Press release

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New approach to extraneous agents testing of immunological veterinary medicinal products (IVMPs)

During its 164th session on 18 June 2019, the European Pharmacopoeia Commission adopted 43 texts related to its new approach to extraneous agents testing of immunological veterinary medicinal products (IVMPs). The new approach constitutes a move away from the description of detailed methods towards greater flexibility and allowing tailoring to individual product needs. From starting material to final product, users will now have to follow an overall risk-management approach to ensure they apply the best testing strategies in the context of a consistent manufacturing process.

Several changes have been made to the European Pharmacopoeia (Ph. Eur.) to accommodate the new approach.

Chapters *2.6.24. Avian viral vaccines: tests for extraneous agents in seed lots* and *2.6.25. Avian live virus vaccines: tests for extraneous agents in batches of finished product*, which contain detailed protocols for testing extraneous agents, will be suppressed as of 1 July 2020.

A new chapter, *2.6.37. Principles for the detection of extraneous viruses in immunological veterinary medicinal products using culture methods*, describing the general principles and giving examples of parameters to be taken into account when dealing with extraneous agents, has been added. This new chapter also introduces more modern technologies or methods that can be used to reveal extraneous agents amplified by culture.

Chapter *5.2.5.*, which was previously dedicated to *Substances of animal origin for the production of IVMPs*, is now entitled *Management of extraneous agents in IVMPS* and covers the entire IVMP production process, providing specific guidance on risk management and allowing modern test methods to be used. A consolidated list of avian agents already published in the Ph. Eur. is appended to the chapter, together with a list of mammalian and fish agents, which are currently outlined in the EMA guideline on requirements for the production and control of IVMPs (EMA/CVMP/IWP/206555/2010-Rev.1).

The general monograph *Vaccines for veterinary use (0062)* has been revised to delete any specifications for the management of extraneous agents and now refers to general chapter *5.2.5*; it also includes updates in a 3Rs perspective (e.g. identification test).

Thirty-eight individual monographs have been revised to remove references to deleted chapters and detailed protocols, and replace them with references to general chapter *5.2.5*.

This is a move from a prescriptive to a more flexible approach, which is scientifically sound and targeted, and allows for the use of fit-for-purpose methods. It is expected that this new approach to extraneous agents testing in IVMPs will enable the use of state-of-the-art methods, with a preference for *in vitro* over less robust *in vivo* methods. The revision will lead to additional deletion of animal tests, such as serological tests for identification of vaccine antigen or detection of extraneous agents in certain specific inactivated vaccines, previously performed on each batch of product.

In advance of the implementation of these 43 texts on 1 July 2020 and in order to help users prepare for the forthcoming changes, the EDQM will organise a symposium entitled “Management of Extraneous Agents in Immunological Veterinary Medicinal Products (IVMPs)”, open to assessors and manufacturers, on 1 and 2 April 2020 in Strasbourg, France. More information will be available on the EDQM website in due course.

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Note for the Editor: Further information is available on the internet site **https://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 worldwide. The European Pharmacopoeia is legally binding in member states.[1] Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

1. There are 39 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, Republic of Moldova, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom and the European Union.*

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