

9 January 2023, Strasbourg, France

Outcome of the 174th session of the European Pharmacopoeia Commission, November 2022

The European Pharmacopoeia Commission (EPC) held its 174th session on 22 and 23 November 2022. The 85 texts adopted by the Commission at this session will be published in European Pharmacopoeia (Ph. Eur.) Supplement 11.3 (July 2023), with an implementation date of 1 January 2024.

These 85 texts included 13 new monographs and 1 new general chapter:

- monographs on:
 - *Dabigatran etexilate mesilate (3095)*, established under the P4 procedure;
 - *Levocetirizine dihydrochloride (3115)*; *Bupivacaine (2761)*;
 - *Gallium (68Ga) oxodotreotide injection (3050)*; *Gallium (68Ga) DOTA-NOC injection (3051)*;
 - *Eclipta prostrata (2852)*; *Helichrysi flos (3089)*; *Horse-chestnut bark (2945)*; *Burdock root (2943)*; *Adhatoda vasica leaf (2738)*;
 - *Lonicera japonica flower (3159)*; *Chrysanthemum flower (3162)*;
- the general chapter entitled *Particle size analysis by image analysis (2.9.48)*.

The Ph. Eur. Commission adopted revised versions of 72 texts. These included:

- the general chapter *Friability of uncoated tablets (2.9.7)*, revised within the [Pharmacopoeial Discussion Group](#) (PDG) to unify the presentation of the apparatus dimensional requirements and to clarify the test criteria;
- the general chapter *Osmolality (2.2.35)*, that now includes a more thorough calibration protocol with detailed preparation of standard solutions.

The Ph. Eur. Commission also decided to add 6 new monographs to its work programme: *Apixaban (3212)*, *Apixaban tablets (3213)*, *Butamirate citrate (3214)*, *Dexmedetomidine hydrochloride (3215)*, *Indigotine disulfonate sodium (3216)* and *Neotame (3218)*.

The full list of adopted texts is available on the [Ph. Eur. Work Programme](#) web page.

Other highlights of this session included:

- the approval of the [Ph. Eur. Priorities for 2022-2025](#);
- the appointment of 886 experts from Ph. Eur. and non-Ph. Eur. member states, as well as 50 chairs of groups of experts or working parties. These included 40 experts appointed by the EPC to join the newly created Working Party on mRNA vaccines, following a call for experts issued last summer. Work on this important topic will start immediately;
- the creation of two new working parties working on High throughput sequencing (HTS WP) and Aluminium in parenteral nutrition solutions (ALU WP);

- the approval of the [Guide on the declassification of documents pertaining to the work of the European Pharmacopoeia](#), available on the website of the European Directorate for the Quality of Medicines & HealthCare (EDQM);
- the approval of a new monograph on a preservative-free simple syrup for the European Paediatric Formulary.

The Commission also granted observer status to the [Ethiopian Food and Drug Administration \(EFDA\)](#).

The 175th session of the Ph. Eur. Commission will take place in hybrid format on 21 and 22 March 2023.

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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.

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.

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.