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147th SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION

At its 147th 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 be high on the work programme for the next three years.

During this 147th session, the Commission appointed the chairs and members of its groups of experts and working parties for a new term running from November 2013 to November 2016. Twenty groups of experts and fifty working parties, comprising more than 720 scientists and regulators, have been (re)appointed. 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 nominated by its Member States.

During the session, 15 new texts covering all therapeutic areas were adopted: *Agaricus phalloides for homoeopathic preparations* (2290), *Agnus castus fruit dry extract* (2309), *Carrier proteins for the production of conjugated polysaccharide vaccines for human use* (5.2.11), *Glucosamine sulfate potassium chloride* (2708), *Homoeopathic pillules, coated* (2786), *Human normal immunoglobulin for subcutaneous administration* (2788), *Ignatia for homoeopathic preparations* (2513), *Macrogols, high molecular mass* (2444), *Meldonium dihydrate* (2624), *Methane* (2413), *Nettle root* (2538), *Nux vomica for homoeopathic preparations* (2514), *Pullulan* (2603), *Sulfadimethoxine* (2741) and *Sulfadimethoxine sodium for veterinary use* (2745).

The Commission also adopted 94 revised monographs and three revised general chapters. All of these texts will become effective on 1 January 2015 and will be published in supplement 8.3 of the Ph. Eur. The list of all adopted texts will be published on the EDQM website.

The Commission also granted observer status to the Taiwan Food and Drug Administration (TFDA) of the Taiwanese Ministry of Health and Welfare. This status will allow the TFDA to participate in the scientific work of the European Pharmacopoeia Commission, 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 Secretariat announced the organisation of an international conference on 6 to 8 October 2014 to mark the 50th anniversary of the EDQM in Strasbourg.

The next Commission session will take place on 25-26 March 2014.

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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.

¹There are thirty-eight members of the <u>European Pharmacopoeia</u> 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-six observers: Albania, Algeria, Argentina, Armenia, Australia, 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.