24th March 2016, Strasbourg, France

NEW CHAIR OF THE EUROPEAN PHARMACOPOEIA COMMISSION ELECTED

During its 154th session, the European Pharmacopoeia (Ph. Eur.) Commission elected Dr Tobias Gosdschan as its Chair for a term from June 2016 to June 2019. He will become the 18th Chair of the Ph. Eur. Commission since its establishment in 1964. Dr Gosdschan will be supported by 2 new Vice-chairs to be elected in June. Together they will guide the work of the Commission for the three coming years.

Dr Gosdschan holds a PhD in Pharmacy from the University of Basel and is Head of the Pharmacopoeia Division at Swissmedic, the Swiss regulatory agency. In this function he is Head of the Swiss Delegation to the Ph. Eur. Commission and Chair of the Swiss Pharmacopoeia Commission. Furthermore, Dr Gosdschan is a member of the Pharmaceutical Preparations (PHP) and Rules of Procedures (ROP) Working Parties of the Ph. Eur. In 2013 he was elected 1st Vice Chair of the Ph. Eur. Commission for a mandate of three years.

During the session, which took place on March 15-16, five new monographs and one new general chapter were adopted:
- a monograph on Gadodiamide (2225), an active substance still under patent protection, which has been elaborated in close collaboration with the innovator (P4 procedure);
- four monographs on herbals used in Traditional Chinese Medicines (TCM): Andrographis herb (2712), Chinese goldthread rhizome (2715), Lycopus herb (2890) and Dioscorea nipponica rhizome (2890);
- a chapter on Host-cell protein assays (2.6.34). This non-binding chapter provides guidance for the development and validation of host-cell protein (HCP) assays used to test products obtained by recombinant DNA technology (more details will be provided in a dedicated Press Release to be published soon).

In addition, four revised general chapters and 40 revised monographs were adopted, amongst them a revised version of the monograph on Water for Injections (0169). This monograph had been revised to include the use of non-distillation technologies for the production of WFI in addition to distillation (see the dedicated Press Release here).

The general monograph on Substances for Pharmaceutical use (2034) has been revised to clarify the requirements associated with the bacterial endotoxin test and to align them with the policy approved by the Ph. Eur. Commission at its 149th session in June 2014. This revision goes hand-in-hand with the revision of chapter 5.1.10 Guidelines for using the test for bacterial endotoxins, published in the Ph. Eur. Supplement 8.8, which includes recommendations for establishing limits and information on how to evaluate the pyrogenicity of substances. The reference to the EMA guideline on the limits of genotoxic impurities has also been replaced by a reference to the new ICH M7 guideline on Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.
These texts will become effective on 1st April 2017 and will be published in Supplement 9.1. The list of adopted texts will be published on the EDQM website to alert users to the future changes they need to be aware of.

In his closing remarks, Dr Jean Louis Robert, who will officially hand the Chair over to his successor in June, thanked the Commission and the two vice-Chairs, Dr Gosdschan and Mr. Erik Wolthers, as well as the Secretariat for the support received during his mandate. He also expressed his sincere gratitude to the EDQM for the continuous and constant guidance they had provided over the last three years.

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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 Member States[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are thirty-eight members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the Former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union.*

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.