Press release

6 May 2020, Strasbourg, France

COVID-19 Pandemic: European Pharmacopoeia Commission session held electronically in historic first

By mid-March this year, announcements regarding the postponement or cancellation of meetings due to the COVID-19 pandemic had been made and an almost global lockdown was underway.
In this unprecedented context, the European Pharmacopoeia (Ph. Eur.) Commission and its 60 groups of experts and working parties, with the support of the national pharmacopoeia authorities and the EDQM, demonstrated their commitment to public health protection by adapting their traditional method of working to the new situation and constraints. Thanks to their efforts, the work of the Ph. Eur. continues to be assured.

The 166th Ph. Eur. Commission session, which would have brought together delegations from Europe and beyond for a face-to-face meeting in Strasbourg, France, was replaced by an electronic adoption of its agenda and work programme.

At this session, the Ph. Eur. Commission adopted 91 texts for publication in Ph. Eur. Supplement 10.4, including 11 new texts:

- One general chapter: *Multivariate statistical process control (5.28)* – more information will be published soon on the EDQM website; and
- Ten monographs, three elaborated under the P1 procedure: *Forsythia fruit (2720)*, *Gallium (68Ga) PSMA-11 injection (3044)* and *Morinda root (2977)*, and seven under the P4 procedure in close collaboration with the innovator: *Regorafenib tablets (3023)*, *Riociguat (3078)*, *Riociguat tablets (3079)*, *Rivaroxaban tablets* (*3021*), *Sorafenib tosilate (2931)*, *Sorafenib tablets (3022)* and *Ticagrelor (3087)*.

Further to the legally binding European Commission decision of 2 April 2019 on *N*-nitrosamine impurities in medicines, revised versions of the 5 monographs on sartans with a tetrazole ring, i.e. *Candesartan cilexetil (2573)*, *Irbesartan (2465)*, *Losartan potassium (2232)*, *Olmesartan medoxomil (2600)* and *Valsartan (2423)*, were adopted for publication in Ph. Eur. Suppl. 10.4 (implementation date: 1 April 2021). The changes are as follows:

- **Production**: requirement to perform a risk assessment of the manufacturing process and implement a control strategy for the detection and control of N-nitrosamine impurities added.
- **Related substances**: interim limits for NDMA and NDEA (which were applicable for the two-year transition period) deleted and replaced with the limit of 0.03 ppm for both substances which will be enforceable after the transition.

The Ph. Eur. Commission also adopted a revised version of the general monograph on *Products of fermentation (1468)*. In the paragraph on *Down-stream processing,* histamine and other biogenic amines from fish and fishery products used in raw materials were added to the list of substances to be reduced to a minimum or removed from the process or processes chosen.

1. There are 40 members of the European Pharmacopoeia Commission: *Austria, Albania, 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 new edition of the *Technical Guide for the elaboration and use of monographs for immunological veterinary medicinal products* (2020) was also approved by the Commission – more information can be found on the EDQM website here.

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 April 2021 and will be published in Supplement 10.4 of the Ph. Eur.
The next session of the Ph. Eur. Commission will take place on 23 June 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 the development, supporting the implementation, and the 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.

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 47 member states.

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