quality
- FAO recommended establishment of an Independent Body for QC of RP vaccine to support the 2nd Continental RP Campaign (PARC And PACE)

ESTABLISHMENT OF AU-PANVAC

INSTITUTIONALIZATION OF AU-PANVAC

- The 4th Conference of African Ministers responsible for Animal Resources held in Addis Ababa (Ethiopia) 11 – 15 April 1994 recommended the institutionalization of PANVAC as a technical center of the then OAU
- February 1998: 67th Ordinary OAU Council of Ministers: elevated PANVAC to Centre of Excellence for Vaccine Production and QC and a status of OAU Specialized Agency

ESTABLISHMENT OF AU-PANVAC

OFFICIAL LAUNCH OF AU-PANVAC

- On 12th March 2004, the Centre was officially launched as an AU Technical Centre within the Department of Rural Economy and Agriculture (DREA) of the AU Commission
- Dec. 2004: AU Executive Council: Structure AU-PANVAC Technical office within DREA
- March 2006: Director appointed

ESTABLISHMENT OF AU-PANVAC

EVALUATION AND REVIEW TEAMS

"The success of the Pan African Rinderpest Campaign...clearly demonstrated that ***"no amount of vehicles, syringes, trained personnel, communication materials would have eliminated Rinderpest if the vaccine batches used were of poor quality"***.

ESTABLISHMENT OF AU-PANVAC

EVALUATION AND REVIEW TEAMS

“It is indeed the secondary and independent level of quality control assessment assured by PANVAC that played a major role in this success and led, at the same time to a sustained improvement in the quality of vaccines against CBPP produced in Africa.”

ESTABLISHMENT OF AU-PANVAC

BASED ON THE SUCCESS OF PARC AND GREP

- Contributions of Quality Control to the eradication of RP considered critical
- Vaccine Quality Control became a major activity of AU-PANVAC since inception in 1986
- Institutionalization of AU-PANVAC as AU technical office was in recognition of its potential as a critical factor in the eradication of other animal diseases

ESTABLISHMENT OF AU-PANVAC

THE SUCCESS OF PARC AND GREP INDICATED THAT

Good Quality Vaccines and effective diagnostic support are essential tools in the prevention and control of Animal diseases

AU-PANVAC MANDATES, MISSION AND VISION

AU-PANVAC MANDATES

1. To provide International Independent Quality Control of Veterinary Vaccines : Produced and Imported
2. Produce and distribute essential biological reagents for animal disease diagnosis and surveillance

AU-PANVAC MANDATES, MISSION AND VISION

AU-PANVAC MANDATES

3. To facilitate the standardization of Veterinary vaccines production and harmonization of their QC techniques
4. To promote the transfer of new vaccine production technologies
5. To provide training and technical support services to Veterinary vaccines and Quality Control laboratories

AU-PANVAC MANDATES, MISSION AND VISION

AU-PANVAC MISSION

"To promote the use of good quality vaccines and reagents for the control and eradication of animal diseases in Africa."

AU-PANVAC MANDATES, MISSION AND VISION

AU-PANVAC VISION

"To build a Recognized Reference Centre in the international arena for Vaccine quality control, technology transfer, production of diagnostic and surveillance reagents and capacity building, driven by and for African professionals."

ACTIVITIES OF AU-PANVAC

1. Quality Control of all Veterinary vaccines produced or imported into Africa
2. The Production of basic Biological Reagents for Disease Surveillance and identification
3. Maintaining Africa free from Rinderpest
4. Collaborating with partners in animal disease control activities

ACTIVITIES OF AU-PANVAC

1. VACCINE QUALITY CONTROL

The major objective of conducting vaccine Quality Control is to guarantee vaccine **Purity**, **Safety** and **Efficacy** **i.e. ensure**

“GOOD QUALITY”

ACTIVITIES OF AU-PANVAC

1. VACCINE QUALITY CONTROL:

A GOOD QUALITY VACCINE MUST BE:

- **PURE**: Not contaminated with harmful pathogens
- **SAFE**: for animal and human use (No adverse effects)
- **EFFICACIOUS**: Possess Immunizing properties
- STORAGE CONDITION: be consistent and should have defined Shelf life

1. VACCINE QUALITY CONTROL

TYPES OF VACCINES CERTIFIED

1 I. BACTERIAL VACCINES

II. VIRAL VACCINES

2 A. LIVE ATTENUATED

B. INACTIVATED OR KILLED

3 i. WET/LIQUID

ii. FREEZE DRIED

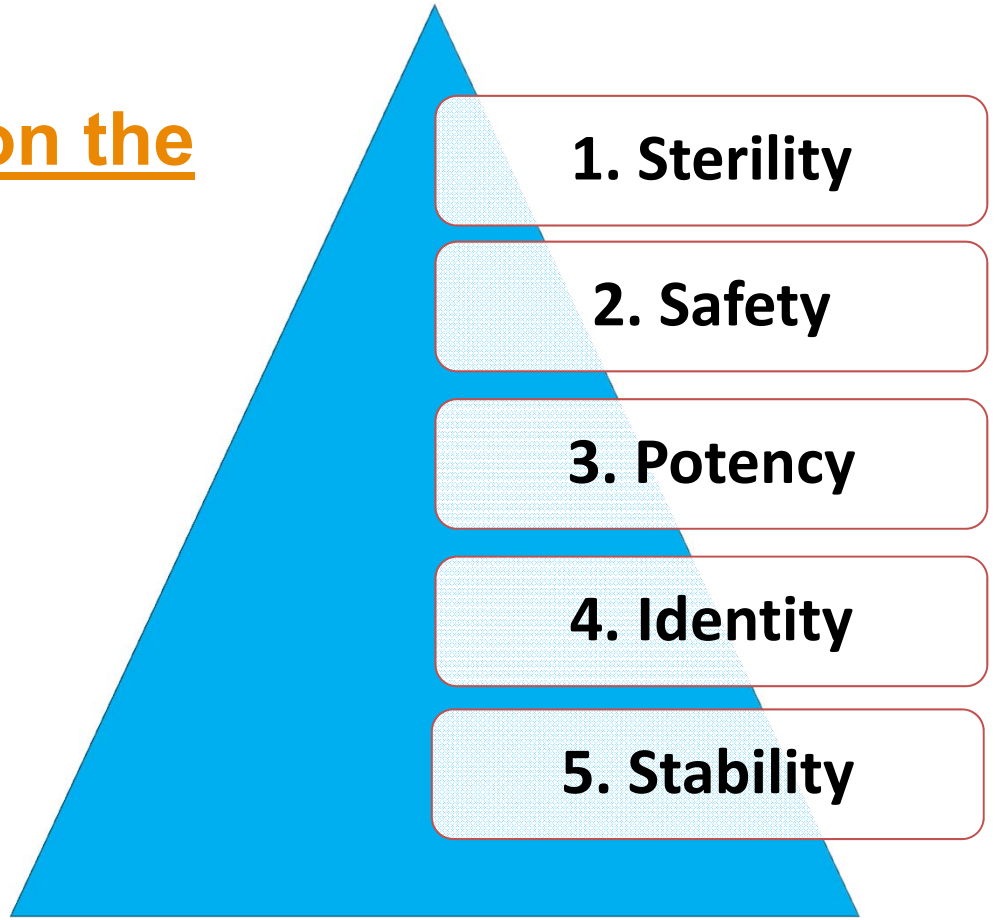
1. VACCINE QUALITY CONTROL

VACCINE QC TESTS

All tests based on the

OIE Manual

2008-20012



1. VACCINE QUALITY CONTROL

1. VACCINE STERILITY TEST

Freedom from contamination test (Sterility test)

- Direct Inoculation in Broth
- Inoculation on Agar
- PCR
- ELISA TEST

1. VACCINE QUALITY CONTROL

1. VACCINE STERILITY TEST

- Bacterial
- Viral (BVD)
- Fungal
- Mycoplasma

1. VACCINE QUALITY CONTROL

2. VACCINE SAFETY TEST

I. Laboratory animals
II. Host animals

LABORATORY MICE

GINEA PIGS

1. VACCINE QUALITY CONTROL

LABORATORY ANIMAL FACILITY

1. Laboratory Animal Breeding and Inoculation

2. Large and Small Animal House

1. VACCINE QUALITY CONTROL

3. VACCINE POTENCY TEST

Invitro tests – Viable Counts/ Titrations Live vaccines

Host Challenge studies – Killed vaccines

Serological tests

1. VACCINE QUALITY CONTROL

4. VACCINE IDENTITY TEST

- Extraction of Nucleic acids
- Preparation of Reaction Mix
- Performance of PCR
- Gel Eletrophoresis and Documentation

1. VACCINE QUALITY CONTROL

4. VACCINE IDENTITY TEST

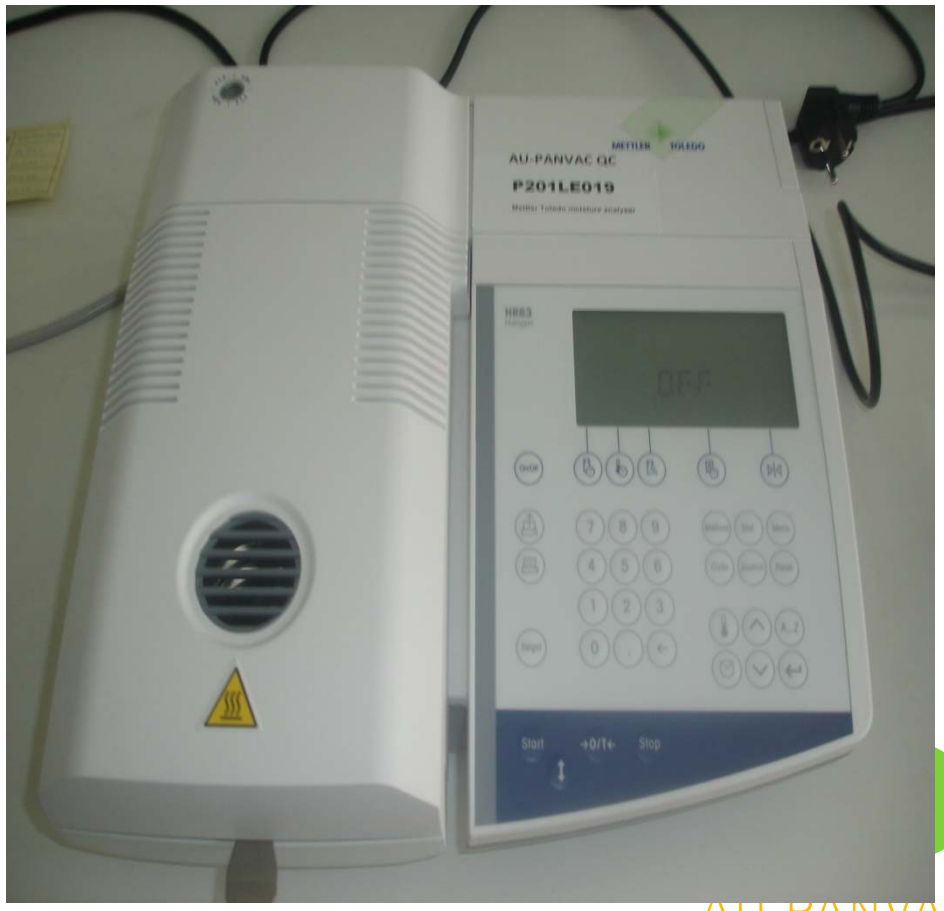
1. VACCINE QUALITY CONTROL

5. VACCINE STABILITY TEST

a. Vacuum test

b. Residual Moisture Estimation

c. Accelerated Stability Studies



Residual Moisture Analyzer

1. VACCINE QUALITY CONTROL

VACCINE BATCHES CERTIFIED BY AU-PANVAC

- **2010**: 122 batches
- **2011**: 106 batches
- **2012**: 153 batches
- **2013**: 288 batches
- **2014**: 319 batches

2. PRODUCTION OF DIAGNOSTIC REAGENTS

PRODUCTION AND DISTRIBUTION OF ESSENTIAL REAGENTS IN AFRICA

- Propagation and maintenance of Cell lines for Reagent Production and Diagnostic purpose

- Development of iELISA and b-ELISA for detection of PPR antibodies

2. PRODUCTION OF DIAGNOSTIC REAGENTS

PRODUCTION AND DISTRIBUTION OF ESSENTIAL REAGENTS IN AFRICA

- Production of antiserum from goat for PPR ELISA test evaluation and validation
- Production of antisera anti-Mccp
- Production of Monoclonal antibodies anti-Mccp

3. MAINTAINING AFRICA FREE FROM RINDERPEST

Specific Mandate by 8th Conference of Ministers: 2010

- All Rinderpest virus strains held in Africa be destroyed and what is deemed necessary handed over to AU/PANVAC for safe storage.
- AU/PANVAC plays a leading role in supporting laboratory networks in Africa – Addis Ababa, Mombassa, Dakar

3. MAINTAINING AFRICA FREE FROM RINDERPEST

Specific Mandate by 8th Conference of Ministers: 2010

- AU MS speed up the process of RP virus sequestration, by completing the FAO/OIE questionnaire regarding the inventory of the virus without any further delay
- MS to take advantage of services and facilities of AU/PANVAC

3. MAINTAINING AFRICA FREE FROM RINDERPEST

IMPLEMENTATION OF RECOMMENDATIONS

1. Ensure the safekeeping of all Rinderpest virus and virus containing materials held in Africa.
2. Ensure the destruction Rinderpest containing materials deemed unnecessary
3. Hold emergency preparedness Rinderpest vaccine and vaccine seed stock for Africa
4. Maintain RP diagnostic capacity at AU-PANVAC (Subject to acceptance of the Joint OIE/FAO C)

3. MAINTAINING AFRICA FREE FROM RINDERPEST

IN COMPLIANCE WITH THE RECOMMENDATIONS

- RP Emergency vaccine Stock: 1.5 Million doses (FAO)
- RP Vaccine seed: > 300 vials (AU/PANVAC REPOSITORY)

3. MAINTAINING AFRICA FREE FROM RINDERPEST

IN COMPLIANCE WITH THE RECOMMENDATIONS

- Acquisition of BSL-3 Laboratory (Launch 14th October 2011 by H.E. The DCP and H.E. The Commissioner and AU MS Ambassadors) E 819, 000: AU, Spain and VACNADA.

- FAO support 166,800 $US : Strengthen PANVAC capacity, 1,5 Million doses RP emergency vaccine stock, Protocols for management and transfer of RP materials, Rights of ownership on RP materials.

3. MAINTAINING AFRICA FREE FROM RINDERPEST

BSL-3 Laboratory

3. MAINTAINING AFRICA FREE FROM RINDERPEST

BSL-3 Laboratory

3. MAINTAINING AFRICA FREE FROM RINDERPEST

Destruction of RP virus materials with documented evidence: Niger (2003)

REPUBLIQUE DU NIGER
MINSTERE DES RESSOURCES ANIMALES
DIERCTION DES LABORATOIRES VETERINAIRES

Niamey , le 24 mars 2003

INVENTAIRE DU STOCK DE VACCINS PERIMES AU MAGASIN

- Vaccin BIVAC : soixante dix huit mille huit cent cinquante (78 850) doses
- Vaccin PESTOVAC : huit cent seize mille trois cent cinquante (816 350) doses
- Vaccin PPR GAROUA : soixante quatorze mille quatre cents (74 400) doses
- Vaccin PERIVAC DAKAR : cent trente six mille trois cent soixante (136 360) doses
- Vaccin CLAVESSEC DAKAR : cent (100) doses

Le magasinier

SOUMANA ABDOULAYE

Le Directeur

Dr SAIDOU ISSOUFOU MAYANA

3. MAINTAINING AFRICA FREE FROM RINDERPEST

Destruction of RP virus materials with documented evidence: Niger (2003)

ETUDE DE MAITRE
BOUBEY ISSOUFOU
HUISSIER DE JUSTICE
COMMISSAIRE PRISEUR
B.P 897 NIAMEY
TEL 93.10.31/97.68.40

REPUBLIQUE DU NIGER

FRATERNITE TRAVAIL PROGRES

PROCES VERBAL DE CONSTAT DE DESTRUCTION DE MEDICAMENTS VETERINAIRES PERIMES

L' An deux mille trois
Et le 24 Mars à17H 30 mn

Suivant entretien verbal en date du 21 Mars 2003, le Directeur Général du **Laboratoire Central de L'Elevage - LABOCEL** - à Niamey (Ministère des Ressources Animales) , a requis ma présence à la séance de destruction des médicaments vétérinaires périmés qui aura lieu le 24 Mars 2003 à 17 h 30 mn dans la cour dudit laboratoire , à l'effet de :

- Constater l'état des médicaments vétérinaires périmés destinés à la destruction entreposés dans le local VETOPHAR ;

- Constater la destruction effective par incinération de ces médicaments vétérinaires périmés ;

- En dresser procès-verbal.

Déférant à cette requête,

Je, Maître **BOUBEY ISSOUFOU** Huissier de Justice Commissaire Priseur près le Tribunal Régional de Niamey, y demeurant et soussigné;

Me suis transporté aux lieux sus-indiqués et à l'heure sus-énoncée et ai procédé aux constatations ci-après :

ETAIENT PRESENTS :

1 . **Dr. SALISSOU MAYANA**	D.G. LABOCEL
2 . **Dr. NABABA ABDOU**	M.R.A / D.S.A
3 . **Dr. AMADOU GARBA**	M.R.A / I.G.S
4. **Dr. BAARE CAYHERINE**	LABOCEL

BOUBEY ISSOUFOU ... HUISSIER DE JUSTICE COMMISSAIRE PRISEUR

3. MAINTAINING AFRICA FREE FROM RINDERPEST

Destruction of RP virus materials with documented evidence: Cameroon (2011)

LANAVET

ASSURANCE QUALITE

Société à capital public au capital de 1.850 millions F.CFA • Contribuable No.108300010749
B.P. 503 Garoua, Cameroun • Téléphone : +237 22 27 13 05
Fax : +237 99 39 89 59 • Internet : www.lanavet.com • E-mail : lanavet@lanavet.com

CERTIFICAT DE VALIDATION DE L'APPAREIL

N°PB01-2011

Date d'intervention : 12/12/2011

I. IDENTIFICATION APPAREIL

Désignation : AUTOCLAVE
Marque : LABOKLAV
Modèle : 160B-FA
N° Série : 02105780
Année de fabrication : 2010

II. METHODE DE VALIDATION :

La validation de l'autoclave est faite à partir des éléments suivants :
- **un ruban adhésif indicateur de stérilisation à l'autoclave :** AMCOR/ A VAPEUR-N°6 119 05 ;
- **un thermomètre à valeur maximale :** ASSISTENT/-10 à 200°C/ N°3205/200 ;

Les tests seront basés sur deux cycles d'autoclavage :
- **Cycle1 :** Température 127°C/ Durée 30 minutes ;
- **Cycle2 :** Température 127°C/ Durée 45 minutes ;

III. Mode Opératoire :

Pour chaque cycle,
Disposer de 500 flacons de 7ml remplis chacun de 2ml d'eau apyrogène puis capsulés et bien sertis ;
Coller un morceau de ruban adhésif indicateur de stérilisation sur 12 flacons ;
Charger tous les flacons dans le panier et placer le thermomètre sur ces flacons ;
Fermer la porte de l'autoclave et démarrer le cycle ;
A la fin de chaque cycle noter la valeur affichée par le thermomètre et la couleur du ruban indicateur ;

IV. Critères d'acceptation :

Les traits blancs du ruban doivent virer au noir et le thermomètre doit afficher une valeur minimale de 127°C.

V. Résultats

Cycle	Durée cycle	Couleur des traits du ruban après autoclavage	Valeur affichée par le thermomètre après autoclavage	Ecart à la consigne	Bon /mauvais
Cycle 1	30 minutes	Noire (pour les 12 flacons)	127°C	0°C	BON
Cycle 2	45 minutes	Noire (pour les 12 flacons)	127,8°C	+0,8°C	BON

VI. Corrections apportées :

Aucune correction apportée

VII. Conclusion

L'équipement est déclaré pour une périodicité d'un an conforme pour des cycles d'autoclavage à 127°C et aux durées de 30 minutes et de 45 minutes

Realisé par
MOHAMADOU Daouda
Ing. Maintenance Industrielle Et Productique

Vérifié par
FOKOU Samuel
Ing. Biotechnologiste

Approuvé
MEFOMDJO Pierrette
Manager Assurance Qualité

MINISTERE DE L'ELEVAGE, DES PECHES ET DES INDUSTRIES ANIMALES
Sous-Direction de l'Accueil du Courrier et de Liaison
Arrivée le 21 DEC 2011
Enregistré S/N° 007807

PROCES VERBAL DE DESTRUCTION DES STOCKS DU VIRUS DE LA PESTE BOVINE AU LANAVET, GAROUA, CAMEROUN

L'an deux mille onze et le 15 décembre, il a été procédé à la destruction du stock de virus de la peste bovine détenu au Laboratoire National Vétérinaire de Garoua, Cameroun.

Ont pris part à cette destruction :

- Dr ABDOULKADIRI Souley, Directeur Général du Laboratoire National Vétérinaire (LANAVET) ;
- Dr. BASCHIROU MOUSSA DEMSA, Directeur des services vétérinaires, Ministère de l'Elevage, des Pêches et des Industries Animales, Délégué du Cameroun à l'OIE ;
- Dr TCHOUBIA Antoine, Président de l'Ordre National des Vétérinaires du Cameroun.
- Dr YAYA Aboubakar, Directeur de Production au LANAVET ;
- M. MOHAMADOU DAOUDA, Chef du service de maintenance du LANAVET.

Les échantillons sont constitués ainsi qu'il suit :

- Souches du virus bovipestique isolée à Mindif en 1986 : 185 flacons ;
- Souche pathogène Bissau : 4 flacons
- Flacons Bivax (vaccin mixte PPCB, peste bovine) : 18 flacons
- Sérum antibovipestique Pirbright : 09 flacons
- Pestobov 100 lot 1PTV319 : 4 flacons
- Bovipestovax lot 01/95, 237, 397, inconnu de juin 1994, 0012, 0428, 1A91, 0705, 0762, 0813, inconnu du juillet 1995 : 78 flacons
- Souches vaccinales Bovipestovax : 275 flacons

Soit au total 573 flacons (cinq cent soixante treize) ont été détruits par autoclavage à la température de 127 °C pendant trente minutes. Après refroidissement et ouverture de l'autoclave, la commission de destruction a procédé à la vérification de la couleur des témoins d'autoclavage (scotches) collés sur les flacons et de la température maximale enregistrée à cœur de l'autoclave, et a validé les résultats.

Fait à Garoua le 15 décembre 2011 en 7 exemplaires originaux pour servir et valoir ce que de droit.

Le Directeur des Services Vétérinaire

Dr TCHOUBIA Antoine

Dr BASCHIROU MOUSSA DEMSA

Dr YAYA Aboubakar

Dr ABDOULKADIRI Souley

M. MOHAMADOU DAOUDA

3. MAINTAINING AFRICA FREE FROM RINDERPEST

IN COMPLIANCE WITH THE RECOMMENDATIONS

- OIE/FAO JAC inspected AU-PANVAC facility for rinderpest holding capacity
- Very positive comments on general infrastructure and capacity
- Recommendations of the committee already implemented

4. COLLABORATIONS WITH PARTNERS

4.1 COLLABORATIONS WITH THE OIE

- Recognition of AU-PANVAC as an OIE Collaborating Centre for Quality Control of veterinary vaccines
- Resolution No. 32 May 2013 OIE General Assembly

4. COLLABORATIONS WITH PARTNERS

4.1 COLLABORATIONS WITH THE OIE

- PPR Sub-grant Project- USD 1,000,000 (one million US dollars) for the period October 2012 – September 2014
- "Strengthen the AU/PANVAC capacities to guarantee the quality of PPR vaccines produced in Africa"- The "Vaccine Standards & Pilot Approach to PPR Control in Africa" project (VSPA) funded by the Bill & Melinda Gates Foundation
- Project concluded and report submitted

4. COLLABORATIONS WITH PARTNERS

4.2 COLLABORATIONS WITH THE FAO

1. Recognition as an FAO World Reference Laboratory for Technical Assistance in Vaccine Quality Control

2. Project; GCP/GLO/302/EC “Towards Global Declaration of Rinderpest Eradication in 2011 and Strategies for a Post-Rinderpest World”

3. USD 166 800, one hundred sixty six thousands and eight hundred US Dollars

4. COLLABORATIONS WITH PARTNERS

4.2 COLLABORATIONS WITH THE FAO

- Ensuring the safe management of rp containing materials – SOPs produced
- Strengthen AU-PANVAC capacity regarding sequestration
- Establish a framework for transfer of Rinderpest containing materials to AU-PANVAC and Rights of Ownership
- Provide 1.5M doses of ERV stock

4. COLLABORATIONS WITH PARTNERS

4.2 COLLABORATIONS WITH THE FAO

SOPs developed:

1. Destruction of Rinderpest Virus and Rinderpest Materials by African Union Member States Laboratory Staff

2. Handling, Packaging and Shipping of Rinderpest Materials by African Union MS Laboratory Staff and Shipment to PANVAC

3. Receiving of Rinderpest Materials by African Union Laboratory Staff at PANVAC

4. Handling of Rinderpest Materials by African Union Laboratory Staff at PANVAC

4. COLLABORATIONS WITH PARTNERS

4.2 COLLABORATIONS WITH THE FAO

RIGHTS OF OWNERSHIP:

1. Agreement between AU/PANVAC and the Country retaining the ownership of live rinderpest virus-containing material stockpiled at AU/PANVAC

2. Agreement for the transfer of the ownership of live rinderpest virus-containing material stockpiled at AU/PANVAC to AU/PANVAC

4. COLLABORATIONS WITH PARTNERS

4.3 COLLABORATIONS WITH AU-IBAR, KYEEMA FOUNDATION and AusAID

1. Supporting food security and capacity building in African Union member states through the “sustainable control of Newcastle disease in village chickens”
2. Amount- USD 1M

4. COLLABORATIONS WITH PARTNERS

PARTICIPANTS AT THE ND LAUNCHING JULY 2013

ANVAC

4. COLLABORATIONS WITH PARTNERS

4.4 COLLABORATIONS WITH GALVmed

3. GALVmed– Global Alliance for Livestock Veterinary Medicine - Several Projects

- ❑ Establishment of a vaccine Process Development Laboratory
- ❑ Specific projects on the improvement of animal disease vaccines

CONCLUSION

1. PANVAC continues to provide services to AU MS in line with its mandates and specific recommendations of the AUMS council of Ministers responsible for animal resources in Africa.
2. AU-PANVAC appreciates all its partners and is keen to collaborate with stakeholder in projects or activities aimed at the realization of its mandates
3. AU-PANVAC is committed to continually strengthening its capacity in order to meet up with the increasing challenges of animal disease control and eradication on the African continent

FINALLY- TO AUMS

AU-PANVAC

is yours,

make use of it!

ACKNOWLEDGMENTS

1. Dr. Karim Tounkara – former Director, AU-PANVAC
2. The OIE (DG, A. Dehove, J. Domenech, Y. Samake, D. Bourzat)
3. FAO
4. BMGF, AUMS vaccine producing laboratories,
5. All partners

THANK YOU

AU-PANVAC!!!

ENSURING THE AVAILABILITY OF GOOD QUALITY VETERINARY VACCINES AND DIAGNOSTIC REAGENTS IN AFRICA !!