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

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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

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

- rinderpest
ESTABLISHMENT OF AU-PANVAC

- 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
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

AU-PANVAC Mandates:

1. International Independent Quality Control of Veterinary Vaccines produced in Africa.

2. Transfer of vaccine production technologies in Africa.

3. Standardization of vaccines production and harmonization of their quality control techniques in Africa.

4. Produce and distribute essential biological reagents for animal disease diagnosis and surveillance.

5. Provide training and technical support services to veterinary laboratories.

AU-PANVAC present status:

- OIE Collaborating Centre
- FAO Reference Centre
- FAO-OIE Rinderpest Holding Facility
AU-PANVAC present status:


ISO 9001:2015 Certified

ISO 17025 in progress
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”
<table>
<thead>
<tr>
<th>PART 1</th>
<th>PART 2</th>
<th>PART 3</th>
<th>PART 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUMMARY</td>
<td>QUALITY</td>
<td>SAFETY</td>
<td>EFFICACY</td>
</tr>
<tr>
<td>1.B 3 Package Leaflet</td>
<td>2.D: In-Process Controls</td>
<td>3.C: Safety to user and environment; residues, interactions.</td>
<td>Part 5 Bibliographical references</td>
</tr>
<tr>
<td></td>
<td>2.E: Controls on Finished Product</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.F: Batch consistency</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.G: Stability</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.H: Other information</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
✓ 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
Types of vaccines certified

1. BACTERIAL VACCINES
   - I. BACTERIAL VACCINES
   - II. VIRAL VACCINES

2. A. LIVE ATTENUATED
   - B. INACTIVATED OR KILLED
     - i. WET/ LIQUID
     - ii. FREEZE DRIED
CONTROLs on finished Products

Control tests on the finished Products

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

1. Identity
2. Sterility
3. Safety
4. Potency
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).
Vaccine QC tests conducted at AU-PANVAC:

1. Identity
2. Sterility
3. Safety
4. Potency
5. Stability

All tests based on the OIE Manual 2008-20012;
As indicated by the Ph Eur.
CONTROLS ON FINISHED PRODUCTS

1. Vaccine Identity Test: PCR

Real Time

Conventional
2. Vaccine Sterility Test (Freedom from contamination)

- **Bacterial**
  - Direct Inoculation in Broth

- **Viral**
  - Inoculation on Agar

- **Fungal**
  - PCR

- **Mycoplasmas**
  - ELISA TEST
3. Vaccine Safety Tests:

I. Laboratory animals
II. Host animals
CONTROLS ON FINISHED PRODUCTS

4. Vaccine Potency Test:

- Invitro tests – Viable Counts/Titrations – Live vaccines
- Host Challenge studies – Killed vaccines
- Serological tests
5. Vaccine Stability Test:

- Vacuum test
- Residual Moisture
CONTROLS ON FINISHED PRODUCTS

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.
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.
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
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

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
THANK YOU

AU-PANVAC!
ADDING VALUE TO ANIMAL HEALTH AND HUMAN LIVES!!
QUESTIONS ?

AU-PANVAC!
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