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Note for the Editors: Further information is available on the internet site: www.edqm.eu

VACCINES FOR VETERINARY USE ADOPTED BY THE EUROPEAN PHARMACOPOEIA COMMISSION AT THE 142nd SESSION: INTERNATIONAL HARMONISATION WITH VICH GUIDELINES 41 AND 44, DELETION OF THE TABST AND 3Rs.

The culmination of several years of extensive and ambitious work to harmonise the European Pharmacopoeia texts for veterinary vaccines and improve their consistency was adopted by the European Pharmacopoeia Commission at its 142nd session.

This work started in the framework of harmonisation with VICH Guidelines (GL) 41 (test for reversion to virulence) and 44 (developmental safety tests), that came into force in 2008 and 2009, and involved around 80 Ph. Eur. vaccine-specific monographs, the general monograph on *Vaccines for veterinary use* and 2 general chapters (5.2.6. and 5.2.9) that had been published in *Pharmeuropa* 23.1 for public enquiry.

Beyond VICH harmonisation and to ensure consistency with European regulations, the European Pharmacopoeia harmonised all the monographs, including monographs for vaccines intended for species that were outside of the scope of the VICH GLs. As a consequence, the safety tests and the tests for increased virulence performed during development of the vaccines were harmonised, and this will greatly reduce the number of animals used for testing.

The general monograph on *Vaccines for veterinary use* was revised to delete the ‘TABST waiver’ and to add a statement referring to “particular circumstances” to cover the need to perform, on an *ad-hoc* basis, further testing, and in particular safety tests.

In the interest of the 3Rs (replacing, refining and reducing the use of animals in tests), the European Pharmacopoeia Commission also adopted the deletion of the target animal batch safety test (TABST) from the European Pharmacopoeia for all veterinary vaccines. The deletion of the TABST goes a step further than the option, available since 2004, of waiving use of the TABST for established vaccines.

These decisions are fully in line with the EDQM’s mission to promote and protect human and animal health, and with the EDQM’s commitment to the 3Rs principles.

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A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.

Note for the Editor: The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopoeia¹ is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

¹There are currently thirty-seven members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia,*



Turkey, United Kingdom and the European Union and twenty-five observers: The World Health Organisation (WHO); 6 member states of the Council of Europe: Albania, Armenia, Georgia, Moldova, Russian Federation and Ukraine; 18 other countries in the world: Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, Senegal, Syria, Tunisia, United States of America.