



Strasbourg, 02/07/2010

EUROPEAN PHARMACOPOEIA COMMISSION: DECISIONS TAKEN DURING its 137th SESSION

The 137th session of the European Pharmacopoeia Commission¹ was the first one chaired by Dr Marianne Ek, the newly elected Chair of the Commission.

During this session, the Commission elected Prof. Dr Jos Hoogmartens (Belgium) and Mrs An Le (France) as new Vice-chairs. The new Presidium will help the Commission to define its priority areas and objectives for the next three years. All the chairs and members of groups of experts and working parties will be appointed for a new term of office at the November session of the Commission.

The following monographs and general chapters were adopted:

- six new monographs (*Cefprozil monohydrate* (2342), *Gabapentine*(2173), *Sophora flower-bud* (2427), *Monophosphoryl lipid A* (2537), *Botulinum toxin type B for injection* (2581)), including one excipient monograph which was elaborated under the P4 Procedure in close collaboration with the respective industrial partners (*Sucralose* (2368)).
- two new general chapters for the *Peptide identification by nuclear magnetic resonance spectrometry* (2.2.64) and *Crystallinity* (5.16).
- four revised general chapters and 49 revised monographs, amongst them a monograph on *Botulinum toxin type A for injection* (2113) which was revised in order to add a paragraph stressing the importance of using alternative methods preferable in terms of animal welfare. This will hopefully encourage users of the European Pharmacopoeia to develop and validate suitable alternative methods to the *in vivo* assay. The new monograph on the *Botulinum toxin type B for injection* mentioned above contains the same kind of recommendation.

These texts shall become effective on 1st July 2011 and will be published in Supplement 7.2.

The Commission took note of the outcome of the recent PDG meeting and the potential way forward.

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.

Dates for sessions in 2011 were also decided: 22nd-23th March, 28th-29th June and 22nd-23th November.

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Note for the Editors

Further information is available on the internet site: www.edqm.eu/en/Whats-new-525.html

The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopoeia is legally binding in European member states.

Similarly, the EDQM develops guidance and standards in the area 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.*



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