European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

1st June 2011

**RAPID IMPLEMENTATION OF REVISED GENERAL CHAPTER 5.2.8**

General chapter *5.2.8 Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products* is identical with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products – Revision 3 (EMA/410/01 rev. 3).

This 3rd technical revision has been undertaken to take into account advancement of science in the area of transmissible spongiform encephalopathies, as well as the evolving situation regarding Bovine Spongiform Encephalopathy (BSE) across the world.

For the classification of countries or regions according to their BSE risk, the revised chapter makes reference to the rules laid down by the World Organisation for Animal Health (OIE), replacing the previous GBR classification. Nevertheless, for countries that were classified according to the GBR criteria but not yet according to the OIE criteria, the existing GBR classification should apply, provided that there is no evidence of significant change in their BSE risk.

New criteria for the sourcing and processing of gelatin and bovine blood derivatives used in the manufacture of medicinal products for human or veterinary use have been introduced, as well as a new subsection on Peptones.

The revised chapter was adopted by the European Pharmacopoeia Commission on 3 May 2011, by correspondence, using the rapid implementation procedure (see Resolution AP-CPH (11) 5 of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) (Partial Agreement)). The implementation date is 1 July 2011, for both the revised chapter and note for guidance.