23 May 2014, Strasbourg, France

ANNUAL MEETING OF THE NATIONAL PHARMACOPOEIA AUTHORITIES OF THE EUROPEAN PHARMACOPOEIA

The annual meeting of the National Pharmacopoeia Authorities (NPAs) of the 37 member States of the European Pharmacopoeia took place in London, UK, on 7/8 April 2014. The meeting was hosted by the Medicines and Healthcare products Regulatory Agency (MHRA). Twenty-three member States participated in this event.

The NPA meeting provides a unique platform for open and informal exchange of information and discussion between the secretariats of national pharmacopoeia authorities and the European Pharmacopoeia and is an important pillar for the successful collaboration of member States in elaborating common and harmonised standards. The main discussion items were:

- The implementation strategy for the future ICH Q3D guideline on Elemental Impurities in the Pharmacopoeia, ensuring continued consistency between the approaches of licensing authorities and the Ph. Eur.
- Current quality topics discussed at the European Medicines Agency's Joint CHMP/CVMP Quality Working Party that have a potential impact on the Ph. Eur., such as the use of co-crystals and other solid state forms of active substances in medicinal products and the quality of transdermal patches.
- Collaboration between pharmacopoeias and quality assessors, official medicines control laboratories and GMP inspectors: NPAs exchanged best practices to ensure good information-flow between the pharmacopoeias and regulators responsible for the quality of medicines and stressed the importance of this continued collaboration with Health Authorities for the benefit of patients.
- Situation of national pharmacopoeias in member States: NPAs shared their current practices with regard to the implementation of the Ph. Eur. in their respective countries and the situation of the remaining national, country-specific pharmacopoeias. It was noted that most of the participating NPAs had discontinued their national pharmacopoeia and were fully focussed on contributing to the Ph. Eur. The Ph. Eur. is therefore the only pharmacopoeia in their countries. Many NPAs translate the titles of Ph. Eur. texts into their national language but tend not to translate the whole Ph. Eur. However, some member States still maintain a national pharmacopoeia to complement the Ph. Eur. with texts of interest in their country only, either by including the Ph. Eur. texts in their National Pharmacopoeia or by publishing a national pharmacopoeia complementary to the Ph. Eur.

The next meeting of the National Pharmacopoeia Authorities will take place in the Netherlands in June 2015.

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

[1]There are now 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) and the World Health Organization (WHO).*