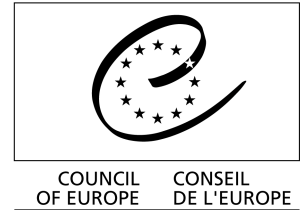




Certification Unit



CP/CB

PUBLIC DOCUMENT

(Level 1)

English only/Anglais seulement

PA/PH/Exp. CEP/T (04) 26

October 2004

Certification of suitability of Monographs of the European Pharmacopoeia

Revision of TSE certificates for the 5th edition of the European Pharmacopoeia

Strasbourg

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The certificates of suitability refer to the specific and general European Pharmacopoeia monographs in force and therefore are revised when necessary according to any new supplement and/or new Edition of European Pharmacopoeia, as well as according to any change in regulatory requirements.

The 5th edition of the European Pharmacopoeia will become mandatory on 1 January 2005. In the context of its implementation, the EDQM Certification Unit has initiated a revision program for all certificates of suitability; as regards TSE certificates the following documents have been taken into account:

- revised general chapter 5.2.8 *Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products* (*)
- scientific reports from the European Food Safety Authority (EFSA) on the GBR reclassification of Canada, Mexico, Norway, South Africa and the USA
- *Risk assessment of ruminant materials from USA and Canada* (EMEA/CHMP/BWP/27/04, dated 21 July 2004) published by the Biotechnology Working Party on 1 September 2004.

An update of some applications has been considered necessary. Only manufacturers of serums and blood derivatives (except Foetal Bovine Serum, Donor Calf Serum, Newborn calf Serum) and bone gelatin would be affected by this update, and EDQM is going to contact the relevant certificates holders directly for more details.

The other certificates are considered in compliance with the current regulatory requirements, provided that the manufacturers did not introduce any unapproved change to the content of their applications. In order to refer to the 5th edition of the European Pharmacopoeia, the current certificates will be revised editorially during the first months of 2005 and sent automatically to the holders.

(*) this chapter is identical with the Note for Guidance EMEA/410/01, which is currently under revision. The revised text will be taken into account as soon as available.