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The role of AU-PANVAC in the harmonisation of the registration of veterinary medicinal products in the SADC region

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PRESENTATION OUTLINE

1. INTRODUCTION
2. ESTABLISHMENT OF AU-PANVAC
3. MAJOR ACTIVITIES OF AU-PANVAC
4. RECOMMENDATIONS OF JOHANNESBURG 2017 AND THE ROLE OF AU-PANVAC
5. CONCLUSION

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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

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

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INTRODUCTION

1. Unfortunately proliferation of poor quality vaccines and sub standard drugs is a major problem

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

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Establishment of 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

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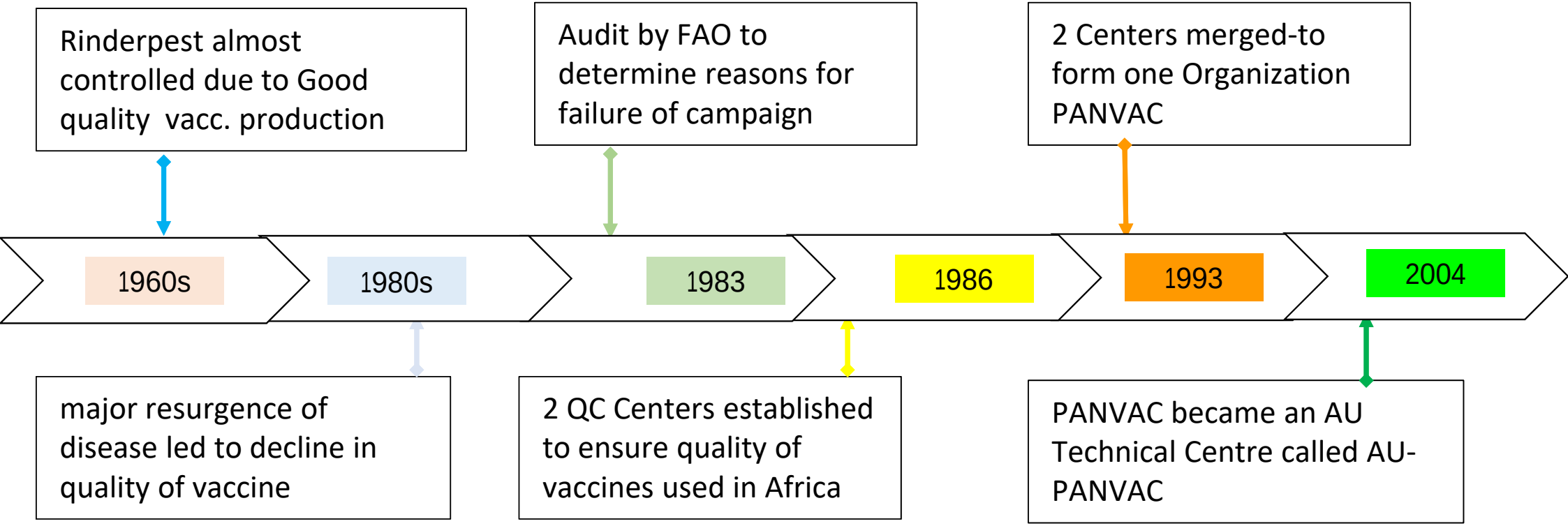
Establishment of AU-PANVAC



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Establishment of 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

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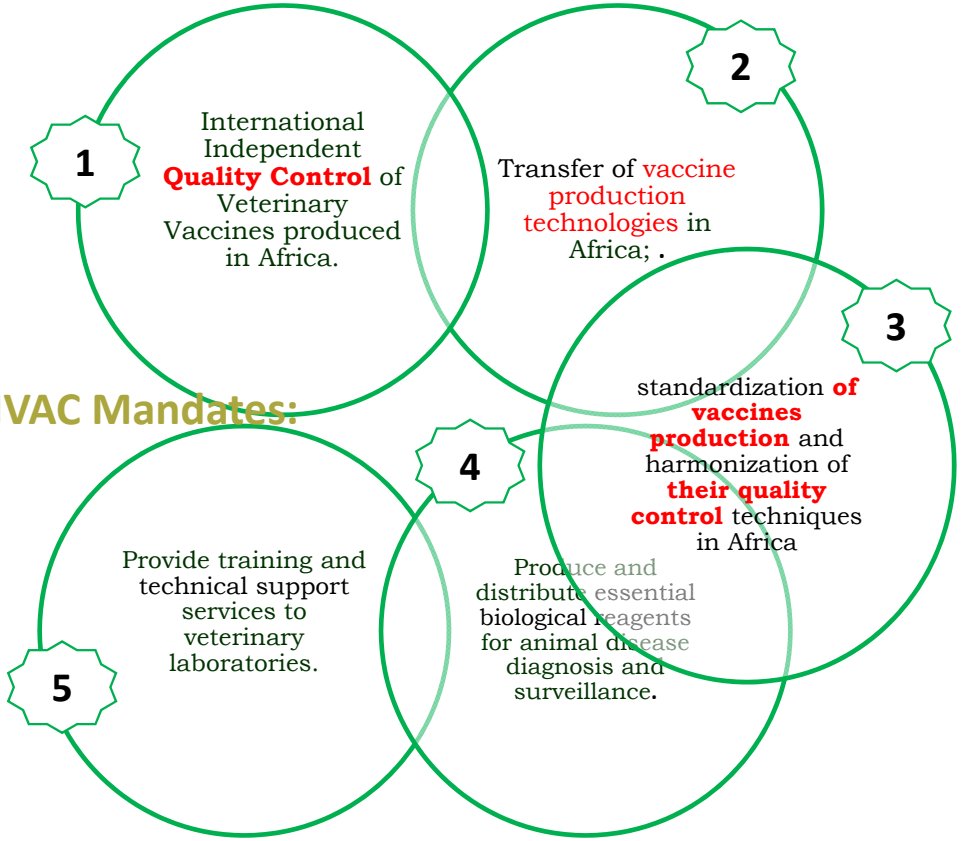
Major Activities of AU-PANVAC

AU-PANVAC Mandates:



AU-PANVAC present status:

- OIE Collaborating Centre
- FAO Reference Centre
- FAO-OIE Rinderpest Holding Facility
- ISO 9001:2015 Certified

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Role of PANVAC in 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 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		

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Role of PANVAC in Registration

- ✓ 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

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CONTROLS ON FINISHED PRODUCTS

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

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CONTROLS ON FINISHED PRODUCTS

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

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CONTROLS ON FINISHED PRODUCTS

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

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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

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CONTROLS ON FINISHED PRODUCTS

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

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Recommendations of Johannesburg 2017

- AU-PANVAC should through its continental mandate
  1. Provide political support for harmonisation initiatives in the SADC region;
  2. Support capacity-building (with OIE, GALVmed, SADC and relevant national stakeholders), in particular in areas relevant to the production of quality veterinary vaccines in the SADC region;
  3. Support and facilitate increased third party testing of vaccines, including as part of post-marketing surveillance

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Recommendations of Johannesburg 2017

- **Political Support**
  - AU-PANVAC is increasing the sensitization of AUC on the implementation of AU-PANVAC mandate regarding vaccine registration
  - The commissioner has shown increased interest on harmonization of vaccines registration and medicine regulation in Africa
  - We are also increasing outreach to Ministers responsible for Animal production in Africa

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Recommendations of Johannesburg 2017

- **Capacity building Support**
- Programme budget for training of AUMS vaccine production laboratories
- Special trainings for labs with specific problems in vaccine production
- Training on request by laboratories to build/ enhance own capacities
- Specific donors want to support specific trainings for AUMS- but not consistent

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Recommendations of Johannesburg 2017

- **Third party testing of vaccines**
- **Accept materials from NRAs for vaccine QC and encourage RAs to submit**
- **Accept vaccines from other gov or NGO to recertify**
- **Receive post marketing surveillance from drug authorities e.g – Uganda, Benin**

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Recommendations of Johannesburg 2017

- **Third party testing of vaccines**
- Special Agreement with DHL, to carry all shipment
- Direct flight to Ethiopia from all AUMS
- Especial arrangement with Ethiopian government on import clearing

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CONCLUSION

1. AU-PANVAC will provide every support necessary for the internalization of this process in the SADC region
2. AU-PANVAC will support all the laboratories & NRAs with specific testing required by the dossier when necessary
3. AU-PANVAC will continue to support vaccine producing labs in Africa to produce Good Quality Vaccines

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THANK YOU

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ADDING VALUE TO ANIMAL HEALTH AND HUMAN LIVES!!