

6 April 2023, Strasbourg, France

Outcome of the 175th session of the European Pharmacopoeia Commission, March 2023

The European Pharmacopoeia Commission (EPC) held its 175th session on 21 and 22 March 2023. The 84 texts adopted by the EPC at this session will be published in European Pharmacopoeia (Ph. Eur.) Supplement 11.4 (October 2023), with an implementation date of 1 April 2024.

These 84 texts included 12 new monographs and one new general chapter:

- monographs on:
 - *Rose flower (2949)*, *Gumweed herb (2951)* and *Alpinia oxyphylla fruit (3161)*;
 - *Etonogestrel (3049)*, *Brivaracetam (3139)*, *Cabazitaxel acetone (3060)*;
 - medicinal products: *Brivaracetam tablets (3140)*, *Brivaracetam injection or infusion (3142)*, *Brivaracetam oral solution (3141)* and *Cabazitaxel acetone concentrate for infusion (3061)*;
 - *Hypromellose acetate succinate (3101)*;
 - *Winter ulcer vaccine (inactivated, oil-adjuvanted, injectable) for salmonids (2151)*;
- and a general chapter entitled *Assay of PhI p 5 allergen (2.7.37)*.

The EPC adopted revised versions of 71 texts. These included:

- two monographs on pharmaceutical waters – *Water for injections (0169)* and *Purified water (0008)* – revised to add the possibility of performing the control of bacterial endotoxins using recombinant factor C;
- 14 monographs on veterinary vaccines, revised to promote animal welfare by:
 - deleting in nine monographs the *in vivo* residual live virus test at final product stage when there is no reversion to virulence, relying instead on the in-process test performed using, in preference, cell cultures. All remaining residual live virus tests are performed *in vitro*;
 - reducing in eight monographs the number of controls for *in vivo* batch potency tests;
 - adding in three monographs humane endpoints (immunogenicity).

The EPC also decided to add 15 new monographs and seven new general chapters to its work programme.

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

In addition to the above, the EPC agreed to rename the Non-Biological Complex (NBC) Working Party “Nanomedicines (NANO) Working Party” to better highlight the types of products and substances covered. Reflection on this topic intensified in response to the stakeholder feedback received at the Nanomedicines symposium organised by the EDQM in June 2022. The experts in the Working Party emphasised the need to work on other types of nanomedicines beyond iron-carbohydrates, such as liposomal formulations, and this is now reflected in the modified terms of reference. Lastly, the EPC approved the second edition of the *Guide for the elaboration of monographs on herbal drugs and herbal drug preparations* and the third version

of the *Technical guide for the elaboration of monographs on medicinal products containing chemically defined active substances*. Both guides are available on the [EDQM website](#).

The 176th session of the EPC will take place in hybrid format on 20 and 21 June 2023.

Contact: Evangelos Tasopoulos, Communication Division, EDQM, Council of Europe
Tel.: +33 (0)3 90 21 53 90 – E-mail: evangelos.tasopoulos@edqm.eu

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.