Press release

2 July 2021, Strasbourg, France

Outcome of the 170th session of the European Pharmacopoeia Commission, June 2021

The European Pharmacopoeia (Ph. Eur.) Commission held its 170th session on 22 and 23 June 2021. As the decision-making body of the Ph. Eur., the Commission adopted 69 texts that will be published in Ph. Eur. Supplement 10.8 and be effective as of 1 July 2022.

These 69 texts included the following 3 new monographs:

- *Chinese motherwort (Leonuri herba) (2785)*
- *Purple coneflower herb expressed juice, stabilised with ethanol (2282)*
- *Purple coneflower expressed juice, stabilised without ethanol (2894)*.

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

At this session, the Commission decided to suspend the monograph *Gonadotrophin, equine serum, for veterinary use (0719)* which means that the monograph will no longer be part of the Ph. Eur. as of Supplement 10.8, but will be kept on its work programme. More information on this will be published soon.

The decision was also taken to engage on a path that should ultimately lead to the complete replacement of the rabbit pyrogen test by suitable *in vitro* alternatives in 59 texts of the Ph. Eur., within approximately 5 years. More information on this can be found in the news item "European Pharmacopoeia to put an end to the rabbit pyrogen test".

Other important decisions related to animal welfare were taken at this session. For example, the test for specific toxicity in guinea pigs was deleted from 17 monographs for vaccines for human use containing the diphtheria component and 3 monographs on clostridial vaccines for veterinary use were revised to replace – or encourage manufacturers to replace – several animal tests by *in vitro* methods and delete the residual toxicity test (previously in mice) on the final product. These milestone 3R achievements will be the subject of dedicated news items to be published at a later date.

This session of the Commission also saw the launch of work on two major new general chapters. The first of these, on phage therapy active substances and medicinal products for human and veterinary use, will establish harmonised quality standards for phage therapy products and provide a framework for their safe use in Europe; the second, a general chapter on high throughput sequencing – a state-of-the-art technique increasingly used for extraneous agent testing during the production of biologicals, particularly vaccines – will contribute to the standardisation of practices in this setting.

Work on the European Paediatric Formulary, whose objective is to remedy gaps in the treatment arsenal specifically for children, continued to make significant progress with the approval of the third PaedForm monograph, *Phosphate 60 mg/mL Oral Solution*, and the addition of one new text, *Midazolam nasal spray*, to its work programme.

This online session successfully brought together over 31 delegations from Ph. Eur. Commission member states, 8 observer states (Armenia, Azerbaijan, India, Japan, the Russian Federation, South Africa and, for the first time since they became observer in 2020, Mexico), as well as

group of experts and working party chairs and the scientific Secretariat to ensure the continuity of the Ph. Eur.'s work in the latter stages of the COVID-19 pandemic.

The next session of the Ph. Eur. Commission will take place online on 23 and 24 November 2021.

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.

Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe
Tel.: +33 (0) 3 88 41 28 15 – E-mail: caroline.letarnec@edqm.eu.

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.