Press release

7 July 2020, Strasbourg, France

Outcome of the 167th session of the European Pharmacopoeia Commission

The 167th session of the European Pharmacopoeia (Ph. Eur.) Commission on 23 June 2020 was the first ever to be held online, due to the COVID-19 pandemic.

This unprecedented meeting successfully brought together over 130 members of the Ph. Eur. Commission, its 60 groups of experts and working parties and the scientific Secretariat, to ensure the continuity of the work of the Ph. Eur. was not disrupted by the pandemic.

At this session, the Commission adopted 75 texts for publication in Ph. Eur. Supplement 10.5, including 64 revised texts and the following 11 new texts:

- the general chapter *Methods of pre-treatment for preparing traditional Chinese drugs: general information (5.18)*;
- ten monographs, eight elaborated under the P1 procedure: *Chaenomeles fruit (2713)*, *Ethanolamine (2847)*, *Ibandronate sodium monohydrate (2771)*, *Intravesical preparations (2811)*, *Pemetrexed disodium 2.5-hydrate (3046)*, *Plasters, medicated (3032)*, *PSMA-1007 (18F) injection (3116)*, *Tetrabutylammonium in radiopharmaceutical preparations (20433)*, and two elaborated under the P4 procedure: *Teriflunomide (3036)* and *Ticagrelor tablets (3097).*

Three monographs on vaccines for veterinary use had been modified after a critical review to promote the 3Rs principles of replacing, reducing and refining the use of animals in scientific procedures:

- *Canine parvovirosis vaccine (live) (0964)* to reduce to a minimum the number of dogs to be used in the safety tests;
- *Equine herpesvirus vaccine (inactivated) (1613)* to stress that an *in vitro* alternative method should preferably be used for the routine batch potency test;
- *Avian infectious bronchitis vaccine (live) (0442)* to allow any suitably validated method to be used to recover the virus from tracheal swabs; although the original method using embryonated hens' eggs can still be employed, the aim is to encourage manufacturers to develop and use suitably validated alternative methods such as PCR.

The Ph. Eur. Commission also adopted the revised text on *Parenteral Preparations (0520)* which had been significantly modified to update the requirements for testing for visible and subvisible particles, the definitions given and the uniformity requirements. Dedicated announcements will be published on additional items in the coming weeks.

At this session, the Ph. Eur. Commission agreed to start a reflection on the feasibility, applicability and consequences of a future text to cover the quality of active pharmaceutical ingredients used for bacteriophage therapy. This work will be undertaken by a new working party, which will be responsible for drafting recommendations to the Ph. Eur. Commission.

In addition, the Ph. Eur. Commission streamlined its work programme for the coming years with regard to texts on homeopathic manufacturing methods and homeopathic stocks, identifying priorities and facilitating clearly defined goals of the corresponding work of its experts.

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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 July 2021 and will be published in Supplement 10.5 of the Ph. Eur.

The next session of the Ph. Eur. Commission will take place on 24-25 November 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.

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 47 member states.