



Strasbourg, 08/12/2009

135th Session of the European Pharmacopoeia Commission, 1-2 DECEMBER 2009, STRASBOURG, FRANCE

In its 135th session, the European Pharmacopoeia Commission adopted a new general chapter on glycan mapping (2.2.59) and 15 new monographs including four monographs on active substances which were elaborated under the P4 Procedure in close collaboration with the respective industrial partners (entacapone, anti-parkinson (2574), levetiracetam, anti-epileptic (2535), meropenem, antibiotic (2234) and ziprasidone hydrochloride, anti-psychotic (2421)).

Nine general chapters were revised amongst them the monograph on methods of preparation of homoeopathic stocks and potentisation (2371) to include 22 new manufacturing methods, originating from national pharmacopoeias or derived from national traditions not yet described in a pharmacopoeia.

115 revised monographs were also adopted. Contributing to the Commission's continuous efforts to reduce animal testing in the European Pharmacopoeia a set of monographs concerning human blood products was revised to introduce a provision for the use of an *in vitro* method as a preferred alternative to the pyrogen test in rabbits.

These texts shall become effective on 1st January 2011 and they will be published in Edition 7.0. The list of all adopted texts will be published on the EDQM website to alert users on the future change to take in account.

The Commission also decided to add to the work programme of the European Pharmacopoeia the revision of monographs for containers using materials based on polypropylene, polyethylene vinyl acetate, as well as the revision of the general chapter on chromatographic separation techniques with a view of evaluating the potential inclusion of provisions for recent developments such as fast-HPLC or UPLC.

The use of reverse osmosis in the preparation of water for injection has been discussed over the past years. Following exchanges with the European Medicines Agency (EMA), the Commission has decided to organise a workshop with all stakeholders to establish a clear view of the state of the technology and to decide whether to integrate this method into the authorised set of methods to prepare water for injection.

With regard to international harmonisation, a collaboration undertaken with the United States Pharmacopoeia (USP) and the Japanese Pharmacopoeia (JP), the Commission was informed about the outcome of the recent Pharmacopoeial Discussion Group (PDG) meeting in St. Louis, USA.

The EDQM also informed the Commission that this was the last session in which Ms Paule Jacquain would participate. To commemorate the occasion, a memento was awarded to her and tribute paid to her outstanding contributions to the work of the European Pharmacopoeia as member and head of the Belgian delegation as well as member and chair of expert groups.

Meeting of the Observers (3-4 December 2009): for the first time, the EDQM organised a specific meeting for observers to the Convention on the elaboration of a European Pharmacopoeia. Observers can participate in the scientific work of the Commission, to benefit from European experience in this area and to gain access to work on the quality control of medicines and the methods of analysis used and other activities of the EDQM. The objective of this meeting was to provide a forum for discussion, to exchange experiences and views and to identify areas of common interest. At the end of the meeting, participants agreed on a number of possibilities for a strengthened collaboration, for example in the elaboration of monographs, participation in PTS studies and other laboratory activities.

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Note for the Editors

The European Pharmacopoeia¹ and the EDQM (a Directorate of the Council of Europe notably in charge of the secretariat of the European Pharmacopoeia) have a mission to protect and promote public and animal health, through the elaboration of quality standards of medicines for human and veterinary use.

Medicines need to be safe, efficacious and of good quality in order to produce the expected therapeutic benefit. The EDQM works closely with its international and European partners to strengthen measures in order to ensure that substandard or counterfeit medicines do not reach the marketplace.

The EDQM's networks collaborate on a daily basis with all the authorities involved in the standardisation, regulation and control of medicines for human and veterinary use. The EDQM has expanded progressively its responsibilities to include additional areas: blood transfusion, organ transplantation, the legal classification of medicines and the co-ordination, on a European scale, of the fight against the production, transportation and distribution of counterfeit medicines. Activities in the field of cosmetic products and food contact materials were transferred to the EDQM in 2009.

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.

¹ There are currently 37 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 23 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.