



**01 December 2016, Strasbourg, France**

## **THE EUROPEAN PHARMACOPOEIA COMMISSION ADOPTS FAR-REACHING TEXTS IMPLEMENTING AND PROMOTING ANIMAL WELFARE**

In accordance with the *European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes*, the Ph. Eur. Commission is committed to the reduction of animal usage wherever possible in pharmacopoeial testing, and encourages those associated with its work to seek alternative procedures. The recent adoption during its 156<sup>th</sup> Session (22-24 November) of the following texts is an illustration of this commitment and will have significant impact on the replacement, reduction and refinement of animal tests in the quality control of medicines.

### **New Ph. Eur. General Chapter Adopted: *Substitution of in vivo methods by in vitro methods for the quality control of vaccines (5.2.14)***

A new general chapter on the *Substitution of in vivo methods by in vitro methods for the quality control of vaccines (5.2.14)* was adopted.

General chapter 5.2.14 aims at facilitating the transition from *in vivo* to *in vitro* methods by providing guidance on how to validate alternative *in vitro* methods in scenarios where a direct head-to-head comparison to an existing *in vivo* method is not possible. Specific recommendations on the substitution of *in vivo* potency and safety tests are provided together with examples.

The general chapter is a non-mandatory text and forms an additional tool in the continuing efforts of the Ph. Eur. Commission to further reduce animal testing and encourage the use of alternative *in vitro* methods.

### **Revisions of the general texts on *Tests for extraneous agents in viral vaccines for human use (2.6.16)* and *Cell substrates for the production of vaccines for human use (5.2.3)***

Technical revisions of the general texts on *Tests for extraneous agents in viral vaccines for human use (2.6.16)* and *Cell substrates for the production of vaccines for human use (5.2.3)* were adopted.

As per the revised general chapter 2.6.16 the testing strategy as regards extraneous agents is to be established based on a risk assessment and the list of tests must be adapted depending on the extraneous agents that have the potential to contaminate the product. Molecular biology methods may be considered for the detection of specific viruses, while broad molecular methods may be considered for broad detection of viruses.

As part of the revisions of both general chapters, the tests in adult mice and guinea pigs were deleted as they were considered redundant due to the presence of other tests providing risk mitigation. In addition, the tests in suckling mice and control eggs are to be used only if a risk assessment indicates that the tests provide risk mitigation.

The texts will be published in the Supplement 9.3 of the European Pharmacopoeia and will become effective on 1st January 2018.

**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](mailto:caroline.letarnec@edqm.eu)

<sup>1</sup>There 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.*



**Note for the Editor:** Further information is available on the internet site [www.edqm.eu](http://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 States<sup>1</sup>. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

*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.*

<sup>1</sup>There 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.*