05 April 2018, Strasbourg, France

Outcome of the 160th Session of the European Pharmacopoeia Commission

At its 160th Session which took place in Strasbourg on 20-21 March 2018, the European Pharmacopoeia (Ph. Eur.) Commission adopted 19 new monographs, 3 new chapters, 51 revised monographs and 15 revised chapters, including:

- six monographs elaborated under the P4 procedure, *Atazanavir sulfate (2898), Everolimus (2918)*, *Fingolimod hydrochloride (2988)*, *Deferiprone oral solution (2987), Lacosamide infusion (2991)* and *Lacosamide oral solution (2990).* This procedure applies to substances still under patent protection;
- a new monograph on *Live biotherapeutic products for human use (3053),* together with two general chapters (2.6.36 and 2.6.38) on the methods to control microbial contamination of these products. This will be the subject of a separate specific press release;
- a revised General chapter on *Infrared absorption spectrophotometry (2.2.24).* A separate press-release will be published on this topic;
- a revised version of the general monograph on *Products of recombinant DNA technology (0784)*. This will be the subject of a separate specific press release.

All adopted texts ensure that the Ph. Eur. content is kept updated and in line with the latest regulatory developments and scientific state of the art; they will be effective on 1 April 2019 and will be published in Supplement 9.7 of the Ph. Eur.

The suppression of the monographs on *Chlorpropamide (1087)*, *oxprenolol hydrochloride (0628)* was endorsed by the Ph. Eur. Commission as of Ph. Eur. Supplement 9.7. As a result of the revision of the monograph for *Water for injections (0169)* – which as of 1 April 2017 allows for purification processes equivalent to distillation for producing WFI (such as reverse osmosis coupled with appropriate techniques), in addition to distillation – the Commission also decided that the monograph for *Water, highly purified (1927)* had become redundant, and therefore decided to suppress it as of Ph. Eur. 9.7.

At this session, the Ph. Eur. Commission also decided:

- to re-activate its Working Party on Gene Therapy products in view of recent developments in the field;
- to engage work on a general chapter on a test for bacterial endotoxins using recombinant Factor C, avoiding the use of a reagent coming from endangered species (horseshoe crab);
- to add 18 new texts to its work program, including four new general chapters [on *congealing point determination (2.2.68), multivariate statistical process control (5.28), test for bacterial endotoxins using recombinant factor C (2.6.32) and Recommendations on testing of particulate contamination – visible particles (5.17.2)*].

The Commission granted observer status to the Republic of Uzbekistan. This status will allow the Uzbek authorities to participate in the scientific work of the European Pharmacopoeia Commission and other EDQM activities, to benefit from European experience in the field of medicinal products for human and veterinary use, to exchange with experts from European licensing authorities and inspectorates and to share the work on the development of international quality controls for medicines and the methods of analysis used.

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