Achievements and issues for Ph. Eur. Group of Experts on Veterinary Vaccines and Sera (15V)

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Monographs Concerned

- *Clostridium novyi* (type B) vaccine for veterinary use (0362)
- *Clostridium perfringens* vaccine for veterinary use (0363)
- *Clostridium septicum* vaccine for veterinary use (0364)
  - Cytotoxic Clostridia

Key Element of the Revision

Tests Concerned

- Residual toxicity (*in process*)
- Antigen content (*in process*)
- Residual toxicity of the final product

- Batch potency test
- Identification

Residual toxicity (*in process*)

Residual toxicity is assessed immediately after detoxification by a test in suitable cell cultures. The result complies with the value specified for the product.

- BSP 130 demonstrated that the move from the mouse test to the test in Vero cells is feasible for *C. septicum* toxoid
- It is assumed that residual toxicity of *C. perfringens* and *C. novyi* toxoids may be assessed in tissue cultures, as well
- According to EU guideline 2010/63 alternative methods must be applied, when available

Antigen content (*in process*)

The antigen content is determined by a suitable *in vitro* method such as total combining power (TCP) using appropriate cell cultures as indicators of toxicity, an enzyme-linked immunosorbent assay (ELISA) or any other validated method

- New test, to monitor consistency of production
- TCP test considered as preferred test, because it is a functional test
- BSP 130 demonstrated that the TCP test using Vero cells is feasible for *C. septicum* toxoid
- It is assumed that the activity of *C. perfringens* and *C. novyi* toxoids can be assessed in a TCP test in tissue cultures, as well

Residual toxicity of the final product

Test deleted

- Justification for this test is no longer given
  - Reversion to toxin probably due to false positive test results
- Sensitivity of the test questioned

Batch potency test Identification

Minor editorial issues

- door openers to promote alternative *in vitro* test methods

Thank you for your attention