



Waiver of Target Animal Batch Safety Test (TABST) VICH Guideline

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Introduction- Safety tests



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- Vaccines by nature are biological products with the inherent capacity to differ from one batch to the other after production
- Consequently manufacturers are generally required to test all finished batches on animals for safety.

What is Target Animal Batch Safety Test (TABST)?



A safety test carried out on every batch of product to demonstrate the safety of the batch in the target species for which the product is intended.

-this test refers to a finished batch from individual final bulk vaccine

Why Target Animal Batch safety Test (TABST)?



- Provides assurance of product safety
- Expected to reveal “unfavorable reactions” attributable to the vaccines
- It is stipulated by 52 EP mono & 3 EU Directives and several guidelines as a routine test on the finished product - trending

Growing concerns about TABST



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- Animal welfare groups on the number of animals used; advocating for the 3Rs : Replacing, Refining and Reducing the use of animals in tests
- Implementation of GMP, GLP, QMS and pharmacovigilance in laboratories
- Development of new and Hight tech equipment and automation and self sterilization

Growing concerns about TABST



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- Improvements in the manufacturing process of veterinary vaccines; seed lot system and subunit vaccines and avirulent strains
- Introduction of new requirements regarding in-process testing, controls on starting materials and environment
- Risks associated with waiver not sufficiently justified.

The VICH Guidelines on TABST



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- VICH developed guidelines to harmonize batch safety tests across regions in order to avoid duplication of tests- 2 developed
- **VICH-GL50** Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use
- **VICH-GL55** Harmonisation of criteria to waive target animal batch safety testing for live Vaccines for veterinary use

Waiver of TABST



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- January 2004 (Supplement 4.6, Ph. Eur., 4Th Edition) Conditional waiver of TABST in the light of experience gained from producing at least 10 consecutive batches
- The requirement for the target animal batch safety test (TABST) for veterinary vaccines was withdrawn from the European Pharmacopoeia, effective as of April 2013.

The Situation in Africa



- TABST is still being implemented based on the requirements of the OIE Manual of diagnostic tests and vaccines for terrestrial animals
- Compliance with Standards is still an issue in some laboratories as such safety cannot be assured
- Consequently, TABST is a routine test for most vaccine production laboratories

The Situation in Africa



- TABST is also implemented by the African Union Pan African Veterinary Vaccine Centre (AU-PANVAC) for the Quality control of Veterinary vaccines
- In Africa, it is mandatory for all Veterinary vaccines to be independently Certified by AU-PANVAC

The Situation in Africa



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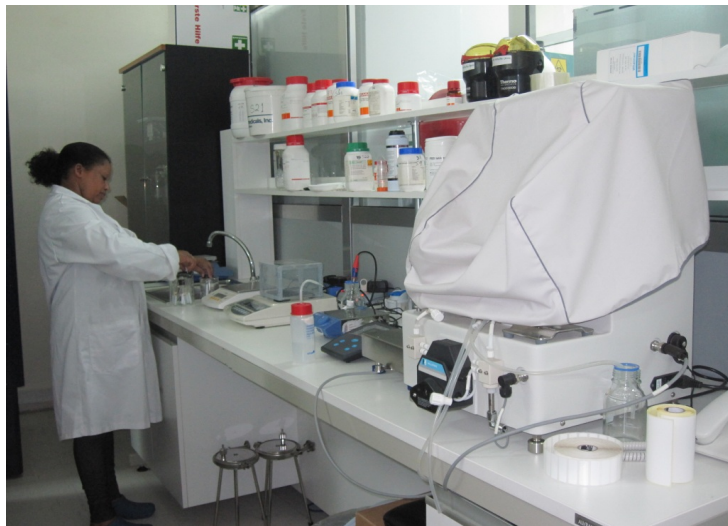
AU-PANVAC - mandated to provide International Independent quality control of all veterinary vaccines produced or imported into Africa



AU-PANVAC Facilities:



AU-PANVAC



MANDATES OF AU-PANVAC



1. AU-PANVAC General Mandates

- i. Certification of all Veterinary vaccines produced or imported into Africa (Vaccine Quality Control)
- ii. Production of essential Biological Reagents for disease surveillance and identification

2. Specific Mandates

1. Harmonization of vaccine registration
2. Maintaining Africa free from rinderpest

3. Collaborations on Projects

1. OIE, FAO, GALVmed, USAID, KYEEMA Foundation etc

Opportunities for Waiver of TABST in Africa



1. Harmonization of Vaccine Registration in ECAS and Centralization of registration in West Africa
2. Adoption of the OIE Standards for the implementation of Safety tests
3. Use of AU-PANVAC as an independent provider of qc services
4. Laboratories eager to comply with international standards
5. It is time to do the right thing !

The way forward for the waiver of TABST Africa



1. Create awareness on the need for waiver of TABST
2. Engage all Stakeholders in the drive for adoption: The OIE, PANVAC and Vaccine Manufacturers
3. Provide credible alternatives to TABST
4. Support laboratories in Africa to comply with international standards
5. If possible provide necessary incentives for implementation



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THANK YOU

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