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Suppression of the Test for Abnormal Toxicity from the European Pharmacopoeia

During its 159th plenary session, held in Strasbourg on 21-22 November 2017, the European Pharmacopoeia Commission endorsed the complete suppression of the test for abnormal toxicity from the European Pharmacopoeia (Ph. Eur.).

As part of this exercise, 49 monographs revised to remove the test for abnormal toxicity were adopted by the Commission; notably, these included 36 monographs on vaccines for human use. In addition, as the general chapter Abnormal Toxicity (2.6.9) will no longer be referenced in any monograph, it will subsequently be rendered obsolete and will also be deleted from the Ph. Eur.

The scientific validity and rationale of the test for abnormal toxicity, which is carried out on animals, has been the subject of debate for some time in Europe. It was originally developed to detect external contaminants in biological products, but over time the introduction of Good Manufacturing Practices and the use of appropriate and stringent quality control measures have rendered its use less necessary. Current scientific evidence suggests that, in light of such debatable relevance, the omission of the test for abnormal toxicity would not compromise the safety of biological medicines.

The Ph. Eur. Commission had already removed this test from routine testing in 1998. The Ph. Eur. Commission then decided to embark on the complete removal of the test for abnormal toxicity from its monographs, which cover areas including vaccines and immunosera for human use, biotherapeutics, allergens, antibiotics, antimycotics and plastic containers. A detailed evaluation was subsequently conducted for each monograph concerned before the decision to suppress the test was taken.

The Ph. Eur. Commission remains fully committed to the reduction of animal use wherever possible in pharmacopoeial testing, in accordance with the *European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes*. The decision to suppress the test for abnormal toxicity at the 159th session of the Ph. Eur. Commission is a strong illustration of this commitment.

The suppression of the test for abnormal toxicity will be reflected in Supplement 9.6 of the European Pharmacopoeia and become effective on 01 January 2019.

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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 thirty-nine 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, 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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