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THE 8TH EDITION OF THE EUROPEAN PHARMACOPOEIA AVAILABLE SOON

Medicines are indispensable for ensuring patients' health and access to good-quality medicines and healthcare is a basic human right. The European Pharmacopoeia was established nearly fifty years ago when eight member states of the Council of Europe decided to join forces to elaborate a common pharmacopoeia that would define harmonised quality specifications and requirements for medicines and their ingredients in Europe. The 1st Edition of the European Pharmacopoeia comprised 120 texts. Today, 37 European countries are collaborating to establish comprehensive and state-of-the-art pharmacopoeial standards.

The upcoming 8th Edition of the European Pharmacopoeia contains more than 2220 monographs and 340 general chapters illustrated with diagrams or chromatograms and 2500 descriptions of reagents. It is comprised of two initial volumes, to be published in July 2013, with an implementation date of 1 January 2014. As for other recent editions, non-cumulative supplements will be issued three times a year following the decisions taken at each session of the European Pharmacopoeia Commission. Thus, the 8th Edition will culminate in a collection of eight non-cumulative supplements (8.1 to 8.8). The 8th Edition will be available in print and electronic versions (online and on USB key) and in French and English, the official languages of the Council of Europe. The online version will also be accessible from mobile devices such as tablet computers and smartphones.

To remain useful and state-of-the-art, any pharmacopoeia needs to be constantly updated. Revisions take account of scientific and technical evolutions, legal and regulatory developments, the increasing demand for generic and biosimilar products, new risks to public health and the globalisation of trade and commerce.

Current developments of the European Pharmacopoeia include:

- the evaluation of the P4Bio pilot phase (*the P4 procedure is dedicated to substances still under patent and developed in close collaboration with the respective manufacturer*), the scope of which has recently been expanded to the elaboration of monographs on a pegylated protein and a monoclonal antibody.

- the establishment of monographs on dosage forms of biopharmaceutical substances, where appropriate and considering quality characteristics as well as clinical properties of the products. Currently, the relevant group of experts is elaborating a monograph for Filgrastim injectable solution. Further candidate products are under discussion.

- the continuous revision of monographs to implement the 3Rs concept (replacement, refinement and reduction) in line with EU Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes.

- the review and revision of existing texts in view of needs arising from Process Analytical Technology (PAT), Real-time release testing (RTRT) or Quality by Design (QbD) concepts .

- the drafting and revision of general chapters in the field of chemometrics, i.e. modelling of analytical data (e.g. multivariate data analysis, data mining, chemical imaging, etc.) and of measurement techniques relying extensively on analytical data modelling (NIR, RAMAN) or other vibrational spectroscopies (IR).

- the elaboration of a general text on raw materials for the production of cellular and gene transfer products including antibodies, basal media (for cell culture), serum/serum replacements, growth factors and cytokines. This follows the recent creation of a dedicated working party and is based on the recommendation made at a conference organised jointly by the EDQM and the EMA on 3 April 2013.

- the elaboration of a recommendation with regard to the development, validation and use of in-house or commercial kits or test methods for the detection and quantification of host cell-derived proteins.

- the review and revision of the monograph on water for injections (WFI) to consider allowing non-distillation technologies for the production of WFI in addition to distillation. The application of the revision is being done in close collaboration with the GMP/GDP Inspectors Working Group and the Joint CHMP/CVMP QWP of the European Medicines Agency.

- further work on heavy metals: the General chapter on *Metal catalyst or metal reagent residues (5.20)* will be revised once the ICH Q3D guideline on elemental impurities will be finalised and approved.

- evaluation of the pilot phase on Finished Product monographs.

At an international level, the Ph. Eur. is continuing its collaboration with the Japanese and United States pharmacopoeias within the framework of the Pharmacopoeial Discussion Group (PDG). The Ph. Eur. is also very supportive of the World Health Organization's initiative to achieve global pharmacopoeial harmonisation. In this context, efforts are being made to harmonise policies and procedures related to monograph development, interactions with stakeholders and collaboration among pharmacopoeias.

Tribute should be paid to the support of member states and the dedication and enthusiasm of all those who contribute to the elaboration of the European Pharmacopoeia.

For more information on how to order the 8th Edition, please visit: www.edqm.eu/store.

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Note for the Editor: Further information is available on the internet site **www.edqm.eu**
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-five observers: *the World Health Organization (WHO); 5 member states of the Council of Europe - Albania, Armenia, Georgia, Moldova and the Russian Federation; and 18 other countries in the world - Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, Senegal, South Africa, 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.