



**Regional Seminar for OIE National Focal Points
for Veterinary Products – 4th Cycle**

**AFRICAN UNION PAN AFRICAN VETERINARY
VACCINE CENTRE (AU-PANVAC)**

**Registration of Veterinary Medicinal
Products: The Role of AU-PANVAC**

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AU-PANVAC



PRESENTATION OUTLINE

- **Introduction**
- **Animal disease control in Africa**
- **Proliferation of poor quality vaccines and drugs**
- **Intervention by the OIE**
- **Role of AU-PANVAC in vaccine registration**
- **Conclusion**





INTRODUCTION

- AU-PANVAC is the African Union Organization responsible for providing International Independent quality control of all veterinary vaccines produced or imported into Africa
- The establishment of an Independent Quality Control Centre in Africa in the 80's was due to the threat of animal diseases, particularly rinderpest





INTRODUCTION

- Livestock diseases (LD) are still a major threat not only to the livestock
- More than 90% of the diseases listed by the OIE occur in Africa
- LD emergence/re-emergence are considered to be one of the biggest constraints to improving livelihoods and Resilience





INTRODUCTION

On account of the importance of animal resources the AU established specialized technical Offices (AU-IBAR, AU-PANVAC and AU-PATTEC) under the Department of Rural Economy and Agriculture in order to achieve sustainable development in this sector .





ANIMAL DISEASE CONTROL IN AFRICA

- Generally accepted that stamping out and movement control is the best method for Animal disease control
- Most major diseases controlled by this method in other parts
- But this is not feasible in most of Africa





ANIMAL DISEASE CONTROL IN AFRICA

So, the only tools available for the control of vaccine preventable diseases are **Good Quality Vaccines** together with effective diagnostic support





PROLIFERATION OF POOR QUALITY VACCINES AND DRUGS

- But the proliferation of poor quality vaccines and sub standard drugs In most countries is a major problem- led to the failure of JP 15
- Absence of regulatory mechanisms for the control veterinary vaccines and drugs in most countries





PROLIFERATION OF POOR QUALITY VACCINES AND DRUGS

ORIGIN OF PANVAC: 1986 PARC - Audit of labs
producing rinderpest vaccines

FAO TCP – 2 Regional quality control and training
centres at dakar and debre zeit

1993 Merger of the 2 centres = pan african
veterinary vaccine centre (PANVAC)

Certification of rp and CBPP Vaccines

March 2004: Establishment of PANVAC under the
Dept of rural Economy and Agriculture of the
African Union



PROLIFERATION OF POOR QUALITY VACCINES AND DRUGS

CURRENT SITUATION

Upsurge of Animal diseases witnessed

Success achieved with Rinderpest could not be duplicated with other diseases

Devastating impact on the livelihoods of many on the African continent



INTERVENTION BY THE OIE

CONCERNED BY THE SITUATION

17th Conference of the OIE Regional
Commission for Africa Asmara, Eritrea
March 2007

- Identified the proliferation of poor quality vaccines and drugs as a major threat to animals, humans and the environment





INTERVENTION BY THE OIE

FOLLOW UP MEETING

Veterinary Medicinal Products in Africa-
Dakar, Senegal 2008.

– Towards the harmonization and
improvement of registration,
distribution and quality control





INTERVENTION BY THE OIE

THE DAKAR MEETING RECOMMENDED

- i. Promotion of good veterinary governance and compliance with OIE international standards.
- ii. the harmonization and improvement of registration, distribution and quality control of veterinary medicinal products
- iii. encourage coordination between REC's and others to move towards regional harmonization in particular for the improvement of registration.





INTERVENTION BY THE OIE

IMPLEMENTATION OF THE DAKAR MEETING

- OIE / GALVmed- Workshop on “the future of harmonization of vaccine registration in Africa” during the OIE National Focal Points meeting in Johannesburg in 2010. 50/29
- Dakar in September 2011 for Francophone countries
- Casablanca in December 2011 for the Maghreb region
- Mombasa, Kenya, in March 2012 for English-speaking countries



INTERVENTION BY THE OIE

RECOMMENDATIONS OF JOHANNESBURG 2010

Pan African Veterinary Vaccine Centre of the African Union (AU / PANVAC) should through its continental mandate play a leading role in the harmonization of the registration of veterinary vaccines on the continent with the support of OIE and GALVmed.





INTERVENTION BY THE OIE

IMPLEMENTATION OF JOHANNESBURG 2010

- AU-PANVAC and GALVmed organized several meetings in RECs
 - Nairobi, Kenya: 21-23 November, 2011)
 - Ouagadougou, Burkina Faso, 8-9 December 2011
 - Dar es Salam (Tanzania): 10-12 June 2013
 - Nairobi (Kenya): 13-15 June 2013
 - Arusha (Tanzania): 23-26 June 2013
 - Kampala(Uganda): 24 September 2013
 - Abuja (Nigeria) – 19 – 21 December 2013
 - Dar Es Salam (Tanzania) -





ROLE OF AU-PANVAC IN VACCINE REGISTRATION

The major role of AU-PANVAC in the Registration of Veterinary vaccines and immunologicals is to ensure that all products registered for use are

Pure, safe and efficacious

i.e.

“OF GOOD QUALITY”



AU-PANVAC



ROLE OF AU-PANVAC IN VACCINE REGISTRATION

Implement vaccine quality control for batches of vaccines submitted for registration or use in the field.



**PAN AFRICAN VETERINARY VACCINE CENTRE
(AU-PANVAC)**

Oie *Collaborating Center for Quality Control
of Veterinary Vaccines*

Debre-Zeit, ETHIOPIA P. O. Box 1746



AU-PANVAC



ROLE OF AU-PANVAC IN VACCINE REGISTRATION

**Provide Technical Assistance to laboratories in
the implementation GMP and Vaccine Quality
Control**



**FAO Reference Centre for Technical
Assistance in Quality Control of Veterinary
Vaccines** (A letter written on the 11th of May 2015)



AU-PANVAC



ROLE OF AU-PANVAC IN VACCINE REGISTRATION

Through its continental mandate, AU-PANVAC currently :

- i. Promotes the adoption of a harmonized registration procedure by AUMS in the different RECs
- ii. Encourages the Mutual recognition of registration procedures by the different RECs
- iii. Supports the Harmonization of Vaccine production techniques in all AUMS production laboratories



ROLE OF AU-PANVAC IN VACCINE REGISTRATION

In the implementation of the required tests for registration of vaccines, AU-PANVAC will :

- i. Support National regulatory authorities in the implementation of the specific tests required for vaccine registration
 - a. Quality
 - b. Safety
 - c. Efficacy





ROLE OF AU-PANVAC IN 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		



ROLE OF AU-PANVAC IN VACCINE REGISTRATION

- ii. Provide technical training to National regulatory authorities on the interpretation and validation of vaccine quality control test data
- iii. Provide advisory support to National laboratories in the implementation of GMP, validation of diagnostic kits and proficiency testing
- iv. Provide vaccine seed and reagents for vaccine production





CONCLUSION

AUPANVAC will provide all necessary support to regulatory agencies for Veterinary vaccines within the African continent and contribute to the reassurance of all concerned that Veterinary vaccines, when duly registered and authorized for use according to labeled instructions, will be Pure, safe, efficacious and of the highest quality.



THANK YOU

AU-PANVAC!!!

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



AU-PANVAC