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Note for the Editors

International Harmonisation of Microbiology Chapters in Pharmacopoeias (2.6.12, 2.6.13 and 5.1.4) was originally driven by ICH Guideline Q6A. The Ph. Eur., lead pharmacopoeia in this project, undertook the elaboration of the internationally harmonised texts via the collaboration of its European Experts (Group 1), and Microbiology specialists from Japan and the United States appointed by the Pharmacopoeial Discussion group (PDG). This resulted into the recent publication of the harmonised chapters in supplement 5.6 of the Ph. Eur. in July 2006 with an implementation date of 1st January 2007 and in USP-NF 29, 2nd supplement with an implementation date of 1st August 2007. The projected date for publication in the Japanese Pharmacopoeia is September 2007 for implementation on 1st October 2007.

These harmonised new Chapters are the result of a long process over several years of proposal, revision, consultation and commenting between experts, the Pharmacopoeial Discussion Group and the public in the pharmaceutical field. Comments, questions and proposals were discussed and re-discussed between the European Pharmacopoeia, United States Pharmacopoeia, and Japanese Pharmacopoeia, their experts and users until the harmonised texts were finally achieved.

The EDQM, a Directorate of the Council of Europe, can be considered as the 'facilitating European body' not only for the harmonisation of Pharmacopoeias but also for the adaptation and extension of European regulations.

Since 1991 the European Pharmacopoeia, and later the EDQM, has developed close links with the others Pharmacopoeias and is actively participating in the Pharmacopoeial Discussion Group. Its' networks collaborate on a daily basis with all the authorities involved in the standardisation, regulation and control of medicines for human and veterinary use. The organisation of such a large information and communication, involving all parties, is one of the channels used by the EDQM to facilitate the implementation of new regulations.

INTERNATIONAL SYMPOSIUM ON "NEW MICROBIOLOGY CHAPTERS OF THE EUROPEAN PHARMACOPOEIA", 2-3 OCTOBER 2006, STRASBOURG FRANCE

The main aims of the symposium organised by the European Directorate for the Quality of Medicines (EDQM, Council of Europe) were:

- To present and to explain the changes and new features in the harmonised chapters and to analyse their impact for users;
- To help professionals to manage the transition period (2007-2010) intended to allow adaptation to the new chapters for the large range of products affected;
- To present the general chapter on alternative methods and its role in facilitating the introduction of modern techniques, taking in account of the viewpoints of regulatory authorities and industry.

Discussions and Round-table discussions took place at the end of each presentation and session and these were aimed at answering the questions of the audience and to explain the rationale behind news and changes in order to share scientific knowledge and expertise.

The conclusions of this symposium will be published later on the EDQM's internet site (www.pheur.org). This symposium was attended by almost 190 participants from 28 different countries.

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 46 member states.

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