



STRASBOURG, 13/05/08

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.

EDQM PARTICIPATES IN AN INTERNATIONAL MEETING ON HEPARINS

The European Directorate for the Quality of Medicines & HealthCare (EDQM, Council of Europe) participated in a recent meeting organised by the United States Food and Drug Administration (FDA) to state the European Pharmacopoeia's position and to share its experience on the current issues concerning the quality of heparins following adverse effects reported earlier this year.

The objectives of this meeting were:

- to share information on sourcing, inspections, recalls and adverse events on a worldwide level,
- to discuss possible analytical and GMP strategies to eliminate contaminants, and
- to define efficient measures to avoid shortages of heparin that would be dramatic for patients.

Following the decisions taken at the last European Pharmacopoeia Commission, the European Pharmacopoeia started immediately revising the monographs concerned. A first ad hoc meeting of the European Group of Experts on Biological Substances was held on 2 April 2008 at the EDQM with interested parties, heparin manufacturers for the most part, to share findings on the contamination and experiences with the test methods available.

A contaminant called over-sulphated chondroitin has been identified which has very similar structure to heparin. It appears very likely that this substance is not entirely natural and that it may have been chemically modified. At this stage, no proof has been found that this substance actually caused the serious allergic reactions reported in patients but testing laboratories are working on this.

Because of their similarity to heparin, contaminants such as over-sulphated chondroitin cannot be detected by current pharmacopoeial tests. Several adapted test methods were proposed for possible inclusion in the heparin monographs; they will be considered by the Expert Group in their efforts to strengthen requirements and controls of the raw material and thus promote patients' safety.

Discussions will continue in a workshop jointly organised by the EDQM, the National Institute for Biological Standards and Control (NIBSC) and the US Pharmacopoeia in Strasbourg on 19-20 June 2008 (<http://www.edqm.eu/site/EDQM-USP-NIBSC-Workshop-Heparin-Products-Strasbourg-France-1174.html>).

The European Pharmacopoeia Commission will formally decide on what short-term action it will take at its next session in June.

[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.](#)

Contact: Caroline Larsen Le-Tarnec

Public Relations Division, EDQM

Tel: + 33 3 88 41 30 30 (Dial 4)

E-mail: Via the Helpdesk on the EDQM website