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

140TH SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION 28-29 JUNE 2011, STRASBOURG, FRANCE

During its 140th session, the European Pharmacopoeia Commission adopted 13 new individual monographs, including:

- two monographs, Duloxetine hydrochloride (2594) and Celecoxib (2591), elaborated under the P4 Procedure - a procedure dedicated to substances still under patent and developed in close collaboration with the respective manufacturers,
- five monographs on herbal drugs used in Traditional Chinese Medicines: Angelica sinensis root (2558), Atractylodes lancea rhizome (2559), Largehead atractylodes rhizome (2560), Drynaria rhizome (2563), and Poria (2475),
- Melphalan (1698), Docetaxel anhydrous (2593), Niaouli oil, cineole type (2468), Black cohosh (2069), Aluminium monostearate (1663), and Sodium iodohippurate dihydrate for radio-pharmaceutical preparations (2352).

The Commission adopted 60 revised texts (56 individual monographs, three analytical methods and a new version of the General Notices). As a result of an extensive project in the EDQM's Biological Standardisation Programme, acellular pertussis antigens of combined vaccines can now also be assayed with the guinea-pig model, using the same group of animals (guinea-pigs) as used for the serological assay of diphtheria and tetanus vaccines, thereby reducing the overall number of animals required. Nine monographs on acellular pertussis combined vaccines have been revised accordingly.

Amongst the 56 individual monographs, the Commission also adopted a revised version of the monograph on Human normal immunoglobulin for intravenous administration (918). The production section was modified by adding "*The method of preparation also includes a step or steps which have been shown to remove thrombosis generating agents. Emphasis is given to the identification of activated coagulation factors and their zymogens and process steps that may cause their activation. Consideration should also be given to other procoagulant agents which could be introduced by the manufacturing process.*" This change was necessary due to recent experience with an immunoglobulin preparation which caused an increased rate of thromboembolic complications. In the light of concerns for public health associated with these thromboembolic events, the revised monograph will be implemented by the accelerated procedure via a resolution and the proposed date of implementation will be 1 January 2012, subject to approval by the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The monograph will be available on the EDQM website at the beginning of September to allow users to take the necessary actions until the implementation date.

Due to the increasing number of fraudulent activities and cases of adulteration, the Commission has decided to add a new section, *Potential Adulteration*, under § 1.4. *MONOGRAPHS* of the General Notices. The appropriateness of including such a section in individual monographs will be decided by the Commission, on a case-by-case basis. The objective of this section will be to make relevant information available to Ph. Eur. users to ensure the proper quality of medicinal products (i.e. active substances, excipients, intermediates products, bulk products and finished products). The new version of the General Notices was adopted by the Commission at its 140th session.

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 1 July 2012 and will be published in Supplement 7.5.



The Commission also approved the creation of a new working party, *Non-Biological Complexes*, which will be responsible for the elaboration of monographs on non-biological complexes (e.g. nanoparticle solutions, such as Iron Sucrose Concentrated Solution). In addition, it has requested the Glass working party to reflect whether the current Ph. Eur. text, *Glass containers for pharmaceutical use* (3.2.1), was appropriately addressing the issues on glass delamination, which had triggered several batch recalls in Europe and overseas in the past few months, or whether measures would need to be taken, e.g. by revising the current text.

The EDQM's 2010 Annual Report was made available to the Commission. Apart from an overview of the activities of the EDQM, the Annual Report contains a summary of new developments and projects, including international relations. The report is available online to download in English and French.

The Commission was also given a short presentation on the new online version of Pharmeuropa, the European Pharmacopoeia forum, which will be free to all users as of Issue No. 24.1 (January 2012). The texts will be published on an on-going basis, but the four issues per year and the four deadlines for comments will remain unchanged, as well as the current channels for providing comments to published draft texts.

The following dates of the 2012 sessions were approved by the Commission:

- 3-4 April,
- 19-20 June,
- 27-28 November.

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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.*