

11 April 2022, Strasbourg, France

Outcome of the 172nd session of the European Pharmacopoeia Commission, March 2022

The European Pharmacopoeia (Ph. Eur.) Commission held its 172nd session on 22 and 23 March 2022. The Commission adopted 78 texts at this session, to be published in Ph. Eur. Supplement 11.1 and be effective as of 1 April 2023.

These 78 texts included six new monographs and one new general chapter:

- monographs on *Berberis aristata stem (2851)* and *Rhubarb dry extract, standardised (1845)*;
- two traditional Chinese medicine monographs: *Saposhnikovia root (2728)* and *Pulsatilla root (2972)*;
- a monograph on *Valganciclovir hydrochloride (2930)*;
- a monograph on *Fulvestrant injection (3096)*, the second on a medicinal product containing a chemically defined active substance elaborated under the P1 procedure (multi-source products);
- a general chapter entitled *Cell-based assay for potency determination of TNF-alpha antagonists (2.7.26)*, together with revised versions of the monographs on *Infliximab, concentrated solution (2928)* and on *Etanercept (2895)*; this topic will be the subject of a separate news item on the European Directorate for the Quality of Medicines & HealthCare (EDQM) website.

The Ph. Eur. Commission adopted revised versions of 71 texts. These included:

- general chapter *5.21. Chemometric methods applied to analytical data*, which was revised to reflect the latest developments in the field;
- general chapter *5.2.2. Chicken flocks free from specified pathogens for the production and quality control of vaccines*, revised to add Avian rotavirus and Fowl-pox virus in table 5.2.2.-1, meaning that all birds used for the establishment of an SPF flock will also have to be tested for freedom from antibodies of Avian rotavirus and Fowl-pox virus as from 1 April 2023;
- the deletion of tests for inorganic substances in the section "sterilised water for injections" of the monograph on *Water for injections (0169)*;
- a general monograph on *Radiopharmaceutical preparations (0125)*, revised substantially to include sections on pH, elemental impurities and particulate contamination. The detailed description on how to perform the physiological distribution has been removed, in accordance with the 3R principles. Overall, textbook-style information has been edited out and the text has been updated to reflect state-of-the-art production and quality control practice;
- general chapter *3.2.9. Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders*, which has been significantly modernised, including the explicit exclusion of natural rubber latex, an acknowledgement that IR absorption spectrophotometry may in itself be selective as an identification test, alignment with the ICH Q3D approach for the control of elemental

impurities, and improvements in the penetrability, fragmentation and self-sealing functional tests.

The Ph. Eur. Commission also decided to engage on the revision of a number of texts, including the monographs on *Water, purified (0008)* and *Water for injections (0169)*, to add the possibility to use recombinant factor C when testing for bacterial endotoxins. The Ph. Eur. Commission approved this revision process, which will lead to an enquiry in the July 2022 issue of *Pharmeuropa* (34.3).

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

The Commission also approved revised versions of the following guides:

- *Technical guide for the elaboration of monographs on medicinal products containing chemically defined active substances*, to capture recent changes in the policies for salts and solvates;
- *Guide for the elaboration of monographs on homoeopathic preparations*.

Separate news items explaining the changes will be published when the revised guides are made available on the EDQM website.

Lastly, the Ph. Eur. Commission decided to add three new monographs to its work programme: *Cranberry expressed juice (3204)*, *Concentrates for haemodialysis (3206)* and *JK-PSMA-7 (¹⁸F) injection (3205)*.

The 173rd session of the Ph. Eur. Commission will take place online on 21 and 22 June 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.

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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 46 member states.