



Strasbourg, 21/03/2009

133rd SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION HELD IN STRASBOURG

During its 133rd session, the European Pharmacopoeia Commission adopted 34 monographs and 13 general chapters.

The European Pharmacopoeia Commission has adopted a new general chapter on the microbiological quality of herbal medicinal products for oral use, which defines the quality of these products according to new categories. It had been reported that the former categories lead to different interpretations from one country to the other. The Commission has adopted a new general chapter on monocyte activation tests: the chapter provides in vitro alternatives to the rabbit pyrogen test and will hopefully contribute to the reduction of use of animal laboratories

With regard to International Harmonisation, a collaboration undertaken with the United States Pharmacopoeia (USP) and the Japanese Pharmacopoeia (JP), the European Pharmacopoeia Commission has adopted 5 general methods to be included in Ph. Eur. chapter 5.8 *Pharmacopoeial harmonisation*, which brings up to 15 the number of methods published in this section of the pharmacopoeia. The chapter refers to equivalent texts published in JP and USP and provides assistance to users willing to employ the methods in the three regions.

Terms of reference for the Heavy Metals Working Party have been adopted.

Since the EU Regulation REACH (Registration, Evaluation, Authorisation and Restriction of Chemical substances) has become operational, the potential impact on the European Pharmacopoeia and its users has been discussed. A first inventory has been carried out to identify direct implications on reagents and substances currently used in the European Pharmacopoeia and the Commission will act with the European Chemical Agency (ECHA). In addition, the Commission will consider the adoption of a general policy in order to avoid the use of potentially hazardous substances in the European Pharmacopoeia.

Similar efforts have been introduced in the past by implementing a general policy in the European Pharmacopoeia concerning the reduction of the use of animal testing in routine quality control with the adoption of the 3Rs policy (Replacement, Reduction and Refinement of animal testing).

The EDQM also informed the Commission that it was the last session in which Dr Randi Winsnes would participate. Dr Susanne Keitel paid tribute to her deep commitment and many contributions to the work of the European Pharmacopoeia as member and Head of the Norwegian delegation, and as a member and President of the European Pharmacopoeia Group of experts on Sera and Vaccines, a position she held for eleven years.

Note for the Editors

The European Pharmacopoeial 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

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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.

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.