28 June 2013, Strasbourg, France

146TH SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION
18-19 June 2013, Strasbourg, France

Following the election of a new Chair, Dr Jean-Louis Robert in the March session, the Commission elected the first Vice-chair, Dr Tobias Gosdschan (Switzerland) and the second Vice-chair, Mr Erik Wolthers (Denmark). The Presidium, which consists of the Chair and the two Vice-chairs, assisted by the Director of the EDQM and by the Secretary to the Commission, will support the Commission in defining criteria for prioritisation of its work and in identifying a set of priorities for the coming three years.

In view of the upcoming (re)appointment of the chairs and members of the Ph. Eur. groups of experts and working parties which will take place at the next Commission session, the revised terms of reference of the 20 groups of experts and of the 50 working parties were officially adopted.

The following monographs and general chapters were adopted:

- two new monographs elaborated under the P4 or P4Bio Procedures - procedures dedicated to substances still under patent and developed in close collaboration with the respective manufacturer: *Vardenafil hydrochloride trihydrate (2782)* and *Human coagulation factor IX (rDNA) (2522);*
- seven new monographs: *Chlormadinone acetate (2702), Quetiapine fumarate (2541), Brimonidine tartrate (2760), Esomeprazole magnesium dihydrate (2787), Valaciclovir hydrochloride, hydrated (2751), Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) (2764)* and *Magnesium phosphoricum for homoeopathic preparations (2505);*
- one new general chapter *Names of herbal drugs used in traditional Chinese medicine (5.22);* Chinese names (in pinyin and sinograms) of the herbal drugs that are the subject of a monograph will be published for transparency in this information chapter. This chapter will be supplemented each time a new monograph on a herbal drug used in traditional Chinese medicine (TCM) is adopted.
- 47 revised monographs and eight revised general chapters, amongst them:
  - A revised version of the General Notices which takes note of the finalised EMA Guideline on Real-Time Release Testing and is aimed at encouraging the use of enhanced approaches to quality control utilising process analytical technology (PAT) and/or real-time release testing (including parametric release) strategies. As regards the 3Rs (reduction, refinement and replacement of animal testing), new provisions for additional systems monitoring the consistency of production with the intention to reduce (and ultimately replace) animal testing have also been added.
  - Seven revised monographs on amino acids: In the test for ninhydrin-positive substances, thin layer chromatography (TLC) has been replaced by chromatography using an amino acid analyser which also allows the quantification of ammonium.
  - A revised version of the chapter *Water: semi-micro determination* (2.5.12.) and of the chapter *Loss on drying* (2.2.32.) in which the possibility to use a suitable certified reference material for instrument performance verification, such as *amoxicillin trihydrate for performance verification CRS*, has been added.

The Commission also agreed to work on the revision of the monograph on *Water for injections (0169)* (WFI) to allow non-distillation technologies for the production of WFI to be included in addition to distillation and to add the monograph on pegfilgrastim to its work programme, following the decision taken by the Commission at its 141st session to expand the scope of the P4Bio Pilot phase.

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. All adopted texts shall become effective on 1 July 2014 and will be published in Supplement 8.2.

Dates for sessions in 2014 were also decided: 25-26 March, 17-18 June and 25-26 November.

Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe
Tel.: +33 (0) 3 88 41 28 15 - E-mail: caroline.letarnec@edqm.eu

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

[1]There are now thirty-eight 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, Ukraine, United Kingdom and the European Union.* There are twenty-four observers: *the World Health Organization (WHO); 5 member states of the Council of Europe - Albania, Armenia, Georgia, Moldova and the Russian Federation; and 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*.

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.