Press release

6 April 2021, Strasbourg, France

Outcome of the 169th session of the European Pharmacopoeia Commission

The 169th session of the European Pharmacopoeia (Ph. Eur.) Commission took place on 23 and 24 March 2021.

At this session, the Commission adopted 68 texts for publication in Ph. Eur. Supplement 10.7, including the following 9 new texts:

- 8 individual monographs:
    - *Nebivolol hydrochloride (2575)*;
    - *Senna fruit dry extract, standardised (3084)* and *Senna fruit dry hydroalcoholic extract, standardised (3127)*;
    - 3 traditional Chinese medicine (TCM) monographs: *Bitter apricot seed (2935)*, *Peach seed (2975)* and *Notopterygium rhizome and root (2662)*;
    - 2 medicinal product monographs elaborated under the P4 procedure: *Deferasirox dispersible tablets (2934)* and *Teriflunomide tablets (3037)*;
- 1 general (information) chapter, *Monographs on essential oils (5.30)*.

The Ph. Eur. Commission also adopted revised versions of 59 texts. These include chapter *2.2.48 Raman Spectroscopy,* which was revised to reflect the latest developments in the field; a dedicated news item on this topic has just been published.

In addition, the work on updating the Ph. Eur. dosage form monographs has continued, with the adoption of the revised text on *Liquid preparations for cutaneous application (0927)*, which now includes uniformity requirements for metered-dose and single-dose preparations with a systemic effect.

Following a consultation with its stakeholders, the Ph. Eur. Commission agreed on a way forward for the elaboration of the monograph on *Oxygen (98 per cent)*: work on the monograph will soon resume and the members of the Commission expressed their sincere gratitude to the specialists involved, applauding their commitment to establishing the best possible quality standards for oxygen monographs.

The Ph. Eur. Commission also decided to add 6 new monographs to its work programme: *Phytomenadione (1036)*, *Phosphorus for homoeopathic preparations (2509)* and 4 TCM monographs, *Cuscutae semen (3189)*, *Epimedii folium (3190)*, *Pogostemonis herba (3192)* and *Mentha haplocalyx herba (3191)*.

The list of all the texts adopted will be made available on the website of the European Directorate for the Quality of Medicines & HealthCare (EDQM): Ph. Eur. Work Programme and Ph. Eur. publication schedule. These texts will be published in Supplement 10.7 of the Ph. Eur. and will enter into force on 1 April 2022.

The next session of the Ph. Eur. Commission will take place on 22 and 23 June 2021.

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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 the development, supporting the implementation, and the 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.

1. There are 40 members of the European Pharmacopoeia Commission: *Albania, 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, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, 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.