

Strasbourg, 22/09/2006

Note for the Editors

To better control the quality of the medicines marketed in Europe and raw materials manufactured now worldwide, the European Pharmacopoeia has developed a general policy on impurities control. It is set out in the general monograph 'Substances for Pharmaceutical Use' and the general chapter 5.10 'Control of impurities in substances for pharmaceutical use'. Antibiotics and peptides are not yet covered by this general policy.

The EDQM, a Directorate of the Council of Europe, can be considered as the 'facilitating European body' for the adaptation and extension of European regulations. Since 1964 the European Pharmacopoeia, and later the EDQM, has developed close links with the other European bodies. 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 consultation and communication, involving all parties, is one of the channels used by the EDQM to receive feedback.

INTERNATIONAL SYMPOSIUM ON "NEW IMPURITIES CONTROL: SETTING SPECIFICATIONS FOR ANTIBIOTICS AND SYNTHETIC PEPTIDES", 21-22 SEPTEMBER 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 discuss a technical and scientific general approach to cover new aspects of Quality and Safety for the two classes of products: antibiotics and synthetic peptides. This approach will then be used in the elaboration and revision of European Pharmacopoeia monographs, and
- to take the views and expectations of all parties involved, such as European authorities and national authorities, manufacturers, inspectors and assessors from all over the world into consideration when revising existing European regulations.

Round-table discussions took place at the end of each session and these were aimed at exploring the two topics further and to open up the debate 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).

A regulatory debriefing session was also held after the plenary symposium with the view to reviewing the proposals and feedback received. A report summarising the discussions will be written by the EDQM and circulated to the relevant European bodies and to the European Pharmacopoeia Commission

This symposium was attended by almost 135 participants from 30 different countries including China and India.

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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