



## **STRASBOURG, 30/06/08**

*Note for the Editors:* The mission of the European Pharmacopoeia and the European Directorate for the Quality of Medicines & HealthCare (EDQM), a Directorate of the Council of Europe responsible for the Secretariat of the European Pharmacopoeia, is to protect and promote public and animal health through the elaboration of quality standards for medicines for human and veterinary use. Medicines need to be safe, effective and of good quality in order to produce the expected therapeutic effect. The EDQM works closely with its international and European partners to ensure that sub-standard or counterfeit medicines do not reach the marketplace. Its networks collaborate on a daily basis with all authorities involved in the standardisation, regulation and control of medicines for human and veterinary use. For more information, please go to: [www.edqm.eu](http://www.edqm.eu).

## **2<sup>ND</sup> WORKSHOP ON THE CHARACTERISATION OF HEPARIN PRODUCTS 19-20 June 2008, Strasbourg, France**

On 19-20 June, 147 experts from 25 countries met in Strasbourg to discuss the characterisation and quality control of heparins. The workshop was jointly organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM, Council of Europe), the National Institute for Biological Standards & Control (NIBSC) and the United States Pharmacopoeia (USP).

The main focus of the workshop was dedicated to unfractionated heparin and the control of impurities related recent contamination problems encountered in the USA and Europe. Speakers from industry, regulatory and control authorities from Australia, Japan, USA and the EU and the three Pharmacopoeias (the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopoeia (USP)), presented their viewpoints and approaches based upon current experiences and recent analyses of samples drawn from their respective markets.

In addition to presentations on Nuclear Magnetic Resonance (NMR) and Capillary Electrophoresis (CE) currently included in the respective revised monographs of the Ph. Eur., JP and USP, the applicability of other analytical methods which might be more adapted to routine quality control were discussed.

One session was specifically dedicated to issues related to Low Molecular Mass (LMM) heparins and the possible need to update the monographs in the respective Pharmacopoeias.

As sourcing of heparins reflects the problems related to the globalisation of the pharmaceutical market, the workshop clearly identified the need for setting a common standard and developing a harmonised approach to define a potency assay based on a common international unitage (IU).

All three Pharmacopoeias have decided to take a two-step approach to the necessary revision of their respective heparin monographs. While there are minor differences between the three regions in the standpoints taken for the immediate revision to include adequate quality control of the recently observed contaminants, in the mid-term, the Pharmacopoeias are committed to establishing harmonised monographs both for heparin and LMM heparins including state-of-the-art quality control.

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