30 November 2018, Strasbourg, France

Outcome of the 162nd Session of the European Pharmacopoeia Commission

At its 162nd Session in Strasbourg on 20-21 November 2018, the European Pharmacopoeia (Ph. Eur.) Commission adopted 16 new texts:

- four general chapters: *Quantification and characterisation of residual host-cell DNA* (*2.6.35*); *Powder flow properties by shear cell methods* (*2.9.49*); Scanning electron microscopy (*2.9.52*) and *Process analytical technology* (*5.25*).
- three monographs elaborated under the P4 procedure for products still under patent protection: *Dronedarone hydrochloride* (*3039*); *Prasugrel hydrochloride* (*3040*) and *Tapentadol hydrochloride* (*3035*);
- as well as monographs on:
    - *Benzydamine hydrochloride* (*2759*)
    - *Tetracaine* (*2909*)
    - *Topiramate* (*2616*)
    - *Vincamine* (*1800*)
    - *Serratula coronata* (*2754*)
    - *Cocoa butter* (*2607*)
    - *Squalene* (*2805*)
    - *Infectious pancreatic necrosis vaccine (inactivated) for Salmonids* (*3063*)
    - *Abelmoschi corolla* (*2827*)

The new chapter on *Quantification and characterisation of residual host-cell DNA* (*2.6.35*) describes analytical methods for the quantification of residual host-cell DNA in biological products produced in cell substrates and for the characterisation of its size. This eagerly awaited chapter, deliberately drafted to allow users a certain degree of flexibility, will serve a wide range of biologicals. More information will be published on the EDQM website in the coming weeks.

The Ph. Eur. Commission also adopted 128 revised texts, including:

- An extensively revised version of the chapter on *Ultraviolet and visible absorption spectrophotometry* (*2.2.25*) which will now also cover UV-Vis detectors for chromatographic systems and process analytical technology applications. More information will be published separately on the EDQM website.
- A revised version of the chapter on *Particulate contamination: visible particles* (*2.9.20*) which has mainly been updated to improve the description of the instrument, to allow the use of LED light sources and to clarify the inspection of coloured containers and preparations. The revised text also now expressly authorises the transfer of the test material to another sample container, where necessary.
- A revised version of Chapter *5.3 Statistical analysis of results of biological assay and tests* which was adopted to correct the formula used to estimate the inter-assay variance for

heterogeneous combination of assay results. Consequently, a new version of the EDQM CombiStats software will be provided to users. More information will be published separately on the EDQM website.

- A revised version of Chapter *2.6.33* on *Residual pertussis toxin*, in which the histamine sensitisation test in mice has been replaced with a standardised CHO cell-clustering assay for residual pertussis toxin testing, based on the results of two EDQM collaborative studies. Ten monographs on acellular pertussis vaccines have also been revised accordingly. This constitutes a major 3Rs achievement. More information will be published on the EDQM website in the coming weeks.

The Ph. Eur. Commission also approved a revised version of the *Guide for the elaboration and use of monographs on vaccines and immunosera for human use*. This guide has undergone a general update to incorporate the experience accumulated over the last decade in elaborating monographs for vaccines and immunosera for human use. More information will be published on the EDQM website in the coming weeks.

The Ph. Eur. Commission also decided to take immediate actions to revise the *Oxytetracycline hydrochloride* (*0198*) monograph in response to issues reported since its implementation in January 2017. In the weeks to come, users will be provided with separate information both on this revision, which will become effective in the 10th Edition of the Ph. Eur., and on all the texts adopted at the latest session.

Another decision taken by the Commission was to restructure *Section 3. Materials for containers and Containers* of the Ph. Eur. to clarify the non-mandatory status of the texts related to medical devices. A new subsection 3.3 will be created for this purpose.

All of the adopted texts help ensure that the Ph. Eur. remains up to date and in line with the latest regulatory developments and scientific state of the art; they will be effective from 1 January 2020 and will be published in 10th Edition of the Ph. Eur.

Finally, the Ph. Eur. Commission decided to add 12 new texts – including a new chapter on *Balances* (*2.1.7*) – to its work programme. The list of all adopted texts will also be made available on this page of the EDQM website, while the Ph. Eur. publication schedule can be found here.

The next session of the Ph. Eur. Commission will take place on 19-20 March 2019.

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 **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 thirty-nine 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, 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.