Press release

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Outcome of the 171st session of the European Pharmacopoeia Commission, November 2021

The 171st session of the European Pharmacopoeia (Ph. Eur.) Commission took place on 23 and 24 November 2021.

At this session, the Commission adopted 75 texts for publication in the 11th Edition of the European Pharmacopoeia: 66 revised texts and nine new texts, including:

- the revised and harmonised (through the Pharmacopoeial Discussion Group) chapter on *Chromatographic separation techniques (2.2.46)*;
- the new general chapter *Implementation of pharmacopoeial procedures (5.26)*;
- the revised and now harmonised monographs *Paraffin, white soft (1799)* and *Paraffin, yellow soft (1554)*;
- two new general chapters, *Assay of Bet v1 allergen (2.7.36)* and *Microbiological examination of human tissues (2.6.39)*;
- the revised monograph *Vaccines for veterinary use (00062)*, including specific requirements for the microbiological quality of non-liquid vaccines for non-parenteral use.

The Ph. Eur. Commission decided to add nine new texts to its work programme:

- *Alteplase concentrated solution (3197)*;
- *DOTA-TATE trifluoroacetate for radiopharmaceutical preparations (3198)*;
- *Edotreotide trifluoroacetate for radiopharmaceutical preparations (3199)*;
- *Etoricoxib API (3200)*;
- *General method for the determination of hydrocarbons in gases (2.5.45)*;
- *Sage leaf (Salvia officinalis), cut (3201)*;
- *Saxagliptin hydrochloride dihydrate (3196)*;
- *Sunitinib (base) (3202)*;
- *Sunitinib (base) capsules (3203)*.

The list of all adopted texts 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. The texts will be published in the 11th Edition of the European Pharmacopoeia and be effective as of 1 January 2023.

The next session of the Ph. Eur. Commission will take place on 22 and 23 March 2022.

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 the development, supporting the implementation, and the monitoring the application of quality standards for safe medicines and their safe use. Its 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.

Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe
Tel.: +33 (0) 3 88 41 28 15 – E-mail: caroline.letarnec@edqm.eu.

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.