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Vaccines for Veterinary Use adopted by the European Pharmacopoeia at the 153rd Session for publication in the 9th Edition - A new step on the 3Rs path

After harmonising the technical requirements for the registration of veterinary vaccine products to align them with VICH guidelines 41 and 44 and deleting the target animal batch safety test (TABST) from the European Pharmacopoeia for all veterinary vaccines – in force since 1st April 2013⁽¹⁾, resulting in a considerable reduction in testing on animals⁽²⁾ – the EDQM is pleased to announce that a new stage has been reached on the 3Rs way.

Promotion of *in-vitro* testing (3Rs) for the control of inactivated veterinary vaccines: around 40 inactivated vaccine-specific monographs and the general monograph *Vaccines for veterinary use* (0062) were adopted including the following changes:

- (a) revision of the requirements for identification: reference to the antibody induction test has been removed for all inactivated vaccines, which allows the user to identify the antigen(s) by any suitable method. This will allow manufacturers to discontinue the animal test and change to *in vitro* tests to identify the vaccine, when appropriate, and strengthens the fact that it may be combined with the batch potency test.
- (b) revision of inactivation testing of all the inactivated veterinary vaccines to give conditions that allow omission of the second inactivation test.

Promotion of the move from final controls to verification of consistency of production

- (c) Further to the introduction of the consistency of production concept in the context of the 3Rs in the General Notices (Supplement 8.2)⁽³⁾, this concept has also been included in the general monograph *Vaccines for veterinary use* (0062) and in the three following vaccine-specific monographs: *Canine leptospirosis vaccine (inactivated)* (0447), *Bovine leptospirosis vaccine (inactivated)* (1939)⁽⁴⁾ and *Infectious bovine rhinotracheitis vaccine (inactivated)* (2674) in order to encourage manufacturers to develop *in vitro* alternatives, even when such tests are not available yet. This has been done in conjunction with the implementation of the revised *Directive 2010/63/EU on the protection of animals used for scientific purposes*, and also takes into account manufacturers' efforts in the development of new test methods and a better control of vaccine production in general (e.g. general improvements in the manufacturing process of veterinary vaccines in recent decades, introduction of new requirements regarding in-process testing and controls on the starting materials).

Promotion of the move from final controls to upstream quality controls

- (d) The introduction of a reference to the new general chapter setting requirements for *Healthy Chicken flocks for the production of inactivated vaccines for veterinary use* (5.2.13) will provide guarantees with regard to extraneous agents contamination, making the test for specified extraneous agents performed on each final product obsolete for the eight following specific monographs: *Equine influenza vaccine (inactivated)* (0249), *Newcastle disease vaccine (inactivated)* (0870), *Avian infectious bronchitis vaccine (inactivated)* (0959), *Avian infectious bursal disease vaccine (inactivated)* (0960), *Porcine influenza vaccine (inactivated)* (0963), *Egg drop syndrome '76 vaccine (inactivated)* (1202), *Avian paramyxovirus 3 vaccine (inactivated)* (1392) and *Feline chlamydiosis vaccine (inactivated)* (2324). This is the first step of a general review of all the current requirements on extraneous agents testing in an attempt to rationalise them while keeping the same guarantees of safety.

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. Indeed, this will significantly contribute to the further reduction of animal-use for the control of veterinary vaccines (3Rs).



Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe
Tel.: +33 (0) 3 88 41 28 15 - E-mail: caroline.letarnec@edqm.eu

References:

1. [EDQM Press Release](#), dated 17 April 2012
2. Report published by the [Veterinary Medicines Directorate](#) (UK) on '[Animal usage in quality control tests for the batch release of Immunological Veterinary Medicinal Products \(IVMPs\) via the UK from 2007 to 2012](#)'.
3. [EDQM Press Release](#), dated 28 June 2013
4. [EDQM Press Release](#), dated 13 February 2012
[Pharmeropa](#) : [Harmonisation of Veterinary Vaccines with VICH Guidelines 41 and 44](#), dated February 2013

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

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 Pharmacopoeia is legally-binding in Member States¹. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

¹There are thirty-eight members of the [European Pharmacopoeia](#) Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the Former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union.*

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