30 Mars 2017, Strasbourg, France

Outcome of the 157th Session of the European Pharmacopeia Commission

The European Pharmacopoeia (Ph. Eur.) Commission adopted 15 new monographs at its 157th Session, which took place in Strasbourg on 21-22 March:

- two monographs elaborated under the P4 procedure (single-source products): *Raltegravir potassium (2887)* and *Tigecycline (2825)*,
- five monographs on: *Formic acid (2809)*, *Choline ([11C]methyl) injection (2462)*, *Gammadex (2769)*, *Sucrose, liquid (2797)* and *Soya phospholipids for injection (2316)*,
- three monographs on herbal drugs and herbal drugs preparations: *Green tea (2668)*, *Guarana (2669)* and *Mate leaf (2678)*,
- five monographs on Traditional Chinese Medicines (TCM): *Houttuynia herb (2722)*, *Platycodon root (2660)*, *Bupleurum root (2562)*, *Szechwan lovage rhizome (2634)* and *Moutan bark (2474)*.

Other adopted texts included 47 revisions, of which 37 on monographs and 10 on general chapters; all were aimed at keeping the Ph. Eur. content updated and in line with regulatory developments and scientific state of the art. To date, the Ph. Eur. has been updated with 183 new or revised texts since the release of the Edition 9.0 last year.

All these texts will become effective on 1 April 2018 and will be published in Supplement 9.4 of the Ph. Eur.; the list of all adopted texts will be made available on the EDQM website.

During the session, the Ph. Eur. Commission also agreed to create a new Working Party on Pyrrolizidine Alkaloids (PA WP), which will be tasked with the definition of a general method for testing Pyrrolizidine Alkaloids (*2.8.26*). This decision was taken upon demand by European regulators and following reports in some Ph. Eur. member states that herbal medicinal products, as well as food, were found to be contaminated with traces of plants containing pyrrolizidine alkaloids.

The next Commission Session will take place on 20-21 June 2017.

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

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 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 world-wide. The European Pharmacopeia 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 thirty-eight 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, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the Former Yugoslav Republic of Macedonia, 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.