



Strasbourg, 18/03/08

Note for the Editors

The European Pharmacopoeia and the EDQM (a Directorate of the Council of Europe notably in charge of the secretariat of the European Pharmacopoeia) have a mission to protect and promote public and animal health, through the elaboration of quality standards of 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 strengthen measures in order to ensure that substandard or counterfeit medicines do not reach the marketplace.

The EDQM's networks collaborate on a daily basis with all the authorities involved in the standardisation, regulation and control of medicines for human and veterinary use. Since December 2006, the EDQM took over activities of the Council of Europe in the domains of blood transfusion and organ transplantation.

130TH SESSION OF THE EUROPEAN PHARMACOPOEIA: IMMEDIATE ACTION TAKEN ON THE SAFETY OF HEPARINS

The European Pharmacopoeia Commission decided during its 130th session to take action immediately to revise heparin monographs in order to strengthen the level of testing required for purity control. Two monographs* are affected by this decision.

Following initial reports in the United States (US), concerns about the safety of heparin, a critical blood thinner, have been raised in Germany, France and possibly in other European countries. 19 deaths and hundreds of serious adverse reactions (allergic symptoms with or without hypotension) have been reported in the US associated with the parenteral use of heparin. A number of cases of adverse reactions have now been observed in Europe. These cases are allegedly linked to impurities in the batches of heparin used in the manufacture of the medicinal products.

The US Food and Drug Administration (FDA) have announced that they are asking all heparin manufacturers to test the drug using two new analytical methods, NMR spectroscopy and capillary electrophoresis. These tests are able to control the new impurities in heparin. The decision of the European Pharmacopoeia Commission to immediately revise two of the three heparin monographs (the third monograph already specifies the additional tests) will ensure that only heparin of adequate safety will be used in medicinal products in Europe.

In addition, an international workshop on heparins will be organised by the EDQM on 19 to 20 June 2008, in Strasbourg, France, and will serve as a platform for further exchanges of experience with experts in the field.

Other topics of interest: The European Pharmacopoeia Commission has adopted a policy for dealing with genotoxic impurities in monographs on substances for human use. Concerns about the presence of such impurities have been growing for some time and have led to the preparation of the CHMP Guideline on the limits of genotoxic impurities (CPMP/SWP/5199/02, EMEA/CHMP/QWP/251344/2006). This guideline addresses the control of genotoxic impurities in licensing procedures for human medicinal products. With the adoption of its policy, the European Pharmacopoeia Commission has formally decided to apply the same principles in the elaboration and, when applicable, in the revision of monographs on substances for human use. This decision illustrates not only the high level of co-operation between the EDQM and the European licensing authorities but also the active role the EDQM is taking within the European regulatory framework.

Obituary: It is with great sadness that the EDQM announces the death of former first secretary of the European Pharmacopoeia Commission (1964-1985) Dr. Herbert S. Grainger (UK) on Monday 10 March 2008. The late Dr. Grainger was a leading figure behind the elaboration of the European Pharmacopoeia, guiding the Commission throughout the preparation of the 1st Edition and initiating the development of the 2nd Edition.

* = Heparin calcium (0332) & Heparin sodium (0333).

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/ European Pharmacopoeia
Tel.: +33 (0) 3 88 41 28 15
E-mail: via the *HelpDesk* on the EDQM website