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

DECISIONS TAKEN DURING THE 139TH SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION

During its 139th session, the European Pharmacopoeia Commission adopted the following new texts:

- seven new individual monographs, including monographs on Difloxacin hydrochloride trihydrate for veterinary use (2239), Olmesartan medoxomil (2600), Bicalutamide (2196), Nicotine ditartrate dihydrate (2599), Water for preparation of extracts (2249) and two monographs, Tadalafil (2606) and Nateglenide (2575), elaborated under the P4 Procedure - a procedure dedicated to substances still under patent and developed in close collaboration with the respective manufacturers.
- two new general monographs on Pillules for homeopathic preparations (2153) and on Homeopathic pillules, impregnated (2079).
- a new analytical method for Determination of methanesulfonyl chloride in methanesulfonic acid (2.5.39). This method was developed by the corresponding Working Party of the Ph. Eur., as it was not possible to combine the method with the one on the *Determination of Methyl, Ethyl and Isopropyl methanesulfonate in active substances* (2.5.38) adopted at the November 2010 session of the Commission.

The Commission also adopted 48 revised texts (37 individual monographs, three general monographs, four analytical methods, three General Chapters and a new version of the Technical guide for the elaboration of monographs). Three of these texts have been revised following the new expression of acceptance criteria in the test for related substances which would be applied for new monographs. Additional information on this topic can be found in *Pharmeuropa* 23.2 (pages 259-260).

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 01 April 2012 and will be published in Supplement 7.4.

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 the work programme. According to tradition, this annual report is made available at the March session. Forty-five 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, the REACH regulation).

The Commission was also informed that *Pharmeuropa*, the European Pharmacopoeia forum, will be paperless, *i.e.* only published online, and free of charge for all users as of Issue No. 24.1 (due for publication in January 2012). To facilitate the transition, Issue No. 23.4 would be made available to users as paper and online versions. Texts would be published on an on-going basis, but the four issues per year and the four comment deadlines would remain unchanged, as well as the current channels for providing comments to published draft texts. The following improvements to *Pharmeuropa* have also been made: readable PDFs, easy printing (including individually or in bulk), customisable e-mails alerts, search functionalities and results lists.

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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 Pharmacopoeia¹ 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.

¹There 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.*