



Strasbourg, 07/07/2009

134th SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION, 30 JUNE - 1 JULY 2009, STRASBOURG, FRANCE

In opening the 134th session of the European Pharmacopoeia Commission on behalf of the Secretary General of the Council of Europe, the Right Honourable Terry Davis, the Director of the EDQM, Dr Susanne Keitel, took the opportunity to remind all members and observers that the Council of Europe is celebrating its 60th anniversary this year. In her speech, Dr Keitel spoke of the history of the Council of Europe, “From the ashes of a war-torn Europe, the Council of Europe has grown into a unique, pan-European organisation based on common values, now encompassing 47 member states”. She pointed out that the ideals promoted by the founding fathers of the Council of Europe 60 years ago still guide the organisation today. The primary aim of the Council of Europe is to create a common democratic and legal area throughout the whole continent, ensuring respect for its fundamental values: human rights, democracy and the rule of law.

In its session, the European Pharmacopoeia Commission adopted 91 monographs and 9 general chapters, amongst them a new general chapter on recommendations on dissolution testing (5.17.1) and two new monographs on Pramipexole dihydrochloride (2416) and Tiotropium bromide (2420) monohydrate, active substances still under patent and elaborated under the P4 Procedure, hence in close collaboration with the respective industrial partners.

Terms of reference for the Rules of Procedure (ROP) and Cell Therapy Products (CTP) Working Parties have been adopted.

With regard to international harmonisation, a collaboration undertaken with the United States Pharmacopoeia (USP) and the Japanese Pharmacopoeia (JP), 6 harmonised texts signed off at the recent [Pharmacopoeial Discussion Group \(PDG\) Yokohama](#) meeting were adopted by the European Pharmacopoeia Commission.

Other ongoing activities: The Commission continued its work in the preparation of the 7th and subsequent editions of the European Pharmacopoeia. In order to improve the user friendliness of the European Pharmacopoeia, it has been decided to group the monographs for all herbal drugs and herbal drug preparations (including traditional Chinese medicines) in a separate chapter in the first volume. This change will be implemented in the 7th Edition of the European Pharmacopoeia.

To be more consistent in the titles of the monographs, the Commission decided that the degree of hydration and the salt shall be indicated and the INN modified names provided. In the light of the consequences of these changes on licensing procedures and in order to give stakeholders sufficient time to adjust, the newly defined titles will be published in *Pharmeuropa* in due time before implementation. Presently it is planned to integrate them into the 8th Edition of the European Pharmacopoeia, to become effective in January 2014.

In view of the effects to the environment, the Commission has decided to go paperless for its next meeting. In addition, this will help realise a number of organisational advantages: greater efficiency in the sharing of information; quick and easy access to documents and flexibility to add items to the session agenda.

The Commission was informed of the EDQM's intention to only publish an electronic version of *Pharmeuropa* in the future. This move will allow draft monographs to be published at an earlier time and improve the accessibility of the publication outside Europe.

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 new 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.

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

Further information on the Council of Europe and its 60 years of history: <http://www.coe.int/60years>

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.

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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.