26 June 2014, Strasbourg, France

149th SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION

During its 149th session, the European Pharmacopoeia Commission adopted six new texts for inclusion in the European Pharmacopoeia.

These include monographs on *Live attenuated intranasal influenza vaccine (2772),* a seasonal influenza vaccine administered by nasal spray, and *Herbal drug extracts (0765), which is accompanied by an information chapter on monographs on herbal drug extracts (5.23).* In this latter case, the monograph has been revised extensively to explain the different types of extracts, to give more detailed explanations concerning the principles underlying the text and to provide a glossary. The information chapter will provide additional information and support for the interpretation of the general monograph.

The Commission also approved a new policy on how to express the requirements for bacterial endotoxins in Ph. Eur. monographs on substances. The new policy will provide support to users in applying the appropriate requirements for bacterial endotoxins for substances used in parenteral preparations. This policy will be published soon in Pharmeuropa.

Concerning its mid-term priorities, the European Pharmacopoeia Commission decided to extend the scope of the general methods in the European Pharmacopoeia and update existing ones, where needed, in line with technical developments related to the quality-by-design paradigm. Most of these texts have an impact on specific monographs and should reflect the latest scientific developments, be up to date and state-of-the-art. A new working party will be created to help prioritising the revision work and to further reflect on the best approaches to deal with this extensive work programme.

As a follow up to the decision taken by the Commission, in March 2014, to start working on monographs on finished products containing chemically defined active substances, the specific working party set up for the pilot project was officially dissolved. The Commission adopted the revised Terms of Reference of the groups of experts for substances still under patent (P4) and for organic chemistry (10 A/B/C/D) to extend their mandate accordingly.

The list of revised monographs and the updated version of the adopted work programme will be published on the EDQM website to inform users of future changes they need to be aware of.
These texts will become effective on 01 June 2015 in the 37 European member states and will be published in Supplement 8.5.

On the occasion of the report to the Commission on activities concerning the Certification of suitability to the European Pharmacopoeia, Dr Mike Morris, the former Chair of the European Pharmacopoeia Commission and of the Certification Steering Committee, highlighted the importance and benefits of the procedure for licensing authorities and for the European Pharmacopoeia.

Dates for sessions in 2015 were also decided: 17-18 March, 16-17 June and 17-18 November.
The next Commission session will take place on 25-26 November 2014.

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

The Convention on the Elaboration of a European Pharmacopoeia, which is celebrating its 50th anniversary in 2014, is a continent-wide initiative for setting common quality standards for medicines. It has the objective of progressively elaborating a common European Pharmacopoeia, which defines a single set of specifications for active substances and excipients used in medicines that will become the official standards applicable within these countries. The European Pharmacopoeia also describes test methods to ensure the quality of these medicines.

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 Pharmacopeia is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are now thirty-eight 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, Ukraine, United Kingdom and the European Union.* There are twenty-seven observers: *Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Brazil, Canada, China, Georgia, Israel, Madagascar, Malaysia, Moldova, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, the Russian Federation, Senegal, South Africa, Syria, Tunisia, United States of America, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).*

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.