AU-PANVAC

# The Role of AU-PANVAC IN THE QUALITY CONTROL/ ASSURANCE OF VETERINARY VACCINES

**NICK NWANKPA**

# PRESENTATION OUTLINE

AU-PANVAC

1. INTRODUCTION
2. ESTABLISHMENT OF AU-PANVAC
3. MAJOR ACTIVITIES OF AU-PANVAC
4. ROLE OF AU-PANVAC IN REGISTRATION OF VACCINES
5. CONCLUSION

# INTRODUCTION

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1. Livestock diseases(LD) are still a major threat to livestock and people particularly in Africa

2. Stamping out and movement control not feasible in most parts of Africa

2. Tools available for control are Good Quality vaccines and immunologicals

# INTRODUCTION

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1. Unfortunately proliferation of poor quality vaccines and sub standard drugs is a majo r problem - led to the failure of JP 15
2. Absence of regulatory mechanisms for the control veterinary vaccines in most countr ies
3. Intervention by the OIE
    1. Asmara, Eritrea 2007
    2. Dakar, Senegal 2008
    3. Johannesburg in 2010

# INTRODUCTION

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## 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

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# INTRODUCTION

AU-PANVAC

AU-PANVAC is the African Union Organization mandated to provide International Independent quality control of all veterinary vaccines produced or imported into Africa

Established due to the threat of animal dis eases

- rinderpest

# ESTABLISHMENT OF AU-PANVAC

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- 60s Rinderpest almost controlled
- 1970's -quality of vaccines produced declined
- 1980's- major resurgence of disease
- 1983 - Audit by FAO
- 1986- 2 QC centers established
- 1993- centers merged-PANVAC
- 2004- became AU Technical Centre

# MAJOR ACTIVITIES OF AU-PANVAC

AU-PANVAC

## 1. General Mandates of AU-PANVAC

Expanded to include vaccines against priority animal diseases

## 2. Specific Mandates of AU-PANVAC

- ❑ Harmonization of Veterinary vaccine registration on the continent
- ❑ Maintaining Africa free from Rinderpest

## 3. Collaboration with partners

- ❑ Projects on vaccine development/improvement and animal disease control efforts

# 1. General Mandates of AU-PANVAC

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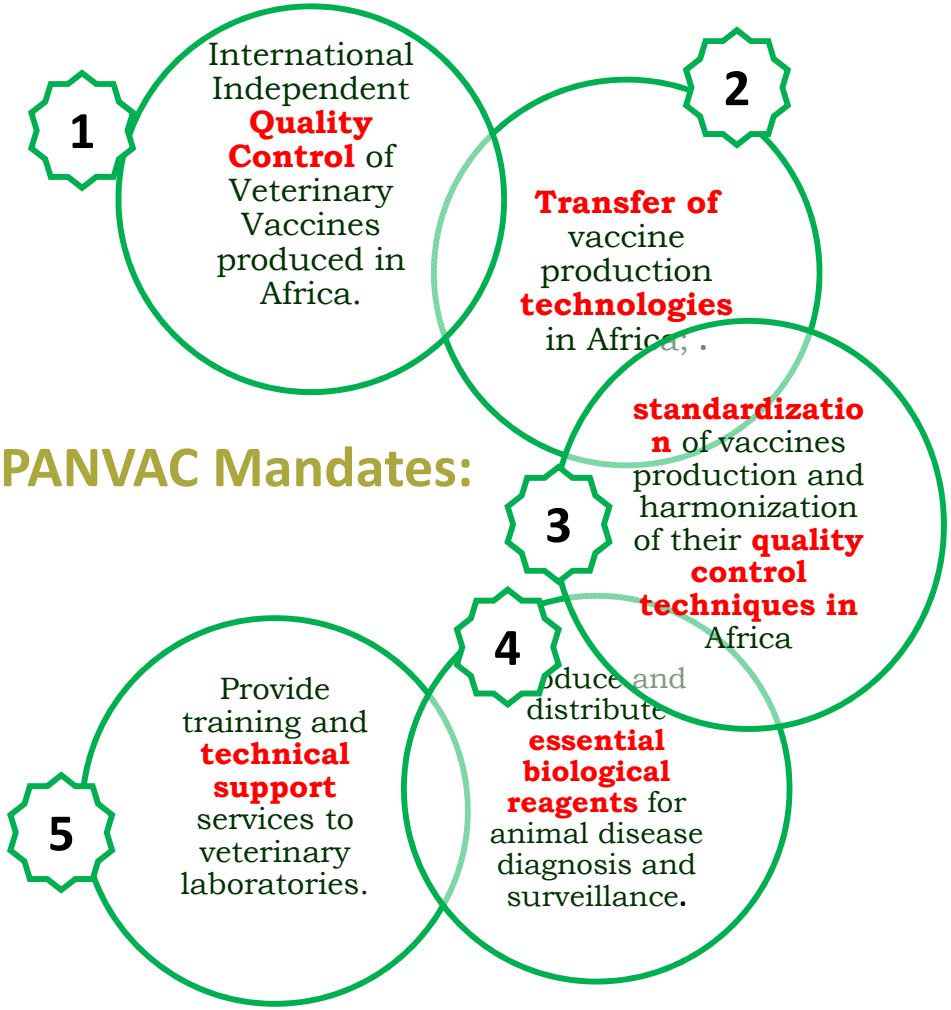
## AU-PANVAC Mandates:




## AU-PANVAC present status:

- OIE Collaborating Centre
- FAO Reference Centre
- FAO-OIE Rinderpest Holding Facility

## AU-PANVAC present status:

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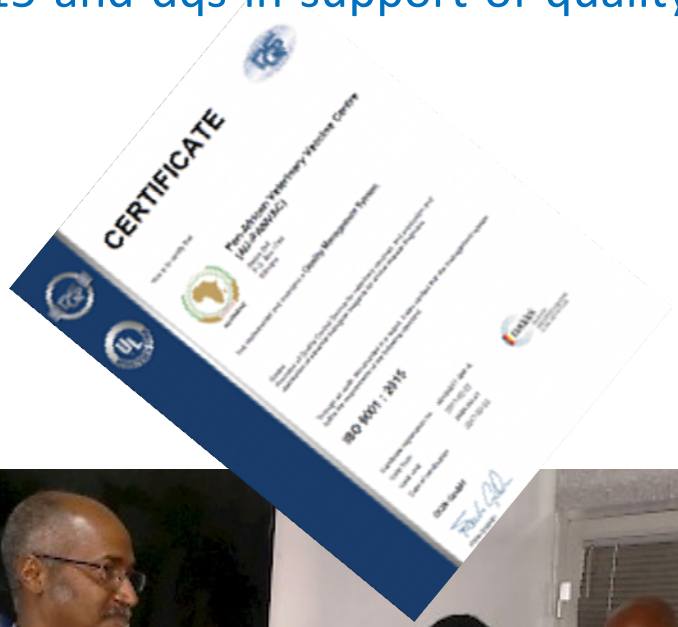
https://www.dqs-holding.com/en/news/iso-9001-2015-and-dqs-in-support-of-quality-vaccines/

ISO 9001:2015
Certified





ISO 17025
in progress

# ROLE OF AU-PANVAC IN REGISTRATION OF VACCINES

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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"**

# Registration Dossier Structure

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| PART 1 | PART 2 | PART 3 | PART 4 |
|---|---|---|---|
| **SUMMARY** | **QUALITY** | **SAFETY** | **EFFICACY** |
| **1.A:** Application form | **2.A:** Composition | **3.A.1 – A2:** **Safety**, Single Dose, Overdose, Repeated Dose | **4.A** Lab Efficacy |
| **1.B 1** SPC | **2.B:** Method of Manufacture | **3.A.3:** Other Safety Studies, e.g. Reversion to Virulence. | **4.B:** Field Efficacy |
| **1.B 2** Label and Carton text | **2.C:** Control of SMs | **3.B:** Field Safety | |
| **1.B .3** Package Leaflet | **2.D:** In-Process Controls | **3.C:** Safety to user and environment; residues, interactions. | **Part 5** Bibliographical references |
| | **2.E:** Controls on Finished Product | | |
| | **2.F:** Batch consistency | | |
| | **2.G:**Stability | | |
| | 2. H: Other information | | |

# Registration Dossier Structure

AU-PANVAC

- ✓ Conduct safety tests on vaccines as requirement for registration(Prt. 3)
- ✓ Laboratory and field efficacy trials (Prt. 4)
- ✓ Conduct controls on finished products (Prt. 2)
- ✓ Retesting vaccines submitted by the NRAs

# CONTROLS ON FINISHED PRODUCTS

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## 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

# CONTROLS ON FINISHED PRODUCTS

AU-PANVAC

## Control tests on the finished Products

1. Appearance
2. **Identification** of (immunogenic) ingredie
3. **Sterility** and purity including testing for *Mycoplasma*
4. **Safety**
5. Batch titre or batch **Potency**

- 1. Identity
- 2. Sterility
- 3. Safety
- 4. Potency

# CONTROLS ON FINISHED PRODUCTS

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## Control tests on the finished Products

6. pH
7. Adjuvant (where applicable)
8. Preservative (where applicable)
9. **Residual humidity** (where applicable)
10. Viscosity (where applicable)
11. Emulsion (where applicable)
12. Inactivation and **residual inactivant** (where applicable).

**5. Stability**

# CONTROLS ON FINISHED PRODUCTS

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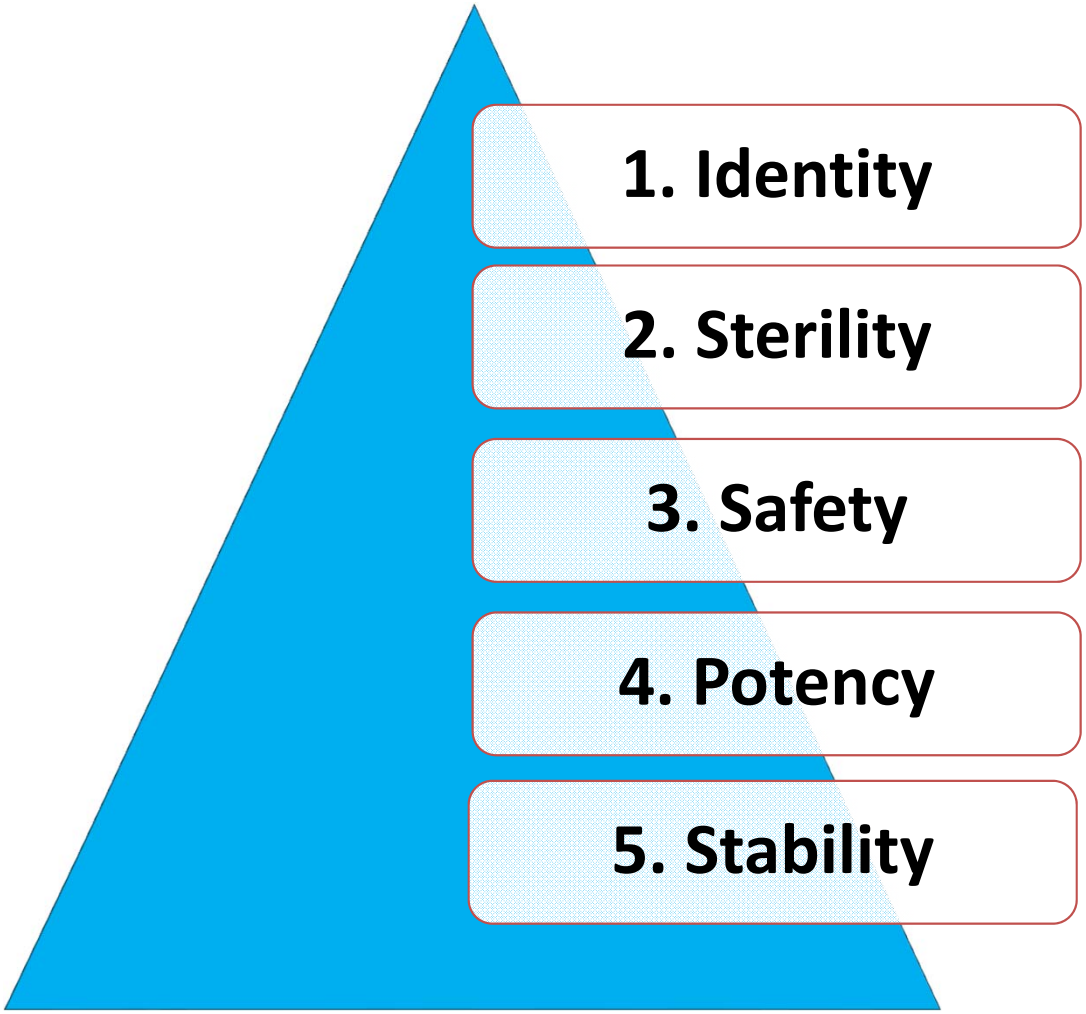
## Vaccine QC tests conducted at AU-PANVAC:




**All tests based on the**

**OIE Manual 2008-20012;**

**As indicated by the**

**Ph Eur.**

# CONTROLS ON FINISHED PRODUCTS

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## 1. Vaccine Identity Test: PCR

Conventional

Real Time

# CONTROLS ON FINISHED PRODUCTS

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## 2. Vaccine Sterility Test (Freedom from contamination)

| | |
|---|---|
| **Bacterial** | Direct Inoculation in Broth |
| **Viral** | Inoculation on Agar |
| **Fungal** | PCR |
| **Mycoplasmas** | ELISA TEST |

# CONTROLS ON FINISHED PRODUCTS

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## 3. Vaccine Safety Tests:

I. Laboratory animals
II. Host animals

# CONTROLS ON FINISHED PRODUCTS

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## 4. Vaccine Potency Test:

Invitro tests – Viable Counts/ Titrations  Live vaccines

Host Challenge studies – Killed vaccines

Serological tests

# CONTROLS ON FINISHED PRODUCTS

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## 5. Vaccine Stability Test:

Vacuum test

Residual Moisture

# CONTROLS ON FINISHED PRODUCTS

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## Quality Control Test Report:

| | |
|---|---|
| If a batch fails Quality Control | A Test Report **only** is issued |
| If a batch passes Quality Control | Test Report and Certificate is issued |

# CONTROLS ON FINISHED PRODUCTS

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## Quality Control Test Certificate:

All vaccine manufacturers should obtain vaccine QC Certificate from AU-PANVAC for batches produced

All NRAs should demand for AU-PANVAC Certificate before accepting vaccines for registration and use

A retesting of vaccines should be requested if vaccine handling, shipment and storage quality not guaranteed

# CONTROLS ON FINISHED PRODUCTS

AU-PANVAC

## Initiation of vaccine testing:

1. **TEST REQUEST**: Inform AU-PANVAC
2. **SUBMIT REQUIRED FORMS**: Forms required for import permit (vaccine submission guidelines)
3. **PACKAGE VACCINES APPROPRIATELY**
4. **SEND AWB Number**: Notify AU-PANVAC before sending
5. **AWAIT ACKNOWLEDGMENT OF VACCINE RECEIPT**: From AU-PANVAC

# CONTROLS ON FINISHED PRODUCTS

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## QC Testing of vaccine at AU-PANVAC:

1. **TESTING CYCLE**: Takes at most one month
2. **PRELIMINARY REPORT**: After one week and subsequently
3. **FINAL REPORT:** At least 3 weeks from submission
4. **REPORT ONLY ISSUED IF**: Vaccine fails quality control
5. **CERTIFICATE AND REPORT ISSUED IF**: Vaccine passes qc test

# CONCLUSION

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1. The African Union appreciates the huge role played by the OIE and GALVmed in this initiative
2. The AU encourages all AUMS to take ownership of this process for the benefit of animal disease control on the continent
3. AU-PANVAC will provide every support necessary for the internalization of this process in the SADC region

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# THANK YOU

***AU-PANVAC !***

***ADDING VALUE TO ANIMAL HEALTH AND HUMAN LIVES!!***

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# QUESTIONS ?

***AU-PANVAC !***

***ADDING VALUE TO ANIMAL HEALTH AND HUMAN LIVES!!***