European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

Title:	**Note concerning CEPs for gelatin and impact of the revised EU Note for Guidance on the TSE risk**
Reference Document:	**PA/PH/CEP (11) 29**

Revision 3 of the EU "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" (EMEA/410/01 Rev.3) will be in force in July 2011and introduces a new requirement for gelatin obtained from bones, which is based on the intended use of the finished product. Gelatin introduced in products for parenteral use should only be manufactured from bones sourced from OIE categories A or B countries, whereas gelatin for oral use may be manufactured from bones from any category of country.

The certificates of suitability granted for gelatin do not take into account the final use of the finished product. Therefore, where a CEP for gelatin is included in a marketing authorization, applicants/holders have to demonstrate in their application(s) for the relevant medicinal product(s), that the source of gelatin is suitable for the intended use. This will be approved by the licensing authorities evaluating the finished medicinal product.