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*Note for the Editors:* Further information is available on the internet site: [www.edqm.eu](http://www.edqm.eu)

## **141<sup>ST</sup> SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION HELD IN STRASBOURG**

On 22-23 November, the European Pharmacopoeia Commission held its 141<sup>st</sup> session. During this meeting, 17 new monographs were adopted, including:

- six monographs, Sildenafil citrate (2270), Pioglitazone hydrochloride (2601), Nevirapine hemihydrate (2479), Lopinavir (2615), Rivastigmine (2629) and Insulin glargine (2571), elaborated under the P4 or P4Bio (*Insuline Glargine*) Procedures - procedures dedicated to substances still under patent and developed in close collaboration with the respective manufacturers. The monograph on *Sildenafil citrate* was elaborated jointly with the United States Pharmacopeia (USP), within the framework of a pilot project for the prospective harmonisation of monographs for active substances,
  - one radiopharmaceutical monograph on Gallium (68Ga) edotreotide injection (2482),
  - one monograph on homeopathic preparations, Anamirta cocculus (2486),
  - five monographs on herbal drugs and herbal drugs preparation: Ginseng dry extract (2356), Pepper (2477), Long pepper (2453), Common selfheal fruit spike (2439) and Instant herbals teas (2620), and three monographs on herbal drugs used in Traditional Chinese Medicines: Coix seed (2454), Magnolia officinalis bark (2567) and Orientvine stem (2450),
  - a monograph on Quinapril hydrochloride (1763),
- and two new general chapters: Voltammetric titration (2.2.65) and Characterisation of crystalline solids by microcalorimetry and solution calorimetry (2.2.61).

The Commission also adopted 90 revised texts including 81 monographs, five General Chapters and four procedures (e.g. the Procedure No. 5 for the Elaboration of Monographs on Homeopathic preparations). Revisions included:

- the General Notices, in which a paragraph "*Implementation of pharmacopoeial methods*" has been added,
- the monograph on Vaccine for human use (153): a new paragraph "*Test for sterility of intermediates prior to final bulks*" will allow for replacement of sterility test with test for low bioburden in certain circumstances, and
- several individual monographs which were revised to avoid the use of reagents which were proscribed under the REACH regulation.

These texts shall become effective on 1 January 2013 and will be published in Supplement 7.6. The list of all adopted texts will be published on the EDQM website.

The Commission also approved the terms of reference of two new working parties:

- *Raw Materials for the production of cellular and gene transfer products Working Party*, which will elaborate texts on such raw materials including antibodies, basal media (for cell culture), serum/serum replacements, growth factors and cytokines.
- *Host-Cell Proteins Working Party* which will draft recommendations with regard to the development, validation and use of in-house or commercial kits or test methods for the detection and quantification of host-cell derived proteins.

The Commission gave mandate to the *Water Working Party* to review the production section of the *Water for Injection* monograph (169) to consider the inclusion of currently available technologies and evaluate whether additional online monitoring is needed.



The Commission received a report on the recent meeting of the Pharmacopoeial Discussion Group (PDG). In this context, delegates emphasised the strong commitment of the Commission to pharmacopoeial harmonisation and applauded the World Health Organization (WHO) for their initiative to bring together representatives of the pharmacopoeias of the world in a meeting in Geneva, Switzerland, in February 2012.

The Secretariat also informed the Commission that Dr Gerard Lee, head of the UK delegation to the European Pharmacopoeia Commission, will retire at the end of the year. In her speech, Dr Susanne Keitel, Director of the EDQM, paid tribute to his dedication and thanked him for his contributions to the work of the European Pharmacopoeia.

The approved 2012 Commission sessions dates are as follows: 3 to 4 April, 19 to 20 June and 27 to 28 November 2012.

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**Note for the editor:** 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<sup>1</sup> is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantations 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.*

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<sup>1</sup>There are currently thirty-seven members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, United Kingdom and the European Union* and twenty-three observers: *The World Health Organisation (WHO)*; 6 member states of the Council of Europe: *Albania, Armenia, Georgia, Moldova, Russian Federation and Ukraine*; 16 other countries in the world: *Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Kazakhstan, Senegal, Syria, Tunisia, United States of America.*