



STRASBOURG, 17/10/2008

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. 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.

EDQM SYMPOSIUM: PHARMACEUTICAL REFERENCE STANDARDS

9-10 October 2008, Strasbourg, France

This international symposium, organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM), was dedicated to discussing current topics and future approaches related to pharmaceutical reference standards.

Pharmaceutical reference standards are essential for the quality control of medicines. The symposium, which attracted more than 170 participants from 31 countries, brought together stakeholders involved in the production, characterisation and use of reference standards to exchange their views and opinions on the different issues related to the subject.

The scientific programme included presentations on the Japanese Pharmacopoeia's, United States Pharmacopoeia's and European Pharmacopoeia's Reference Standards Programmes, as well as the World Health Organisation's biologicals programme, viewpoints from the regulators (EU, USA and the Russian Federation), audits and inspections, characterisation of primary reference standards and the establishment and use of secondary standards. Issues related to the development of chemical, herbal and biological reference standards and their role in the quality of medicines were addressed in two separate workshops. The programme also included a poster session and a roundtable discussion.

The following issues were highlighted during the two days:

- the establishment and use of reference standards are closely linked to the specifications and test methods of pharmacopoeial monographs;
- globalisation of the pharmaceutical markets necessitates the harmonisation of monographs and their reference standards;
- it is important to use state-of-the-art techniques when characterising reference standards, keeping in mind the intended use;
- when used in the application of pharmacopoeial monographs, reference standards are legally binding and consequently hold a unique status, in a specific regulatory environment which international norms need to recognise and clarify;
- pharmacopoeial reference standards used for demonstrating compliance with pharmacopoeial monographs do not necessarily require the indication of the uncertainty of measurement of the assigned value as this concept is already built into the product specification;
- it is important to have a harmonised approach for biologicals based on International Units. In this context, the special circumstances under which International Units may be replaced by S.I. Units* for the assignment of potency in biological preparations were discussed;
- it is increasingly necessary to establish and prepare reference standards for herbal drugs and preparations.

The EDQM and European Pharmacopoeia Commission will take into account the outcome of the symposium discussions when making future policy and work programme decisions.

* International System of Units

[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.](#)

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