



23 June 2015, Strasbourg, France

152nd SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION

The European Pharmacopoeia Commission held its 152nd session in Strasbourg on 16-17 June 2015. The session was opened by the Council of Europe's Director General of Democracy, Ms Snežana Samardžić-Marković, who congratulated the Commission on its great achievements in providing harmonised standards for the quality of medicines throughout the continent.

In her speech, she spoke of the unique role of the European Pharmacopoeia in the provision of safe, effective and good quality medicines and highlighted some of the Commission's recent accomplishments and activities, including the adoption of the first [finished product monograph](#), its continuous involvement in international harmonisation initiatives, the project for the elaboration of a pan-European paediatric formulary carried out together with the [Committee for Pharmaceuticals and Pharmaceutical Care of the Council of Europe](#) and the [EDQM's ISO 9001:2008 Certification](#) for pharmacopoeial activities. She stated that "the Commission is clearly committed to propelling the European Pharmacopoeia into a new era" and wished it continued success.

During the session, the Commission adopted six new texts for inclusion in the European Pharmacopoeia, 31 revised monographs and six revised general chapters, amongst them:

- A new general monograph on *Chemical precursors for radiopharmaceutical preparations* (2902). In setting quality requirements for all chemical precursors for the preparation of radiopharmaceuticals, a gap has been filled in a fast evolving field (*this will be the subject of a separate press release in the near future*).
- A revised version of the *Guidelines for using the test for bacterial endotoxins* (5.1.10): the chapter includes new recommendations on the need to perform risk assessment when using the bacterial endotoxin test as a pyrogenicity test, due to the potential contamination by non-endotoxin pyrogens; a new section on how to set limits for bacterial endotoxins has been added to the chapter and will help users to decide on suitable limits to apply to their products.
- A revised version of the general chapter on *Potentiometric determination of pH* (2.2.3).
- A revised version of the general chapter 5.4 *Residual solvents* to align the latter to the latest version of the ICH Q3C (R5).
- A revised version of the chapter on *Pyrogens* (2.6.8), which recommends replacing this test by the *Monocyte-activation test* (chapter 2.6.30) wherever possible and after product-specific validation, therefore avoiding the use of live animals. The revision is in line with the [European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes](#).

These texts will become effective on 1st July 2016 in the 37 European signatory States and will be published in Supplement 8.8. The list of all adopted texts will be published on the EDQM website to inform users of future changes they need to be aware of.

The next Commission session will take place on 17-18th November 2015. Dates for sessions in 2016 were also decided: 15-16th March, 14-15th June and 22nd-23rd November.

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Note for the Editor: Further information is available on the internet site www.edqm.eu

The EDQM is a leading organisation that protects public health by enabling the development, supporting the 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 Pharmacopeia is legally-binding in European Member States. 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.