Press release

8 December 2023, Strasbourg, France

Outcome of the 177th session of the European Pharmacopoeia Commission, November 2023

The European Pharmacopoeia Commission (EPC) held its 177th session on 21 and 22 November 2023. The EPC adopted 77 texts at this session, to be published in European Pharmacopoeia (Ph. Eur.) Supplement 11.6 (July 2024) and be effective as of 1 January 2025.

These 77 texts included nine new individual monographs on:

- *Chloroxylenol (2980)*, *Etravirine (3121)* and *Ursodoxicoltaurine dihydrate (3150)*;
- *Clematis rhizome and root (2527)*, *Hedge mustard (2942)*, *Loquat leaf (2978)* and *Sesame seed (2979)*;
- *Ioflupane (123I) injection (3144)*;
- *Golimumab concentrated solution (3103)*.

New versions of 68 texts were also adopted, including the monograph on *Propylene Glycol (0430)*. The monograph was revised in response to the public health risk posed by the discovery of ethylene glycol (EG) and diethylene glycol (DEG) contamination in several medicinal products in African and Asian countries (WHO alerts No. 6-7/2022, No. 1/2023 and No. 4-6/2023). Further updates to the monograph include an identification test by infrared (IR) spectrophotometry and a modernised procedure for the Acidity test. The monograph has been pre-published on the website of the European Directorate for the Quality of Medicines & HealthCare (EDQM) to give users advance warning of the upcoming change.

It was also agreed to look closer into potentially revising monographs on substances at risk of adulteration with EG and DEG and to liaise with international stakeholders on the topic.

In addition, the EPC decided on a path that should lead to deletion of the general chapters on *Histamine (2.6.10)* and *Depressor substances (2.6.11)*, describing tests performed on guinea pigs and cats, respectively, from the Ph. Eur. Fourteen monographs that either refer to chapter *2.6.10* or include a general statement in their Production section that is a remainder of the test, will therefore have to be revised. This decision is yet another indication of the EPC's continuous efforts in the field of animal welfare.

At the same time, the EPC agreed to elaborate a new general chapter addressing detection of histamine by physico-chemical or immunochemical methods in products of fermentation.

Other highlights of this session included the decision on the strategy for *N*-nitrosamine impurities in individual monographs. More information on this will follow in a dedicated news item.

The list of all adopted texts will be made available on the Ph. Eur. Work Programme web page in the coming weeks.

The 178th session of the EPC will take place in hybrid format on 19 and 20 March 2024.

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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 the development, supporting the implementation and 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] The EDQM also 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 46 member states.

1. The European Pharmacopoeia Commission comprises 40 members: 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, Türkiye, Ukraine, United Kingdom and the European Union.