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148th SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION

During its 148th session, the European Pharmacopoeia Commission adopted eight new monographs for inclusion in the European Pharmacopoeia, amongst them two active substances (*Imatinib mesilate* (2736) and *Rosuvastatin calcium (2631))* still under patent protection which were elaborated in close collaboration with the respective innovator companies (P4 procedure). As is done for all texts of the European Pharmacopoeia, the draft monographs were published for public consultation to ensure their robustness and adequacy. "With the adoption of these two new monographs, the P4 procedure has once again demonstrated its usefulness to ensure the European Pharmacopoeia keeps abreast with developments in medical practice, covering the quality of innovative products " said Dr Jean-Louis Robert, Chair of the European Pharmacopoeia Commission.

Other monographs and general texts that were adopted included *Eplerenone (2765), Tizanidine hydrochloride (2578), Tolterodine tartrate (2781), Polyoxypropylene stearyl ether (2602), Methyl, ethyl* and *isopropyl toluenesulfonate in active substances (2.5.40)* and *Lycii fructus (2612).* These texts will become effective on 01 April 2015 in the 37 European countries and will be published in Supplement 8.4.

The list of revised monographs and the updated version of the adopted work programme will be published on the EDQM website to inform users of future changes they need to be aware of.

The European Pharmacopoeia Commission unanimously decided to grant Azerbaijan observer status. This brings the number of observers to twenty-seven, spread over six continents. As an observer, Azerbaijan can participate in the scientific work of the European Pharmacopoeia Commission and its expert meetings. It can now also attend Commission sessions and become involved in other EDQM activities such as in the fields of official medicines and cosmetic control laboratories, blood transfusion and organ transplantation, and combatting counterfeiting. Observer status also facilitates development of a mutually-beneficial relationship and sharing of expertise on issues pertinent to the pharmaceutical and healthcare sector.

The next Commission session will take place on 17 to 18 June 2014.

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Note for the Editor: Further information is available on the internet site **www.edqm.eu**
The Convention on the Elaboration of a European Pharmacopoeia, which is celebrating its 50th anniversary in 2014, is a continent-wide initiative for setting common quality standards for medicines. It has the objective of progressively elaborating a common European Pharmacopoeia, which defines a single set of specifications for active substances and excipients used in medicines that will become the official standards applicable within these countries. The European Pharmacopoeia also describes test methods to ensure the quality of these medicines.

[1]There are thirty-eight members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union.*

There are twenty-seven observers: *Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Brazil, Canada, China, Georgia, Israel, Madagascar, Malaysia, Moldova, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, the Russian Federation, Senegal, South Africa, Syria, Tunisia, United States of America, the Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare and the World Health Organization (WHO).*

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.