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

DECISIONS TAKEN DURING THE 138th SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION

Dr Marianne Ek, Chair of the European Pharmacopoeia Commission, presented the mission of the newly elected Presidium for the three coming years. Advancing the work of international harmonisation and compliance with the EU REACH (Registration, Evaluation, Authorisation and Restriction of Chemical substances) Regulation are high on the agenda of the new Presidium.

During the 138th session, the Commission appointed all the chairs and members of groups of experts and working parties for a new term running from November 2010 to November 2013.

The following monographs and general chapters were adopted:

- twenty-two new monographs, including five monographs elaborated under the P4 Procedure, a procedure dedicated to substances still under patent and developed in close collaboration with the respective manufacturers [*Rizatriptan benzoate* (2585), *Montelukast sodium* (2583), *Voriconazole* (2576), *Candesartan cilexetil* (2573) and *Fulvestrant* (2443)]. The monographs on *Rizatriptan benzoate* and *Montelukast sodium* were elaborated with the United States Pharmacopoeia (USP), within the framework of a pilot project for the prospective harmonisation of monographs for active substances. The monograph on *Rizatriptan benzoate* was also approved by the corresponding Expert Committee of the USP.
- two new general chapters on the *Determination of Methyl, Ethyl and Isopropyl methanesulfonate in active substances* (2.5.38) and *Preparations for nebulisation: characterization* (2.9.44), and five general texts including one new technical guide for plasma-derived products;
- three revised general chapters and sixty-one revised monographs.

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. These texts will come into effect on 1st January 2012 and will be published in Supplement 7.3.

The Commission has also approved the request for the revision of 215 monographs as a consequence of the EU REACH Regulation.

The Commission took note of the outcome of the recent PDG meeting and the potential way forward.

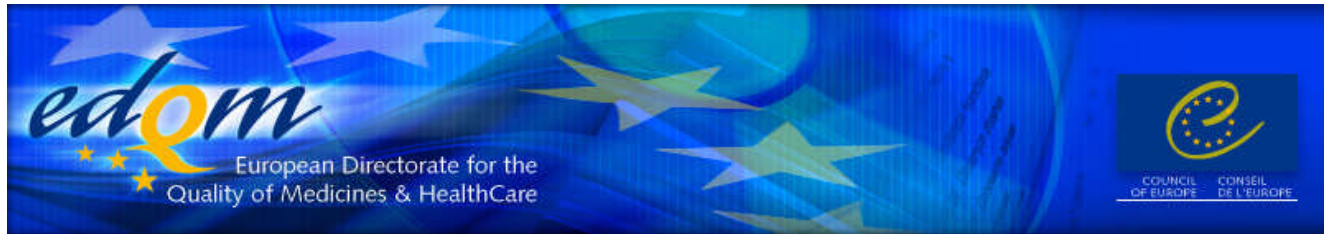
The Secretariat also informed the Commission that the mandates for Dr. Lukas Bruckner (Veterinary sera and vaccines), Prof. Ulrike Holzgrabe (Organic chemistry – Synthetic and semi-synthetic products), Prof. Jan Karlsen (Powder characterisation techniques), Prof. Rainer Seitz (Human blood and blood products), Prof. Alfons Verbruggen (Radioactive compounds), and Prof. Arnold Vlietinck (Phytochemistry A) as Chairs of a Group of Experts had come to an end after a particularly long and fruitful collaboration. Dr. Ernst Keller will also be retiring after nearly 25 years of membership in chemical expert groups. Dr. Susanne Keitel, Director of the EDQM, paid tribute to their deep commitment and many contributions to the work of the European Pharmacopoeia as members and Chairs of the European Pharmacopoeia Groups of Experts.

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Note for the editor: The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopoeia ¹is legally-

¹ ¹There are currently thirty-seven members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia*



binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantations and consumer health issues.

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.

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.