EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use
Committee for Medicinal Products for Veterinary Use

Recommendation to marketing authorisation holders for veterinary vaccines, highlighting the need to update marketing authorisations to remove the target animal batch safety test (TABST) following removal of the requirement from the European Pharmacopoeia monographs

Applicable to veterinary vaccines

The requirement for the target animal batch safety test (TABST) for veterinary vaccines has been formally withdrawn from the European Pharmacopoeia, effective as of April 2013.

Article 13 of Directive 2010/63/EU on the protection of animals used for scientific purposes[1], states that "Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union".

In order to comply with the provisions of Directive 2010/63/EU MAHs must update their marketing authorisations in order to remove the TABST. Guidance on the relevant actions to be undertaken was issued by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv) in its July-September 2012 and October-November 2012 reports, available at http://www.hma.eu/151.html. These documents also contain information on veterinary vaccines for which an exception to the need to remove the TABST exists.

[1] Available at http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm

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