Press release

11 December 2019, Strasbourg, France

Outcome of the 165th Session of the European Pharmacopoeia Commission

During its 165th session, held in Strasbourg on 26 and 27 November 2019, the European Pharmacopoeia (Ph. Eur.) Commission (re)appointed more than 850 experts to its current 21 groups of experts and 39 active working parties for a new term running from November 2019 to November 2022.

On behalf of the EDQM, Director Susanne Keitel thanked all chairs and members whose mandates had come to an end and highlighted that the work of the European Pharmacopoeia is based on the support, dedication and hard work of the experts of the Ph. Eur. network.

The Ph. Eur. Commission adopted 13 new monographs (9) and general chapters (4), including:

- monographs elaborated under the P4 procedure (single-source products, still under patent protection):
  - *Deferasirox (2933)*
  - *Dronedarone tablets (3038)*
  - *Rivaroxaban (2932)*

- general chapters:
  - *Depyrogenation of items used in the production of parenteral preparations (5.1.12)*
  - *Recommendations on testing of particulate contamination: visible particles (5.17.2)*
  - *Test for bacterial endotoxins using recombinant factor C (2.6.32)*

and 143 revised texts (129 monographs and 14 general texts).

The revised monographs include the general monograph *Substances for pharmaceutical use (2034)*, clarifying that the implementation of tests under the second identification is subject to national regulation, as well as 17 tetanus vaccine monographs in which two animal tests were removed, following a thorough reassessment of toxicity-testing requirements for tetanus vaccines.

The list of all adopted texts will be made available on the EDQM website: Ph. Eur. Work Programme and Ph. Eur. publication schedule. These texts will be effective as of 1 January 2021 and will be published in Ph. Eur. Supplement 10.3. Dedicated announcements will be published on additional items in the coming weeks.

The next session of the Ph. Eur. Commission will take place on 24 and 25 March 2020.

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Note for the Editor: Further information is available on the internet site **https://www.edqm.eu/**. The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our 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.

1. There are 39 members of the European Pharmacopoeia Commission: *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.*

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1949.2019

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Press release

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