29 June 2018, Strasbourg, France

Outcome of the 161st Session of the European Pharmacopoeia Commission

At its 161st Session, which took place in Strasbourg on 19-20 June 2018, the European Pharmacopoeia (Ph. Eur.) Commission adopted 10 new monographs, 1 new chapter, 92 revised monographs and 7 revised chapters; new texts include:

- four monographs elaborated under the P4 procedure: *Nilotinib hydrochloride monohydrate (2993), Regorafenib monohydrate (3012), Deferiprone tablets (2986)* and *Lacosamide tablets (2989).* This procedure applies to products still under patent protection;
- one monograph on a medicinal product containing a biotherapeutic active substance: *Filgrastim injection (2848)*;
- new monographs for *Levofloxacin hemihydrate (2598), Mebeverine hydrochloride (2097), Meningococcal group A, C, Y, W135 (3066), Polyamide suture, sterile, in distributor for veterinary use (3083)* and *Ophiopogon japonicus root (3000)*;
- one new chapter: *Foam index* (*2.8.24)*.

The Ph. Eur. Commission adopted a revised version of the monograph on low-molecular-mass heparins *(0828)*, which includes a more reproducible and technically easier calibration method using a Broad Standard Table. Revised texts of the widely used general chapters on *Loss on Drying (2.2.32)* and *Osmolality (2.2.35)* were also adopted. Numerous individual monographs have been revised in the framework of the implementation of the ICH Q3D guideline in the Ph. Eur.

All of the adopted texts help to ensure that the Ph. Eur. content is kept up to date and in line with the latest regulatory developments and scientific state of the art; they will be effective from 1 July 2019 and will be published in Supplement 9.8 of the Ph. Eur.

The suppression of the monographs *Dihydroergotamine tartrate (0600)*, *Polyamide 6 suture, sterile, in distributor for veterinary use (0609)* and *Polyamide 6/6 suture, sterile, in distributor for veterinary use (0610)* – the latter two being suppressed following the adoption of the new monograph on *Polyamide suture, sterile, in distributor for veterinary use (3083)* – was endorsed by the Ph. Eur. Commission as of Ph. Eur. Supplement 9.8.

During this session, the Ph. Eur. Commission also approved:

- a revised version of the Technical Guide for the elaboration of monographs on synthetic peptides and rDNA proteins. This revised version takes account of recent developments in the field and includes a new section on the flexibility of Ph. Eur. requirements that addresses the complexity of biotherapeutic products.
- a revised version of the Guide for the elaboration of monographs on radiopharmaceutical preparations, which contains a whole section on the validation of analytical methods used to

assess the quality of these medicinal products. This will be the subject of a specific press release.

- a document containing examples of validation protocols for alternative microbiological methods according to chapter *5.1.6 Alternative methods for control of microbiological quality*. This document will further facilitate use of modern, rapid microbiological methods.

Finally, the Ph. Eur. Commission decided to add 17 new monographs and one new general chapter – *Tablet Compression Characterisation (2.9.55)* – to its work programme.

The next session of the Ph. Eur. Commission will take place on 20-21 November 2018.

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.

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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 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.*

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