



**18 April 2012, Strasbourg, France**

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

## **142<sup>nd</sup> SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION - NEW OBSERVER TO THE EUROPEAN PHARMACOPOEIA COMMISSION 3-4 APRIL 2012, STRASBOURG, FRANCE**

The EDQM is pleased to announce that the Republic of Guinea has been granted observer status to the European Pharmacopoeia Commission at its 142<sup>nd</sup> session. The decision now brings to 25 the number of observers of the Commission.

During the session, the European Pharmacopoeia Commission adopted 20 new individual monographs and one general monograph, two general chapters and one method of analysis, including:

- two monographs, *Ciclesonide* (2703) and *Pemetrexed disodium heptahydrate* (2637), elaborated under the P4 Procedure - a procedure dedicated to substances still under patent and developed in close collaboration with their respective manufacturers.
- one general chapter on *Metal catalysts or metal reagents residues* (5.20) and one method for the *Determination of metal catalysts or metal reagent residues* (2.4.20); chapter 5.20 is a reproduction of the EMA guideline on the specification limits for residues of metal catalysts or metal reagents. The methodology described in general method 2.4.20 describes the general approach for the determination of metal catalysts or metal reagent residues in substances for pharmaceutical use and is to be applied wherever possible.
- one general chapter on *Demonstration of uniformity of dosage units using large sample sizes* (2.9.47) which can be utilised by applicants, e.g. when increased information from non-destructive NIR process controls is available.
- one general monograph on *Pharmaceutical preparations* which is intended to be a reference source of standards in the European Pharmacopoeia on active substances, excipients and dosage forms that can be applied in the preparation/manufacture of pharmaceuticals.
- three monographs on herbal drugs used in Traditional Chinese Medicines: *Clematis armandii stem* (2463), *Magnolia officinalis flower* (2568) and *Salvia miltiorrhiza root* (2663).
- five vaccine monographs: *Salmonella enteritidis vaccine (live, oral) for chickens* (2520), *Salmonella typhimurium vaccine (live, oral) for chickens* (2521), *Turkey infectious rhinotracheitis vaccine (live)* (2461), *Bordetella bronchiseptica vaccine (live) for dogs* (2525), and *Yersiniosis vaccine (inactivated) for salmonids* (1950).
- one monograph on a precursor for a radiopharmaceutical preparation, *Succimer for radiopharmaceutical preparations* (2545), and another on a propellant gas, *Norflurane* (2257).

The Commission adopted 127 revised texts (122 individual monographs and five general texts including analytical methods). Amongst the revised monographs, 73 inactivated and live vaccines for veterinary use were updated with the aim of harmonising the technical requirements for the registration of veterinary vaccine products to align them with VICH guidelines 41 and 44. This measure will result in a considerable reduction in testing on animals (please refer to the specific [press release](#)). Also in the context of the 3Rs, it is to be noted that the monograph on *Rabies vaccine (inactivated) for veterinary use* (0451) has been revised to include further details on the serological assay to be used whenever possible as an alternative to the potency assay using live animals. The revised texts also include a revised version of the general monograph *Substances for pharmaceutical use* (2034) in which the Production and Related substances sections have been updated following the elaboration of general methods for the determination of methyl, ethyl and isopropyl methanesulfonate in methanesulfonic acid (2.5.37) and in active substances (2.5.38).

The list of all adopted texts will be published on the EDQM website to alert users to the future changes they need to be aware of. These texts will come into effect on April 2013 and will be published in Supplement 7.7.



As envisaged in the *Guide for Work of the European Pharmacopoeia*, the Chairs of the various Groups of Experts and Working Parties are supposed to report regularly to the Commission on progress with their work programmes. According to tradition, this annual report is made available at the first session of the year. Forty-eight reports were therefore presented to the Commission highlighting the achievements, opportunities and challenges faced by the groups in advancing their work programme (e.g. support from stakeholders and users in providing data and/or samples, need for additional expertise, challenges relating to international harmonisation).

The Secretariat informed the Commission that Dr. Kaarina Sinivuo, head of the Finnish delegation to the European Pharmacopoeia Commission, will soon retire. In a speech to the Commission, Dr. Susanne Keitel, Director of the EDQM, acknowledged her long-standing dedication and outstanding contribution to the work of the European Pharmacopoeia.

Dates for the next sessions of the Commission are: 19-20 June 2012 and 27-28 November 2012.

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*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.*

**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 transplantation and consumer health issues.

<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-five observers: *The World Health Organisation (WHO); 6 member states of the Council of Europe: Albania, Armenia, Georgia, Moldova, Russian Federation and Ukraine; 18 other countries in the world: Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, Senegal, Syria, Tunisia, United States of America.*

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