



03 April 2017, Strasbourg, France

Test for Abnormal Toxicity: towards possible deletion from the European Pharmacopoeia

The European Pharmacopoeia Commission is seeking public feedback on its proposal to remove the requirements for a test for abnormal toxicity from 49 monographs of the European Pharmacopoeia (Ph. Eur.). Published in the *Pharmeuropa* issue of April 2017¹, this consultation will run until June 2017 for all users, and will be extended until August for National Pharmacopoeia Authorities. Interested parties are invited to provide their comments through the Procedure for commenting on *Pharmeuropa* drafts².

The decision to consult the public on the test for abnormal toxicity follows on from the conclusions reached at scientific conferences held in 2015 with the European Partnership for Alternative Approaches to Animal Testing (EPAA) – an initiative driven by the EU Commission and manufacturers, and with the International Alliance for Biological Standardization (IABS)³. Discussions at these conferences led to a consensus among the experts that the time was ripe for considering the actual relevance of the test for abnormal toxicity in regulatory requirements.

The scientific validity and rationale of the test for abnormal toxicity has been the subject of debate for some time in Europe. The test was originally developed for detecting 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 their 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 already removed the test for abnormal toxicity from routine testing in 1998. The requirements related to abnormal toxicity were moved from the “Tests” section to the “Production” section in the Ph. Eur. monographs. As a result, the obligation to assess abnormal toxicity for all batches was removed; and the test only had to be carried out during the initial production phase and to be repeated whenever there was a significant change in the production process.

Tests using live animals are controversial in terms of animal welfare and their possible deletion from the Ph. Eur. will allow for full alignment with the *European Convention for the Protection of Vertebrate Animals used for experimental and other scientific purposes* of the Council of Europe and with the EU animal welfare legislation (*Directive 2010/63/EU on the Protection of Animals used for scientific purposes*), which require a solid scientific rationale to support any testing requirements using live animals.

¹ *Pharmeuropa* 29.2 of April 2017. *Pharmeuropa Online*: <http://pharmeuropa.edqm.eu/home/>

² More information on public enquiries is published in *Pharmeuropa Online* under “Useful information”.

³ These scientific conferences took place in the Netherlands in 2015: “Modern science for better quality control of medicinal products: Towards global harmonisation of 3Rs in biologicals”, organised by the EPAA (a report can be found [here](#)), and “3Rs Alternatives and consistency testing in vaccine lot release testing” organised by the IABS.



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

Note for the Editor

The EDQM is an organisation that leads the protection of 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. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

Further information is available on the web site www.edqm.eu

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, 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.*

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.