



29 November 2016, Strasbourg, France

156th SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION

At its 156th session, the European Pharmacopoeia Commission approved the priorities for the three coming years, which are aimed at maintaining the scientific excellence, leading role and influence of the Ph. Eur. worldwide. Supporting the activities of the Ph. Eur. at an international level, reflecting on how to involve observers even more actively and reviewing current Ph. Eur. working processes and procedures in order to keep pace with the evolving environment in which the Ph. Eur. operates, will feature strongly in the work programme for the next three years.

The Commission appointed the chairs and members of its groups of experts and working parties for a new term running from November 2016 to November 2019. More than 720 experts have been (re)appointed to the twenty active groups of experts and thirty-seven working parties. On behalf of the EDQM, the Director, Dr Keitel, thanked all chairs and members whose mandates had come to an end and highlighted that the work of the European Pharmacopoeia is based on the support, dedication and hard work of the experts of the Ph. Eur. network.

During the session, 14 new texts were adopted:

- Three monographs elaborated under the P4 procedure (single-source products)*: *Rupatadine fumarate* (2888); *Human coagulation factor IX (rDNA) powder for solution for injection* (2994) and on *Etanercept* (2895).
- One monograph on Radiopharmaceutical preparations*: *Sodium pertechnetate (99mTc) injection (accelerator-produced)* (2891).
- Two new monographs on antibiotics: *Tacrolimus* (2244) and *Tylosin phosphate for veterinary use* (2802)
- Three new monographs on gases: *Carbon monoxide intermix (5 per cent in nitrogen)* (2904), *Methane intermix (2 per cent) in nitrogen* (2905) and *Acetylene intermix (1 per cent in nitrogen)* (2903)
- Monographs on: *Nicardipine hydrochloride* (2776); *Ammonium carbonate for homoeopathic preparations* (2916) and *Magnolia biondii flower bud* (2742)
- Two new general chapters*: *In vivo assay substitution with in vitro methods for quality control of vaccines* (5.2.14) and *Chemical imaging* (5.24.).

The Commission also adopted 52 revised monographs including 8 dosage form monographs and 11 revised general chapters.

The Commission further fine-tuned the Ph. Eur. implementation strategy of the ICH Q3D guideline on elemental impurities and adopted the revised versions of the general monographs* on *Substances for pharmaceutical use* (2034) and *Pharmaceutical preparations* (2619), of the general chapters on *Elemental Impurities* (5.20) and on *Determination of elemental impurities* (2.4.20).

All of these texts will become effective on 1 January 2018 and will be published in supplement 9.3 of the Ph. Eur. The list of all adopted texts will be published on the EDQM website.

The Commission also granted observer status to India. This status will allow the Indian 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 Commission session will take place on 21-22 March 2017.

*Specific press releases will be published soon

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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 Pharmacopoeia is legally-binding in Member States¹. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

¹There 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.