08 July 2019, Strasbourg, France

164TH SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION (18 June 2019)

Following the election of its new Chair, Prof. Torbjörn Arvidsson, at its March session, the European Pharmacopoeia (Ph. Eur.) Commission elected Prof. Salvador Cañigueral as its first Vice-chair and Mr Goran Benkovic as its second Vice-chair, for a term of three years. The Presidium, which consists of the Chair and the two Vice-chairs, assisted by the Director of the EDQM and the Secretary to the Commission, will support the Ph. Eur. Commission in defining criteria for prioritisation of its work and establishing a set of priorities for the coming three years.

During its 164th session, the Ph. Eur. Commission adopted:

- one new monograph on *Olanzapine embonate monohydrate* (elaborated under the P4 procedure);
- one new general chapter on *Principles for the detection of extraneous viruses in IVMPs by using culture methods (2.6.37)*;
- 47 revised monographs and four revised general chapters.

These will be published in Ph. Eur. Supplement 10.2 and will come into effect in July 2020.

Two general chapters will also be suppressed from the Ph. Eur. as of Supplement 10.2:

- *Avian viral vaccines: tests for extraneous agents in seed lots (2.6.24)*
- *Avian live virus vaccines: tests for extraneous agents in batches of finished product (2.6.25)*

The deletion of these two chapters is due to the implementation of a new strategy for management of extraneous agents in immunological veterinary medicinal products, which will be the subject of a separate press release.

The Ph. Eur. Commission further reflected on its strategy in response to the detection of *N*-nitrosamine impurities in batches of sartans with a tetrazole ring. The following 5 individual monographs have already been revised to align the Ph. Eur. requirements to the *European Commission Decision C(2019) 2698 final* for the transitional period of 2 years:

- *Valsartan (2423)*
- *Candesartan cilexetil (2573)*
- *Irbesartan (2465)*
- *Losartan potassium (2232)*
- *Olmesartan medoxomil (2600)*

The revised monographs will be published in Edition 10.0 (publication date: July 2019; implementation date: 1 January 2020). The Ph. Eur. Commission discussed the need to further revise these monographs to remain compliant with the *European Commission Decision C(2019) 2698 final* after the 2-year transitional period ends in April 2021. The revised version of these monographs will be submitted at the 166th session of the Ph. Eur. Commission (March 2020) for publication in Supplement 10.4 (implementation date: 1 April

2021). They will not be published in Pharmeuropa for public enquiry as the changes will be made in line with the *European Commission Decision C(2019) 2698 final* which is applicable in all EU Member states (and with EEA relevance). More information will be provided to users in due time.

In November 2018, at its 162nd session, the Ph. Eur. Commission decided to elaborate a new general chapter on the control of *N*-nitrosamine impurities in APIs *(2.5.42)*. This chapter was allocated to the Ph. Eur. General Methods Working Party. Methods developed by the OMCL Network for the specific testing of *N*-nitrosamines in sartans will be used as a basis. The draft chapter will be published in Pharmeuropa for public enquiry as soon as it is ready (the publication timeline in Pharmeuropa is not yet known).

The Ph. Eur. Commission also discussed the outcome of a survey on the dissolution test included in individual Finished Product Monographs (FPMs) on solid oral dosage forms (FPMs are monographs on medicinal products containing chemically defined active substances). This survey was launched in mid-January 2019 to consult Ph. Eur. users on whether the current approach to dissolution testing in Ph. Eur. FPMs should be modified. Two options were under consideration: include a mandatory dissolution test in individual FPMs or do not include a mandatory dissolution test in individual FPMs (in which case, the performance of dissolution testing would remain mandatory through the requirements of the dosage form monograph and a potential suitable method might still be provided as an example for information only). No clear conclusion could be drawn from the results of the survey, although a slight preference for option 1 was expressed. All feedback received is being considered by the Ph. Eur. Commission, who will reflect on the most appropriate approach.

The next session of the Ph. Eur. Commission will take place on 26-27 November 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 Republic of North Macedonia, Turkey, Ukraine, United Kingdom and the European Union.*