The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

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GELATIN FOR USE IN PHARMACEUTICALS: EXPLANATORY NOTE[1] (13 DECEMBER 2000) ON THE MANUFACTURE OF GELATIN IN RELATIONSHIP TO THE CPMP NOTE FOR GUIDANCE ON MINIMISING THE RISK OF TRANSMITTING ANIMAL SPONGIFORM ENCEPHALOPATHY AGENTS VIA MEDICINAL PRODUCTS (CPMP/BWP/1230/98 rev 1)

The CPMP in consultation with trade organisations of the pharmaceutical industry (EFPIA) and the gelatin manufacturers (GME) have indicated that acid gelatin is still a necessary ingredient of some medicinal products.

Following the complementary approach developed in the CPMP Note for Guidance, proper sourcing of the starting material (bones) will render the gelatin acceptable if the following approach is adopted, such as sourcing bones from the following categories of countries (according to the classification made by the European Commission's Scientific Steering Committee, SSC):

- Category I and II countries for gelatin produced by the acid process,
- Category I, II and III countries for gelatin produced by the alkali process

This approach should be applied prospectively.

[1] This explanatory note should be considered as an appendix of the CPMP Note for Guidance on Minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products (CPMP/BWP/1230/98, rev 1) and will be integrated in this guidance at its next revision.

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