28 March 2019, Strasbourg, France

Outcome of the 163rd Session of the European Pharmacopoeia Commission

During its 163rd session, held in Strasbourg on 19-20 March 2019, the European Pharmacopoeia (Ph. Eur.) Commission elected Prof. Torbjörn Arvidsson (Sweden) as its Chair. As the 19th Chair of the Ph. Eur. Commission since its establishment in 1964, Prof. Arvidsson will be supported by two Vice-chairs who will be elected in June. Together they will guide the work of the Commission for a term of three years, from June 2019 to June 2022.

The Ph. Eur. Commission adopted nine new monographs:

- *Rosuvastatin tablets (3008)*, the first monograph on a finished product elaborated under the P1 procedure (multi-source products); a separate news item will be published soon.
- *Almotriptan malate (2970)*
- *Donepezil hydrochloride (2582)* and
- *Donepezil hydrochloride monohydrate (3067)*
- *Raspberry leaf (2950)*
- *Calendula flower (1297)*
- *Hawthorn berries (1220)*
- *Adonis vernalis for homoeopathic preparations (2832)*
- *Rehmannia root (2569)*

and 43 revised texts (40 monographs and 3 general texts). The list of all adopted texts will be made available on of the EDQM website: *Ph. Eur. Work Programme* and *Ph. Eur. publication schedule*. These texts will be effective as of 1 April 2020 and will be published in Supplement 10.1 of the Ph. Eur.

Following the identification of nitrosamine contamination in active pharmaceutical ingredients of the sartan class, the Commission also adopted revisions of the following monographs:

- *Valsartan (2423)*
- *Candesartan cilexetil (2573)*
- *Irbesartan (2465)*
- *Losartan potassium (2232)*
- *Olmesartan medoxomil (2600)*

The "Production" and "Tests" sections of these monographs were revised to align, as far as possible, requirements on the control of nitrosamines with the recommendations issued by the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency as published on 1 February 2019 (for more information: Sartan medicines: companies to review manufacturing processes to avoid presence of nitrosamine impurities). A separate news item will be published soon.

[1]There are thirty-nine 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, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, The Republic of North Macedonia, Turkey, Ukraine, United Kingdom and the European Union.*

In preparation for the (re)appointment of all Ph. Eur. Groups of Experts and Working Parties at the November session, the Ph. Eur. Commission approved a revised version of its "Terms of reference and profile for members of Groups of Experts and Working Parties". More information can be found in the Call for experts of the Ph. Eur.

Dr. Tobias Gosdschan, the outgoing Chair of the Ph. Eur. Commission, will officially hand over to his successor in June. In his closing remarks, Dr. Gosdschan thanked the Commission and the two vice-Chairs, Prof. Torbjörn Arvidsson and Dr. Hilda Köszegi Szalai (Hungary), as well as the Secretariat, for the excellent support received during his mandate. He also expressed his sincere gratitude to all contributors to the Ph. Eur., including all chairs and experts in the Groups of Experts and Working Parties, as well as the staff from the EDQM and the National Pharmacopoeia Authorities.

The next session of the Ph. Eur. Commission will take place on 18 June 2019.

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Note for the Editor: Further information is available on the internet site **https://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 worldwide. The European Pharmacopoeia 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.

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.

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