Press release

4 December 2020, Strasbourg, France

Outcome of the 168th session of the European Pharmacopoeia Commission

The 168th session of the European Pharmacopoeia (Ph. Eur.) Commission took place on 24 and 25 November 2020.

At this session, the Commission adopted 114 texts for publication in Ph. Eur. Supplement 10.6, including 101 revised texts and the following 13 new texts:

- 4 general chapters: *Particulate contamination: sub-visible particles in non-injectable liquid preparations (2.9.53)*, *Balances for analytical purposes (2.1.7)*, *N-Nitrosamines in active substances (2.5.42)* and *Contaminant pyrrolizidine alkaloids (2.8.26)*; and
- 9 individual monographs: *Trazodone hydrochloride (2857)*, *Phenoxybenzamine hydrochloride (2983)*, *Methylaminolevulinate hydrochloride (3073)*, *Vibriosis vaccine (inactivated) for sea bass (3090)*, *Fluticasone furoate (2768)*, *Toxicodendron quercifolium for homoeopathic preparations (2519)*, *Sanguinaria canadensis for homoeopathic preparations (2687)*, *Thunberg fritillary bulb (2588)* and *Scrophularia root (2973)*.

Further information on specific outcomes will be published on the website of the European Directorate for the Quality of Medicines & HealthCare (EDQM) soon, including the new Ph. Eur. approach for dissolution or disintegration tests described in a revised version of Ph. Eur. chapter 1. *General Notices*, the general chapters *N-Nitrosamines in active substances (2.5.42)* and *Contaminant pyrrolizidine alkaloids (2.8.26)* and the monograph *Thunberg fritillary bulb (2588)*.

The Ph. Eur. Commission also adopted several revised versions of dosage form monographs and changes to dosage form testing. These include a revision of the general monograph *Eye preparations (1163)* with new requirements for sub-visible particle contamination in preparations intended for use in the injured eye or during surgical procedures, and a revision of general monograph *Ear preparations (0652)* with a focus on the applicability of the test for uniformity of mass.

The Ph. Eur. Commission decided to add two new texts to its work programme: a general chapter on *Cell based preparations (5.32)* and a general monograph on *Gene therapy medicinal products for human use (3186)*.

The list of all adopted texts will be made available on the EDQM website: Ph. Eur. Work Programme and Ph. Eur. publication schedule. These texts will be published in Supplement 10.6 of the Ph. Eur. and be effective as of 1 January 2022.

The next session of the Ph. Eur. Commission will take place on 23 and 24 March 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.