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EDQM welcomes WHO recommendation to discontinue innocuity test in guidelines on vaccines and biologicals

The EDQM has welcomed the recommendation of the WHO Expert Committee on Biological Standardization (ECBS) to omit the abnormal toxicity test (also called the innocuity test) in all future WHO documents on vaccines and other biological products, and to disregard the inclusion of this test in previously published WHO Technical Report Series documents. The ECBS recommendations, issued at the Committee's 69th meeting[1], are based on the consideration that the omission of the abnormal toxicity test would not compromise the quality and safety of vaccines and other biological products.

The European Pharmacopoeia (Ph. Eur.) Commission endorsed the complete suppression of the test for abnormal toxicity from the European Pharmacopoeia (Ph. Eur.) in November 2017. As part of this exercise, 49 monographs were revised to remove references to the test for abnormal toxicity and it was decided to completely suppress general chapter *Abnormal Toxicity (2.6.9),* as it would no longer be referenced in the Ph. Eur. The decision is reflected in Supplement 9.6 of the Ph. Eur. and will become effective as of 1 January 2019. This testifies to the commitment of the EDQM and of the Ph. Eur. Commission to reduce the use of animals in pharmacopoeial testing, in line with the Council of Europe's Convention (ETS 123) for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes.

The international dimension brought in by the WHO Expert Committee was welcomed by Susanne Keitel, Director of the EDQM: "The ECBS recommendation reflects today's globalised dimension of medicines production and gives international prominence to the need to question and, wherever possible, replace the use of animals to test modern medicines".

Animal tests such as the abnormal toxicity test were developed for the safety testing of human vaccines at a time when limited scientific knowledge for the quality control of biological products existed. Over the past decades, the strenuous work of the Ph. Eur. Commission and its counterparts at global level has allowed for the identification of viable alternatives to the use of animals for tests, while still ensuring high levels of protection for human health. In particular, today's manufacturing processes, including the Good Manufacturing Practices (GMP) and in-process quality controls, can ensure a more appropriate level of quality and safety for vaccines and other biological products than the abnormal toxicity test.

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[1] During its 69th meeting, held from 29 October to 2 November 2018 at WHO headquarters in Geneva, Switzerland, the WHO Expert Committee on Biological Standardization (ECBS) recommended "the immediate discontinuation of the inclusion of the innocuity test in all future WHO documents on vaccines and other biologicals published in the Technical Report Series (including WHO Recommendations, Guidelines and manuals)". More detail on the recommendations can be found in the summary of the 69th meeting of the WHO Expert Committee on Biological Standardization.

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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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