

International harmonisation: Progress in establishing VICH guidelines on waiving criteria for general batch safety tests of veterinary vaccines

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General batch safety tests for veterinary vaccines as the Laboratory Animal Batch Safety Test (LABST) or the Target Animal Batch Safety Test (TABST) are supposed to demonstrate that a vaccine does not cause abnormal local or systemic reactions. However, over the last 25 years, the relevance of the TABST and LABST was questioned due to the introduction of more specific safety and purity tests, strict control of starting material and the introduction of Good Manufacturing Practice. Retrospective analysis of LABST and TABST data revealed that both tests are not able to detect batches causing safety problems and therefore are no longer justifiable. The LABST (or abnormal toxicity test) had already been removed from European Pharmacopoeia monographs for veterinary vaccines in 1997, and the TABST in a step-wise approach until its complete deletion in 2013. However, outside of Europe and European Pharmacopoeia countries, general safety tests may still be required for batch release.

In 2008, Europe proposed to The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) to aim at harmonisation of general batch safety tests across the VICH regions (USA, Japan, Europe) in order to minimise the need to perform separate studies for regulatory authorities of different countries. However, due to the great divergence in requirements between the regions it was agreed to adopt a phased approach. In 2014, VICH GL50 establishing harmonised criteria on data requirements for waiving of the TABST for inactivated vaccines came into force. A comparable guideline for live vaccines (VICH GL55) together with an updated GL50(R) were published in 2017 and came into force in May 2018. Since 2016, the VICH experts are working on a guideline on harmonisation of criteria for waiving the LABST for veterinary vaccines. The poster will summarise these developments.

References:

VICH (2017) VICH GL50 Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use

VICH (2017) VICH GL55 Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use

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