



Strasbourg, 28/11/08

132nd SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION HELD IN STRASBOURG

In its 132nd session, the European Pharmacopoeia Commission adopted 23 new monographs and general chapters including human papillomavirus vaccine (rDNA). Two important new general methods will allow the control of extremely toxic substances in herbal drugs: determination of ochratoxine A and a screening test for aristolochic acids. Forty-nine monographs and general chapters were revised including the general monograph on gene transfer medicinal products for human use. These texts shall become effective on 1st January 2010 and they will be published in Supplement 6.6. The list of all adopted texts will be published on the EDQM website to alert users on the future changes to take in account.

Other topics of interest: Following the success of the P4 procedure (elaboration of monographs for active pharmaceutical ingredients (APIs) still under patent), a pilot phase on prospective harmonisation of API between the European and the United States Pharmacopoeia (USP) is well underway. In addition, the Commission adopted a pilot phase for a P4 procedure for biologicals. This reflects the Commission's intention to keep the European Pharmacopoeia state-of-the-art and in line with progress in technology and medical practice. The terms of reference for a new expert group and *ad-hoc* working parties on, respectively, Plastic materials, plastic containers and closures (group 16), Dialysis (DIA working party) and Inductively-Coupled Plasma (ICP working party) were adopted. These new groups will provide expertise to the Commission in their specific areas.

The European Pharmacopoeia Commission pursues its activity with regard to reduction, replacement and refinement of tests on animals: four monographs on blood products were revised to allow for the use of an *in vitro* test such as the bacterial endotoxin test as a replacement of the pyrogen test. The test for abnormal toxicity has been removed from the general monographs on allergens; as a result, the test does not have to be carried out routinely anymore for all allergen products.

The European Pharmacopoeia Commission accepted the request from Armenia for observer status and is very much looking forward to having Armenia participate in the work of the European Pharmacopoeia and share information and experience.

The EDQM also informed the Commission that it was the last session in which Dr Dietrich Schnädelbach would participate. To commemorate the occasion, a memento was awarded to him and tribute paid to his outstanding contributions to the work of the European Pharmacopoeia as member and head of the German delegation, member and chair of expert groups and working parties and notably as Vice-President and President of the European Pharmacopoeia Commission from 1992 to 1998.

Obituary: The European Pharmacopoeia Commission observed a moment of silence in tribute of Prof. Jacobus van Noordwijk. From the very start of the elaboration of the European Pharmacopoeia in 1964, he was an eminent member and later Vice-President of the European Pharmacopoeia Commission. He was one of the founding members of the biological activities of the EDQM.



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. Since December 2006, the EDQM has taken over activities of the Council of Europe in the fields of 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.

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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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.*