
**STRASBOURG, 26/03/2010**

## 136TH SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION
## 23-24 MARCH 2010, STRASBOURG, FRANCE

Following the official opening of the session, Jacques Beslin, deputy director of Afnor Certification, the French standardisation body, awarded the EDQM the ISO 9001 certificate for their activities in the Certification of Suitability to the Monographs of the European Pharmacopoeia Procedure (assessment and inspection activities) which had been issued on December 17, 2009, following a three day on-site audit.

In its 136th session, the European Pharmacopoeia Commission adopted 10 new monographs, including three monographs on active substances which were elaborated under the P4 Procedure in close collaboration with the respective industrial partners (clopidogrel hydrogen sulphate, antiplatelet agent, oseltamivir phosphate, antiviral agent in the treatment of the flu and atorvastatine calcium, antilipemic agent). The Commission also adopted two new general chapters, including a general method for the determination of methyl, ethyl and isopropyl methanesulfonates in methanesulfonic acid. The elaboration of this chapter had been requested following an incident related to the appearance of a potentially genotoxic impurity in Nelfinavir mesilate tablets, an antriretroviral drug used in the treatment of HIV.

Four revised general chapters and 33 revised monographs were also adopted, amongst them two monographs on heparin sodium and heparin calcium with a rapid implementation date on 1st August 2010. The latter have been further revised to ensure appropriate quality control of unfractionated heparin. The style and presentation of all these texts have also been updated in order to bring them in line with the latest version of the Style Guide.

The monograph for oxygen 93% was adopted by the Commission. It had been elaborated in response to requests from regulatory authorities in Europe since the gas is a medicinal substance that has been in use for over 25 years and for which no published pharmacopoeial standard is available. Oxygen 93% addresses the need for the supply of oxygen to sites where access for cylinders or liquid oxygen supply is difficult or impossible. The monograph takes account of this novel supply situation.

These texts shall become effective on 1st July 2011 and will be published in Supplement 7.1. 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.

The Commission also has given its green light to the revision of all monographs on vaccines for veterinary use, as a consequence of work at the level of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH). The deletion of the overdose test for inactivated vaccines following the implementation of VICH GL 44 (Target Animal Safety) had a consequence on the target animal batch safety test (TABST) prescribed in inactivated vaccine monographs. Indeed, the overdose test, carried out during development, was previously needed for the definition of suitable criteria in the TABST, a test performed for the release of each batch of vaccine. If the revision of the relevant monographs succeeds, which will consist in the deletion of the TABST in all relevant monographs, this will constitute a major breakthrough in the field of Animal Welfare as it will significantly contribute to reducing the number of animal tests.

During its session, the Commission elected Dr Marianne Ek as Chair for a term running from June 2010 to June 2013.

Dr Marianne Ek is head of the Swedish pharmacopoeia commission and deputy head of the laboratory at the Medical Products Agency (MPA) in Uppsala, Sweden. She joined the MPA in 1983 as a pharmacist in the chemistry section and was later promoted to head of the chemistry section in 1991. Between 1991 and 2006, she

held a number of senior positions at the MPA before being appointed deputy head of the laboratory in 2006. Dr. Ek has been a member of the Swedish pharmacopoeia commission since 1990, vice-chair between 1999 and 2001 and chair in 2002. She is responsible for Swedish pharmacopoeial activites since 1993. In 1995, she became a member of the Swedish delegation to the European Pharmacopoeia Commission. She was appointed head of the delegation in 1996 and has been an expert in group 9 and is an expert in groups 10B, P4 and the working party "Rules of Procedure". She is also chair of the working party "P4BIO". Dr. Ek also lectures at the University of Uppsala where she has been supervisor of students doing their undergraduate thesis. She is author of several scientific papers in international scientific journals and holds a PhD (1983) in chemistry and a BSc (1975) in chemistry, mathematics and physics from the University of Uppsala.

Dr Marianne Ek becomes the 16th Chair of the European Pharmacopoeia Commission since 1964 and will be appointed to her new duties in June 2010 for the 137th session of the Commission. She succeeds Prof. Henk De Jong who has chaired the Commission since June 2007.

Prof. Henk De Jong in his closing remarks outlined the considerable progress that had been achieved in the priority areas defined by the Commission. Closing the 136th Session, Prof. Henk De Jong congratulated Dr Marianne Ek on her election, and thanked the two Vice-chairs, Dr Marianne Ek and Dr Ged Lee, for the good collaboration in the Presidium, and all the Commission members for their support. He also expressed sincere thanks to the Director, Dr Susanne Keitel, to Mrs Cathie Vielle as Secretary to the European Pharmacopoeia Commission and to all the staff at EDQM for their hard work and tremendous support during the last three years in particular.

At the 137th Session, the Commission will elect two new Vice-chairs and a new Presidium that will help define its priority areas and objectives for the next three years.

**Contact**: Caroline Larsen Le-Tarnec
Public Relations Division, EDQM
Tel.: +33 (0) 3 88 41 28 15
E-mail: caroline.letarnec@edqm.eu
Further information is available on the internet site: www.edqm.eu.

**Note for the Editors**

The European Pharmacopoeia 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.***